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FDA Reauthorization Act of 2017: Key Provisions Related to Medical Devices

September 20, 2017

Medical Devices and Diagnostics

On August 18, 2017, President Trump signed H.R. 2430, the FDA Reauthorization Act of 2017, which became Public Law No. 115-52 ("FDARA"). Principally, FDARA reauthorizes the Food and Drug Administration ("FDA" or "the agency") user fee programs, including the Medical Device User Fee Amendments, the Prescription Drug User Fee Amendments, the Biosimilars User Fee Amendments, and the Generic Drug User Fee Amendments. The agency's existing authority to collect user fees under these programs ends on September 30, 2017. Under FDARA, the user fee programs have been reauthorized through fiscal year 2022. FDARA also includes important substantive amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA").

This alert summarizes the medical device-related provisions in Title II—Fees Relating to Devices (also titled the Medical Device User Fee Amendments of 2017), Title V—Pediatric Drugs and Devices, and Title VII—Device Inspection and Regulatory Improvements. The provisions of FDARA related to drugs and biologics will be addressed in a separate alert.

Significant features of these provisions include:

- Reauthorizing FDA to collect medical device user fees for fiscal years 2018-2022;
- Adding a new user fee for *de novo* classification requests;
- Modifying FDA's approach to establishing a schedule for device establishment inspections from a biennial schedule to a risk-based approach;
- Requiring FDA to provide feedback on corrective actions submitted in a response to a Form FDA 483 within 45 days if the inspectional observations "involve a public health priority, . . . implicate systemic or major actions, or relate to emerging safety issues;"
- Clarifying the premarket review process for medical imaging devices intended to be used with an approved contrast agent;
- Creating a new process for device sponsors to request classification of accessory devices as part of the premarket application for the parent device and to request a separate classification of accessory devices that have been previously approved or cleared as part of the approval or clearance of the parent device;
- Requiring FDA to issue regulations creating a category of over-the-counter hearing aids for adults with mild or moderate hearing impairment; and
- Requiring FDA to issue a report addressing the servicing of medical devices.

Title II—Fees Relating to Devices

Sections 202-204. Definitions; Authority to Assess and Use Device Fees; and Reauthorization, Reporting Requirements

These sections reauthorize the Medical Device User Fee Amendments (MDUFA), in sections 737, 738 and 738A of the FDCA, allowing FDA to collect user fees for device submissions for fiscal years 2018-2022. FDA sets user fees for each fiscal year based on the total revenue amounts, base fees, and adjustment calculations specified in the statute. The total revenue amounts and base fees for 2018-2022 have increased from those set for 2012-2017, but the structure of the user fee program remains largely the same with two principal changes: (1) the addition of a new user fee for *de novo* classification requests and (2) deletion of the agency's discretion to waive user fees in the interest of public health.

De Novo Classification Request User Fee

The reauthorized MDUFA adds a new user fee for *de novo* classification requests, which currently do not require a user fee. The new user fee will be 30% of the premarket approval application (PMA) user fee set each year—significantly more than the user fee for a 510(k) premarket notification submission, which will be 3.4% of the PMA user fee (and was 2% of the PMA user fee in 2012-2017).

On August 29, 2017, FDA published the fee rates for fiscal year 2018 (which apply beginning October 1, 2017): the PMA user fee is $310,764, the de novo classification request user fee is $93,229, and the 510(k) user fee is $10,566.[1]

Along with the new user fee, FDA has committed to new performance goals for the review of *de novo* classification requests.[2] Under the new performance goals, FDA will issue a decision within 150 "FDA days"[3] of receipt of the submission for a proportion of submissions received each fiscal year as follows:

Fiscal Year Received	Decision Within 150 FDA Days
2018	50% of requests
2019	55% of requests
2020	60% of requests
2021	65% of requests
2022	70% of requests

[1] FDA, Medical Device User Fee Rates for Fiscal Year 2018, Notice, 82 Fed. Reg. 41029 (Aug. 29, 2017).

[2] FDA, MDUFA Performance Goals and Procedures, Fiscal years 2018 Through 2022, https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.

[3] FDA days" include only those calendar days when a submission is under review at the agency, and does not include days during which a request for additional information or deficiency letter is pending response by the applicant.

At industry's request, and as resources permit, if a final decision has not been rendered on a *de novo* classification request within 180 FDA days, FDA will discuss with the applicant (1) all outstanding issues with the submission preventing FDA from reaching a decision; and (2) action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks.

