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FDA Issues Draft Guidance on Payor Communications to Address Statutory Changes

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On June 2, 2026, the U.S. Food and Drug Administration (FDA) issued draft guidance on how drug and device companies may communicate health care economic information (HCEI) with payors (e.g., health insurance companies), formulary committees (e.g., pharmacy and therapeutics committees) and similar entities. The guidance, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers*, is now open for comment.

When finalized, this guidance will replace FDA's June 2018 final guidance on the same topic. The 2026 revision incorporates statutory changes from section 3630 of the 2023 Consolidated Appropriations Act, which extended the Food, Drug, and Cosmetic Act's HCEI framework in section 502(a) to devices, and added new section 502(gg). Under section 502(gg), "no drug or device shall be deemed misbranded" based on certain truthful and non-misleading communications to payors about investigational products or investigational uses of approved, cleared or licensed products.

Other than incorporating these statutory changes, the 2026 draft guidance does not break significant new ground—FDA largely carried forward its 2018 positions on HCEI communications. Under section 502(a), HCEI communications are not false or misleading if they (1) relate to an approved indication, (2) are based on competent and reliable scientific evidence (CARSE), and (3) include required disclosures about material differences from FDA-approved labeling. Consistent with prior guidance, FDA does not limit the format for communicating CARSE (evidence dossiers, reprinted peer-reviewed journals and payor brochures all remain acceptable). One notable structural change: the 2026 draft eliminates the

separate device section from the 2018 guidance and integrates drug and device guidance together.

The draft also addresses communications about unapproved products and unapproved uses —information payors often need to make coverage and reimbursement decisions before a product reaches the market. Section 502(gg) provides a safe harbor for truthful and non-misleading information about investigational products or investigational uses. Notably, FDA expresses a posture of "non-objection" beyond the statute's literal terms: the agency will not object to communications about **any** unapproved product or unapproved use—even those that "may not be considered investigational"—so long as the communication is consistent with the section 502(gg) framework.

A few notable shifts distinguish this draft guidance from the 2018 guidance:

Statutory footing replaces enforcement discretion. The draft guidance reflects that communications about unapproved products now have a statutory anchor in section 502(gg), whereas the 2018 framework rested on FDA's stated intention not to object.

Disclosure obligations are now mandatory. The draft guidance also reflects that contextual disclosures FDA previously recommended (e.g., information about the stage of development and material limitations of study design) are now required by statute. The statute also imposes a continuing obligation to update payors when previously communicated information becomes materially outdated.

Devices are now fully integrated. The 2018 guidance addressed device HCEI separately because the statute at the time applied only to drugs. With section 502(a) now covering devices, the 2026 draft treats drug and device manufacturers under a unified framework.

While it is helpful that this draft guidance is incorporating recent statutory changes, this relatively discrete release comes at a time when FDA is pursuing a number of initiatives that specifically focus on coverage, reimbursement and payment considerations prior to drug or device approval or clearance, such as the Commissioner's National Priority Voucher program for drugs and the RAPID coverage pathway for devices. The comment period for the draft guidance, which ends August 3, 2026, offers an opportunity to seek clarifications or recommend different approaches.

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