Deadline Approaching: OIG Seeks Input on Anti-Kickback Safe Harbors for Clinical Trial Participant Remuneration



On June 24, 2026, the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS") issued a **Request for Information** ("RFI") seeking stakeholder input on payments received by individuals in connection with clinical trial participation. Specifically, OIG is seeking to identify ways it might: (i) modify or add new safe harbors to the Federal anti-kickback statute ("AKS") or exceptions to the civil monetary penalty provision prohibiting inducements to beneficiaries (the "Beneficiary Inducements CMP"); or (ii) issue or revise guidance addressing arrangements intended to facilitate clinical trial participation while safeguarding against fraud and abuse.

The RFI follows on the heels of HHS's Operation TrialBlazer initiative, which has identified patient access and engagement as a priority area for revitalizing U.S. clinical research. That initiative has already acknowledged that trial participation imposes real financial burdens on patients (i.e. things like cost-sharing, unplanned tax consequences from trial-related payments, and potential effects on program eligibility (e.g., Medicaid)). Accordingly, OIG appears to be leveraging this RFI to explore whether the fraud and abuse rules themselves serve as a form of barrier or burden to Americans' – and especially government beneficiaries' – ability to access clinical research.

Current OIG Thinking and Issue at Hand

- The AKS and the Beneficiary Inducements CMP were both written broadly, and neither statute carves out an exception for remuneration tied to clinical trial participation. As a result, OIG currently treats remuneration provided to clinical trial participants, including cost-sharing waivers, transportation, childcare expenses, and stipends, as potentially falling within the broad reach of the AKS and the Beneficiary Inducements CMP, meaning such payments may be considered presumptively suspect unless they fit within an existing safe harbor or exception.
- OIG has issued 10 favorable advisory opinions over the past two decades allowing for certain forms of cost-sharing waivers for clinical trial participants, but has not addressed other forms of remuneration to clinical trial participants. Further, while these opinions establish that OIG is comfortable with cost-sharing relief in the right circumstances, the advisory opinions themselves are fact-specific and binding only on the requesting party.

OIG's Request

Rather than proposing specific regulatory text, OIG has opted to cast a wide net. The RFI poses 14 questions spanning from whether remuneration works as an enrollment tool in the first place to the

mechanics of a potential safe harbor (i.e. value caps, permissible payors, IRB oversight, and clinical research phase-specific distinctions). OIG has asked that commenters back their positions with data, studies, or concrete examples where possible. In other words, a generalized comment expressing support for "more flexibility" is unlikely to carry the same weight as specifics tied to actual trial experience.

The RFI poses 14 specific questions to stakeholders, and OIG asks that commenters support claims with relevant data, studies, analyses, and other citations.

Topics covered include:

- Whether offering Federal health care program enrollees remuneration actually facilitates clinical trial participation;
- Whether the AKS or Beneficiary Inducements CMP are perceived as barriers to providing appropriate remuneration;
- What categories and levels of remuneration (e.g., travel, lodging, childcare, stipends, time compensation) are useful to facilitate participation, and which carry heightened fraud and abuse risk;
- What value caps, limits, or restrictions on who may provide remuneration would guard against fraud and abuse;
- The role of Institutional Review Boards (IRBs) as a safeguard over the type, amount, and frequency of remuneration;
- Whether remuneration considerations differ across trial phases (Phase 1–4) and types of trials (e.g., government-sponsored vs. industry-sponsored);
- Whether safeguards are needed to prevent participants from being steered toward non-trial items or services offered by the party providing the remuneration;
- Whether limitations on advertising remuneration are needed to protect trial integrity;
- What additional or modified safe harbors or CMP exceptions may be necessary, and what key provisions they should include; and
- Whether OIG could address some issues through guidance (e.g., Special Advisory Bulletins, FAQs) rather than formal regulation.

Stakeholder Considerations

OIG has signaled openness to addressing some issues through a Special Advisory Bulletin or FAQ rather than formal rulemaking. Given the length of the rulemaking process, stakeholders may consider advocating for interim guidance as the most pragmatic path to near-term certainty for sponsors currently designing or enrolling trials.

This RFI is a particularly timely opportunity for rare disease-focused sponsors, sites, and patient advocacy organizations. For example, qualified treatment centers for certain rare disease therapies are often limited to a small number of sites nationally (or globally), and participants frequently face significant travel and lodging burdens, caregiver support needs, and other questions about remuneration that OIG can squarely address through this guidance. Rare disease stakeholders may be best positioned to give OIG concrete, data-supported input on categories like qualified-treatment-center travel support and caregiver assistance that general commentary from more geographically distributed therapeutic areas may not capture.