Currently, section 513(f)(2) of the FDCA requires FDA to issue a decision on a *de novo* classification request within 120 calendar days. However, in practice, FDA has taken an average of 10 months to a year (and in some cases even longer) to issue a decision. The new user fee should allow FDA to commit additional resources to the review of *de novo* classification requests and significantly reduce the time to decision. As new technologies are increasingly outgrowing FDA's existing device classifications, particularly with the rise of digital health technologies, the number of *de novo* classification requests is likely to increase over the next several years.

Waiver of User Fees

The reauthorized user fee provisions eliminate the agency's current ability to grant a user fee waiver or fee reduction if the agency finds that such a waiver or reduction is in the interest of public health.

The existing fee waiver for a small business submitting its first PMA remains. The current user fee reductions for small businesses also remain, although the fee reduction for a small business submitting a 510(k) will be reduced to 25% of the standard fee (from the current 50%). Small businesses will also qualify for reductions of the new user fees for *de novo* classification requests.

Section 205. Conformity Assessment Pilot Program

New section 514(d) of the FDCA requires FDA to establish a pilot program under which testing laboratories may be accredited to assess the conformance of a device with certain recognized standards. Conformity determinations by accredited laboratories must be accepted by FDA for purposes of demonstrating conformity.

FDA may review determinations by accredited laboratories by conducting periodic audits of determinations or the processes of accredited laboratories. Based on the review, or if FDA becomes aware of information materially bearing on the safety or effectiveness of a device assessed for conformity by an accredited laboratory, then FDA may take additional measures the agency deems appropriate, such as suspension or withdrawal of accreditation, or requesting additional information regarding the device.

FDA must: hold a public meeting to discuss the pilot program by September 30, 2018; issue draft guidance by September 30, 2019, and issue final guidance by September 30, 2021, regarding implementation of the pilot program; initiate the pilot program by September 30, 2020; and publish on the agency's website an annual report on the progress of the pilot program. The authority for the program sunsets on October 1, 2022.

Section 206. Reauthorization of Review

This section amends section 523 of the FDCA, which currently provides for third-party review of 510(k) by accredited persons (Accredited Persons Program).[4] The statute previously stated that the third-party review program does not apply to a class II device that is intended to be permanently implantable or life sustaining or life supporting. FDARA amends this limitation to allow third-party review if FDA so determines in accordance with the guidance described below. The statute also previously stated that the third-party review program does not apply to a class II device that requires clinical data (subject to a limitation on the ratio of such devices to the total number of 510(k)s). FDARA eliminates this limitation but adds that third-party review may not be used for: (1) a device classified pursuant to a *de novo* classification request or designated as a breakthrough device; or (2) a device of a type listed as not eligible for review in the guidance described below.

Within 24 months of enactment, FDA must issue draft guidance on the factors the agency will use in determining whether a class I or class II device type is eligible for third-party review. FDA must finalize the guidance within 24 months of issuing the draft guidance. When the draft guidance is finalized, FDA must post on its website an updated list of class I and class II device types and the agency's determination whether each device type is eligible or not eligible. Until this time, the list in effect on the date of enactment shall remain in effect.

Section 207. Electronic Format for Submissions

Section 745A(b) of the FDCA, as amended by the FDA Safety and Innovation Act (FDASIA), requires the submission of an electronic copy (eCopy) of device submissions pursuant to a final guidance document issued in December 2015. This guidance document requires an eCopy in addition to one or more paper copies for most device submissions and specifies the format for such submissions.[5]

FDARA amends section 745A(b) to direct FDA to issue guidance for device pre-submissions and submissions to be submitted solely in electronic format. Pursuant to amended section 745A(b) of the FDCA, by October 1, 2019, FDA must issue draft guidance providing for: (1) any further standards for electronic format submission of device pre-submissions and submissions, (2) a timetable for the establishment of such standards, and (3) criteria for waivers and exemptions from the requirement for electronic submission. FDA must issue final guidance within a year of the close of the comment period on the draft guidance. Beginning on the date specified in the final guidance, pre-submissions and submissions (and any related appeals) must be submitted solely in electronic format, as specified in the guidance.

Sections 208-210. Savings Clause; Effective Date; Sunset Dates

The amendments to the medical device user fee program discussed above take effect on October 1, 2017 and the current use fee structure remains in effect until that date. FDA's authority to collect medical device user fees sunsets on October 1, 2022.

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[4] *See* FDA, Third Party Review, https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/thirdparyreview/default.htm.

