

Hours: 192.265. (For policy questions regarding this collection contact Lauren Fuentes at 410-786-2290 or [lauren.fuentes@cms.hhs.gov](mailto:lauren.fuentes@cms.hhs.gov)).

**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-N-2177]

#### Laboratory Developed Tests: Small Entity Compliance Guide; Guidance for Laboratory Manufacturers 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 “Laboratory Developed Tests: Small Entity Compliance Guide.” The laboratory developed tests (LDT) final rule amended FDA’s regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. This small entity compliance guide (SECG) is intended to help small entities comply with applicable medical device regulations, consistent with the LDT final rule, including the phasing out of FDA’s general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 25, 2024.

**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-N-2177 for “Laboratory Developed Tests: Small Entity Compliance Guide.” 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 “Laboratory Developed Tests: Small Entity Compliance Guide” 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:** Brittany Schuck, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5422, Silver Spring, MD 20993-0002, 301-796-5199, [LDTFinalRule@fda.hhs.gov](mailto:LDTFinalRule@fda.hhs.gov); or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of May 6, 2024 (89 FR 37286), FDA issued a final rule to amend its regulations to make explicit that IVDs are devices under the FD&C Act including when the

manufacturer of the IVD is a laboratory. The final rule, which is codified at 21 CFR 809.3, is effective July 5, 2024. In conjunction with this amendment, the FDA is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs. This phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance. FDA has prepared this SECG to assist small entities in complying with the requirements established in FDA regulations, as they apply to IVDs, including LDTs.

This level 2 guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach may be used if such approach 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>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Laboratory Developed Tests: Small Entity Compliance Guide; Guidance for Laboratory Manufacturers and Food and Drug Administration Staff” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00007036 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 following collections of information have been approved by OMB: OMB control number 0910–0437, Medical Device Reporting; OMB control number 0910–0359, Corrections and Removals; OMB control number 0910–0625, Device Registration and Listing; OMB control number 0910–0485, Device Labeling; OMB control number 0910–0078, Investigational Device Exemption; OMB control number 0910–0073, Quality Systems, including § 820.198 (complaint files); OMB control number 0910–0231, Premarket Approval; OMB control number 0910–0332, Humanitarian Device Exemption; OMB control number 0910–0120, Premarket Notification; OMB control number 0910–0844 De Novo Requests; OMB control number 0910–0338, Biologics License Applications Procedures & Requirements; OMB control number 0910–0052, Blood Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices; OMB control number 0910–0014, Investigational use requirements under 42 U.S.C. 262 and 21 CFR part 312 for certain devices that are biological products; and OMB control number 0910–0756, FDA’s final guidance document entitled “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.”

Dated: June 18, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program Core Medical Services Waiver Form

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than July 25, 2024. The form will become effective on October 1, 2024.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–3983.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Ryan White HIV/AIDS Program Core Medical Services Waiver Form, OMB No. 0906–0065—Revision

*Abstract:* In accordance with sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act, recipients are required to spend not less than 75 percent of funds on core medical services for individuals identified with HIV and who are eligible under the statute, after reserving permissible amounts for administrative and clinical quality management (CQM) costs. The statute also grants the Secretary authority to waive this requirement for a Ryan White HIV/AIDS Program (RWHAP) Part A, B, or C recipient if certain requirements are met, and a waiver request is submitted to HRSA for approval.

As currently implemented by HRSA, in order to be approved, (1) core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient’s service area within 30 days. This access must be without regard to payer source, and without the need to spend at least 75 percent of funds