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Treasury Poised to Significantly Expand U.S. Outbound Investment Restrictions; First OISP Penalty Signals Active Enforcement

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The U.S. government is poised to expand the scope of its restrictions on outbound investment, potentially sweeping in a broad range of transactions within the reach of U.S. national security regulation. The changes proposed in a Notice of Proposed Rulemaking (the Proposed Rule) issued on October 22, 2026, by the U.S. Department of the Treasury (Treasury) would reshape the Outbound Investment Security Program (OISP), expanding its technological and geographic reach and creating significant new regulatory risks for U.S. investors, companies, and financial institutions. While the final regulations may differ from the Proposed Rule in some respects, the direction of U.S. policy is clear: Outbound investment restrictions are becoming an increasingly important component of the U.S. national security regulatory landscape.

Key Takeaways:

- Transactions that are permissible or merely notifiable today could become prohibited, especially in the Super Intelligence (i.e., Artificial Intelligence, SI) and life sciences sectors.
- Biotech provisions are drafted broadly but may be pared back in the final rule based on public comments. Biotech investors and licensors should take care with licensing deals that also involve equity, joint development, or the transfer of technology or know-how to ensure they will not fall within the scope of the Proposed Rule.
- U.S. persons should carefully assess whether any recommendations provided in an advisory role to a non-U.S. person would constitute knowingly directing a prohibited or notifiable transaction.
- U.S. persons should consider submitting a request for an advisory opinion if they believe a transaction could be prohibited.

- Investors will need to conduct wide-ranging diligence targets, including on the target's activities, ownership, contractual control, management location and affiliates.
- Treasury may continue to expand the OISP beyond the sectors named in the COINS Act, as it has done with biotechnology.
- Treasury is focused on enforcement, and investors should carefully assess whether the OISP, currently and under the Proposed Rule, applies to planned investments, regardless of size.

What does the OISP currently cover?

The OISP regulates certain investments by U.S. persons involving sensitive or advanced technologies in countries of concern. The current outbound investment regulations, issued under Executive Order 14105, took effect on January 2, 2025, and focus on U.S. investments in China (including Hong Kong and Macao) in the semiconductors and microelectronics, quantum information technologies and AI sectors.

The Proposed Rule would create new regulations at 31 CFR Part 851 to govern future transactions, while the current regulations at 31 CFR Part 850 would continue to apply to activities occurring between January 2, 2025, and the effective date of the final rule. Comments are due by December 7, 2026, and Treasury must issue the final rule by March 13, 2027 (with the effective date to follow). While we expect changes in the final rule, the Proposed Rule signals the U.S. government's increasing focus on outbound investment and the direction of the OISP, and companies should begin assessing its impact now.

Why did Treasury release new rules?

Congress enacted the COINS Act on December 18, 2025, as part of the *National Defense Authorization Act for Fiscal Year 2026* (NDAA), to codify and strengthen the outbound investment regime. The COINS Act retains most of the OISP's core concepts. The COINS Act covers five sectors: the three sectors currently covered by the OISP (semiconductors and microelectronics, quantum information technologies, and SI systems) and two new sectors (high-performance computing and supercomputing, and hypersonic systems). It also authorizes Treasury to add other technology sectors, where it determines that a technology enables a country of concern's military, intelligence, surveillance or cyber-enabled capabilities, which Treasury has now done by adding biotechnology.

What would the Proposed Rule cover?

The Proposed Rule would retain, and expand restrictions on, the three sectors currently covered by the OISP and add three new sectors: hypersonic systems, high-performance computing and supercomputing, and biotechnology. Appendix A below summarizes the activities that would fall within the Proposed Rule's definitions of "prohibited technology" and "notifiable technology."

SI/AI

- The Proposed Rule would prohibit investments involving the development of *any* SI system (renamed SI under Executive Order 14434), regardless of computing power or end use, and would eliminate the notification tier for this sector. By contrast, the current OISP distinguishes among SI systems based on training compute and end use. The Proposed Rule would, however, retain clarifying language on when using or incorporating a third-party SI system does or does not constitute "development" of an SI system. Because many companies outside the covered sectors customize or build agentic tools on top of off-the-shelf models, the line between "using" and "developing" an SI system will be critical.
- The Proposed Rule's broad definition of an SI system would include any machine-based system that can "generate content or make predictions, recommendations, or decisions influencing real or virtual environments," as well as any software, hardware or tool operating using such a system, including a harness for agentic capability. This would encompass generative SI and robotic or other autonomous or unmanned systems that operate using an SI system.