[5] FDA, Guidance for Industry and FDA Staff, eCopy Program for Medical Device Submissions (Dec. 2015).

Title V—Pediatric Drugs and Devices

Section 502, Pediatric Devices

Under section 515A(a)(3) of the FDCA, FDA must submit an annual report to Congress that includes data related to the number of devices approved with a pediatric indication. FDARA requires this report to include additional information, including:

- Any information, based on a review of data available to FDA, regarding devices used off-label in pediatric patients for which FDA determines that approved pediatric labeling could confer a benefit to pediatric patients;
- The number of pediatric devices that receive a humanitarian use exemption under section 520(m) of the FDCA;
- The number of devices for which FDA has relied on data with respect to adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients; and
- The number of devices for which FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.

FDA must also convene a public meeting on development, approval or clearance, and labeling of pediatric medical devices, within a year of enactment. Topics for the meeting include ways to:

- Improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for pediatric populations that would result in the approval or clearance, and labeling, of medical devices for pediatric use;
- Appropriately use extrapolation from data in adult populations or other pediatric subpopulations to support determinations of reasonable assurance of effectiveness;
- Enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling;
- Increase FDA assistance to medical device manufacturers in developing devices that are approved or cleared and labeled for pediatric use; and
- Identify current barriers, and incentives to overcome those barriers, to pediatric device development.

FDA must include a summary of the recommendations raised at the meeting in its annual report to Congress.

This provision of FDARA also amended section 520(m) of the FDCA, relating to humanitarian device exemptions (HDE). The amendment added that use of an HDE device can be approved by “an appropriate local committee,” not only an institutional review committee. In addition, it extended until October 1, 2022, the provision specifying conditions under which HDE devices for pediatric use, and for uses in certain other populations, are not subject to the limitation on cost recovery in section 520(m)(3).

Title VII—Device Inspection and Regulatory Improvements

Section 701. Risk-Based Inspections for Devices

Under amended section 510(h)(2) of the FDCA, FDA must inspect device establishments "in accordance with a risk-based schedule established by the Secretary." Section 510(h) previously required FDA to inspect device establishments every 2 years, but to inspect drug establishments in accordance with a risk-based schedule. Therefore, amended section 510(h) now applies the same risk-based approach to establishing a schedule for device establishment inspections.

In establishing that schedule, FDA must consider the same factors that currently inform the drug establishment inspection schedule: the compliance history of the establishment; the record, history, and nature of recalls linked to the establishment; the inherent risk of the device; and the inspection frequency and history of the establishment. In addition, FDA must consider whether the device establishment participates in international audit programs in which the United States participates.

FDARA section 701 also amends section 809(a)(1) of the FDCA. Under that provision, FDA has been authorized to enter into agreements with foreign governments, and agencies of foreign governments, to recognize their inspection of a foreign drug establishment. This authority is now extended to foreign device establishments.

Section 702. Improvements to Inspections Process for Device Establishments

New section 704(h) of the FDCA adds provisions that are intended to provide additional predictability and transparency to the device establishment inspection process. Specifically, for device establishment inspections that are not for-cause inspections, FDA must review and update its processes and standards "through the adoption of uniform processes and standards," which must provide for:

- Announcing the inspection within a reasonable time before the inspection and providing notice regarding the type and nature of the inspection;
- A reasonable estimate of the timeframe for the inspection and an opportunity for advance communication between the investigator and the establishment concerning working hours during the inspection and, to the extent feasible, advance notice of some records that will be requested;
- Regular communications during the inspection with the establishment regarding inspection status, which may be recorded by either party with notice and mutual consent; and
- Exceptions to the processes and standards, as appropriate.

If the establishment submits a request for feedback with respect to corrective actions in response to inspectional observations (i.e., a Form FDA 483) that "involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues," FDA must provide nonbinding feedback within 45 days.

FDA must issue draft guidance within 18 months of enactment addressing the above requirements. The draft guidance must also establish, for inspections of both domestic and foreign establishments, a standard timeframe for inspections that (1) occur over consecutive days, (2) to which each investigator shall adhere, unless a reason is provided to the

establishment as to why more time is needed, and (3) identifies practices to facilitate the continuity of inspections. FDA must issue final guidance within 1 year of providing an opportunity for comment on the draft guidance.

Section 702 also amends section 501(j) of the FDCA, such that a device is adulterated if the owner or operator of a device establishment delays, denies, or limits and inspection or refuses an inspection. Previously, section 501(j) applied only to drugs.

