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## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

### 31 CFR Part 560

### Iranian Transactions and Sanctions Regulations

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Final rule.

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**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending the Iranian Transactions and Sanctions Regulations (ITSR) to reflect OFAC's licensing policies and address inquiries from the regulated public. This final rule makes changes relating to authorized sales of agricultural commodities, medicine, and medical devices to Iran pursuant to the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA), as amended, and clarifies the definition of the terms goods of Iranian origin and Iranian-origin goods.

**DATES:** Effective: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202-622-2480, Assistant Director for Regulatory Affairs, tel.: 202-622-4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202-622-2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202-622-2410.

**SUPPLEMENTARY INFORMATION:**

**Electronic Availability**

This document and additional information concerning OFAC are available from OFAC's website ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)).

## **Background**

### **TSRA Amendments**

OFAC first issued regulations to implement TSRA (22 U.S.C. 7201 et seq.) on July 12, 2001 (66 FR 36683). Since then, OFAC has amended the licensing provisions of the ITSR (and its predecessor, the Iranian Transactions Regulations), 31 CFR part 560, as they relate to the exportation and reexportation of agricultural commodities, medicine, or medical devices to Iran on a number of occasions. As set forth in more detail below, OFAC is adopting a final rule to amend the licensing provisions of the ITSR to expand the scope of medical devices and agricultural commodities generally authorized for export or reexport to Iran and, in response to feedback from the regulated public regarding improving patient safety, provide new or expanded authorizations relating to training, replacement parts, software and services related to the operation, maintenance, and repair of medical devices, and items that are broken or connected to product recalls or other safety concerns.

### **Statutory Background**

TSRA provides that, with certain exceptions, the President may not impose a unilateral agricultural sanction or unilateral medical sanction against a foreign country or foreign entity unless, at least 60 days before imposing such a

sanction, the President submits a report to Congress describing the proposed sanction and the reasons for it and Congress enacts a joint resolution approving the report. See 22 U.S.C. 7202. Section 906 of TSRA, however, requires in pertinent part that the export of agricultural commodities, medicine, or medical devices to the government of a country that has been determined by the Secretary of State, pursuant to, inter alia, Section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), to have repeatedly provided support for acts of international terrorism,<sup>1</sup> or to any entity in such a country, shall be made pursuant to one-year licenses issued by the United States Government, except that the requirements of such one-year licenses shall be no more restrictive than general licenses administered by the Department of the Treasury. See 22 U.S.C. 7205(a)(1). Section 906 also specifies that procedures shall be in place to deny licenses for exports of agricultural commodities, medicine, or medical devices to any entity within such country promoting international terrorism.

As provided in Section 221 of the USA PATRIOT Act (Pub. L. 107-56) (codified at 22 U.S.C. 7210), nothing in TSRA shall limit the application or scope of any law, including any Executive order or regulation promulgated pursuant to such law, establishing criminal or civil penalties for the unlawful export of any agricultural commodity, medicine, or medical device to: a Foreign Terrorist Organization; a foreign organization, group, or person designated pursuant to Executive Orders 12947 or 13224 (sanctions on terrorists and certain supporters

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<sup>1</sup> The Secretary of State made such a determination with respect to Iran on January 19, 1984.

of terrorism); weapons of mass destruction or missile proliferators; or designated narcotics trafficking entities. In addition, TSRA provides in Section 904(2) that the restrictions on the imposition of unilateral agricultural sanctions or unilateral medical sanctions shall not affect any authority or requirement to impose a sanction to the extent such sanction applies to any agricultural commodity, medicine, or medical device that is controlled on the United States Munitions List (USML), controlled on any control list established under the Export Administration Act of 1979 or any successor statute, or used to facilitate the design, development, or production of chemical or biological weapons, missiles, or weapons of mass destruction. See 22 U.S.C. 7203(2).

#### Specific TSRA-Related Regulatory Amendments

On October 22, 2012, OFAC adopted a final rule that, among other things, added a general license in § 560.530(a)(3) of the ITSR that authorized the exportation or reexportation of medicine and basic medical supplies to the Government of Iran, to individuals or entities in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions (see 77 FR 64664). The term “basic medical supplies” was defined to mean those medical devices, as defined in the ITSR, that were included on the List of Basic Medical Supplies made available on OFAC’s website and published in the Federal Register, but did not include replacement parts. On April 17, 2014, OFAC adopted a final rule that, among other things,

updated the definition of “basic medical supplies” to exclude the word “basic” and make related conforming changes, including renaming the list on OFAC’s website as the “List of Medical Supplies” (see 79 FR 18990). On November 2, 2015 and April 12, 2016, OFAC updated the List of Medical Supplies to add additional medical devices to the list.