Next Steps

Stakeholders wishing to submit comments must do so no later than **August 24, 2026 at 5:00 p.m. ET** (60 days from the Federal Register publication date of June 24, 2026).

Interested stakeholders should reach out to Matt Wetzel (**mwetzel@goodwinlaw.com**) and Amelia Nell (**anell@goodwinlaw.com**) with any questions or assistance with preparing and submitting a response to OIG's RFI.

BIOSECURE Update – 1260H List Released



The Department of Defense has published its updated Section 1260H list of "Chinese military companies" this week, and WuXi AppTec along with 27 other new entities were identified on the list. (Federal Register notice available here: **https://public-inspection.federalregister.gov/2026-11571.pdf**.) DoD noted that WuXi AppTec is named on the basis of indirect ownership by China's state enterprise body (SASAC) and indirect affiliations with China's defense science agency (SASTIND) and the People's Liberation Army. The list also includes BGI Group (and 7 listed affiliates), MGI Tech Co., Ltd., Novogene Company Limited, and Origincell Technology Co., Ltd.

What does this mean?

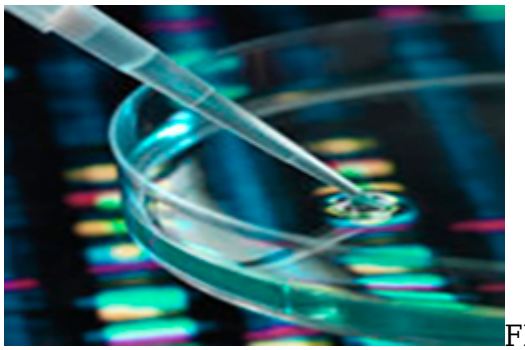
Under the enacted BIOSECURE Act (Section 851 of the FY2026 NDAA), a 1260H listing is the first step toward becoming a "biotechnology company of concern" (BCC) that triggers BIOSECURE's federal procurement/contracting restrictions. Next, OMB must still separately publish a list of BCCs, which will include entities identified on the updated 1260H list. This list must be published by December 2026. Once the list is published, the Act's prohibitions do not take effect until 60 days after the regulations are subsequently revised (likely sometime in 2027). Pre-effective-date contracts are grandfathered for five years from that FAR revision date.

What should companies do?

Companies should review their existing agreements with entities named on the 1260H list to understand whether any BIOSECURE-related provisions may have been triggered and should continue to operate with awareness of the likelihood of forthcoming BCC designations. We can also expect the OMB biotechnology determination process to move quickly given continued recent Congressional pressure.

For further information, please feel free to connect with Matt Wetzel (**mwetzel@goodwinlaw.com**), Liza Craig (**lcraig@goodwinlaw.com**), Justin Pierce (**jpierce@goodwinlaw.com**), David Chen (**DavidChen@goodwinlaw.com**) and Gozde Guckaya (**gguckaya@goodwinlaw.com**) to schedule time.

Move Fast: FDA is Accepting Submissions for the Pilot Program Class for FDA Commissioner's National Priority Voucher Program



FDA is now accepting submissions to the Commissioner's National Priority Voucher (CNPV) pilot program, and with only five vouchers to be awarded as part of the initial year of the program, the competition is anticipated to be fierce. It has been a little over a month since the FDA **announced** the CNPV pilot program, and the FDA has now provided additional information to help interested companies through the process and criteria for applying for these vouchers.

On June 17, 2025, the FDA announced that through the CNPV program, selected sponsors will receive non-transferable vouchers that can be redeemed for expedited review of their drug or biologic product candidates. The FDA touts the CNPV program as a "novel" priority program that "shortens [the agency's] review time from approximately 10-12 months to 1-2 months following a sponsor's final drug application submission." The vouchers awarded through the program can be applied to drug or biologic product candidates in any area of medicine and will focus on companies that are aligned with the following national priorities:

1. Addressing a health crisis in the US,
2. Delivering more innovative cures for the American people,
3. Increasing affordability,
4. Addressing unmet public health needs, and
5. Increasing domestic drug manufacturing as a national security issue.

In an update posted July 22, 2025, the FDA provided **examples** of each of the national priorities that could make a company or its drug candidate eligible for a CNPV voucher. Of notable interest to the rare disease community, FDA's example for addressing a large unmet medical need specifically includes condition(s) that available therapies do not adequately diagnose or treat, "including drugs to treat or prevent rare diseases."