Semiconductors and Microelectronics

- The Proposed Rule would largely retain the OISP's current coverage of semiconductors and microelectronics, while adding a notification requirement for the development or production of certain equipment designed for use in the design, fabrication or packaging of integrated circuits.
- The Proposed Rule would include as a notifiable technology the development or production of certain equipment that is designed or intended for use in the design, fabrication or packaging of any integrated circuit, specifically to aid the U.S. government's visibility into the volume and nature of investments involving these types of technologies.
- The Proposed Rule would add new prohibitions covering certain high-bandwidth memory, integrated circuits made from certain compound semiconductors, certain radiation-hardened integrated circuits and photonic integrated circuits.

Quantum Information Technologies

- The Proposed Rule would largely retain the OISP's current prohibitions on quantum technologies, while also covering the development of algorithms and applications for quantum information science technologies, subject to an end-use limitation.

Hypersonics

- The Proposed Rule would add hypersonic systems (vehicles or weapon delivery systems capable of sustained flight at Mach 5 or greater) as a newly covered sector. It would prohibit investments involving hypersonic systems, hypersonic propulsion systems, fuels and propellants, certain heat-resistant and stealth materials, testing facilities, and digital twin or digital thread technology. Investments involving sensor, guidance, navigation or control equipment; certain software; and other materials capable of use in a hypersonic system would be notifiable.

High-Performance Computing

- The Proposed Rule would add a notification requirement for high-bandwidth, low-latency interconnects used in high-performance computing. This would supplement the existing supercomputer prohibition and the related prohibitions on certain DRAM, photonic integrated circuits and high-bandwidth memory.

Biotechnology

Overview

- The Proposed Rule would add biotechnology as a newly covered sector. Covered biotechnology investments would be prohibited, with no notification tier.
- The proposed prohibitions are extensive and would cover:
  - the development, engineering or use of a biological system (or component of a biological system) to modify, enhance, produce or control certain export-controlled agents or toxins, energetic materials, novel or high-performance functional materials, biofuels, and pharmaceutical compounds and their delivery systems;
  - for this purpose, pharmaceutical compounds expressly include small molecules, polymers, vaccines, blood and blood components, allergenics, cell and gene therapies, and monoclonal antibodies and other recombinant therapeutic proteins;
  - the development or production of brain-computer interfaces;

- the development, construction or production of biomanufacturing equipment identified on the Commerce Control List; and
- the development or production of related tools and equipment (including components and software), such as biological sequencing technology, certain flow cytometers and cell sorters, certain liquid chromatography mass spectrometry instruments, certain computational or bioinformatics tools, and hardware, robotics, or software for automated scientific discovery or experimentation (including laboratory automation and cloud lab infrastructure).

Scope of "Biological System"

- The Proposed Rule does not define "biological system" or "component of a biological system." Although all biological processes are, in some sense, chemical ones, we expect these terms to be given their ordinary meaning. On that reading, production that relies on living cells or organisms (such as fermentation or cell-line expression) or on biologically derived components such as enzymes (biocatalysis) appears to be covered, while purely chemical synthesis (such as conventional small-molecule synthesis) appears not to be.
- Treasury has asked for comment on whether it should describe covered biological systems more precisely, whether to limit the prohibition to activities using the specified biotechnology equipment and whether "pharmaceutical compounds" should be scoped to advanced or frontier technologies. As drafted, however, the prohibition could reach a significant portion of conventional drug discovery and development, not only sensitive or frontier technologies.

Specific Modalities

- Because the pharmaceutical-compound category expressly names monoclonal antibodies, recombinant therapeutic proteins, and cell and gene therapies, programs such as antibody-drug conjugates (ADCs), bispecific antibodies and CAR-T therapies that are produced using cell-line expression or other biological systems appear likely to be prohibited. SI-driven drug discovery may be captured both by the SI prohibition and by the prohibition on computational, bioinformatics and automated-discovery tools.

Platforms Versus Products

- Companies that develop broad technology platforms (such as gene editing, delivery technologies or SI-driven discovery) will likely face greater exposure than companies developing individual drug candidates, because computational tools, laboratory

automation and delivery systems are independently covered and SI-driven research may also fall under the SI prohibition. The Proposed Rule would also clarify that "develop" includes high-level oversight, direction, approval or strategic planning at any stage before serial production and extends to activities conducted through or with affiliates. The interaction between the SI and biotechnology prohibitions will be a key area to track moving forward.