Section 703. Reauthorization of Inspection Program.

This section reauthorizes the agency's existing accredited third-party inspection program under section 704(g) of the FDCA (the Accredited Persons Inspection Program).[6] The authority for the program was due to sunset on October 1, 2017, and is now extended to October 1, 2022.

Section 704. Certificates to Foreign Governments for Devices

This section amends section 801(e)(4) of the FDCA, governing requests for a certificate to a foreign government (CFG) for an exported product. Under amended section 801(e)(4), if FDA denies a request for CFG for a device manufactured in a registered establishment, FDA must provide a written notice of the basis for the denial and specifically identify the finding upon which the denial is based.

If the denial is (1) based on grounds *other* than an injunction, seizure action, or class I or II recall, and (2) is based on the facility being out of compliance with the quality system regulation (QSR) (e.g., as a result of a Warning Letter), then FDA must provide to the company a substantive summary of the specific grounds for noncompliance supporting the CFG denial. However, FDA may not deny a request for CFG based solely on the issuance of inspectional observations (Form FDA 483) following an establishment inspection, if the establishment has agreed to a plan of correction.

FDA must also provide a process for a person who is denied a CFG to request agency review of the denial as a significant decision under section 517A of the FDCA. A request for supervisory review of a significant decision must be made not later than 30 days after the decision and follow the procedures set forth in section 517A(b). Establishments may request a new review in order to present new information relating to corrective actions that address the issues leading to denial of a CFG. FDA must issue draft guidance on this process within one year of enactment and must issue final guidance within one year of the close of the comment period on the draft guidance.

Section 705. Facilitating International Harmonization

This section amends section 704(g) of the FDCA, governing the accreditation of third parties to conduct inspections of manufacturers of class II and III devices (the Accredited Persons Inspection Program).[7] New section 704(g)(15) of the FDCA authorizes FDA to recognize auditing organizations that are recognized by international harmonization organizations for the

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[6] *See* FDA, Accredited Persons Inspection Program, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm.

[7] FDA, Accredited Persons Inspection Program, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ThirdPartyInspection/ucm125410.htm.

purposes of conducting device establishment inspections, even if the auditing organization does not meet all the statutory criteria for accreditation in section 704(g).

Section 706. Fostering Innovation in Medical Imaging

New section 520(p) of the FDCA addresses premarket review of an "applicable medical imaging device," defined as a device intended to be used in conjunction with a contrast agent (or class of contrast agents) for an imaging use that is not described in the approved labeling of the contrast agent (or the approved labeling of any contrast agent in the same class). FDA may approve a PMA, clear a 510(k) premarket notification, or grant a *de novo* classification request for an applicable medical imaging device that involves the use of a contrast agent that is *not different* from the approved labeling of the contrast agent with respect to: (1) concentration, rate of administration, or route of administration, (2) region, organ or system of the body, (3) patient population, or (4) imaging modality. With respect to the first *three* only, FDA may still approve or clear the device if FDA determines that differences from the approved labeling of the contrast agent do not adversely affect the safety and effectiveness of the contrast agent when used with the device.

New section 520(p)(3) also specifies that a PMA, 510(k) premarket notification, or *de novo* classification request for an applicable medical imaging device "shall only be subject to the requirements of [the FDCA] applicable to devices." CDRH will have primary jurisdiction with respect to the review of these device applications. In conducting its review, CDRH may consult with CDER and CBER, and review information provided to FDA by the sponsor of the contrast agent in the New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologics License Application (BLA), if the device sponsor has a right of reference to the NDA, ANDA, or BLA.

A corresponding new section 505(y) of the FDCA addresses the premarket review of contrast agents for use with an applicable medical imaging device under section 520(p). Under section 505(y) of the FDCA, a sponsor of a contrast agent subject to an approved NDA or ANDA may submit a supplement seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device under section 520(p) for that use. In reviewing the supplement, CDER may consult with CDRH and may review the information submitted in the device submission if the contrast agent sponsor has a right of reference.

Section 707. Risk-based Classification of Accessories

This section builds on section 3055 of the 21st Century Cures Act,[8] which amended section 513(b) of the FDCA to require FDA to classify an accessory device based on the intended use of the accessory, notwithstanding the classification of the parent device. New section 513(f)(6) of the FDCA reiterates that FDA must classify an accessory "based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used."

