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Treasury Proposes Expansion of U.S. Outbound Investment Security Program Under COINS Act

Go-To Guide:

- The U.S. Department of the Treasury has proposed regulations implementing the Comprehensive Outbound Investment National Security Act, which Congress enacted as part of the FY 2026 National Defense Authorization Act. The proposal would build on and substantially revise the existing U.S. Outbound Investment Security Program.
- The proposed framework would expand the technologies potentially subject to outbound investment restrictions beyond the original OISP focus on semiconductors and microelectronics, quantum information technologies, and artificial intelligence. The COINS Act expressly adds high-performance computing/supercomputing and hypersonic systems, and Treasury's proposal would add biotechnology as an additional covered sector.
- The proposal would retain the OISP's basic architecture of prohibiting certain transactions but would require notification for others. It would revise key definitions, covered transactions, diligence expectations, exceptions, and technical thresholds.
- The proposed addition of biotechnology is particularly notable for life sciences companies, investors, venture funds, pharmaceutical companies, research organizations, and other participants in cross-border transactions involving biotechnology capabilities.

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- Companies and investors considering transactions that may involve the proposal's covered technology sectors (including where the investment target is located in the United States) may wish to assess the proposed rules now and consider whether to submit comments. Comments are due Dec. 7, 2026.

On Oct. 22, 2026, the U.S. Department of the Treasury issued a Notice of Proposed Rulemaking (NPRM) to implement the Comprehensive Outbound Investment National Security (COINS) Act, enacted in December 2025 as part of the National Defense Authorization Act for Fiscal Year 2026. The COINS Act codified and expanded the U.S. government's outbound-investment regime, which currently operates under Treasury's Outbound Investment Security Program (OISP).

Treasury's proposal represents the next step in the evolution of a regulatory regime that began with the August 2023 executive order on outbound investment and became operational when Treasury's original OISP regulations took effect Jan. 2, 2025. As discussed in our prior GT Alerts, White House Issues Executive Order Restricting Outbound Investment and U.S. Outbound Investment Security Program Takes Effect January 2025, the existing OISP created prohibitions and notification requirements for certain U.S. investments involving China, Hong Kong, and Macau in semiconductors and microelectronics, quantum information technologies, and artificial intelligence.

The COINS Act moves that framework onto a statutory footing and expands the technologies Congress has directed Treasury to regulate. Treasury's proposed regulations would formalize — and expand upon — the COINS Act directives. The NPRM also proposes to expand the industry sectors affected by the OISP, which would bring certain biotechnology investments within the outbound-investment regime for the first time.

From the Existing OISP to the COINS Act

The existing OISP was established under Executive Order 14105 and Treasury's implementing regulations at 31 C.F.R. Part 850. It regulates certain transactions by U.S. persons involving covered foreign persons engaged in specified semiconductor and microelectronics, quantum information technology, and artificial intelligence activities. Depending on the particular technology and activity involved, a covered transaction may either be prohibited or subject to a post-closing notification requirement.

The COINS Act preserves that basic structure. It directs Treasury to adopt regulations requiring U.S. persons to notify Treasury regarding certain transactions involving covered foreign persons engaged in notifiable technologies, while prohibiting certain transactions involving covered foreign persons engaged in prohibited technologies.

The statute also broadens the potential substantive reach of the program. Congress authorized Treasury to establish technical parameters for prohibited and notifiable technologies across five sectors:

- semiconductor technologies and microelectronics;
- artificial intelligence systems;
- quantum information technologies;
- high-performance computing and supercomputing; and
- hypersonic systems.

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Pursuant to the authority granted by the COINS Act, Treasury proposed adding biotechnology as a prohibited sector in this NPRM (in addition to the statutory sectors listed above).

Biotechnology May Enter the Outbound Investment Framework

The proposed inclusion of biotechnology is one of the NPRM's most notable developments and may have substantial implications for U.S. and international life sciences businesses and investors. The proposed biotechnology prohibitions include specified activities involving biological systems used to modify, enhance, produce, or control pharmaceutical compounds and their delivery systems, including vaccines, cell and gene therapies, and monoclonal antibodies, as well as certain enabling technologies and equipment. Therefore, parties may wish to focus on the target's specific activities and capabilities during diligence. If adopted, covered transactions involving these specified biotechnology activities would be prohibited, subject to applicable exceptions or exemptions; the proposal does not provide a biotechnology notification tier.

The proposal is also part of a broader shift in the U.S. government's treatment of China-linked life sciences activity. As discussed in our September 2026 GT Alert, 2 Tracks, 1 Enterprise Strategy: U.S. National Security Policy is Changing Life Sciences Competition with China, U.S. national security policy increasingly intersects with life sciences transactions through rules affecting capital, licensing, intellectual property, research, data, manufacturing, and supply chains.

Treasury's proposal would bring outbound investment controls more directly into this landscape. As a result, life sciences companies and investors contemplating China-linked financings, acquisitions, joint ventures, licensing arrangements, or other cross-border structures may wish to consider outbound investment restrictions alongside existing transaction-specific regulatory requirements. The proposal may apply differently to a standalone cash license than to an arrangement that also includes equity, equity-like financing, or a joint venture.