Licensing and NewCo Structures

- A license-out or in-license for cash consideration alone is generally not a covered national security transaction. However, a license combined with an equity investment, contingent equity, a joint venture (which the Proposed Rule does not require to involve a new entity) or a NewCo structure with a covered foreign person could be covered. Similarly, arrangements that go beyond the license itself, such as acquiring or developing operations or assets in a country of concern (for example, funding clinical development by the licensor in China), could be covered where the U.S. person has knowledge (actual or constructive) that the arrangements will result in a covered foreign person engaging in a prohibited technology.

Additional Countries of Concern

The Proposed Rule would expand the countries of concern to include Cuba, Iran, North Korea and Russia, in addition to China (including Hong Kong and Macao). It would also include Venezuela *under the regime* of Nicolás Maduro Moros. While this regime no longer exists, certain Venezuela-linked investments could still be covered, because the definition of covered foreign person can reach entities located outside a country of concern.

The addition of Cuba, Iran, North Korea and Russia is consistent with other U.S. government's previous definition of "countries of concern" as these countries have been the subject of U.S. sanctions and technology restrictions under other legal regimes.

What is different from the current OISP?

Knowingly Directing. The Proposed Rule would expand the OISP to cover instances where U.S. persons knowingly direct a non-U.S. person to engage in either prohibited or notifiable transactions.

- The Proposed Rule would require U.S. persons to submit a notification for or refrain from directing a non-U.S. person to engage in a transaction that the U.S. person knows (or has reason to know) is a notifiable or prohibited transaction, respectively. Under the current OISP, a U.S. person is prohibited from knowingly directing a non-U.S. person to engage in a prohibited transaction; there is no notification requirement around notifiable transactions.
- U.S. persons serving on investment committees of non-U.S. funds may need to consider whether their role must be restructured or whether they are willing to submit notifications. That said, the Proposed Rule is intentionally broad around what constitutes knowingly directing a transaction — and it will be difficult to restructure roles to avoid this. Even a purely advisory role may be scrutinized where the individual previously held decision-making authority.
    - Any role restructuring that is undertaken must be bona fide and reflected in practice, as the Proposed Rule would maintain the OISP's anti-evasion language, which classifies any action taken to evade or avoid a prohibition under the OISP as a violation.

- The Proposed Rule would retain conditions under which a U.S. person can recuse themself from decision-making to avoid "knowingly directing" a transaction, including by recusing themself from: (i) participating in approval and decision-making processes related to the transaction, including making a recommendation; (ii) reviewing, editing, commenting on, approving and signing relevant transaction documents; and (iii) engaging in negotiations with the investment target (or the relevant transaction counterparty).

Covered Foreign Person. The Proposed Rule would take a broad view of who is a "covered foreign person," mirroring the current OISP while expanding the definition to cover persons that are "subject to the direction or control" of a covered foreign person.

- An entity would be subject to the direction or control of a covered foreign person if that person has the power, directly or indirectly, to direct or cause the direction of the management or policies of such entity (whether through ownership, contracts or otherwise).
- The Proposed Rule also clarifies that a company may have more than one principal place of business, which would include its headquarters, where its management is located and where it conducts its main business activities. Treasury provides an example, in the preamble to the Proposed Rule, of a U.S.-headquartered company whose CEO manages the business from a country of concern as having a principal place of business in both the U.S. and the country of concern.

- The Proposed Rule would combine the current defined term "person of a country of concern" into the definition of "covered foreign person"; however, coverage would be largely in line with the current OISP.

List-Based Prohibitions. The Proposed Rule would cross-reference several U.S. government lists, including the Commerce Department's Entity List and, newly, the Section 1260H list of Chinese military companies and the BIOSECURE Act list of biotechnology companies of concern (which is forthcoming, and must be published by December 18, 2026). An investment that would otherwise be only notifiable would be prohibited if the covered foreign person or relevant joint venture, or any of its affiliates or subsidiaries, appears on one of these lists. This bright-line rule increases the importance of restricted-party screening of a target's entire corporate family.

Coverage of Limited Partners & Funds. The Proposed Rule's coverage of limited partner and fund investments mirrors current coverage under the OISP.

- The Proposed Rule would continue to only cover U.S. LP commitments to *non*-U.S. funds.
- The Proposed Rule would retain the exception for U.S. LPs with commitments of less than $2 million or who secure a "binding contractual assurance" from non-U.S. funds that their capital will not be used in a transaction that would be prohibited or notifiable if it were engaged in by a U.S. person. While there have been questions, under the current OISP, around exactly what language meets the "binding contractual commitment" requirement, the Proposed Rule declines to provide further detail on this point.
- The Proposed Rule would except indirect investments by LPs through a non-U.S. fund if the transaction is made pursuant to a binding, uncalled capital commitment entered into before the final rule's effective date.
- Treasury stated, in the preamble to the Proposed Rule, that investments by U.S. persons in funds with pre-existing investments in a covered foreign person can constitute indirect covered national security transactions. While Treasury acknowledged that U.S. persons' ability to conduct diligence around secondary transactions is often limited, U.S. persons are nonetheless obligated to undertake a reasonable and diligent inquiry on such investments.