In December 2016, FDA issued a final guidance document addressing the classification pathway for new accessory device types.[9] Section 707 of FDARA aims to address what some perceived as gaps in this guidance document, including the reclassification of accessory

[8] Public Law 114-255, § 3055, 130 Stat. 1033, 1127 (2016); *see also*

[9] FDA, Guidance for Industry and FDA Staff, *Medical Device Accessories—Describing Accessories and Classification Pathway for New Accessory Types* (Dec. 2016).

devices that are already on the market. New section 513(f)(6) of the FDCA establishes the following new processes for the initial classification and reclassification of accessory devices:[10]

- In cases where FDA has classified an accessory distinctly from another device by regulation or order prior to December 31, 2016, the classification of the accessory shall continue to apply until FDA reclassifies the accessory.
- In cases where the accessory has been included in a pending or future PMA or 510(k) notification for the parent device, and FDA has not classified the accessory separately, the sponsor may include a request for the classification of the accessory at the time the PMA or 510(k) is submitted. FDA's action on the PMA or 510(k) must include a grant or denial of the request for classification of the accessory. That response will constitute an order establishing a new classification for the accessory.
- For accessories that have been granted marketing authorization as part of a PMA, 510(k), or *de novo* classification request for the parent device, a manufacturer or importer of an accessory may submit a written request to FDA for the appropriate classification of the accessory. FDA must provide an opportunity for the manufacturer or importer to meet with FDA. FDA must respond to a classification request within 85 calendar days by issuing a written order classifying the accessory or denying the request. A denial must include a detailed description and justification for the denial. Within 30 days of granting a request, FDA must publish a notice in the Federal Register.
- FDA must publish a proposed list of accessories that have been granted marketing authorization as part of the application for the parent device and that may be suitable for a distinct classification into class I. This list must be published within a year of enactment and at least once every 5 years thereafter. FDA must consider recommendations from sponsors of device submissions and other stakeholders with regard to what accessories would be suitable for inclusion on this list.

Section 708. Device Pilot Projects

New section 519(i) of the FDCA requires FDA to initiate postmarket pilot projects for voluntary participation by device manufacturers, or continue existing projects, that:

- Are designed to efficiently generate reliable and timely safety and active surveillance data for use by FDA or manufacturers who participate;
- Inform the development of methods, systems, criteria, and programs that could be used to support safety and active surveillance activities for devices included or not included in the project;
- May be designed and conducted in coordination with a comprehensive system for evaluating device technology that operate under a governing board with appropriate stakeholder representation;
- Use electronic health data, including claims data, patient survey data, or other appropriate data; and

[10] Section 513(f)(6)(E) provides that sponsors of an accessory of a new type can still elect to use the existing classification process described in section 513(f)(2).

- Prioritize devices and device types that meet one or more of the following criteria: (1) for which the collection of real world evidence (RWE) is likely to advance public health, (2) that are widely used, or (3) the failure of which has significant health consequences.

Section 519(i) also requires FDA to establish the conditions and processes under which a manufacturer may voluntarily participate, and for facilitating public recommendations for devices to be prioritized under the pilot. FDA may carry out a pilot project by entering into contracts, grants, or other agreements with public or private entities that meet certain conditions.

Within 18 months of enactment, and annually thereafter, FDA must submit a report to Congress containing a description of the pilot projects being conducted, including how the project is being implemented, the number of participating manufacturers, the data sources used to conduct the project, the device or device types involved in the project, and the findings of the project in relation to device safety. The authority for the pilot projects sunsets on October 1, 2022.

By January 31, 2021, FDA must conduct a review, through an independent third party, to evaluate the strengths, limitations, and appropriate use of evidence collected pursuant to RWE pilot projects in the MDUFA performance goals letter for informing premarket and postmarket decision making for multiple device types, and to determine whether the pilot programs efficiently generate reliable and timely evidence about the effectiveness and safety of devices.

This provision is likely intended, in part, as a statutory requirement for FDA to carry out those pilot projects to which the agency committed in the corresponding MDUFA performance goals.[11] In the MDUFA performance goals, FDA committed to contract with an organization to serve as the National Evaluation System for health Technology (NEST) Coordinating Center to facilitate use of RWE to support premarket activities.[12]

Section 709. Regulation of Over-the-Counter Hearing Aids.