Also on April 17, 2014, OFAC expanded an existing general license in § 560.530(a)(2) that authorized the exportation and reexportation of food to authorize the exportation or reexportation of the broader category of agricultural commodities, with certain specified exceptions, to the Government of Iran, to individuals or entities in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions (see 79 FR 18980). OFAC also added a general license in § 560.530(a)(4) authorizing the exportation or reexportation of replacement parts for certain medical devices, provided that the replacement parts are designated as EAR99 or, in the case of replacement parts that are not subject to the EAR, would be designated as EAR99 if they were located in the United States, and further provided that the replacement parts are limited to a one-for-one basis of exchange (i.e., only one replacement part can be exported or reexported to replace a broken or non-operational component).

Since these amendments, in consultation with the Department of State, OFAC has routinely issued specific licenses authorizing the exportation or

reexportation of certain additional medical devices and agricultural commodities to the Government of Iran, to individuals or entities in Iran, or to persons in third countries purchasing such goods specifically for resale to any of the foregoing. In addition, OFAC has continued to receive feedback from the regulated public and review its TSRA licensing procedures, particularly the procedures for licensing exports and reexports of medical devices and agricultural commodities.

As a result of this review, OFAC today is amending the general license relating to authorized sales of certain medical devices in § 560.530(a)(3) to expand the scope of medical devices that may be exported or reexported to Iran without specific authorization. OFAC is also narrowing the list of agricultural commodities excluded from the general license relating to authorized sales of agricultural commodities in § 560.530(a)(2). In addition, in response to feedback from the regulated public regarding improving patient safety, OFAC is making the following changes: expanding existing general licenses to authorize the provision of training for the safe and effective use or operation of agricultural commodities, medicine, and medical devices; expanding an existing general license authorizing the exportation or reexportation to Iran of replacement parts to permit certain additional replacement parts to be exported or reexported and stored for future use; adding a new general license to authorize the exportation and reexportation to Iran of software and services related to the operation, maintenance, and repair of medical devices previously exported pursuant to an OFAC authorization; and adding a new general license to authorize the

importation into the United States of items previously exported pursuant to an OFAC authorization in connection with product recalls, adverse events, or other safety concerns, as set forth in more detail below.

Additional medical devices. OFAC is amending the existing general license in § 560.530(a)(3) relating to authorized exports or reexports of certain medical devices specified on the List of Medical Supplies. As amended, the general license has been expanded to authorize the exportation or reexportation to Iran of all items meeting the definition of the term “medical device” as set forth in § 560.530(e)(3), except for certain medical devices that are explicitly excluded from the authorization as specified in a new List of Medical Devices Requiring Specific Authorization, which is maintained on OFAC’s website on the Iran Sanctions page, as set forth in revised § 560.530(a)(3)(ii). The List of Medical Devices Requiring Specific Authorization will also be published in the Federal Register, as will any changes to this list. The exportation and reexportation of the specified excluded medical devices requires specific authorization from OFAC, as reflected in amended § 560.530(a)(1)(ii)(C). Medical devices other than those specified on the new List of Medical Devices Requiring Specific Authorization may be exported or reexported to Iran without separate authorization from OFAC. In light of these changes, this rule also eliminates reference to the List of Medical Supplies.

Excluded agricultural commodities. OFAC is also narrowing the list of excluded agricultural commodities set forth in § 560.530(a)(2)(ii). Pursuant to this amendment, the general license in § 560.530(a)(2) now authorizes the exportation or reexportation to Iran of shrimp and shrimp eggs.

Training. OFAC is adding a new provision in § 560.530(a)(2)(iv) to generally authorize the provision of training necessary and ordinarily incident to the safe and effective use of agricultural commodities exported or reexported pursuant to the general license in § 560.530(a)(2). OFAC similarly is adding a new provision in § 560.530(a)(3)(v) to authorize the provision of training necessary and ordinarily incident to the safe and effective use or operation of medicine and medical devices exported or reexported pursuant to the general license in § 560.530(a)(3).