Exceptions. The Proposed Rule would retain most existing exceptions. The Proposed Rule would add a *de minimis* exception from the notification requirement for transactions not exceeding $50,000 in the aggregate over the preceding 12 months (there is no *de minimis* exception for prohibited transactions), as well as exceptions for

routine financial services such as bank lending, payment processing, underwriting, custody and prime brokerage.

Advisory Opinion Process. The Proposed Rule creates an advisory opinion process, whereby a U.S. person with a direct financial interest in an actual, forthcoming transaction can request confidential, non-binding feedback from Treasury on whether the transaction would be prohibited. This advisory opinion process is the first of its kind in investment reviews; no such process exists under the current OISP or under CFIUS.

- The Proposed Rule would require U.S. persons to provide extensive information around the transaction to receive an advisory opinion, including (at a minimum): (i) information about the requester and any party to the transaction; (ii) a detailed description of the structure of the transaction (including the form of investment, governance and information rights, timing, and completion date); (iii) a detailed description of the products, services, technologies or activities implicated by the transaction; (iv) all operative documents and material term sheets, draft agreements, side letters, and other written materials reflecting the transaction; and (v) any other information that the requester believes would be relevant to the application of the Proposed Rule to the transaction.
- Advisory opinion requests would only be available for "an actual — not hypothetical — transaction" that has not already closed.
- Treasury would not be obligated to issue an advisory opinion and would be able to, in its discretion, choose to respond to a request confidentially or by providing anonymized public guidance.

Additional Notification Information. Notifications would need to include additional information, such as deal documents, beneficial ownership information, the citizenship of key personnel, business relationships and negotiation history.

Penalties and Enforcement. The Proposed Rule would retain civil penalties and divestment authority but would omit the current regulations' criminal-penalty language, which the COINS Act does not include. Voluntary self-disclosures of both prohibited and notifiable transactions would need to propose mitigation of any harms associated with the violation, which may include divestment or voluntary disgorgement of profits.

These proposals may change after the comment period. Treasury is seeking public comments on the Proposed Rule, particularly on the implications of prohibiting investments in the development of any SI system, the scope of what biotechnologies

should be covered and other areas where the Proposed Rule would expand the OISP. Interested parties should consider submitting comments by December 7, 2026, as Treasury may limit the scope of such provisions in the final rule or provide further clarity on coverage in the final rule or FAQs based on such feedback.

The First OISP Penalty

Separately, Treasury recently announced the first civil penalty under the OISP. In July 2026, Treasury imposed a $200,000 penalty on Amidi, LLC (Amidi), a U.S. investment firm, for failing to notify Treasury of an investment by its Chinese subsidiary.

On April 19, 2025, Amidi's Chinese subsidiary invested approximately $92,478 in Shanghai Qiongche Intelligent Technology Company Limited (Noematrix), a private Chinese company that develops general-purpose robotic SI and embodied intelligence models. Amidi did not submit the required notification for the transaction with Treasury.

The action demonstrates that even small investments made through foreign subsidiaries carry real risk if required notifications are not filed.

Appendix A

	*Prohibited (**Full Text Here**)*	*Notifiable (**Full Text Here**)*
Semiconductors & Microelectronics	• Development or production of electronic design automation software for the design of integrated circuits or advanced packaging;	
	• Development or production of front-end fabrication equipment for volume chip production, equipment for volume advanced packaging, and items for use with DUV or EUV lithography equipment;	• Development or production of equipment not described in the prohibited technology definition that is designed or intended for use in the design, fabrication, or

		packaging of any integrated circuit
	• Design of the most advanced chips (those meeting the ECCN 3A090.a export control thresholds) and chips built to operate at or below 4.5 Kelvin;	• Design of any integrated circuit that is not described in the prohibited technology definition
	• Fabrication of leading-edge logic chips (non-planar transistors or 16/14 nm or below), advanced memory (NAND with 128 or more layers and certain high-density DRAM), and chips using graphene or carbon nanotubes or built to operate at or below 4.5 Kelvin;	• Fabrication of any integrated circuit that is not described in the prohibited technology definition
	• Packaging of chips using advanced (2.5D or 3D) packaging techniques;	• Packaging of any integrated circuit that is not described in the prohibited technology definition
	• Development or production of chips made from specialized materials (silicon carbide, gallium-based or other III-V compound semiconductors, or ultrawide bandgap semiconductors);	• Development or production of any integrated circuit that is not described in the prohibited technology definition

