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What Can You Tell Payors Preapproval? FDA Clarifies Safe Harbors

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On June 3, 2026, the US Food and Drug Administration (FDA) issued new draft guidance titled, "Drug and Device Manufacturer Communications With Payors, Formulary Committees,and Similar Entities — Questions and Answers" (2026 draft guidance). Once finalized, the 2026 draft guidance will replace the 2018 final guidance of the same title. FDA is accepting public comments through August 3, 2026.

The 2026 draft guidance implements statutory changes introduced by the Pre-approval Information Exchange (PIE) Act (Section 3630 of the Consolidated Appropriations Act, 2023), which added Section 502(gg) to the Federal Food, Drug, and Cosmetic Act (FDCA). While the guidance does not represent a wholesale overhaul to how FDA considers preapproval payor communications, several updates carry meaningful compliance implications for both drug and device manufacturers seeking to communicate with certain third parties about unapproved products or uses.

Background

Under both the 2018 guidance and long-standing FDA policy, manufacturers have been permitted to communicate certain information about unapproved products and unapproved uses of approved or cleared products to payors, formulary committees and similar entities – such as healthcare economic information (HCEI) – in advance of FDA approval or clearance. The 2018 guidance established a nonbinding framework under which FDA "did not intend to object" to such communications when conducted within specified parameters. The PIE Act added an explicit statutory safe harbor to that framework, and the 2026 draft guidance implements and elaborates on that statutory structure.

Like the 2018 guidance, and consistent with the relevant statutory language, the 2026 draft guidance applies only to communications with payors, formulary committees and similar entities with knowledge and expertise in healthcare economic analysis. Communications directed at other audiences, such as healthcare providers or consumers, regarding unapproved medical products or unapproved uses of approved or cleared medical products "are beyond the scope of this guidance." FDA acknowledges the role that these payor communications can play in coverage and reimbursement assessments and determinations, "recogniz[ing] that in some situations, payors need to plan for and make coverage and reimbursement decisions for medical products and uses far in advance of the effective date of such decisions." The agency further recognizes "the value of payors receiving truthful and not misleading information about unapproved medical products and unapproved uses of approved/cleared medical products, as described in [Section 502(gg) of the FDCA], in order to inform their decision-making."

Key updates in the 2026 draft guidance

1. **Incorporation of the statutory safe harbor under Section 502(gg)**

The PIE Act created a statutory safe harbor under Section 502(gg) of the FDCA, providing that a drug or device shall not be deemed "misbranded" solely on the basis of qualifying payor communications. The 2026 draft guidance incorporates this statutory language, replacing the 2018 guidance's prior nonbinding "does not intend to object" policy with the binding statutory conditions. To qualify for the safe harbor, communications must:

- Fall within the enumerated "product information" types – including product descriptions, anticipated approval or clearance timelines, pricing information, patient utilization projections and factual presentations of study results that do not characterize safety or effectiveness.
- Be truthful and not misleading.

- Include required disclosures regarding the product's unapproved or uncleared status, stage of development, study design limitations, current approved labeling (if applicable) and any material updates to previously communicated information.
- Not include representations that the product has been approved or cleared, or that its safety and effectiveness has been established.

2. **Medical devices now expressly on equal footing with drugs**

One of the more significant structural changes under the PIE Act, also incorporated into the 2026 draft guidance, is the full integration of medical devices (in addition to drugs) into the statutory framework. The PIE Act amended Section 502(a) of the FDCA to explicitly extend the HCEI provisions to medical devices. Under the 2018 guidance, devices were addressed only through a nonbinding "generally applicable" FDA policy – meaning device manufacturers lacked a statutory hook when engaging in these communications. Consistent with the PIE Act, the 2026 draft guidance expressly applies to both drugs and devices. More specifically, it consolidates drugs and devices under a single unified framework and removes the prior separate device section entirely. Device manufacturers can now point to a formal statutory safe harbor when participating in preapproval/clearance HCEI communications with payors.

