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July 2013

OFAC Expands General License for Export of Basic Medical Supplies to Iran; Provides Additional Guidance

On July 25, 2013, the Office of Foreign Asset Control ("OFAC") announced the significant expansion of its List of Basic Medical Supplies ("LBMS"). Simultaneously, OFAC issued clarifying *Guidance on the Sale of Food, Agricultural Commodities, Medicine, and Medical Devices by Non-U.S. Persons to Iran*. These actions are intended by OFAC to demonstrate the United States' commitment to safeguarding humanitarian aid to and within Iran.

The Expanded General License

Background

As part of its October 2012 reissuance of the Iranian Transactions and Sanctions Regulations ("ITSR"), OFAC added a new General License to authorize the exportation or re-exportation of certain medical supplies to Iran. Previously, the export of such items required a license under the **Trade Sanctions Reform Act** ("TSRA"). Items that previously required a specific TSRA license, but which can now be exported under the General License, include basic medical supplies (**items identified on the LBMS**), as well as EAR99 medicines and medical devices, defined respectively as "drugs" and "devices" in section 201 of the **Federal Food, Drug, and Cosmetic Act**.

When OFAC issued the General License, it indicated that the LBMS would include those medical supplies on the Department of Commerce Bureau of Industry and Security ("BIS") **list of EAR99 Medical Devices**. Under TSRA, an exporter could request a specific OFAC license for the export of an item on the BIS List without seeking a BIS Commodity Classification Request. However, OFAC's initial LBMS was narrower than the list of EAR99 medical devices that BIS had made available for TSRA licensing purposes for the preceding decade.

The Expanded Definition of Basic Medical Supplies

With its July 25 issuance, OFAC has increased the number of items that qualify for export under the General License from 46 to over 200. The LBMS is now, generally speaking, more expansive than the list of EAR99 medical devices maintained by the Department of Commerce. Notable additions include electrocardiography machines ("EKGs"), electroencephalography machines ("EEGs"), and dialysis machines, as well as other equipment used by hospitals, clinics, and medical facilities. The LBMS also encompasses EAR99-classified components, accessories, and optional equipment that are designed for, and are for use with, an EAR99-classified medical device included on the LBMS. These items can now be exported to Iran without a specific license. However, the LBMS does not include replacement parts for such devices.

Restrictions Remain

Despite the expansion of OFAC's definition of basic medical supplies, significant restrictions remain in place. First, though significantly broader than its predecessor, the revised LBMS is not all-encompassing, and exporters and re-exporters must review their specific products against the LBMS to determine whether they qualify for the General License.

Second, the General License does not authorize exports or re-exports to military or law enforcement entities, nor does it authorize exports or re-exports to persons whose property and interests in property are blocked under counter-proliferation, counter-terrorism, counter-narcotics, or other authorities administered by OFAC, including such persons identified on the Specially Designated Nationals and Blocked Persons ("SDN") List. When engaging in activities pursuant to the General License, exporters and re-exporters are obligated to undertake due diligence regarding all parties to the transactions, including consignees and end-users.

Exporters utilizing marine transport must be especially cautious regarding Iranian transactions,

including the export of basic medical supplies to Iran. In 2011, Tidewater Middle East Company was added to the SDN List, due to its affiliation with the Iranian Islamic Revolutionary Guard Corps. OFAC's General License does not alter the prohibition on trade with Tidewater, which has operations at the main ports in Iran, and describes itself as the "largest and most active container operator in Iran," performing "more than 90% of container operations in the ports." Due to Tidewater's extensive operations, companies trading through Iranian ports should carefully review their operations to ensure that they are not utilizing ports or terminals operated by Tidewater. This applies to all trades, including those which would otherwise qualify for export under the General License. For those transactions that are not eligible for export under the General License, a *specific* OFAC license must be obtained prior to export.

New Guidance

Guidance on the Sale of Food, Agricultural Commodities, Medicine, and Medical Devices by Non-U.S. Persons to Iran

OFAC also issued new guidance on the sale of food, agricultural commodities, medicine, and medical devices (collectively, "Humanitarian Sales") by Non-U.S. Persons to Iran. The new guidance is intended to clarify OFAC's February 6, 2013, *Clarifying Guidance: Humanitarian Assistance and Related Exports to the Iranian People*.

The U.S. Iranian Financial Sanctions Regulations ("IFSR") contain broad authorizations that allow for Humanitarian Sales by U.S. persons or from the United States to Iran. Similar allowances are provided for like Humanitarian Sales to Iran by non-U.S. persons. The new guidance underscores that these Humanitarian Sales to Iran do *not* alone trigger sanctions under U.S. law. Likewise, the financing or facilitation of Humanitarian Sales by non-U.S. persons does not trigger U.S. sanctions, so long as the transaction does not involve blocked parties or proscribed conduct (e.g., routing a payment directly from Iran to the United States, or vice versa, or otherwise evading other U.S. sanctions authorities).

Importantly, the new guidance sets forth that "the conduct or facilitation of payments for such sales by foreign banks are not subject to U.S. sanctions when the payments originate from accounts of the Central Bank of Iran ("CBI") or from accounts of Iranian commercial banks that have not been designated by the U.S." The guidance provides the following example:

Iranian oil revenues held in CBI or non-designated Iranian bank accounts at foreign banks may be used to finance exports of food, agricultural commodities, medicine, or medical devices to Iran – from the country in which the account is held or from any other foreign country – without triggering sanctions for the foreign bank under the [IFSR].

Overall, the new guidance is reflective of the United States' intent to safeguard humanitarian efforts in Iran by ensuring that international entities understand the broad scope of the humanitarian allowances delineated by the IFSR. Exporters should be mindful that the terms "food," "agricultural commodities," "medicine," and "medical devices" are defined by the IFSR and should consult the regulations in order to determine whether a certain product qualifies for a humanitarian allowance.

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For additional details on how the Iranian sanctions may impact your international business activities, please contact any attorneys in our [**International Trade and Customs Group**](#) for assistance.