Additional replacement parts. OFAC is amending the existing general license in § 560.530(a)(4) authorizing exports or reexports of and related transactions for replacement parts for certain medical devices that are designated as EAR99 or, in the case of replacement parts that are not subject to the EAR, would be designated as EAR99 if they were located in the United States, on a one-for-one export or reexport basis of exchange. As amended, the general license removes the requirement for a one-for-one basis of exchange and allows the exportation and reexportation of such replacement parts provided that they are intended to replace a broken or nonoperational component of a medical device

previously exported or reexported to Iran pursuant to an OFAC authorization or that the exportation or reexportation of the replacement part is ordinarily incident and necessary to the proper preventative maintenance of such a medical device, and further provided that the number of replacement parts that are exported or reexported to and stored in Iran does not exceed the number of corresponding parts in use in relevant medical devices in Iran.

Software and services related to the operation, maintenance, and repair of medical devices. OFAC is adding a new general license in § 560.530(a)(5) to authorize the exportation or reexportation to Iran of software and services related to the operation, maintenance, and repair of medical devices that previously were exported or reexported to Iran pursuant to an OFAC authorization, provided that, among other things, such software is designated as EAR99, or in the case of software that is not subject to the EAR, would be designated as EAR99 if it were located in the United States . In § 560.530(a)(5)(i), OFAC is adding an authorization for the exportation or reexportation to Iran of software necessary for the installation and operation of medical devices authorized for export or reexport by OFAC. In § 560.530(a)(5)(ii), OFAC is adding an authorization to allow the exportation or reexportation of software updates for those devices. In § 560.530(a)(5)(iii), OFAC is adding an authorization for repair services for medical devices authorized for export or reexport to Iran by OFAC, including inspection, testing, calibration, and diagnostic services to ensure patient safety or effective operation of such medical devices.

Importation of items that are broken, defective, or non-operational or in connection with product recalls, adverse events, or other safety concerns. OFAC also is adding a new general license in § 560.530(a)(6) to authorize the importation into the United States of certain U.S.-origin agricultural commodities, medicine, and medical devices that previously were exported or reexported to Iran pursuant to the authorization in § 560.530 and that are broken, defective, or non-operational or connected to product recalls, adverse events, or other safety concerns.

Conforming change to section headings. In light of the addition of several new general licenses in § 560.530, OFAC is also making a conforming change to the section heading to reflect the additions. As the new general licenses require the payment and financing terms set forth in § 560.532, OFAC is making a similar conforming change to that section heading to reflect the additions.

### **Amendment to Definition of “Goods of Iranian Origin” and “Iranian-Origin Goods”**

To address inquiries from the regulated public, including with regard to the status of goods on vessels and aircraft, OFAC also is amending the definition in § 560.306 of the terms goods of Iranian origin and Iranian-origin goods to clarify that this definition does not include certain categories of goods, provided

that such goods were not grown, produced, manufactured, extracted, or processed in Iran. First, the amended definition excludes goods exported or reexported to Iran under an authorization issued pursuant to this part (e.g., a medical device or a personal communications device exported or reexported to Iran pursuant to a general or specific license issued pursuant to this part) and that have subsequently been reexported from and are located outside of Iran. Second, the amended definition also clarifies that it does not include goods transported on a vessel or aircraft, as well as the underlying vessel or aircraft itself, that passed through Iranian territorial waters or stopped at a port or place in Iran en route to a destination outside of Iran and that have not otherwise come into contact with Iran. A note clarifies that, pursuant to this section, goods that are temporarily offloaded from a vessel in Iranian territorial waters or at a port in Iran and reloaded onto the same vessel or another vessel in the same location en route to a destination outside of Iran and that have not otherwise come into contact with Iran are not considered goods of Iranian origin. Similarly, goods that are offloaded from an aircraft at a place in Iran and reloaded onto the same aircraft or another aircraft in the same location en route to a destination outside of Iran and that have not otherwise come into contact with Iran are not considered goods of Iranian origin. This amended definition is relevant to the prohibitions in §§ 560.201 and 560.206 of the ITSR, which remain in place; it is not relevant to the prohibitions in §§ 560.204, 560.205, and 560.211 on exports of goods to Iran and on transactions in goods involving blocked persons, which also remain in place.

