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U.S. Treasury Department Amends Iran Regulations, Including Issuing New and Expanded General Licenses for Medicine, Medical Devices, and Agricultural Commodities

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International Trade Controls

The U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC") recently amended the Iranian Transactions and Sanctions Regulations ("ITSR," 31 C.F.R. Part 560) to expand the scope of general licenses for the export and reexport to Iran of medicine, medical devices, and agricultural commodities. The changes are particularly significant for medical devices, permitting exports and reexports without specific licensing from OFAC of a greater range of medical devices and related software, services, training, and replacement parts.

As part of the changes, which took effect on December 23, 2016, OFAC also revised a key definition in the ITSR of "goods of Iranian origin" or "Iranian-origin goods."

Expansion of General Licenses for Trade in Medicine, Medical Devices, and Agricultural Commodities

The ITSR broadly prohibit U.S. persons and non-U.S. entities that they own or control from trade with or involving Iran, including exports or reexports to Iran, without licensing by OFAC. "U.S. persons" are companies organized under U.S. law (and their non-U.S. branches); U.S. citizens and lawful permanent residents ("green-card" holders), wherever located or employed; and any person physically present in the United States. In addition, the ITSR and related export control regulations administered by the U.S. Commerce Department also prohibit non-U.S. persons from reexporting to Iran items that contain more than *de minimis* controlled U.S.-origin content (by value) or that were exported from the United States specifically or predominantly for Iran.

However, for some years, the ITSR have provided general licenses authorizing the export and reexport of qualifying medicine, medical devices, and agricultural products to or for Iran, subject to certain conditions. The general licenses are available for use by "covered persons," which include U.S. persons and the non-U.S. companies they own or control, as well as any person exporting or reexporting to Iran a qualified item subject to the U.S. Export Administration Regulations ("EAR") administered by the Commerce Department.

OFAC's recent changes expand the scope of these general licenses. In particular, the general license authorizing the export/reexport of medical devices to Iran has been amended to cover a significantly broader range of medical devices. The changes also specifically note that "safe and

effective use" training may be provided with respect to medicine, medical devices, and agricultural products exported or reexported under the general licenses. Additionally, the general license relating to replacement parts for medical devices has been expanded to authorize the export/reexport of medical device replacement parts to stock for future use. Finally, two new general licenses have been added to the ITSR, permitting the export/reexport of certain software and services necessary for the operation, maintenance, and repair of medical devices, as well as the import from Iran into the United States of certain U.S.-origin items previously exported/reexported under the ITSR if, among other things, they are broken, defective, or non-operational.

Most other elements of the general licenses remain the same: In all cases, the items to be exported or reexported to Iran under the general licenses must be non-sensitive for export control purposes—they must either be classified as EAR99 or (for items not subject to the EAR) they must be the type of item that would be classified as EAR99 if subject to the EAR. In addition, other conditions relating to trade in medicine, medical devices, and agricultural commodities remain, including limitations on the types of payment terms that can be used and the prohibition on providing items or services to Iranian military, intelligence, or law enforcement purchasers or importers or to blocked persons (unless the blocked party is blocked solely because it is the Government of Iran or an entity that the Government of Iran owns or controls).

Expanded Scope of General License for Export/Reexport of Medical Devices

Previously, the ITSR general license had authorized the export and reexport to Iran only of medical devices specifically identified on a "positive" list of approved medical supplies. Other medical devices not on the list required specific licensing from OFAC. Many of the items on the list were described in very general terms, and exporters were sometimes uncertain whether their products were intended to be covered. Exporters and reexporters who did not think or were not sure their items qualified had to apply to OFAC for specific licensing.

In the changes announced late last month, OFAC expanded the ITSR's general license for the export and reexport of medical devices by adopting a "negative" list of excluded medical devices, rather than a positive list of approved items. The general license now authorizes the sale and export/reexport to Iran of all non-sensitive medical devices, except for those devices specifically identified on an OFAC "List of Medical Devices Requiring Specific Authorization." All other EAR99 medical devices can be exported under the general license, subject to the terms of the license.

The list of items published by OFAC as requiring specific licensing for export/reexport to Iran includes oxygen generators, certain diagnostic medical imaging equipment, pumps with a flow rate of greater than one liter per minute, and various types of laboratory equipment. The List of Medical Devices Requiring Specific Authorization also notes that specific licensing is required for items "within the scope of" the Statement of Understanding - Medical Equipment that appears at EAR Part 774, Supp. No. 3[1] and items that are excluded from entries on the EAR's

[1] The Statement of Understanding - Medical Equipment provides that equipment that is "specially designed for medical end-use" that incorporates commodities or software controlled on the EAR's Commerce Control List ("CCL") for reasons *other than* Nuclear Nonproliferation (NP), Missile Technology (MT), or Chemical & Biological Weapons (CB) is treated as EAR99. The exclusion from eligibility for the expanded general license of items subject to this Statement of Understanding is unclear as it relates, for

CCL solely because they are medical equipment, or specifically designed or modified for medical equipment or medical purposes.[2]

The change in focus to permit the export/reexport under the general license of all eligible medical devices classified as EAR99 that are not specifically excluded should have the effect of considerably expanding the ability of exporters/reexporters to provide such items to Iran without the uncertainty of whether items fit within eligible categories of supplies, as had been the case previously.