Here are four things to know about the CNPV program, based on the information the FDA has provided thus far:

- **Participation Process**: Interested and eligible companies should submit a statement of interest to FDA through the **CNPV Program Submission** page. Interested companies can submit a maximum of one statement of interest each, although the FDA has indicated that vouchers can be granted for review of a specific drug or as an undesignated voucher, allowing

a company to use the voucher for review of an application for a drug "at the company's discretion subject to consistency with the program's objectives." The FDA will select companies based on the submitted statement of interest for "possible acceptance" into the pilot program. These statements are short—just 350 words or fewer—and should discuss one national priority the drug development program addresses and any specific issue(s) for which the company may be seeking enhanced communications with FDA to facilitate program development. If the program addresses more than one national priority, companies should identify the primary national priority in their statement of interest.

- **Submission and Review Process**: The CNPV program submissions will be evaluated by a senior, multi-disciplinary committee of experts, led by FDA's Office of Chief Medical and Scientific Officer, and the committee will pre-review the submitted statements of interest and convene for a 1-day "tumor board style" meeting. The Commissioner's **YouTube announcement** for the program explains that such meetings allows experts "to consider hard questions in light of all the latest clinical evidence," and the CNPV committee plans to utilize a similar approach. Companies must be prepared to respond promptly to any FDA inquiries about their submission. FDA is accepting statements of interest on a rolling basis, and although there is not a specific deadline for submissions, we recommend that interested companies act with urgency in order to get considered for the initial pilot program class.
- **CNPV Voucher Benefits**: As **highlighted** by FDA, a CNPV voucher entitles the company holding it to enhanced communications and rolling review to allow for a shortened review time. The FDA plans to provide a limited number of vouchers to companies aligned with US national priorities. A non-transferable voucher issued by the FDA could either be directed at a specific product or awarded to a company as an "undesignated voucher" that the company could use for a new drug at its discretion and consistent with the CNPV program's objectives. The FDA has published a frequently asked questions document, "**FAQs: Commissioner's National Priority Voucher Program**," and notes that this page will be updated regularly as questions arise.
- **Alignment with President Trump's Executive Order**: Among the national priorities that the CNPV program seeks to advance is the goal to increase affordability of drugs and biologics, and that goal is a direct focus of President Trump's May 12, 2025, **Executive Order** on drug pricing, signaling the Administration's goal of "equalizing" prices among the United States and other developed countries throughout the world. Among other directives, the Executive Order directs FDA to contemplate approaches that may involve pricing (for example, examining whether case-by-case importation of products would be appropriate if manufacturers do not lower their prices or whether there may be some sort of action with respect to the product's approval). *See **Goodwin Alert** on the Most Favored Nation Drug Pricing Executive Order*. Companies are paying attention. In just the last couple weeks, two large drug makers have announced direct-to-consumer programs to offer a low-cost option to patients.

If a company is selected as one of the five pilot participants in the initial year of the CNPV program, the FDA states that the "voucher process must be commenced within two years" after receipt of the CNPV, although we note that the current information provided by the Agency does not expressly state whether an NDA or BLA must be submitted within two years. Since the voucher can be applied to a product "at any stage of development," we anticipate that this two-year timeframe may be an area where FDA will provide more clarity as it selects sponsors for the program.

We encourage interested stakeholders to reach out to a member of the Goodwin **Life Sciences Regulatory and Compliance** team for further questions or assistance with submitting a statement of interest for the CNPV program.

DOJ-HHS Announces False Claims Act Working Group, Emphasizes Healthcare Fraud Enforcement Priorities



The Trump administration recently announced the renewal of a new cross-agency collaboration between the Department of Justice (DOJ) and the Department of Health and Human Services (HHS) in the form of the **DOJ-HHS False Claims Act Working Group**. The Working Group will be jointly led by Deputy Assistant Attorney General (DAAG) of the Commercial Litigation Branch Brenna Jenny, HHS Acting General Counsel Sean Keveney, and HHS Office of Inspector General Acting Chief Counsel Susan Edwards, and will include the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity and U.S. Attorneys' Offices.

Read the full alert **here.**

Most Favored Nation Drug Pricing Executive Order Resurrects Prior President Trump Policy



On May 12, 2025, President Trump signed the most recent Executive Order on drug pricing, **Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients**. This latest Executive Order simultaneously pushes key stakeholders (i.e. foreign governments and drug manufacturers) to modify their current practices while threatening potential most-favored nation (MFN)-based price caps and other scrutiny. The Executive Order Fact Sheet is available **here**.

Read the full alert **here**.

