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International Trade & Regulatory ADVISORY ■

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OFAC Eases Restrictions on Medical and Agricultural Exports to Iran

On December 23, 2016, the Treasury Department's Office of Foreign Assets Control (OFAC) issued a final rule amending the Iranian Transactions and Sanctions Regulations (ITSR) to expand the scope of permissible exports and reexports of medicine, medical devices and agricultural commodities to Iran and clarify the terms "Iranian origin" and "Iranian-origin goods." The Final Rule significantly expands the scope of the general license for medical devices to Iran, authorizing manufacturers to export **all** medical devices satisfying the definition in the Federal Food, Drug, and Cosmetic Act (FFDCA) that are also designated EAR99 or would be if located in the United States with the exception of certain devices appearing on a special exclusion list.

Expanded General License for Medical Devices

Since October 2012, OFAC has provided a general license for the exportation or reexportation of certain listed medical devices to Iran. The Final Rule expands the general license to authorize medical device manufacturers to export all medical devices that fall within the definition of "device" in Section 201 of the FFDCA and are designated as EAR99, or in the case of an item not subject to the Export Administration Regulations (EAR), would be designated EAR99 if located in the United States, provided that the item is not on the List of Medical Devices Requiring Specific Authorization. The conduct of related transactions is also authorized to the extent payment terms and financing are consistent with Section 560.532; however, military, intelligence and law enforcement end-users remain prohibited.

Companies should review the special exclusion list to determine if their medical devices appear on that list since such items are not authorized by the general license and specific authorization from OFAC is required. Importantly, in addition to the listed items, the List of Medical Devices Requiring Specific Authorization contains a note excluding from the general license any item: (1) "within the scope of the Statement of Understanding – medical equipment at Supplement No. 3 to Part 774 of the [EAR]"; or (2) "excluded from an otherwise applicable Export Control Classification Number (ECCN) on the Commerce Control List of the EAR because it is medical equipment, or because it is designed or modified for medical equipment or medical purposes," and therefore does "not qualify for exportation to Iran under section 560.530(a)(3)(i) of the [ITSR]."

Eased Restrictions on Medical Device Training and Maintenance and Repair

In addition to expanding the list of medical devices authorized for export or reexport to Iran, OFAC added a new license authorizing training "necessary and ordinarily incident to the safe and effective use or operation of medicine and medical devices exported or reexported" under the medical device general license as well as a license for maintenance and repair activities. The general licenses for training and maintenance and repair do not authorize the provision of any services or goods to military, intelligence or law enforcement entities and persons.

New general license for medical device training

OFAC issued Frequently Asked Question (FAQ) 484, which provides a nonexhaustive list of training activities that OFAC considers "necessary and ordinarily incident to" the safe and effective use or operation of medicine and medical devices under the new general license:

- Dissemination of product information on the intended use of the device.
- Comparisons of other devices and options.
- Manufacturer's instructions for use, labeling, warning, contraindications, storage and maintenance of the medicine or device to be necessary and ordinarily incident to the safe and effective use of medicines and medical devices.
- Training of health care professionals to use medical devices safely in order to achieve the desired patient outcome.
- Training on procedures for cleaning and inspecting devices regularly to ensure that they are functioning correctly.
- Ongoing training and periodic testing to ensure that users stay competent.
- Training on procedures for adverse events or device failure.

Expanded general license for replacement parts for medical devices

The Final Rule also expands the general license at ITSR § 560.530(a)(4) for replacement parts by eliminating the one-for-one exchange requirement. The general license now authorizes the export or reexport of replacement parts for storage for later use, as well as related transactions, provided that the replacement parts are intended to replace a broken or nonoperational component or "ordinarily incident and necessary" to proper preventive maintenance of a medical device previously exported or reexported to Iran pursuant to an OFAC authorization and 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 the relevant medical devices in Iran. In addition, the replacement parts must be designated EAR99, or in the case of replacement parts not subject to the EAR, would be designated EAR99 if located in the United States.

New general license for software and services related to the operation, maintenance and repair of medical devices

OFAC also added a new general license at ITSR § 560.530(a)(5) to authorize the exportation or reexportation to Iran of software and services necessary to the operation, maintenance and repair of medical devices and replacement parts that were previously exported or reexported to Iran. As with the other general licenses related to medical devices, the software must be designated EAR99, or in the case of software that is not subject to the EAR, would be designated EAR99 if it were located in the United States. The export and reexport of software updates for those devices is also authorized. In addition, the license authorizes the provision of repair services for medical devices authorized for export or reexport to Iran to ensure patient safety and effective operation of those devices.

Eased Restrictions on Agricultural Commodities

The Final Rule also eases restrictions on certain agricultural commodities and generally authorizes training for agricultural commodities exported pursuant to the general license. Pursuant to the Final Rule, the general license in Section 560.530(a)(2) now authorizes the exportation or reexportation to Iran of shrimp and shrimp eggs. In addition, OFAC added a new provision in Section 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 to the general license for agricultural commodities.

New General License for U.S. Imports of U.S.-origin Agricultural Products, Medicine and Medical Devices

OFAC also added a new general license to authorize the import into the United States of U.S.-origin agricultural products, medicine and medicinal devices, including parts, components and accessories that were exported or reexported under OFAC authorization, and are broken, defective or nonoperational, or are connected to product recalls, adverse events or other safety concerns, and related transactions. No imports are permitted from any Iranian military, intelligence or law enforcement purchasers or importers.

Clarifications to Definitions of "Iranian Origin" and "Iranian-Origin Goods"

Finally, the Final Rule attempts to clarify the terms "Iranian Origin" and "Iranian-Origin Goods" contained in Section 560.306, particularly for the status of goods on vessels and aircraft. Pursuant to these revised definitions, "Iranian origin" and "Iranian-origin goods" do not include the following categories:

- Goods exported or reexported to Iran pursuant to the ITSR that are subsequently reexported from and are located outside Iran.
- Goods transported on a vessel or aircraft that have not come into contact with Iran other than passing though Iranian territorial waters or stopping in Iran en route to another country outside of Iran.

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