

114TH CONGRESS
1ST SESSION

H. R. 2422

To amend the Federal Food, Drug, and Cosmetic Act with respect to third-party quality system assessment.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. SHIMKUS introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to third-party quality system assessment.

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. THIRD-PARTY QUALITY SYSTEM ASSESSMENT.**

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

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

10 “(a) ACCREDITATION AND ASSESSMENT.—

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

5 “(A) to accredit persons to assess whether
6 a requestor’s quality system, including its de-
7 sign controls, can reasonably assure the safety
8 and effectiveness of in-scope devices subject to
9 device-related changes (as defined in paragraph
10 (2));

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

16 “(C) under which the Secretary shall rely
17 on such certifications for purposes of deter-
18 mining the safety and effectiveness of in-scope
19 devices subject to the device-related changes in-
20 volved, in lieu of compliance with the following
21 submission requirements:

22 “(i) A thirty-day notice (as defined in
23 paragraph (2)).

24 “(ii) A Special PMA supplement (as
25 defined in paragraph (2)).

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) manufacturing changes subject to
7 a 30-day notice;

8 “(ii) changes that qualify for a Spe-
9 cial PMA supplement; and

10 “(iii) such other changes relating to
11 the devices or the device manufacturing
12 process as the Secretary determines appro-
13 priate;

14 “(B) the term ‘in-scope device’ means a
15 device within the scope of devices agreed to by
16 the requestor and the accredited person for pur-
17 poses of a request for certification under this
18 section;

19 “(C) the term ‘quality system’ means a
20 quality system described in section 520(f);

21 “(D) the term ‘requestor’ means a device
22 manufacturer that is seeking certification under
23 this section of a quality system used by such
24 manufacturer;

1 “(E) the term ‘Special PMA’ means a Spe-
2 cial PMA supplement under section 814.39(d)
3 of title 21, Code of Federal Regulations (or any
4 successor regulations); and

5 “(F) the term ‘thirty-day notice’ means a
6 notice described in section 515(d)(6).

7 “(3) ACCREDITATION PROCESS; ACCREDITATION
8 RENEWAL.—Except as inconsistent with this section,
9 the process and qualifications for accreditation of
10 persons and renewal of such accreditation under sec-
11 tion 704(g) shall apply with respect to accreditation
12 of persons and renewal of such accreditation under
13 this section.

14 “(4) USE OF ACCREDITED PARTIES TO CON-
15 DUCT ASSESSMENTS.—

16 “(A) INITIATION OF ASSESSMENT SERV-
17 ICES.—

18 “(i) DATE ASSESSMENTS AUTHOR-
19 IZED.—Beginning after issuance of the
20 final guidance under paragraph (5), an ac-
21 credited person may conduct an assess-
22 ment under this section.

23 “(ii) INITIATION OF ASSESSMENTS.—
24 Use of one or more accredited persons to
25 assess a requestor’s quality system under

1 this section with respect to in-scope devices
2 shall be at the initiation of the person who
3 registers and lists the devices at issue
4 under section 510.

5 “(B) COMPENSATION.—Compensation for
6 such accredited persons shall—

7 “(i) be determined by agreement be-
8 tween the accredited person and the person
9 who engages the services of the accredited
10 person; and

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

13 “(C) ACCREDITED PERSON SELECTION.—
14 Each person who chooses to use an accredited
15 person to assess a requestor’s quality system,
16 as described in this section, shall select the ac-
17 credited person from a list of such persons pub-
18 lished by the Secretary in accordance with sec-
19 tion 704(g)(4).

20 “(5) GUIDANCE; CRITERIA FOR CERTIFI-
21 CATION.—

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

1 “(B) CONTENTS; CERTIFICATION CRI-
 2 TERIA.—The guidance under this paragraph
 3 shall include specification of—

4 “(i) evaluative criteria to be used by
 5 an accredited person to assess and as ap-
 6 plicable certify a requestor’s quality system
 7 under this section with respect to in-scope
 8 devices ; and

9 “(ii) criteria for accredited persons to
 10 apply a waiver of and exemptions from the
 11 certification criteria under clause (i).

12 “(C) TIMEFRAME FOR ISSUING GUID-
 13 ANCE.—The Secretary shall issue under this
 14 paragraph—

15 “(i) draft guidance not later than 12
 16 months after the enactment of the 21st
 17 Century Cures Act; and

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

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

22 “(1) ASSESSMENT SUMMARY; CERTIFI-
 23 CATION.—

24 “(A) SUBMISSION OF ASSESSMENT TO SEC-
 25 RETARY.—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 as applicable shall include—

“(I) the accredited person's certification that the requestor has satisfied the criteria 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

1 date on which the Secretary receives the
2 summary under subparagraph (A); and

3 “(ii) the assessment summary and
4 certification of the requestor shall be
5 deemed accepted by the Secretary on such
6 30th day.

7 “(C) ACTIONS BY SECRETARY.—

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

19 “(I) additional information is
20 needed to support such certification;

21 “(II) such assessment or certifi-
22 cation is unwarranted; or

23 “(III) such action with regard to
24 the certification is otherwise justified

1 according to such factors and criteria
2 as the Secretary finds appropriate.

