

E-ALERT | International Trade Controls

November 5, 2012

DEVELOPMENTS IN U.S. SANCTIONS AGAINST IRAN

SUBSTANTIAL REVISION AND UPDATING OF THE IRANIAN TRANSACTIONS REGULATIONS, REISSUED AS THE “IRANIAN TRANSACTIONS AND SANCTIONS REGULATIONS”

On October 22, 2012, the Department of the Treasury’s Office of Foreign Assets Control (“OFAC”) published a [final rule](#) substantially revising and reissuing the former Iranian Transactions Regulations (“ITR”), and renaming them the “Iranian Transactions and Sanctions Regulations” (“ITSR”).

This revision serves principally to implement the blocking provisions and other sanctions imposed under Executive Order 13599 and subsections 1245(c) and (d)(1)(B) of the National Defense Authorization Act for Fiscal Year 2012, Public Law 112-81 (“NDAA”). These sanctions, described in detail in our e-alerts of [January 4, 2012](#) and [February 9, 2012](#), block all property and interests in property of the Government of Iran (including the Central Bank of Iran), all Iranian financial institutions, and all persons owned or controlled by, or acting for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to the Order. These blocking sanctions already had the force of law under the Executive Order; the ITSR provisions codify these sanctions and clarify and provide more detail on their scope.

The revised ITSR further contain several provisions that will be relevant to those who export or reexport medicines or medical devices under the Trade Sanctions Reform and Export Enhancement Act of 2000 (“TSRA”). Specifically, the revised regulations provide new general licenses that (a) authorize the supply of most non-sensitive commercial medicines and some basic medical supplies to Iran, including the Government of Iran, without specific licensing from OFAC, provided certain conditions are met; and (b) authorize certain payment terms for the commercial sale of eligible food, medicine, and medical devices under either a specific or general license.

Other notable changes include new restrictions on processing payments or transferring funds to or from Iranian banks or accounts held by Iranian parties, in some cases even when the underlying transaction is authorized; and an expansion of the prohibition against evasion to prohibit anyone from causing or conspiring in a violation of the ITSR.

We are well-positioned to help companies and individuals analyze the impact of these revised regulations on their business.

BACKGROUND ON IRAN SANCTIONS

Since 1995, the ITR have prohibited virtually all direct and indirect transactions involving Iran or the Government of Iran by U.S. persons or with a nexus to the United States, unless authorized by OFAC or otherwise exempted by statute. As described in our e-alert of [February 9, 2012](#), while the ITR did not previously block the property of the Iranian government or Iranian banks, Executive Order 13599 and Section 1245 of the NDAA require U.S. persons to block all property and interests in property of

the Government of Iran, including the Central Bank of Iran, that come into their possession or control.

Further, as described in our e-alert of [October 15, 2012](#), President Obama issued Executive Order 13628 on October 9, 2012, to implement various provisions of the Iran Threat Reduction and Syria Human Rights Act of 2012 (“ITRSHRA”). Among other measures, Executive Order 13628 implemented Section 218 of the ITRSHRA by prohibiting any entity, wherever located, that is owned or controlled by a U.S. person from knowingly engaging in any transaction with the Government of Iran or any person subject to the jurisdiction of the Government of Iran, if that transaction would be prohibited if engaged in by a U.S. person or in the United States. The result is that any subsidiary or affiliate that is owned or controlled by a U.S. person is required to comply with the U.S. sanctions against Iran to the same extent as is the U.S. parent that owns or controls it. Interestingly, under the ITRSHRA and Executive Order 13628, civil liability is imposed on the U.S. parent companies if their controlled subsidiaries engage in such prohibited transactions.