## **Public Participation**

Because the amendment of the ITSR involves a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601-612) does not apply.

## **Paperwork Reduction Act**

The collections of information related to the ITSR are contained in 31 CFR part 501 (the Reporting, Procedures and Penalties Regulations). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505-0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

## **List of Subjects in 31 CFR Part 560**

Administrative practice and procedure, Agricultural commodities, Banks, Banking, Iran, Medicine, Medical devices.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control amends 31 CFR part 560 as follows:

**PART 560 – IRANIAN TRANSACTIONS AND SANCTIONS  
REGULATIONS**

1. The authority citation for part 560 continues to read as follows:

**Authority:** 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 2349aa-9; 22 U.S.C. 7201-7211; 31 U.S.C. 321(b); 50 U.S.C. 1601-1651, 1701-1706; Pub. L. 101-410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110-96, 121 Stat. 1011 (50 U.S.C. 1705 note); Pub. L. 111-195, 124 Stat. 1312 (22 U.S.C. 8501-8551); Pub. L. 112-81, 125 Stat. 1298 (22 U.S.C. 8513a); Pub. L. 112-158, 126 Stat. 1214 (22 U.S.C. 8701-8795); E.O. 12613, 52 FR 41940, 3 CFR, 1987 Comp., p. 256; E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 12959, 60 FR 24757, 3 CFR, 1995 Comp., p. 356; E.O. 13059, 62 FR 44531, 3 CFR, 1997 Comp., p. 217; E.O. 13599, 77 FR 6659, 3 CFR, 2012 Comp., p. 215; E.O. 13628, 77 FR 62139, 3 CFR, 2012 Comp., p. 314.

**Subpart C—General Definitions**

2. Amend § 560.306 by revising paragraph (a), redesignating paragraphs (b) through (d) as paragraphs (c) through (e), and adding new paragraph (b) to read as follows:

**§ 560.306 Iranian-origin goods or services; goods or services owned or controlled by the Government of Iran.**

(a) Except as provided in paragraph (b) of this section, the terms goods of Iranian origin and Iranian-origin goods include:

(1) Goods grown, produced, manufactured, extracted, or processed in Iran;  
and

(2) Goods that have entered into Iranian commerce.

(b) The terms goods of Iranian origin and Iranian-origin goods do not include the following categories of goods, provided that such goods were not grown, produced, manufactured, extracted, or processed in Iran:

(1) Goods exported or reexported to Iran under an authorization issued pursuant to this part and that have subsequently been reexported from and are located outside of Iran; or

(2) Goods transported on a vessel or aircraft, as well as the vessel or aircraft itself, that passed through Iranian territorial waters or stopped at a port or place in Iran en route to a destination outside of Iran and that have not otherwise come into contact with Iran.

**Note to paragraph (b)(2) of § 560.306:** Pursuant to this section, goods that are temporarily offloaded from a vessel in Iranian territorial waters or at a port or place in Iran and reloaded onto the same vessel or another vessel in the same location en route to a destination outside of Iran and that have not otherwise come into contact with Iran are not considered goods of Iranian origin. Similarly, goods that are offloaded from an aircraft at a place in Iran and reloaded onto the same aircraft or another aircraft in the same location en route to a destination outside of Iran and that have not otherwise come into contact with Iran are not considered goods of Iranian origin.

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### **Subpart E—Licenses, Authorizations, and Statements of Licensing Policy**

3. Amend § 560.530 as follows:

- a. Revise the section heading and paragraphs (a)(1)(ii)(C) and (D) and (a)(2)(ii) and (iii);
- b. Add paragraph (a)(2)(iv);

- c. Revise paragraphs (a)(3)(i), (ii), and (iv);
- d. Add paragraph (a)(3)(v);
- e. Revise paragraphs (a)(4)(i) and (ii);
- f. Add paragraphs (a)(5) and (6); and
- g. Revise paragraph (c)(5).

The revisions and additions read as follows:

**§ 560.530 Commercial sales, exportation, and reexportation of agricultural commodities, medicine, medical devices, and certain related software and services.**

(a)(1) \* \* \*

(ii) \* \* \*

(C) The excluded medical devices specified in paragraph (a)(3)(ii) of this section; and

(D) Agricultural commodities (as defined in paragraph (e)(1) of this section), medicine (as defined in paragraph (e)(2) of this section), and medical devices (as defined in paragraph (e)(3) of this section) to military, intelligence, or law enforcement purchasers or importers.

