

The BIOSECURE Act

Briefing for the Coalition for Government Procurement Pharmaceutical Committee

Wednesday, April 29, 2026

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BIOSECURE Overview

- BIOSECURE passed as part of the 2026 National Defense Authorization Act (NDAA) on December 18, 2025.
- It will take **2.5-3 years** to become effective (Q3/Q4 2028).
- What this law will do:
 - It will prohibit USG from acquiring biotechnology services or equipment from “companies of concern” - focusing on “**inbound**” biotechnology from identified CDMOs deemed to be linked to Chinese or foreign adversary govt/military
 - Differs from “**outbound**” restrictions such as the DOJ Bulk Sensitive Data Rule, which prohibits U.S. persons from giving Chinese companies and residents, and other foreign adversaries, access to U.S. bulk sensitive personal data.
- Key BIOSECURE policy considerations:
 - National security – primarily China/foreign adversary access to US genomic data
 - Onshoring/rebuilding of US domestic industrial base

BIOSECURE Prohibitions

■ ***Key prohibition:***

- Federal agencies are prohibited from entering/extending/renewing procurement contracts (or grants) with any company that
 - “knowingly” provides “biotechnology equipment” or “biotechnology services” from a “biotech company of concern” (BCC) in performance of the contract (or grant).
- BCCs comprise biotechnology CDMOs/CMOs listed on ***DoD’s “1260H” list*** of Chinese military companies ***or*** a ***new OMB list*** ... lists to be updated annually
 - BCCs are not “named” in the statute and no automatic coverage through “affiliation” (unlike prior bills)

■ ***BIOSECURE does not apply a ban on doing business with BCCs.***

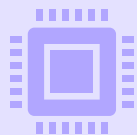
- Rather, it renders covered items ineligible to be acquired by the Federal government. *Whether to forego Federal contracts or to cut ties with any BCC to remain eligible is therefore a business decision.*

Biotechnology Equipment and Services



Equipment “designed for use in the research, development, production, or analysis of biological materials”

Equipment ranges from genetic sequencers to the software, firmware, and other digital components necessary for their use



Services “for the research, development, production, analysis, detection, or provision of information, including data storage and transmission related to biological materials,” including:

Advice, consultations, and support related to biotechnology equipment

“[D]isease detection, genealogical information, and related services”



Catchall provision allows Office of Management and Budget (OMB) (with US executive branch agency heads) to supplement this definition as OMB “determines appropriate in the interest of national security.”

BIOSECURE Timeline

- Statutory implementation timeline (could be longer or shorter):
 - Dec. 18, 2025: BIOSECURE enactment
 - Dec. 18, 2026: OMB to issue list of BCCs
 - June 16, 2027: OMB to issue BIOSECURE guidance
 - June 16, 2028: Update to the Federal Acquisition Regulation (FAR)
 - Sept. 2028: Effective date for 1260H companies
 - Oct. 2028: Effective date for OMB list companies
- Prospective only: applies to USG contracts/grants awarded **after** BIOSECURE goes into effect.
- “Grandfathering”: Biotechnology equip/services provided to USG contractors under pre-existing contracts with BCCs are subject to “grandfathering” that lasts for 5 years after effective date of BIOSECURE (grandfathering period for BCCs added after initial list/FAR update unclear).

BIOSECURE Applicability

■ Applicability of BIOSECURE:

- **Federal contracts and grants, but not Federal health programs**: Payment for biotechnology equipment and services under Medicare and Medicaid programs is not impacted by BIOSECURE.
- **Waiver**: only available on a limited case-by-case basis for up to 1.5 yrs or for national emergency.
- **Application to R&D/Downstream Services**: Under BIOSECURE, the USG may not contract with an entity that “uses biotechnology equipment or services provided by a [BCC] ... in the performance of the contract...”
Implementation vis-à-vis biopharma companies that ultimately ***supply product into the Federal market***:
 - **R&D**: early stage R&D performed by BCCs likely would not be considered a “biotechnology service” provided “in the performance of” a USG drug supply contract. (But could be if under a grant for R&D.)
 - **CDMO manufacture of API/product**: But “biotechnology services” necessary for the supply of drug/biologic product under USG contract or grant could include ***manufacture of API or final drug product***.
- **State BIOSECURE laws**: several states have implemented/ proposed, similar laws – some **prohibit use**.

Considerations surrounding engagement with BCCs

- Most pharma/biotech companies have Federal Supply Schedule contracts with USG per statutory requirement (Veterans Health Care Act of 1992). **Consider the importance of FSS revenue** and any other potential revenue from other Federal supply contracts (VA/DoD/HHS) are anticipated.
 - Maintaining contracts with BCCs to provide biotechnology services necessary for the performance of a Federal contract (to supply any particular product(s)) could render product ineligible to be procured by the USG.
 - Deemed not to be an FSS/VHCA compliance issue; where covered drugs are offered but unable to be listed on FSS should be no impact to VA Master Agreement.
- **Consider supply chain** – whether subcontractors may be providing prohibited equipment or services
- **Consider whether Federal grants/funding awards** are contemplated
- **Consider specific services or equipment** being provided (or contemplated to be provided) by any BCC. Could any item be considered “biotechnology equipment or services”?
- **Consider timing of when the BIOSECURE restrictions could apply** given Federal contract award dates (esp. with new “Evergreen” FSS) and grandfathering provisions.

Considerations re engagement with BCCs (cont'd)

- **Identify and review all agreements, including contracts, purchase orders, and MOUs with BCCs (and affiliates) + other labs, CMOs, CDMOs in China**
- **Consider potential exit strategies**
 - Assess any existing termination clauses
 - Consider potential amendments to scope/ rights to exit based on company being listed as BCC and ability to keep IP / data / assets (e.g., cell lines)
- **Assess potential to pivot to make alternative plans with other business partners, and consider timing**
 - Timing of applicability of law
 - Timing to exit existing agreements and to move ahead with other labs

BIOSECURE horizon scanning

- We will be watching for:
 - updates to the 1260H list and publication of the OMB list
 - updates to FAR + new USG contract clauses implementing BIOSECURE
- Potential for ***oversight or criticism*** of companies that continue to partner with BCCs
- For any new transaction, check for
 - current status of BIOSECURE
 - new legislative or executive actions seeking to limit clinical trials, investments, data transfers, licensing contracts or other partnerships with BCCs that may be adjacent to BIOSECURE

Questions?



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