IMPLEMENTATION OF IRANIAN GOVERNMENT BLOCKING

Many of the key new sections of the ITSR serve to implement the blocking provisions of Executive Order 13599 and subsections 1245(c) and (d)(1)(B) of the NDAA for all entities associated with the Government of Iran and Iranian financial institutions, including related changes to definitions and licensing provisions. In general, these changes do not create new obligations for exporters; rather, these provisions codify existing obligations. Key new or different provisions include:

- New Section 560.211: Blocks all property and interests in property of the Government of Iran and Iranian financial institutions, and persons owned or controlled by them, or who have acted or purported to act on their behalf, that are or come into the United States or the possession or control of any U.S. person. Any entity designated with an “[IRAN]” tag on OFAC’s List of Specially Designated Nationals and Blocked Persons (“SDN List”) is now subject to such blocking, as well as any other entity meeting the definitions of “Government of Iran” or “Iranian financial institution,” and any entity owned or controlled by or acting on behalf of such a blocked person.
- Sections 560.301-327: Include new and different definitions consistent with the new blocking provisions. Key new definitions include “blocked property” (560.322), “interest” (560.323), “Iranian financial institution” (560.324), “Iranian account” (560.319), “property” (560.325), “transfer” (560.326), and “U.S. financial institution” (560.327). These definitions have broad scope and are generally similar to definitions found in other OFAC blocking programs.
- Section 560.314 continues to define a “U.S. person” to mean any citizen or permanent resident of the United States; any person or entity while in the United States; and any corporation or entity “organized under the laws of the United States or any jurisdiction within the United States.” The definition does not by its terms include foreign-incorporated subsidiaries owned or controlled by U.S. companies. Nonetheless, it appears that, pursuant to ITRSHRA and Executive Order 13628, the blocking provisions and all other provisions of the newly-reissued ITSR apply not only to “U.S. persons” as defined, but also to any entity wherever located or incorporated that is owned or controlled by a U.S. person. We understand that OFAC is separately working on guidance to implement this and other aspects of Executive Order 13628.
- New Section 560.212: Consistent with E.O. 13599, Section 560.212 declares null and void any transfer that violates any provision of Part 560 and involves property or an interest in property blocked under Section 560.211.
- New Section 560.213: Requires U.S. persons holding funds blocked under Section 560.211 to put those funds in a blocked interest-bearing account in the United States, and funds held outside the United States to be held outside the United States in interest-bearing accounts.

- New Section 560.423: Makes clear that the blocking provisions of Section 560.211 apply to dealings in blocked property by U.S. persons outside the United States.
- New Section 560.425: Clarifies that entities in which a blocked person owns at least a 50 percent interest are themselves treated as blocked persons under Section 560.211. This codifies an existing OFAC policy statement that previously had been published on OFAC's website and which also appears in other country-based sanctions programs.
- New Section 560.426: Prohibits charitable contributions made by, to, or for the benefit of, or received from, any person blocked under Section 560.211.
- New Section 560.427: Clarifies that the prohibitions in the ITSR apply to 1) the transfer of funds from the United States or a U.S. person to Iran or the Government of Iran; 2) the provision to Iran or the Government of Iran of insurance services, investment or brokerage services, banking services, or other services and 3) U.S. depository institutions and U.S.-registered brokers or dealers in securities seeking to perform services with respect to Iranian accounts.
- Revised Section 560.502: Provides that transactions with parties blocked by Part 560 that are authorized by a specific license issued prior to February 6, 2012 continue to be authorized until the stated expiration date of the license. For licenses with no specific expiration date, the rules are more complicated:
 - For a license issued under Part 560 but not Part 535 (the separate Iranian Assets Control Regulations), any authorization in the license for transactions with parties blocked under Part 560 already expired as of April 6, 2012, and the entire license will now expire entirely as of January 22, 2013.
 - For a license issued under both Part 560 and Part 535, transactions with parties blocked under Part 560 continue to be authorized, and the license shall remain in effect according to its terms.
 - More broadly, Section 560.502 does not authorize payments or transfers from blocked property or debits to blocked accounts unless the license explicitly authorizes such payment or transfer.

PAYMENTS AND TRANSFERS

The new ITSR also revised some existing provisions related to payments and transfers of funds or property to or from Iran.

