In the **Federal Register** of December 30, 2024 (89 FR 106504), FDA published a notice announcing the availability of a draft guidance entitled ''M15 General Principles for Model-Informed Drug Development.'' The notice gave interested persons an opportunity to submit comments by February 28, 2025.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in February 2026.

This guidance finalizes the draft guidance of the same title issued on December 30, 2024. The guidance provides general recommendations for the planning, model evaluation, and documentation of evidence derived from MIDD. In response to public comments, the guidance updates definitions of key terms and clarifies concepts introduced in the framework for assessment of MIDD evidence. It revises the general considerations for model evaluation. The guidance also updates recommendations on interactions between drug developers and regulatory agencies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''M15 General Principles for Model-Informed Drug Development.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control numbers 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1307]

Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry titled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' This revised draft guidance, when finalized, will provide answers to common questions regarding the communication of health care economic information (HCEI) about approved prescription drugs and approved/cleared (as defined in the guidance) medical devices (collectively referred to in the guidance as approved/cleared medical products) by medical product manufacturers, packers, distributors, and their representatives (collectively referred to as firms) to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis, carrying out their responsibilities for the selection of medical products for coverage or reimbursement (collectively referred to as payors). This revised draft guidance also provides answers to common questions about firms' dissemination of information to payors about medical products that are not yet approved/cleared for any use (collectively referred to as unapproved medical products) and firms' dissemination of information to payors about unapproved uses of approved/cleared medical products.

DATES: Submit either electronic or written comments on the draft guidance by August 3, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1307 for ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (*see* 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the guidance: Twyla Mosey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3203, Silver Spring, MD 20993–0002, 301–796–1200; Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911; or Stephanie Philbin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5513, Silver Spring, MD 20993–0002, 301–837–7151.

With regard to the proposed collection of information: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5683, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry titled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' This revised draft guidance incorporates updates to the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by section 3630 of the Consolidated Appropriations Act, 2023 and, when final, will replace the final guidance of the same title issued in June 2018. This revised draft guidance provides answers to common questions regarding firms' communications of HCEI about their approved/cleared medical products to payors. In addition, the guidance addresses common questions relating to firms' dissemination to payors of information about unapproved medical products and about unapproved uses of approved/cleared medical products. In this guidance, the term payors collectively refers to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis that are responsible for making medical product selection or acquisition, formulary management, and/or coverage and reimbursement decisions on a population basis regarding medical products on behalf of health care organizations, which may include entities such as integrated health care delivery networks, hospitals, and hospital systems.

FDA is aware that payors seek a range of information on effectiveness, safety, and cost-effectiveness of approved/cleared medical products, including information from firms, to help support their medical product selection, formulary management, and/or coverage and reimbursement decisions on a population basis. This information may differ from and may be in addition to the information FDA reviews in order to make medical product approval or clearance decisions. HCEI and product information provided by firms to payors about their medical products must be truthful and not misleading (see section 502(a) and 502(gg) of the FD&C Act (21 U.S.C. 352(a) and 352(gg))).

With respect to HCEI regarding approved/cleared medical products, section 502(a) of the FD&C Act, as amended by section 114 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), section 3037 of the 21st Century Cures Act (Pub. L. 114–255), and section 3630 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), includes a provision regarding communication of HCEI about such medical products to payors. Section 502(a) of the FD&C Act indicates that HCEI provided to payors carrying out their responsibilities for the selection of medical products for coverage or reimbursement shall not be considered to be false or misleading if the HCEI (1) relates to an FDA-approved indication for the medical product (in this guidance, *approved* is defined to include cleared, among other things), (2) is based on competent and reliable scientific evidence, and (3) includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the FDA-approved labeling for the medical product (in this guidance, the term *FDA-approved labeling* includes FDA-required labeling). Section III.A of this guidance provides FDA's current thinking on key concepts in section 502(a) of the FD&C Act and recommendations for how firms can communicate HCEI about approved/cleared medical products to payors in accordance with section 502(a). This information is intended to help ensure that payors have information needed to make informed medical product selection, formulary management, and/or coverage and reimbursement decisions and to help ensure that the information is not false or misleading. Section III.A also discusses how FDA's requirements for submission of promotional materials apply to HCEI about approved drugs disseminated by firms to payors. Section 502(a) of the FD&C Act provides that HCEI disseminated in accordance with its terms is not false or misleading. If a firm disseminates to an appropriate audience HCEI that is of the type of information described in section 502(a) of the FD&C Act, *i.e.,* HCEI that relates to an approved indication and is based on

competent and reliable scientific evidence (CARSE), as each of these elements is described in the guidance, FDA does not intend to consider such information false or misleading. In addition, FDA does not intend to use HCEI about approved/cleared medical products disseminated consistent with this guidance, standing alone, as evidence of a new intended use.

