OFAC Eases Restrictions on the Export of Medical Devices to Iran

01/11/17

Skadden

Four Times Square
New York, NY 10036
212.735.3000

skadden.com

On December 22, 2016, the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) announced amendments to the general license (GL) that authorizes the export or re-export of certain medical devices to Iran. With these amendments, OFAC has substantially expanded the scope of medical devices generally authorized for export or re-export to Iran without the need for a specific license. These changes — which also include new or expanded authorizations related to training, replacement parts, software and services for the operation, maintenance and repair of medical devices — went into effect on December 23, 2016.

Although the GL authorizes a wider spectrum of activities without the need to apply to OFAC for a specific license, a number of important limitations and restrictions remain, including more generally with respect to dealings involving Iran for which the United States retains an embargo. It therefore remains crucial to maintain a robust sanctions compliance policy, including thorough counterparty and product due diligence, to determine whether a particular transaction is indeed covered by the GL. Affected parties may want to review their compliance policy and related training programs in light of this revised framework for medical devices.

Highlighted below are key changes to the GL brought about by the December 2016 amendment.

Medical Devices Eligible Under the GL for Export or Re-Export to Iran

Previously, to be included within the scope of the GL a medical device[1] had to be on a "whitelist" of identified devices maintained by OFAC. In other words, unless the medical device appeared on OFAC's whitelist, it was not possible to rely on the GL to export the item to Iran.

The December 2016 amendment flips this principle; now, a medical device exported or re-exported to Iran is presumed to be within the scope of the GL unless it is included on OFAC's "blacklist" of items requiring specific authorization. The blacklist of excluded medical devices is available on OFAC's website on the Iran sanctions page, www.treasury.gov/resource-center/sanctions/Programs/Pages/iran.aspx.

It is important to note, however, that even under the amended GL, certain restrictions remain in place. For example, as under the prior GL, all medical devices exported or re-exported under the GL must be shipped within a 12-month period beginning on the date of the contract for export or re-export, and the transactions must meet specific financing and payment terms. Additionally, the GL does not authorize (i) the exportation or re-exportation of medical devices to military, intelligence or law enforcement purchasers or importers, or (ii) otherwise proscribed conduct, such as the involvement of individuals or entities on OFAC's List of Specially Designated Nationals and Blocked Persons.

Exporters to Iran and those that process or support the transactions must also bear in mind that, as with the prior version of the GL, the amended GL only authorizes exports or re-exports by "covered persons." For the exportation or re-exportation of goods, software and technology (collectively "items") subject to the Export Administration Regulations (EAR), a "covered person" can be either a U.S. person[2] or a non-U.S.

[1] The general license defines a "medical device" as "an item that falls within the definition of 'device' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and that, in the case of an item subject to the EAR, is designated as EAR99, or in the case of an item not subject to the EAR, that would be designated as EAR99 if it were located in the United States." 31 C.F.R. § 560.530(e)(3).

[2] The applicable OFAC regulations define a U.S. person as "any U.S. citizen, permanent resident alien, entity organized under the laws of the United States (including foreign branches), or any person (*i.e.,* individual or entity) in the United States." 31 C.F.R. § 560.314.

person. Generally speaking, items are "subject to the EAR" when they are of U.S. origin, are produced outside the United States but incorporate greater than 10 percent U.S.-origin content or, regardless of origin, are exported from the United States. For items that are *not* subject to the EAR, however, a "covered person" is a U.S. person or a foreign entity owned or controlled by a U.S. person. Therefore, for example, a non-U.S. entity that is not owned or controlled by a U.S. person that wishes to export medical devices to Iran that are not subject to the EAR is not covered by the GL. Consequently, U.S. persons facilitating, processing or providing a related service with respect to such a transaction may not benefit from the authorization in the GL and could require a separate license from OFAC to engage in such activities. Therefore, it is crucial to ensure that the terms of the GL are fully met.

Related Training

The GL now includes express language authorizing, subject to certain restrictions, the provision by a covered person of training necessary and ordinarily incident to the safe and effective use of medical devices exported or re-exported to Iran.

Replacement Parts

Even before the December 2016 amendment, the GL contained provisions authorizing the provision of certain replacement parts. The amended GL expands upon this authorization. In particular, the GL now not only allows covered persons, subject to certain restrictions, to export or re-export parts to replace defective components of a medical device, but it also allows covered persons to export or re-export replacement parts necessary and ordinarily incident to the proper preventative maintenance of the medical device. The number of replacement parts stored in Iran must not, however, exceed the number of corresponding operational parts currently in use in relevant medical devices in Iran.

Defective parts that are being replaced must be promptly exported, re-exported or otherwise provided to a non-Iranian entity located outside of Iran selected by the supplier of the replacement parts. To facilitate the return of the defective parts, the GL authorizes importing into the United States U.S.-origin medical devices, including parts, components or accessories, that previously were authorized for export or re-export to Iran and that are broken, defective or non-operational, or are connected to product recalls, adverse events or other safety concerns.

Software Necessary for the Operation, Maintenance and Repair of Medical Devices

The GL newly authorizes the exportation or re-exportation by a covered person to Iran of certain software necessary for the installation and operation of medical devices or replacement parts exported or re-exported under the GL, and the conduct of related transactions.

Similarly, the provision 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 were exported or re-exported under the GL is also authorized. Such software updates may be exported or re-exported only to the same end user to whom the original software was exported or re-exported.

Services Necessary for the Operation, Maintenance and Repair of Medical Devices

Finally, the amended GL authorizes, subject to certain restrictions, the exportation or re-exportation by a covered person of services necessary to maintain and repair medical devices that were exported or re-exported under the GL. These services include inspection, testing, calibration or repair services to ensure patient safety or effective operation, and the conduct of related transactions.

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

Jamie L. Boucher
Washington, D.C.
202.371.7369
jamie.boucher@skadden.com

Nathaniel Bolin
Washington, D.C.
202.371.7893
nathaniel.bolin@skadden.com

Sidne Koenigsberg
Paris
33.1.55.27.11.39
sidne.koenigsberg@skadden.com

William J. Sweet, Jr.
Washington, D.C.
202.371.7030
william.sweet@skadden.com

Eytan J. Fisch
Washington, D.C.
202.371.7314
eytan.fisch@skadden.com

Ondrej Chvosta
Washington, D.C.
202.371.7579
ondrej.chvosta@skadden.com