- Section 560.405: Provides a general authorization for transactions that are “ordinarily incident” and “necessary” to a licensed transaction. The revisions restrict the scope of this general license by excluding any payments or transfers of funds, or any transactions involving a debit to a blocked account or transfer of blocked property. Thus any payment or transfer of funds of any kind – including receiving payments for sales of licensed goods – must be separately authorized under a specific license or under another general license.
- Section 560.516: Provides a limited general license for certain U.S. financial institutions to process certain payments. The former regulations included a subsection authorizing payment processing as long as the underlying transaction was not prohibited by Part 560; that authorization is eliminated in the new ITSR. The revised section now provides that U.S. depository institutions, and U.S. brokers and securities dealers, are authorized to process transfers of funds to or from Iran, or for the benefit of persons in Iran or the Government of Iran, only if the transfer is ordinarily incident to and necessary to an underlying transaction that is authorized by a specific or general OFAC license and does not involve debiting or crediting an Iranian account. An “Iranian account” includes not only accounts of the Government of Iran,

Iranian financial institutions and other blocked parties, but also any account held by persons located in and ordinarily resident in Iran. In Frequently Asked Questions guidance posted on its website, OFAC advises that this general license does not authorize a U.S. licensed party other than a U.S. depository institution, broker or dealer to deal directly with any money service businesses or hawalas, wherever located.

- Section 560.532: Provides a general license for payments and financing for licensed exports and reexports of medicines, basic medical supplies and agricultural products, which is discussed in the next section.

CHANGES TO PROVISIONS RELATING TO THE SALE OF FOOD, MEDICINE, AND MEDICAL DEVICES

While most of the revisions in the new ITSR substantially tighten sanctions and blocking measures against Iran and its government, the new ITSR also significantly loosen the restrictions governing TSRA licenses for the sale, export and reexport of food, medicine, and medical devices. Several policies which were previously available only on OFAC's website are now included within the ITSR; certain new provisions and limitations are added; and, most notably, new general licenses for the sale of certain products without specific licensing and for certain payment terms are added.

General License for the Sale of EAR99 Food, Medicine, and Basic Medical Devices

The revised regulations provide a new general license that authorizes sales of medicines and basic medical devices to Iran without a specific license. (The existing general license for sales of food also continues to be available.)

The new general license available at Section 560.530(a)(3) authorizes the sale of medicines and "basic medical supplies" to any individual or entity in Iran, including the Government of Iran, that would otherwise be prohibited, along with related transactions, such as making shipping arrangements, entering into contracts, and arranging for payment. Notably, a number of conditions and limitations apply.

The general licenses for the export of food, medicines and basic medical supplies do not apply for the export of such items to military or law enforcement purchasers or importers. The terms "military" and "law enforcement" are not defined, and OFAC has not provided additional guidance as to its interpretation of these terms.

The general licenses also do not apply to the export or reexport of any medicine, medical device or agricultural commodity that is controlled on the Commerce Control List established under the Export Administration Act of 1979 or on the United States Munitions List established under the International Traffic in Arms Regulations; or to any item used to facilitate the development or production of a chemical or biological weapon or weapon of mass destruction. Thus the general licenses in effect authorize only the export of medicines and basic medical supplies that are non-sensitive, commercial products classified as EAR99 under the Commerce Department's Export Administration Regulations.

The revised Section 560.530 defines the term "medicine" to have the same meaning as the term "drug" under the Federal Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C. 321). However, not all medicines, so defined, are eligible for the new general license. The general license excludes all non-NSAID analgesics, cholinergics, anticholinergics, opioids, narcotics, benzodiazapenes, and bioactive peptides.

Further, the revised regulations also exclude “cosmetics” altogether from the ITSR definition of “medicine”; such “cosmetics” are apparently not eligible for TSRA licensing (either by general license or by specific license) even if they otherwise meet the FD&C Act definition of “drug.” OFAC has not provided any additional formal guidance concerning the scope of the exclusion for “cosmetics” and how it may apply to products that can be defined as both medicines and cosmetics under the FD&C Act. When we contacted the director of OFAC’s TSRA licensing program about this issue, he explained that the new exclusion of “cosmetics” is not intended to exclude all products that meet the FD&C Act definitions of both a “drug” and a “cosmetic.” He said that the definition is intended to exclude products for which the purpose is primarily cosmetic even if the product also meets the definition of a drug. What constitutes a purpose that is “primarily” cosmetic remains uncertain, however, and exporters with products that qualify as both a drug and a cosmetic may wish to seek more specific guidance from OFAC prior to reliance on this general license.