FDA also recognizes that due in part to payors' need, in some situations, to plan for and make coverage and reimbursement decisions far in advance of the effective date of such decisions, payors are also interested in receiving information from medical product firms about unapproved medical products and about unapproved uses of approved/cleared medical products. Section III.B of this guidance discusses FDA's thinking with respect to communication by firms to payors regarding unapproved medical products and unapproved uses of approved/cleared medical products. As with firms' communications to payors of HCEI about approved/cleared medical products, it is essential that information provided by firms about their unapproved medical products and about unapproved uses of their approved/cleared medical products be truthful and non-misleading. Section 502(gg) of the FD&C Act provides that medical products shall not be deemed to be misbranded under section 502(f)(1) through a communication by a firm to a payor about investigational medical products or investigational uses of approved/cleared medical products if such communication is (1) the type of product information as defined in section 502(gg)(2); (2) truthful and not misleading; (3) presented with the information set forth in section 502(gg)(1)(A); and (4) not presented with the information set forth in section 502(gg)(1)(B). While section 502(gg) of the FD&C Act addresses investigational medical products or investigational uses of medical products, FDA does not intend to object under section 502(f)(1) on the basis of a firm's communication of product information to payors about unapproved medical products or unapproved uses of medical products, even where such unapproved medical products or uses may not be considered investigational, if the communication of product information is consistent with section 502(gg).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop any final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers

OMB Control Number 0910–0686—Revision

As noted, the revised draft guidance document ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers'' provides answers to common questions regarding firms' communications of HCEI about their approved/cleared medical products to payors. In addition, the guidance addresses common questions relating to firms' dissemination to payors of information about unapproved medical products and about unapproved uses of approved/cleared medical products.

The revised draft guidance incorporates recent updates to the FD&C Act. Section 3630 of the Consolidated Appropriations Act, 2023, ''Facilitating Exchange of Product Information Prior To Approval,'' amended section 502(a) of the FD&C Act to make the provisions regarding communication of HCEI to payors under section 502(a) applicable to devices. In addition, a new subsection (gg) was added to section 502 of the FD&C Act that addresses firms' provision of information to payors regarding investigational medical products and investigational uses of approved/cleared medical products. This revised draft guidance includes updates to reflect the revised statutory text, including updates to align the guidance recommendations with the new section 502(gg) of the FD&C Act, which provides ''no drug or device shall be deemed to be misbranded'' under section 502(f)(1) (21 U.S.C. 352(f)(1)) because of certain truthful and not misleading information provided to payors. While section 502(gg) of the FD&C Act applies to information about investigational medical products and investigational uses of medical products that are approved/cleared, section III.B of the revised draft guidance applies to information about all unapproved medical products and unapproved uses of medical products. We request OMB approval of these changes to our statutory authority for this collection of information.

Although section 3630 of the Consolidated Appropriations Act, 2023 amended section 502(a) of the FD&C Act to make the provisions regarding communication of HCEI to payors under section 502(a) applicable to devices, we previously had included recommendations to communicate HCEI about devices in the final guidance of the same title issued in June 2018. Thus, in our burden estimate for that guidance, we included burden hours for both drugs and devices (83 FR 27605). We also included burden hours for both drugs and devices when we sought reauthorization of OMB approval in 2021 (86 FR 39035). For efficiency reasons, OMB control number 0910–0857 was consolidated into 0910–0686. As a result, the information collection

burden estimates currently approved under 0910–0686 incorporate the burden of communicating HCEI about both drugs and devices.

As stated above, the analysis of the collection of information and its related burden on respondents for this guidance included the burden related to HCEI about both drugs and devices; thus, for this revised guidance there is no additional estimated burden beyond the burden hours that were included in the PRA analysis of the final guidance issued in June 2018, as reauthorized in 2021. We are, however, revising the information collection currently approved under OMB control number 0910–0686 to reflect the changes to our statutory authority for this collection of information.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved prescription drugs.	600	13	7,800	20	156,000
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved or cleared devices.	260	10	2,600	20	52,000
Recommended information to be included when firms choose to disseminate information about unapproved medical products or unapproved uses of approved or cleared medical products.	853	2	1,706	0.5 (30 minutes)	853
Follow-up information to payors regarding previously communicated information about unapproved medical products or unapproved uses of approved or cleared medical products.	427	2	854	2	1,708
Total			12,960		210,561

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the postmarketing submissions of promotional materials using Form FDA 2253 (*https://www.fda.gov/media/73013/download*) received in calendar year (CY) 2023 for approved human prescription drugs (including prescription biological products) and approved or cleared medical devices, FDA estimates that approximately 600 manufacturers will disseminate 7,800 distinct HCEI materials for approved human prescription drugs annually. FDA estimates that approximately 260 manufacturers will disseminate 2,600 distinct HCEI materials for approved or cleared devices annually. FDA further estimates that firms will expend approximately 20 hours to compile and draft the information that the guidance recommends should be included when disseminating HCEI materials for approved human prescription drugs and approved or cleared devices.

Based on the number of human prescription medical products approved or cleared and number of efficacy supplements approved or cleared in a CY (*i.e.,* approving or clearing a new use for an approved medical product), FDA estimates that approximately 853 manufacturers will prepare 11,706 distinct communications of information to payors about their unapproved medical products or unapproved uses of approved or cleared medical products annually. FDA estimates firms will expend approximately 0.5 hours to compile and draft the information that the guidance recommends should be provided with communications to payors about unapproved medical products or unapproved uses of approved or cleared medical products. Additionally, FDA estimates that 50 percent of the firms will expend approximately 2 hours annually to compile and provide 854 distinct communications of follow-up information regarding previously communicated information to payors about their unapproved medical products or unapproved uses of approved or cleared medical products.

Our estimated burden for the information collection reflects an overall increase of 7,883 hours and a corresponding increase of 472 disclosures. We attribute this adjustment to an increase in the number of HCEI materials disseminated over the last few years.

This revised draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 314 relating to submission of investigational new drug applications and Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use) have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to submission of labeling in a biologics license application have been approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 801 and 809 relating to Medical Device Labeling have been approved under OMB control number 0910–0485.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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