(2) \* \* \*

(ii) Excluded agricultural commodities. Paragraph (a)(2)(i) of this section does not authorize the exportation or reexportation of the following items: castor beans, castor bean seeds, certified pathogen-free eggs (unfertilized or fertilized), dried egg albumin, live animals (excluding live cattle, shrimp, and shrimp eggs), embryos (excluding cattle embryos), Rosary/Jequirity peas, non-food-grade gelatin powder, peptones and their derivatives, super absorbent polymers, western red cedar, or all fertilizers.

(iii) Excluded persons. Paragraph (a)(2)(i) of this section does not authorize the exportation or reexportation of agricultural commodities to military, intelligence, or law enforcement purchasers or importers.

(iv) General license for related training. The provision by a covered person (as defined in paragraph (e)(4) of this section) of training necessary and ordinarily incident to the safe and effective use of agricultural commodities exported or reexported pursuant to paragraph (a)(2) of this section to the Government of Iran, to any individual or entity in Iran, or to persons in a third country purchasing such goods specifically for resale to any of the foregoing is authorized, provided that:

(A) Unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532;

(B) Any technology released pursuant to this authorization is designated as EAR99; and

(C) Such training is not provided to any military, intelligence, or law enforcement entity, or any official or agent thereof.

\* \* \* \* \*

(3)(i) General license for the exportation or reexportation of medicine and medical devices. Except as provided in paragraphs (a)(3)(ii) through (iv) of this section, the exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) of medicine (as defined in paragraph (e)(2) of this section) and medical devices (as defined in paragraph (e)(3) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, and the conduct of related transactions, including the making of shipping and cargo inspection arrangements, obtaining of insurance, arrangement of financing and payment, shipping of the goods, receipt of payment, and entry into contracts (including executory contracts), are hereby authorized, provided that, unless

otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532; and further provided that all such exports or reexports are shipped within the 12-month period beginning on the date of the signing of the contract for export or reexport.

(ii) Excluded medical devices. Paragraph (a)(3)(i) of this section does not authorize the exportation or reexportation of medical devices on the List of Medical Devices Requiring Specific Authorization, which is maintained on OFAC's website ([www.treasury.gov/ofac](http://www.treasury.gov/ofac)) on the Iran Sanctions page.

\* \* \* \* \*

(iv) Excluded persons. Paragraph (a)(3)(i) of this section does not authorize the exportation or reexportation of medicine or medical devices to military, intelligence, or law enforcement purchasers or importers.

(v) General license for related training. The provision by a covered person (as defined in paragraph (e)(4) of this section) of training necessary and ordinarily incident to the safe and effective use of medicine and medical devices exported or reexported pursuant to paragraph (a)(3) of this section to the Government of Iran, to any individual or entity in Iran, or to persons in a third country purchasing such goods specifically for resale to any of the foregoing is authorized, provided that:

(A) Unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532;

(B) Any technology released pursuant to this authorization is designated as EAR99; and

(C) Such training is not provided to any military, intelligence, or law enforcement entity, or any official or agent thereof.

\* \* \* \* \*

(4) \* \* \*

(i) Except as provided in paragraph (a)(4)(ii) of this section, the exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) of replacement parts to the Government of Iran, to any individual or entity in Iran, or to persons in third countries purchasing specifically for resale to any of the foregoing, for medical devices (as defined in paragraph (e)(3) of this section) exported or reexported pursuant to paragraph (a)(1) or (a)(3)(i) of this section, and the conduct of related transactions, including the making of shipping and cargo inspection arrangements, obtaining of insurance, arrangement of financing and payment, shipping of the goods, receipt of payment, and entry into

contracts (including executory contracts), are hereby authorized, provided that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532; and further provided that:

(A) Such replacement parts are designated as EAR99, or, in the case of replacement parts that are not subject to the Export Administration Regulations, 15 CFR parts 730 through 774 (EAR), would be designated as EAR99 if they were located in the United States;

(B) Such replacement parts are exported or reexported to replace a broken or nonoperational component of a medical device that previously was exported or reexported pursuant to paragraph (a)(3)(i) of this section, or the exportation or reexportation of such replacement parts is necessary and ordinarily incident to the proper preventative maintenance of such a medical device;

(C) The number of replacement parts that are exported or reexported and stored in Iran does not exceed the number of corresponding operational parts currently in use in relevant medical devices in Iran; and

(D) The broken or non-operational replacement parts that are being replaced are promptly exported, reexported, or otherwise provided to a non-

Iranian entity located outside of Iran selected by the supplier of the replacement parts.