Next, Section 560.530 also provides a general license for exports and reexports to Iran of certain basic medical supplies. In the past, any medical device that met the definition of “devices” under the FD&C Act has been eligible for specific licensing to Iran. The new regulations define “basic medical supplies” that are eligible for the general license more narrowly to include only those medical devices that are identified on a new [List of Basic Medical Supplies](#) published on OFAC’s website. Exporters should note that, while there is some overlap, OFAC’s new List of Basic Medical Supplies is considerably shorter than the [Illustrative List of EAR99 Medical Devices](#) published by the Commerce Department that designates medical devices that do not require an official Commerce Department export classification ruling (CCATS) as EAR99 to be eligible for TSRA licensing. Parties who previously exported basic medical devices on the BIS Illustrative List under specific licensing from OFAC without providing official CCATS rulings should carefully review the new OFAC List of Basic Medical Supplies to determine whether their products are eligible for the new general license instead.

Medicines and medical devices that do not qualify for the new general license should continue to be eligible for specific TSRA licensing as before. Unlike the prior regulations, the new ITSR are silent on the question of whether CCATS rulings will now be required for devices that are listed on the Commerce Department’s Illustrative List of Medical Devices but that are not on the new OFAC List of Basic Medical Supplies. We have contacted the director of OFAC’s TSRA licensing program for informal guidance on this issue. He has confirmed that OFAC will not require applicants to submit CCATS rulings for products that are clearly covered by the BIS Illustrative List, and that it is unlikely that OFAC will require a CCATS ruling to license a product if it has previously granted a specific license without a CCATS ruling. The OFAC licensing office recommends, however, that TSRA license applications specifically indicate how products are covered by the Illustrative List and that, when in doubt, the applicant should provide a CCATS ruling to avoid delay.

Finally, as is the case under specific licensing from OFAC, the general license requires all exports and reexports made pursuant to the general license to be shipped within the 12 month period beginning on the date of signing of a contract for export or reexport.

General License for Payment Terms for Food, Medicines, and Medical Devices

The revised ITSR specify the payment terms that are authorized for sales, exports and reexports under the general licenses or specific OFAC licenses under TSRA. The general license found at new Section 560.532 generally allows for the payment terms that were available to exporters shipping under specific TSRA licensing, including:

- Payment of cash in advance;

- Sales on an open account, provided that the account receivable may not be transferred by the person extending the credit;
- Financing by third-country financial institutions that are not U.S. persons, Iranian financial institutions, or the Government of Iran (which may be confirmed or advised by U.S. financial institutions); or
- A letter of credit issued by an Iranian financial institution whose property and interests are blocked solely pursuant to Part 560, provided that such letter of credit is initially advised, confirmed, or otherwise dealt in by a third-country financial institution that is not a U.S. person.

OTHER NOTABLE CHANGES

Other notable new features or changes in the new ITSR include the following:

- Section 560.203 is broadened: This section, which addresses prohibited evasion and attempted violations, has been clarified and broadened in potentially significant ways. The prior version of this section prohibited transactions “by any U.S. person or within the United States” to evade or avoid, or attempt to violate, the sanctions regulations. The new version eliminates entirely the reference to conduct by a U.S. person or occurring within the United States. In addition, the prohibition as revised now expressly reaches conduct that “causes” a violation of the ITSR, and conspiracies to violate the ITSR, as well as evasion, avoidance or attempts. The intended scope appears to reach even non-U.S. persons not owned or controlled by a U.S. person that are found to have caused or conspired in an ITSR violation by a U.S. person.
- Section 560.511 is eliminated: This section previously authorized the export or supply of certain non-sensitive goods or technology (classified as EAR99) from the United States for substantial transformation or incorporation as a *de minimis* (<10 percent by value) part of foreign-made products for ultimate supply to Iran or the Government of Iran. It is removed from the ITSR because OFAC considers it no longer consistent with U.S. policy.
- Other new general licenses authorize certain journalistic activities and establishment of news bureaus (560.519); certain sales of real estate in Iran and the transfer of proceeds to the United States (560.543); and certain services related to public conferences, performances or exhibitions outside Iran (560.554).

CONCLUSION

We are well-positioned to assist clients in understanding the impact that the above-described regulations will have on their operations, and in interpreting the various other Iran measures that have recently been enacted.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our international trade controls group:

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