3. **Mandatory follow-up communications**

Perhaps the most operationally significant change reflected in the PIE Act and incorporated into the 2026 draft guidance is the elevation of the follow-up obligation from a nonbinding recommendation to a statutory requirement. Under the PIE Act and the 2026 draft guidance, manufacturers must provide updated information to payors if previously communicated information becomes materially outdated – for example, due to failure to meet a primary endpoint, a clinical hold or a determination that an application is not ready for approval.

This change creates a meaningful compliance infrastructure challenge. Many manufacturers – especially those working through their first product approval – may not have a systematic process to track which payors or formulary committees received which preapproval communications, making it difficult to reliably trigger follow-up obligations when information becomes outdated. Manufacturers should assess whether their existing policies and procedures are adequate to meet this statutory requirement.

4. **Greater disclosure about clinical development**

FDA reaffirms its policy of not objecting to payor communications about unapproved uses of approved or cleared products, even where such uses are not actively under investigation, provided the communication is consistent with Section 502(gg). However, the 2026 draft guidance picks up on key language in Section 502(gg) that is not present with the Section 502(a) HCEI language – the requirement to disclose "[i]nformation related to the stage of product development" (e.g., the status of any study or studies in which the product or new use is being investigated and how that relates to the overall development plan, whether a marketing application for the product or new use has been submitted to FDA, or when such a submission is planned), as well as material aspects of any such study designs, methodologies and limitations.

This disclosure obligation appeared in a single Q&A response in the 2018 guidance but is now a statutory requirement under the PIE Act. Sponsors must now consider whether and when they are ready to share this type of information with payors, formulary committees and/or similar entities to remain within the Section 502(gg) safe harbor. Doing so will necessarily require sponsors to assess how to protect confidential commercial information while still making the disclosures needed to qualify for the statutory safe harbor.

Implications for sponsors

Although the 2026 draft guidance does not represent a dramatic departure from the previous FDA guidance about HCEI practice, the elevation of key conditions to statutory requirements means that existing payor communication frameworks, templates and policies should be reviewed and updated as appropriate. In particular, companies should consider the following action items:

- **Review disclosure language.** Assess whether current disclosure language in payor-facing materials satisfies the Section 502(gg)(1)(A) statutory requirements, which are now binding rather than advisory.
- **Align device communications with the unified statutory standard.** Device manufacturers should review their payor

communication programs in light of the updated statutory framework that expressly applies to devices.

- **Build or update follow-up communication-tracking processes.** Sponsors should evaluate whether they have sufficient infrastructure to identify which payors received which preapproval communications, and to trigger mandatory follow-up when material information changes. Existing policies should be reviewed – and, where needed, a separate policy covering payor and formulary committee interactions should be developed.
- **Reinforce MLR review for HCEI materials.** To ensure that communications satisfy the disclosure requirements and all other conditions under Section 502(gg), sponsors should route HCEI materials through a Medical, Legal and Regulatory (MLR) review or similar formal review process to confirm that the materials are accurate, nonmisleading and appropriately contextualized within the overall medical product development plan.

Comment deadline: August 3, 2026

FDA is soliciting public comments on the 2026 draft guidance through August 3, 2026. Companies that engage in preapproval/clearance payor communications – particularly those with comments on the mandatory follow-up obligation, the disclosure of medical product development information or device-specific implementation questions – may wish to consider submitting comments.

If you have questions about the 2026 draft guidance, how it affects your existing payor communication program or whether to submit comments, please contact your Cooley relationship attorney or any member of Cooley's life sciences and healthcare regulatory practice group.

Key Contacts

Sonia Nath **Washington, DC**	**snath@cooley.com** **+1 202 776 2120**
Eric Greig Washington, DC	egreig@cooley.com +1 202 728 7095
Stephanie P. Hales Washington, DC	shales@cooley.com +1 202 776 2175
Son Nguyen Washington, DC	snguyen@cooley.com +1 202 728 7100

Wyatt Kernell Colorado	wkernell@cooley.com +1 720 566 4490