3 “(ii) ACCEPTANCE OF CERTIFI-
4 CATION.—If following action by the Sec-
5 retary under clause (i) with respect to a
6 certification, the Secretary determines that
7 such certification is acceptable, the Sec-
8 retary shall issue written notice to the ap-
9 plicable accredited person indicating such
10 acceptance.

11 “(2) NOTIFICATIONS TO SECRETARY BY CER-
12 TIFIED MANUFACTURERS FOR PROGRAM EVALUA-
13 TION PURPOSES.—

14 “(A) PERIODIC NOTIFICATION FOR MANU-
15 FACTURING CHANGES OTHERWISE SUBJECT TO
16 THIRTY-DAY NOTICE.—A requestor certified
17 under this section that effectuates device-re-
18 lated changes with respect to in-scope devices,
19 without prior submission of a thirty-day notice,
20 shall provide notification to the Secretary of
21 such changes in the requestor’s next periodic
22 report under section 814.84(b) of title 21, Code
23 of Federal Regulations (or any successor regu-
24 lation). Such notification shall—

25 “(i) describe the changes made; and

1 “(ii) indicate the effective dates of
2 such changes.

3 “(B) PERIODIC NOTIFICATION FOR DE-
4 VICE-RELATED CHANGES OTHERWISE SUBJECT
5 TO SPECIAL PMA SUPPLEMENT.—A requestor
6 certified under this section that effectuates de-
7 vice-related changes with respect to in-scope de-
8 vices, without prior submission of a Special
9 PMA Supplement, shall provide notification to
10 the Secretary of such changes in the requestor’s
11 next periodic report under section 814.84(b) of
12 title 21, Code of Federal Regulations (or any
13 successor regulation). Such notification shall—

14 “(i) describe the changes made, in-
15 cluding a full explanation of the basis for
16 the changes; and

17 “(ii) indicate the effective dates of
18 such changes.

19 “(C) USE OF NOTIFICATIONS FOR PRO-
20 GRAM EVALUATION PURPOSES.—Information
21 submitted to the Secretary under subpara-
22 graphs (A) and (B) shall be used by the Sec-
23 retary for purposes of the program evaluation
24 under subsection (d).

1 “(c) DURATION AND EFFECT OF CERTIFICATION.—

2 A certification under this section—

3 “(1) shall remain in effect for a period of two
4 years from the date such certification is accepted by
5 the Secretary, subject to paragraph (6);

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

8 “(3) shall continue to apply with respect to de-
9 vice-related changes made during such 2-year period,
10 provided the certification remains in effect, irrespec-
11 tive of whether such certification is renewed after
12 such 2-year period;

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

18 “(5) shall have no effect on the authority of the
19 Secretary to conduct an inspection or otherwise de-
20 termine the requestor’s conformance with the appli-
21 cable requirements of this Act; and

22 “(6) shall be considered to be revoked if the
23 Secretary provides written notification to the cer-
24 tified requestor that its quality system does not sat-
25 isfy the certification criteria issued under subsection

1 (a)(5) with respect to the in-scope devices at issue,
2 such that the applicable submission requirements
3 specified in subsection (a)(1)(C) must be met for
4 changes made after receipt of such written notifica-
5 tion, with respect to such devices.

6 “(d) PROGRAM EVALUATION; SUNSET.—

7 “(1) PROGRAM EVALUATION AND REPORT.—

8 “(A) EVALUATION.—The Secretary shall
9 complete an evaluation of the third-party qual-
10 ity system assessment program under this sec-
11 tion no later than January 31, 2021, based
12 on—

13 “(i) analysis of information from a
14 representative group of device manufactur-
15 ers obtained from notifications provided by
16 certified requestors under subsection
17 (b)(2); and

18 “(ii) such other available information
19 and data as the Secretary determines ap-
20 propriate.

21 “(B) REPORT.—No later than 1 year after
22 completing the evaluation under subparagraph
23 (A), the Secretary shall issue a report of the
24 evaluation’s findings on the website of the Food
25 and Drug Administration, which shall include

1 the Secretary's recommendations with respect
2 to continuation and as applicable expansion of
3 the program under this section to include addi-
4 tional types of submissions and additional types
5 of changes beyond those identified in subsection
6 (a)(1)(C), including changes to devices cleared
7 under section 510(k). At the discretion of the
8 Secretary, the program may be expanded prior
9 to January 31, 2021.

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

12 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to limit the authority of the Sec-
14 retary to request and review the complete assessment of
15 a certified requestor under this section on a for-cause
16 basis.”.

17 (b) CONFORMING AMENDMENTS.—

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

24 (2) REQUIREMENTS FOR THIRTY-DAY NO-
25 TICE.—Section 515(d)(6)(A)(ii) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 360e(d)(6)(A)(ii)) is amended by inserting “, subject
3 to section 524B,” after “the date on which the Sec-
4 retary receives the notice”.

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