Goodwin's 2025 Rare Disease Symposium: Momentum Builds for Addressing Critical Diagnosis and Treatment Gaps



Attendees at this year's **symposium** were optimistic about the potential for progress, citing momentum from new FDA initiatives, growing legislative support, and increased global innovation in research and development. These efforts, alongside increased patient advocacy and a presidential administration focused on speeding patient access, could lead to significant advances in rare disease treatments and cures in 2025.

Read the full insight **here**.

How the Trump Administration Could Reshape Regulation in the Life Sciences Sector


Based on recent policy signals and statements from incoming administration officials, a picture of potential regulatory and policy changes that could affect biotech, pharmaceutical, and medical device companies in coming months and years is emerging.

Anticipated changes span multiple regulatory fronts: a revamped approach to antitrust review at the Federal Trade Commission (FTC), continued momentum on biosecurity measures, and a fundamental rethinking of agency regulation to streamline “red tape” and accelerate patient access to innovative treatments. The Trump administration’s stated focus on “making America healthy again” suggests a broader transformation in how healthcare is delivered and regulated, with emphasis on nutrition, prevention, longevity, enhanced physician autonomy, and a more holistic approach to health to reduce the burdens of chronic disease.

While some changes may create opportunities for innovation and growth, others could pose compliance and operational challenges. Understanding these emerging dynamics will be crucial for industry stakeholders as they position themselves for success under the new administration.

The following six sections are based on discussions from a regulatory panel held on January 15 at the **Goodwin + KPMG 6th Annual Symposium**, which was held during the 2025 JPM Healthcare Conference.

Read the full insight **here**.

New Momentum for a Time-Limited Conditional Approval Pathway for Rare Disease Drugs

On October 4, 2024, a US House version of the revised Promising Pathway Act (PPA) 2.0 was introduced, sponsored by Rep. Bruce Westerman (R-AR). The bill (**H.R.9938**) mirrors a US Senate version that was introduced in May 2024 (**S.4426**) that would authorize the US Food and Drug Administration (FDA) to grant time-limited conditional approval to drugs for rapidly progressive, terminal diseases with substantial unmet need for treatments that are eligible for the Orphan Drug Act and result in a substantially shortened lifespan, substantial reduction in quality of life, or other substantial adverse health effects.

Read the full insight **here**.

Lawsuit Filed Challenging FDA Final Rule

Regulating Laboratory Developed Tests

On May 29, 2024, a lawsuit was filed in the U.S. District Court for the Eastern District of Texas, challenging the U.S. Food and Drug Administration's **final rule** concerning the regulatory status of laboratory developed tests ("LDTs") under the Federal Food, Drug and Cosmetic Act ("FDCA"). As detailed in our prior analysis (**here**), the final rule amended the FDA's existing regulations to make explicit the agency's interpretation that LDTs are "devices" under the FDCA, and established a five-stage plan to phaseout the agency's current general policy of "enforcement discretion" with respect to LDTs.

With the final rule's July 5 effective date looming, two entities—a trade association and a laboratory—filed suit in federal court to overturn the final rule. In this Insight, we briefly summarize the legal theories advanced in the lawsuit and likely next steps.

Read the full alert **here**.

FDA Finalizes Rule and Sets Course to Phase In Oversight of Laboratory Developed Tests

On May 6, 2024, following more than a decade of discourse with interested stakeholders on potential approaches to regulation of laboratory developed tests (LDTs), the U.S. Food and Drug Administration (FDA) published its **final rule** setting forth its framework for oversight of LDTs. The final rule and accompanying policy to phase out the agency's general policy of "enforcement discretion" for LDTs comes roughly six months after FDA published its **proposed rule** that outlined the agency's proposed approach to increasing oversight over LDTs. As detailed in our prior analyses of the proposed rule (see **here** and **here**), FDA proposed to

implement a **phaseout policy** that would, across five stages and within four years, apply to clinical laboratories offering tests as LDTs the same regulatory requirements applicable to in vitro diagnostics (IVDs).

The proposed rule received more than **6,500 comments**, and while FDA did not change its amendments to the regulation or meaningfully modify the phaseout timeline, FDA has significantly modified its phaseout policy to extend full or partial enforcement discretion to additional categories of LDTs, creating a framework whereby the agency intends to take a more targeted enforcement approach, particularly in the near-term, to addressing LDTs.

You can read our more in our **Insight**, where **Steven Tjoe**, **Matt Wetzel**, and **Sukrti Thonse** highlight the key features of the final rule and five-stage phaseout policy. Be sure to bookmark our dedicated **LDT Resource Page** to stay informed on the latest news and analyses on LDTs.