In contrast to the general license for medical devices, the scope of the general licenses for export/reexport to Iran of medicine and agricultural commodities was already quite broad, and remains largely unchanged, with one exception: OFAC has expanded the agricultural commodities eligible for the general license to include shrimp and shrimp eggs, which had previously been excluded.

General Licenses for Training in "Safe and Effective Use"

The ITSR general licenses for the export and reexport of medicine, medical devices, and agricultural commodities also have been revised to specifically provide that they cover training necessary and ordinarily incident to the safe and effective use and operation of eligible medicine and medical devices, and the safe and effective use of agricultural commodities. In all cases, the eligible items must have been exported or reexported to Iran pursuant to the general licenses. Further, any technology that is released in order to provide training under this authorization must be classified as EAR99 (or would be classified as EAR99 if subject to the EAR).

OFAC has updated its FAQs, at FAQ 484, to provide examples of training activities and information that it considers to be "necessary and ordinarily incident" to safe and effective use, including:

- Dissemination of product information on a device's intended use;
- Comparisons to other devices and options;
- Instructions from manufacturers pertaining to the use, labeling, warning, contraindications, storage, and maintenance of the medicine or device;
- Training healthcare professionals to use medical devices safely to achieve the desired patient outcome;

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example, to medical devices that incorporate computers or software that are controlled only for antiterrorism (AT) reasons and that are EAR99 pursuant to the Statement of Understanding. Not covering such items under the general license would be significant, since numerous medical devices contain such software and/or hardware.

[2] For example, Export Control Classification Number ("ECCN") 2B119 on the CCL controls for missile technology (MT) and antiterrorism (AT) reasons certain balancing machines, but not those designed or modified for dental or other medical equipment. These balancing machines would not be eligible for export or reexport to Iran under the expanded medical device general license.

- Training on procedures for cleaning and inspecting devices regularly to ensure they are functioning correctly;
- Ongoing training and periodic testing to ensure users remain competent; and
- Training on procedures for adverse events or device failure.

Expanded General License to Authorize Export and Reexport of Replacement Parts for Future Use

OFAC also has expanded the ITSR general license related to the export and reexport of medical device replacement parts. Prior to this expansion, medical device replacement parts could be exported or reexported only on a "one-for-one" replacement basis, in which the part being exported/reexported was exchanged with a medical device part or component which required replacement. This "one-for-one" restriction now has been removed. Under the new regulation, medical device replacement parts classified as EAR99 (or which would be so classified if they were subject to the EAR) may be exported or reexported to be held in stock in Iran, so long as they are intended to replace a broken or non-operational component of a medical device that was previously exported or reexported under OFAC authorization, or if providing the replacement part is "necessary and ordinarily incident to the proper preventative maintenance of such a medical device." Importantly, however, the number of replacement parts exported or reexported to be stored as stock in Iran for such future use cannot exceed the number of corresponding parts in use in medical devices previously exported or reexported to Iran under OFAC authorization.

OFAC also has specified that broken or non-operational parts which are being replaced in a medical device must be "promptly exported, reexported, or otherwise provided to a non-Iranian entity located outside of Iran selected by the supplier of the replacement parts."

New General License Authorizes Export and Reexport of Certain Medical Device Software and Services

OFAC's amendments to the ITSR added a new general license that authorizes the export or reexport to Iran of certain software and services necessary for the operation, maintenance, and repair of medical devices supplied to Iran under OFAC authorization.

In particular, the new general license now explicitly authorizes the export or reexport of software required for installing and operating medical devices, provided the software is EAR99 (or would be EAR99 if subject to the EAR). The general license also authorizes export and reexport of EAR99 software updates; specifically, "software intended for and limited to the provision of safety and service updates and the correction of system or operational errors. . . ." This is a significant expansion that recognizes the importance of software to modern medical devices, and the importance of regular software updates, patches, and bug fixes throughout the lifecycle of the device to ensure its safe and effective use. The software updates that may be exported or reexported are limited to the same end user who received the original software.

In addition, the new general license permits the export or reexport of repair services, including "inspection, testing, calibration, or repair services to ensure patient safety or effective operation" of medical devices previously exported or reexported to Iran under OFAC authorization. Such services must not "substantively alter the functional capabilities of the medical device as originally authorized for export or reexport. . ."