(ii) Excluded persons. Paragraph (a)(4)(i) of this section does not authorize the exportation or reexportation of replacement parts for medical devices to military, intelligence, or law enforcement purchasers or importers.

\* \* \* \* \*

(5) General license for services and software necessary for the operation, maintenance, and repair of medical devices--(i) Operational software. Except as provided in paragraph (a)(5)(iv) of this section, the exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in a third country purchasing specifically for resale to any of the foregoing, of software necessary for the installation and operation of medical devices or replacement parts exported or reexported pursuant to this section, and the conduct of related transactions, are hereby authorized, provided that such software is designated as EAR99, or in the case of software that is not subject to the EAR, would be designated as EAR99 if it were located in the United States, and further provided that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532.

(ii) Software updates. Except as provided in paragraph (a)(5)(iv) of this section, the exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in a third country purchasing specifically for resale to any of the foregoing, of software intended for and limited to the provision of safety and service updates and the correction of system or operational errors in medical devices, replacement parts, and associated software that previously were exported, reexported, or provided pursuant to this part, and the conduct of related transactions, are hereby authorized, provided that such software is designated as EAR99, or in the case of software that is not subject to the EAR, would be designated as EAR99 if it were located in the United States, and further provided that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532. Such software updates may be exported or reexported only to the same end user to whom the original software was exported or reexported.

(iii) Maintenance and Repair Services. Except as provided in paragraph (a)(5)(iv) of this section, the exportation or reexportation by a covered person (as defined in paragraph (e)(4) of this section) to the Government of Iran, to any individual or entity in Iran, or to persons in a third country purchasing specifically for resale to any of the foregoing, of services necessary to maintain and repair

medical devices that previously were exported or reexported pursuant to this section, including inspection, testing, calibration, or repair services to ensure patient safety or effective operation, and the conduct of related transactions, are hereby authorized, provided that such services do not substantively alter the functional capacities of the medical device as originally authorized for export or reexport, and further provided that, unless otherwise authorized by specific license, payment terms and financing for sales pursuant to this general license are limited to, and consistent with, those authorized by § 560.532.

(iv) Excluded persons. Paragraphs (a)(5)(i) through (iii) of this section do not authorize the exportation or reexportation of software, software updates, or maintenance and repair services for medical devices to military, intelligence, or law enforcement purchasers or importers.

(6)(i) General license for the importation of certain U.S.-origin agricultural commodities, medicine, and medical devices. Except as provided in paragraph (a)(6)(ii) of this section, the importation into the United States of U.S.-origin agricultural commodities, medicine, and medical devices, including parts, components, or accessories thereof, that previously were exported or reexported pursuant to the authorizations in this section and that are broken, defective, or non-operational, or are connected to product recalls, adverse events, or other safety concerns, and the conduct of related transactions, are hereby authorized.

(ii) Excluded persons. Paragraph (a)(6)(i) of this section does not authorize the importation into the United States of U.S.-origin agricultural commodities, medicine, and medical devices that previously were exported or reexported pursuant to the authorizations in this section as broken, defective, or non-operational, or in connection with product recalls, adverse events, or other safety concerns, from military, intelligence, or law enforcement purchasers or importers.

\* \* \* \* \*

(c) \* \* \*

(5) For items subject to the EAR, an Official Commodity Classification of EAR99 issued by the Department of Commerce's Bureau of Industry and Security (BIS), certifying that the product is designated as EAR99, is required to be submitted to OFAC with the request for a license authorizing the exportation or reexportation of all fertilizers, live horses, western red cedar, or the excluded medical devices specified in paragraph (a)(3)(ii) of this section. See 15 CFR 748.3 for instructions for obtaining an Official Commodity Classification of EAR99 from BIS.

\* \* \* \* \*

4. Amend § 560.532 by revising the section heading to read as follows:

**§ 560.532 Payment for and financing of exports and reexports of agricultural commodities, medicine, and medical devices, and certain related software and services.**

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John E. Smith,  
Acting Director, Office of Foreign Assets Control.

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