Coverage would depend on the full arrangement and the proposed covered-transaction definitions, rather than the licensing label alone. For example, a U.S. pharmaceutical company's standalone cash license of rights to a therapeutic from a Chinese biotech may fall outside the proposal if it does not otherwise meet a covered-transaction category. A related minority equity investment in the licensor would require separate review and might be prohibited if the licensor is a covered foreign person engaged in a specified prohibited biotechnology activity, subject to applicable exceptions or exemptions.

The implications may extend beyond traditional investment firms. Depending on the final definitions and technical parameters, the proposed rules may become relevant to strategic investments and other transactions undertaken by pharmaceutical and biotechnology companies themselves. This makes identifying the precise biotechnology activities captured by the final regulations particularly important for industry participants.

Key Elements of Treasury's NPRM

Beyond the expansion of covered technology sectors, Treasury's NPRM addresses many of the core concepts governing how the revised program would operate. According to Treasury, the proposal addresses:

- requirements applicable to U.S. persons, including requirements relating to their controlled foreign entities;
- categories of covered national security transactions;

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- the scope of covered foreign persons;
- excepted transactions;
- technical specifications delineating prohibited and notifiable technologies and products;
- information U.S. persons would be required to provide in notifications;
- a process for requesting non-binding feedback and submitting confidential information;
- the knowledge standard and expectations concerning a U.S. person's reasonable and diligent inquiry before undertaking a transaction; and
- conduct constituting a violation and the penalties applicable to violations.

These provisions will be particularly important for transaction diligence. The existing regime places substantial importance on the U.S. person's knowledge standard related to an investment target's activities. GT's prior OISP Alert therefore noted that investors should consider incorporating OISP analysis into transaction diligence and obtaining current advice as the new program is implemented.

The proposed rules reinforce the importance of that approach by expressly addressing the diligence Treasury would expect U.S. persons to undertake before completing potentially covered investments. Notably, even companies outside of China and other "countries of concern" – including U.S. companies – may constitute "covered foreign persons," which might create scenarios where U.S. entities are navigating these requirements from the perspective of both a U.S. person and a covered foreign person. Accordingly, investors may need to undertake the case-by-case analyses outlined above even when the investment target is a U.S. company.

Considerations for Companies and Investors

The proposed rules have not yet been adopted. However, the NPRM presents an opportunity for stakeholders to submit comments ahead of the regulatory framework being finalized. Treasury has specifically requested stakeholder feedback on the scope of covered transactions, definitions, notification requirements, penalties, and enforcement. After considering public comments, Treasury will establish the effective date of the revised program in its final implementing regulations.

Among other steps, potentially affected companies and investors may wish to:

- *Review transaction pipelines.* Stakeholders should consider identifying pending or contemplated investments, acquisitions, joint ventures, and other transactions involving countries of concern and activities within the additional technology sectors identified by Congress and Treasury.
- *Assess biotechnology exposure.* Life sciences companies, private equity and venture capital sponsors, corporate venture arms, and other investors may wish to identify investments involving biotechnology activities that may fall within the proposed technical definitions.
- *Review expanded technologies*. The NPRM expands, or adds to, the definition of the five technology areas within the statutory definitions of notifiable and prohibited technology. Parties should consider reviewing their current investments and operations to determine whether such activities fall under the proposal's expanded technology areas.
- *Revisit diligence procedures.* Existing OISP diligence processes may need to be modified to address an expanded universe of technologies and counterparties and Treasury's reasonable-and-diligent-inquiry expectations.

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- *Consider transaction documentation.* Parties may wish to evaluate whether representations, covenants, information rights, closing conditions, and other contractual protections adequately address outbound-investment requirements as the regulatory framework changes.
- *Coordinate related national-security reviews.* Outbound investment analysis may increasingly need to be integrated with CFIUS, export controls, sanctions, research-security requirements, and sector-specific restrictions, particularly in technology and life sciences transactions.
- *Consider submitting comments.* Comments on the NPRM are due Dec. 7, 2026. Life sciences stakeholders should consider Treasury's request for feedback on whether pharmaceutical compounds and covered equipment should be scoped more narrowly toward advanced or frontier technologies, including the potential implications for public health and U.S. businesses.

Looking Ahead

The NPRM illustrates the continued expansion of outbound investment regulation from a novel executive-branch program into a broader, congressionally mandated national security framework. Whereas the original OISP centered on three categories of advanced technology, the COINS Act and Treasury's proposal would extend the regime into additional strategically sensitive sectors and, through Treasury's proposed inclusion of biotechnology, further into the life sciences industry.

The rule is not yet final. Treasury will consider comments before issuing final implementing regulations, and those regulations will establish the effective date for the revised program. Until then, the existing OISP remains operative.

Companies, investment funds, and other parties involved in cross-border transactions should monitor the rulemaking. They may wish to evaluate how the expanded framework might affect investment diligence, transaction structuring, and longer-term investment strategies.

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