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CLIENT MEMORANDUM

OFAC Issues New Regulations, Broadly Liberalizing the Rules for Selling Medical Devices to Iran

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On December 23, 2016, the U.S. Treasury Department's Office of Foreign Assets Control ("OFAC") published a Federal Register notice that implements important changes to the Iranian Transactions and Sanctions Regulations. The changes broadly expand the scope of the general license for exporting medical devices to Iran and dramatically ease the licensing issues related to these transactions. OFAC also eased the restrictions on exports of agricultural products and medicines. The OFAC notice can be found here.

The new regulations greatly expand existing general licenses related to the sale of medical devices in Iran and mark a watershed in OFAC's approach to medical device licensing for Iran, including moving from a "white list" of authorized medical devices to a general authorization for the export of medical devices with listed exceptions. More specifically, OFAC has created new general licenses to broadly authorize the following:

- the sale and export of all medical devices except those listed on the newly created "List of Medical Devices Requiring Specific Authorization," which are excluded from the general license;
- the provision of training for the safe and effective use or operation of medical devices;
- the exportation or reexportation to Iran of replacement parts;

- the storage of replacement parts for future use;
- 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
- 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.

Changes Related to the Sale of Medical Devices to Iran

The new regulations represent a fundamental change in OFAC's approach for Iran with respect to the licensing of medical devices classified as EAR99 under the U.S. Export Administration Regulations. Under the prior regulations, OFAC published a positive list of items, known as the "List of Medical Supplies," that were permitted to be exported to Iran under a general license. OFAC has now moved to a negative list, meaning that all EAR99 medical devices will be authorized for sale and export to Iran EXCEPT those that are explicitly excluded as specified in a new "List of Medical Devices Requiring Specific Authorization," which will be maintained on OFAC's website on the Iran Sanctions page. The exportation or reexportation of medical devices to military, intelligence, or law enforcement purchasers or importers remains prohibited.

With respect to training, OFAC had added a new provision to the regulations to broadly authorize the provision of training necessary and ordinarily incident to the safe and effective use or operation of medical devices exported or reexported pursuant to the newly expanded general license. Two limitations apply: any technology released pursuant to the general license must be classified as EAR99; and such training may not be provided to any military, intelligence, or law enforcement entity, or any official or agent thereof.

The new general license for replacement parts removes the limitation of a one-for-one replacement and broadly authorizes the exportation and reexportation of replacement parts for authorized medical devices, both those that are intended to replace a broken or nonoperational component of a medical device previously authorized for sale to Iran and where such replacement parts are ordinarily incident and necessary to the proper preventative maintenance of medical devices sold pursuant to the general license. Some limitations apply. The replacement parts must be classified as EAR99 and cannot be sold to military, intelligence, or law enforcement entity, or any official or agent thereof. The number of such replacement parts that are exported or reexported to and stored in Iran must be limited to the number of corresponding parts in use in relevant medical devices in Iran. In addition, the broken or nonoperational replacement parts that are being replaced must be promptly exported, reexported, or otherwise provided to a non-Iranian entity located outside of Iran.

OFAC has also created a new general license authorizing the sale and exportation of EAR99 software necessary for the installation and operation of authorized medical devices or replacement parts and the conduct of related transactions. Software updates are also authorized when intended for and limited to safety and service updates and the correction of system or operational errors in medical devices, replacement parts, and associated software that were previously

exported pursuant to a valid OFAC license/general license. Again, this is limited to EAR99 software, and the updates may be exported or reexported only to the same end user that received the original software.

The new general license also covers services for the repair of authorized medical devices. More specifically, the general license authorizes the provision of services necessary to maintain and repair medical devices that previously were exported or reexported pursuant to an OFAC general or specific license, including inspection, testing, calibration, or repair services to ensure patient safety or effective operation of the devices. The services may not substantively alter the functional capacities of the medical device as originally authorized for export or reexport or be provided to a military, intelligence, or law enforcement entity.

Finally, OFAC has provided a new general license to authorize the importation into the United States of medical devices that were previously authorized for export or reexport to Iran that are broken, defective, or nonoperational or connected to product recalls, adverse events, or other safety concerns.

Other Changes

In addition to the medical device changes discussed above, OFAC also created a general license to provide training related to the safe and effective use of OFAC authorized agricultural commodities. In addition, training related to the safe and effective use of medicine is also authorized under a general license. In both cases, any technology released must be classified as EAR99; and no training may be provided to any military, intelligence, or law enforcement entity, or any official or agent thereof.

Finally, the new regulations clarify the definition of goods that have entered into Iranian commerce, stating that these goods do not include: (1) goods exported or reexported to Iran under a valid OFAC authorization; or (2) goods transported on a vessel or aircraft, as well as the vessel or aircraft itself, that 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.

Conclusion

The changes to the OFAC regulations should greatly ease the licensing and administrative compliance burdens for those involved in the sale of medical devices to Iran. Exporters should ensure they remain compliant with the remaining limitations of the general licenses, including conducting sufficient due diligence on end users in Iran.

If you have any questions regarding this memorandum, please contact David Mortlock (202-303-1136; dmortlock@willkie.com), Miriam A. Bishop (202-303-1126; mbishop@willkie.com) or the attorney with whom you regularly work.

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