New General License Authorizes Imports of Certain Medicine, Medical Devices, and Agricultural Commodities Previously Exported or Reexported Pursuant to OFAC Authorization

OFAC has added a new general license that authorizes the importation into the United States of certain U.S.-origin agricultural commodities, medicine, and medical devices (including relevant parts, components, or accessories of devices) which were previously exported or reexported to Iran under OFAC authorization and which require return for specific purposes. Specifically, OFAC has authorized these imports in the event that items are "broken, defective, or non-operational, or are connected to product recalls, adverse events, or other safety concerns."

Previously, such imports required specific OFAC licensing, which could be time-consuming to obtain and which could hinder the investigation into items that had failed or been the subject of quality or performance concerns. However, the new general license does not by its terms address returns of non-U.S. products to the United States or returns of U.S. products to locations outside the United States.

Revised Definition of "Goods of Iranian Origin" or "Iranian-Origin Goods"

The ITSR broadly prohibit U.S. persons and non-U.S. companies that U.S. persons own or control from engaging in any transaction or dealing in or related to "goods of Iranian origin" or "Iranian-origin goods," as well as the import into the United States by any person of such goods. The ITSR have broadly defined such goods to include not only goods produced in Iran but also any goods that have "entered into Iranian commerce."

The recent ITSR amendments narrowed in certain key respects the definition of the terms "Iranian-origin goods" and "goods of Iranian origin," as set out in ITSR § 560.306. In particular, OFAC has excluded from these terms the following two categories of goods, so long as such goods were not grown, produced, manufactured, extracted, or processed in Iran:

1. Goods exported or reexported to Iran under an OFAC authorization issued pursuant to the ITSR and that have subsequently been reexported from and are located outside of Iran; and
2. Goods transported on a vessel or aircraft, as well as the vessel or aircraft itself, that has passed though 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.

The first part of the revised definition clarifies that qualifying non-Iranian goods reexported from Iran, such as medical devices or personal communications devices exported or reexported to Iran under OFAC authorization, are not "Iranian-origin goods" or "goods of Iranian origin" after they leave Iran. Note, however, that goods that enter Iranian commerce without OFAC authorization and then leave Iran continue to be treated as "Iranian-origin goods" or "goods of Iranian origin" for purposes of the ITSR.

The second part of the revised definition marks a significant revision of the ITSR as to the status of goods whose only connection with Iran is that they are on vessels or aircraft that call in Iran en route to other destinations and may be temporarily offloaded or transferred at the Iranian port/airport from one vessel/aircraft to another—an increasingly important issue given that trade with Iran has expanded in the wake of the Iran nuclear deal and correspondent easing of certain U.S. and EU sanctions. The revision means that U.S. persons and their owned and controlled non-U.S. affiliates are not prohibited from thereafter dealing with such goods.

In a note to ITSR § 560.306(b)(2), OFAC explained that goods do not "come into contact with Iran" if they are "temporarily offloaded" from a vessel or aircraft only to later be reloaded onto the same or another vessel or aircraft in the same location or port. On the other hand, OFAC issued a new FAQ 486, which clarifies that goods do "come into contact with Iran" if, for example, they are removed from a port or airport in Iran, transported through Iran by truck or train, or processed by Iranian Customs. Thus, the primary factors in determining whether items on vessels or aircraft calling in Iran are considered to have become "goods of Iranian origin" or "Iranian-origin goods" under ITSR § 530.306(b)(2) appear to be whether the goods have left the boundaries of a particular Iranian port or airport or cleared Iranian Customs.

Notably, the revisions to the definition of "goods of Iranian origin" and "Iranian-origin goods" do not change other key prohibitions in the ITSR. Importantly, ITSR § 560.204 continues to prohibit U.S. persons and (through ITSR § 560.215) their owned or controlled non-U.S. affiliates from exporting, reexporting, selling, or supplying goods, technology, or services to Iran or to third parties with knowledge or reason to know that the items are intended directly or indirectly for Iran or for use in the production of, for commingling with, or for incorporation into goods, technology, or services to be supplied directly or indirectly, exclusively or predominantly, to Iran, unless authorized by OFAC. And ITSR § 560.403 continues to provide that the prohibitions in ITSR § 560.204 (and also the prohibitions in ITSR §§ 560.206 and 560.208) apply to export, reexport, or supply transactions which require a transshipment or transit of goods or technology through Iran to third countries. The changes also do not alter the requirement that property of the Government of Iran and Iranian financial institutions, and entities that they own or control, must be blocked when it comes into the United States or the possession or control of a U.S. person.

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We are well-positioned to advise companies on the impact of and compliance with Iran sanctions laws and regulations. If you have any questions concerning the material discussed in this client alert, please contact the following members of our International Trade practice:

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