including their prescription drug benefits. Because of the specialized nature of the prescription drug benefit, many of the Medicaid managed care plans (MCOs, PIHPS, or PAHPS) either own, or contract with, PBMs to administer the pharmacy benefit. In 42 CFR 438.3(s), Medicaid MCOs, PIHPs, and PAHPs that provide coverage of covered outpatient drugs (CODs) are required to structure any contract that it has with any subcontractor (*e.g.,* PBM) for the delivery or administration of the COD benefit so that the subcontractor is required to report separately the amounts related to the incurred claims described in § 438.8(e)(2) to the managed care plan. Included are (1) reimbursements for the CODs, (2) payments for other patient services, (3) dispensing or administering providers fees, and (4) subcontractor administrative fees. The provision will ensure that medical loss ratios (MLRs) reported by MCOs, PIHPs and PAHPs that use subcontractors in the delivery of COD coverage will be more accurate and transparent. The separate payment requirements will help States and managed care plans better understand whether they are appropriately and efficiently paying for the delivery of CODs, a significant part of which is funded by the Federal Government. *Form Number:* CMS–10855 (OMB control number 0938–1445); *Frequency:* Annually and once; *Affected Public:* Private sector and State, Local, or Tribal Governments; *Number of Respondents:* 604; *Number of Responses:* 604; *Total Annual Hours:* 8,614. (For questions regarding this collection, contact: Robert Giles at 410–786–4050).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5365]

Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency.'' This guidance describes the factors FDA intends to assess in deciding whether to issue an enforcement policy regarding in vitro diagnostic test manufacturers' offering of certain unapproved in vitro diagnostic tests and unapproved uses of approved in vitro diagnostic tests during a declared emergency.

DATES: The announcement of the guidance is published in the **Federal Register** on September 23, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2023–D–5365 for ''Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a

single hard copy of the guidance document entitled ''Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

During an emergency, appropriately safe and effective in vitro diagnostic tests are critical to the diagnosis, treatment, tracking, and interruption of transmission of infectious diseases during outbreaks, as well as for diagnosing and treating diseases or conditions caused by chemical, biological, radiological, and nuclear threat agents. FDA is issuing this guidance to describe the factors FDA plans to assess in deciding whether to issue an enforcement policy regarding in vitro diagnostic test manufacturers' offering of certain unapproved in vitro diagnostic tests and unapproved uses of approved in vitro diagnostic tests for the diagnosis of a disease or other condition to help quickly increase in vitro diagnostic test availability when appropriate during a relevant declared emergency under section 564 of the Federal Food, Drug, and Cosmetic Act.

This guidance describes the factors FDA intends to assess in deciding whether to issue an enforcement policy, including: (1) the need for accelerated availability of in vitro diagnostic tests; (2) the known or potential risks of such in vitro diagnostic tests; (3) the availability of appropriate alternative in vitro diagnostic tests that are authorized or approved; and (4) the availability of sufficient mitigations to address risks of false results. When issuing an enforcement policy, FDA generally intends to describe the circumstances in which the Agency intends to exercise enforcement discretion, including, for example, when the in vitro diagnostic test has been validated. FDA may also identify the initial duration in which an enforcement policy is intended to be in effect.

This guidance finalizes the draft guidance entitled ''Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency.'' FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

A notice of availability of the draft guidance appeared in the **Federal Register** of May 6, 2024 (89 FR 37232). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying that the scope of the guidance is in vitro diagnostic tests.

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 ''Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00007009 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
''Emergency Use Authorization of Medical Products and Related Authorities''.	Emergency Use Authorization	0910–0595
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
803	Medical Device Reporting	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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