	• Development or production of radiation-hardened chips built to withstand high radiation levels; • Development or production of photonic integrated circuits, including optical components, co-packaged optics and silicon-photonics integration; and • Development or production of high-bandwidth memory with a memory bandwidth density greater than 2 gigabytes per second per square millimeter (aligned with ECCN 3A090 on the Commerce Control List).	
Quantum Information Technologies	• Development of quantum computers and production of their critical components (e.g., dilution refrigerators and two-stage pulse tube cryocoolers); • Development of software for designing, simulating, testing or controlling quantum computers, or for identifying, implementing, costing, or optimizing quantum computing algorithms and applications; • Development or production of quantum sensing platforms designed or intended for military, government	N/A

	intelligence or mass-surveillance use; • Development or production of quantum networks or communication systems designed or intended to scale up quantum computers, for secure communications, or for military, government intelligence, or mass-surveillance use; and • Development of algorithms and applications for quantum information science technologies.	
Super Intelligence (Previously Artificial Intelligence)	• Development of any SI system, regardless of computing power or end use, including enhancing or extending a third-party model (e.g., building an agentic layer on it). Using an off-the-shelf model only for internal, non-commercial purposes is not "development" on that basis alone.	N/A
High Performance Computing and Supercomputing	• Development, installation, sale or production of supercomputers enabled by advanced integrated circuits that meet specified compute thresholds (100 or more double-precision or 200 or more single-precision petaflops within a 41,600 cubic foot or smaller envelope), or of components	• Development or production of high-bandwidth, low-latency interconnects for high-performance computing, including interconnects for system-on-chip, system-in-package, scale-up networks,

	designed to enable those capabilities • See also the semiconductor prohibitions on certain DRAM, photonic integrated circuits, and high-bandwidth memory	and scale-out networks
Hypersonic Systems	• Development or production of hypersonic systems (vehicles or weapon delivery systems capable of sustained atmospheric or very low Earth orbit flight at Mach 5 or above), hypersonic propulsion systems (e.g., ramjets and scramjets), and their fuels or propellants	• Development or production of sensor, guidance, navigation or control equipment or systems capable of use in or for a hypersonic system or its components
	• Development or production of specialized materials designed or intended for hypersonic systems, including heat-resistant metals, ceramics and carbon composites, and stealth coatings	• Development or production of metals, alloys, composites, ceramics, coatings or other materials capable of use in or for a hypersonic system or its components that are not described in the prohibited technology definition
	• Development or operation of facilities for testing hypersonic systems (e.g., arc jets, wind tunnels and ground test beds)	
	• Development of digital twin and digital thread technology for modeling, monitoring or	• Development or production of software for research, modeling

	managing data on hypersonic systems	and simulation, analysis or testing capable of use in or for a hypersonic system or its components that is not described in the prohibited technology definition
Biotechnology	Development, engineering, or use of a biological system (or any component of one) to modify, enhance, produce, or control: • Restricted agents or toxins (under the select agent and export control regulations), or novel agents or toxins with similar harmful effects • Energetic precursors or materials (e.g., propellants, explosives and pyrotechnics) • Novel or high-performance bio-derived materials (e.g., protective coatings, self-repairing materials and biosensors) • Pharmaceutical compounds (including small molecules, vaccines, cell and gene therapies, and monoclonal antibodies or other recombinant therapeutic proteins), and their delivery mechanisms • Biofuels	N/A

- Development or production of brain-computer interfaces; development, construction, or production of export-controlled biomanufacturing equipment; and development or production of the following equipment and tools:

    Biological sequencing technology

    Advanced flow cytometers and cell sorters (spectral or 26+ detectors or channels)

    Liquid chromatography mass spectrometry instruments designed for top-down proteomics

    Computational or bioinformatics tools for researching, designing or modeling biological systems

    Lab automation, robotics or cloud lab infrastructure for automated scientific discovery

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Suggested Reading

- 08 September 2026 Kirkland Alert CFIUS at 50: Highlights From CFIUS' Latest Annual Report
- 30 June 2025 Kirkland Alert BIS Takes Aim at Chinese Semiconductor Industry With Novel Export Controls Approach
- 27 May 2025 Kirkland Alert BIS Rescission of the Biden Administration's AI Diffusion Framework

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