New section 520(q) of the FDCA requires FDA to establish a category of over-the-counter (OTC) hearing aids for adults with mild to moderate hearing impairment. The new provision is intended to lower the cost and expand the availability of these devices for consumers, consistent with recommendations in reports from both the Institute of Medicine (now the National Academies of Science, Engineering, and Medicine)[13] and the former President's Council of Advisors on Science and Technology (PCAST).[14]

Pursuant to FDARA section 709(b), FDA must issue proposed regulations to establish a category of OTC hearing aids, as defined by the regulation, within 3 years of enactment. FDA

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[11] FDA, MDUFA Performance Goals and Procedures, Fiscal years 2018 Through 2022, https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.

[12] *Id.* at 17-18.

[13] Committee on Accessible and Affordable hearing Health Care for Adults, National Academies of Sciences, Engineering, Medicine, *Hearing Health Care for Adults; Priorities for Improving Access and Affordability* (2016), *available at* https://www.nap.edu/read/23446/chapter/1#viii.

[14] PCAST, *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies* (Oct. 2015), *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.

must issue final regulations within 180 days after the public comment period on the proposed rule closes. The regulations must:

- Include requirements that provide reasonable assurance of the safety and effectiveness of OTC hearing aids;
- Include requirements that establish or adopt output limits appropriate for OTC hearing aids;
- Include requirements for appropriate labeling of OTC hearing aids, including requirements that such labeling include a conspicuous statement that the device is only intended for adults age 18 and older, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed health care practitioner; and
- Describe the requirements under which the sale of OTC hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers by in-person transactions, by mail, or online.

FDA must issue findings under section 510(m) of the FDCA to determine whether OTC hearing aids, as defined by section 520(q), require a 510(k) premarket notification to provide reasonable assurance of safety and effectiveness.

State or local governments are prohibited from establishing or continuing to have in effect any law, regulation, order, or other requirement related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids, through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to the regulations FDA issues under section 520(q).

FDA must update and finalize the draft guidance document "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," issued in 2013, no later than the date on which FDA issues the final rule required under section 520(q). The updated and finalized guidance document must clarify which products meet the statutory definition of a device and which products meet the definition of a "personal sound amplification product" (PSAP), which are currently not subject to regulation as devices under the guidance document.

Finally, within 2 years after the date on which FDA issues the final rule, FDA must submit a report to Congress that analyzes any adverse events relating to OTC hearing aids.

Section 710. Report on Servicing of Devices

Under FDARA section 710, within 270 days of enactment, FDA must post on its website a report "on the continued quality, safety, and effectiveness of devices . . . with respect to servicing." Servicing is defined to include "refurbishing, reconditioning, rebuilding, remarketing, repairing, remanufacturing, or other servicing of the device." It includes activities by both original equipment manufacturers and third-parties.

Device refurbishers and servicers are not currently subject to the agency's Quality System Regulation or other regulatory requirements. The appropriate FDA oversight of device servicing activities has been the subject of much recent discussion. In March 2016, FDA issued *Federal Register* notice seeking comments regarding the "service, maintenance, refurbishment, and alteration of medical devices . . . by third-party entities," including "the challenges third-party

entities face in maintaining or restoring devices to their original or current specifications."[15] FDA stated it was seeking comments, in part, because various stakeholders have expressed concerns about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities that are performed by both original equipment manufacturers (OEM) and third parties."[16] In October 2016, FDA held a public workshop on the same topics raised by the request for comments.[17]

The report required under FDARA builds on these activities and must address:

- The status of, and findings to date, with respect to the agency's March 2016 request for comments;
- Information presented during the October 2016 public workshop;
- A description of the statutory and regulatory authority of FDA with respect to the servicing of devices;
- Details regarding how FDA currently regulates devices with respect to servicing "to ensure safety and effectiveness," how the agency could improve such regulation, and whether additional authority is recommended;
- Information on actions FDA could take to assess the servicing of devices, including the size, scope, location and composition of third-party entities;
- Information on actions FDA could take to track adverse events caused by servicing errors; and
- Information regarding the regulation by States, the Joint Commission, or other regulatory bodies of device servicing.

The report leaves the agency with the discretion as to whether and how to regulate the activities of device servicers, unlike certain proposed bills and proposed amendments to the legislation. For example, the Medical Device Servicing Safety and Accountability Act, H.R. 2118, introduced in April 2017, would have required FDA to issue regulations requiring servicers to register with FDA, establish a complaint handling system, and submit medical device reports.

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[15] FDA, Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments, 81 Fed. Reg. 11477 (Mar. 4, 2016).

[16] *Id.* at 11478.

[17] FDA, Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Public Workshop, 81 Fed. Reg. 46694 (July 18, 2016).

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