specific proposal prior to adoption, consistent with Board policy.[33]

The Board also welcomes input on whether there are other actions it should consider as the industry and public reflect on the continued importance of checks. The Board separately released a request for information on ''Potential Actions to Address Payments Fraud,'' including check fraud.[34] Accordingly, the Board is not specifically seeking input on check fraud in this RFI and asks for comments in response to this RFI to focus on Reserve Bank check operations and the continued use of checks more broadly. Respondents are encouraged to respond to the following questions.

1. What is your view of the importance of the Reserve Banks' check services in the United States today? How should the Federal Reserve's role in the provision of check services evolve over the next 3 years and over the next 10 years?

2. What aspects of the Reserve Banks' current check services (for example, deposit deadline options, how quickly checks are processed, discrepancy resolution services, and options for sending a check back as a return) are the most critical, and why?

3. Generally speaking, what would be the impact of different potential strategies for the Reserve Banks' check services, including those discussed above: (1) continuing Reserve Banks' check services largely as they exist today with significantly degraded reliability over time, (2) significantly simplifying Reserve Banks' check services, (3) substantially winding down Reserve Banks' check services, or (4) upgrading the Reserve Banks' check-processing infrastructure to support existing services and reliability? Are there other strategies you believe the Reserve Banks should consider?

4. Would you, your organization, or your community be willing to incur additional costs and fees to continue to use or process checks as you do today? Why or why not? Would you, your organization, or your community be willing to make additional investments such as enhancements to check security features in support of continued use of checks in the future? Why or why not?

5. If your organization relies on the Reserve Banks' check services, directly or indirectly, to what extent could alternative providers offer similar services that meet your needs over the next 3 years and over the next 10 years? For instance, are there unique benefits of the check services provided by the Federal Reserve that are not otherwise available in the industry?

6. How important are checks to you, your organization, or your community, and how challenging would it be to use alternative payment methods? How might the importance of checks and the challenges associated with using other payment methods change over the next 3 years and over the next 10 years?

7. What are the unique aspects of checks that lead users to continue to use checks?

8. How could other payment methods offer the same benefits as checks if they do not already? Are there any barriers that prevent alternative payment methods from offering the same benefits as checks, or other constraints on adoption of these alternatives?

9. Do you have any planned or ongoing efforts to transition from checks to electronic payments, and why or why not? How can particular communities that may still need to rely on checks, such as the elderly, rural populations, and low- or moderate-income households, be better served?

10. What benefits and risks to the payments system and to the public should the Board consider as it assesses potential strategies for the Reserve Banks' check services?

In addition to these questions above, the Board invites comments on any other considerations it should assess as it evaluates the future of the Reserve Banks' check services.

By order of the Board of Governors of the Federal Reserve System.

**Benjamin W. McDonough,**

*Deputy Secretary of the Board.*

[FR Doc. 2025–22272 Filed 12–8–25; 8:45 am]

**BILLING CODE 6210–01–P**

[33] *See* Principles for the Pricing of Federal Reserve Bank Services, 46 FR 1338, 1339 (Jan. 6, 1981), available at *https://www.federalreserve.gov/paymentsystems/pfs_principles.htm.*

[34] The Fraud RFI was a joint release by the Board, the Federal Deposit Insurance Corporation (FDIC), and the Office of the Comptroller of the Currency (OCC). Comments were due by September 18, 2025. *See* Board, OCC, and FDIC, ''Request for Information on Potential Actions To Address Payments Fraud,'' **Federal Register** (June 20, 2025), *https://www.federalregister.gov/documents/2025/06/20/2025-11280/request-for-information-on-potential-actions-to-address-payments-fraud.*

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2025–N–2195]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Humanitarian Use Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by January 8, 2026.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0332. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Medical Devices; Humanitarian Use Devices—21 CFR part 814

*OMB Control Number 0910–0332—Extension*

This collection of information implements the humanitarian use devices (HUDs) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)) and part 814, subpart H (21 CFR part 814, subpart H). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the

effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) is designed to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the United States; (2) would not be available to a person with a disease or condition unless an exemption is granted and there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose such disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2) of the FD&C Act. The information collected will assist FDA in making determinations on the following: (1) whether to grant HUD designation of a medical device; (2) whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

HUDs approved under a HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (*i.e.,* for profit), except in narrow circumstances. Section 520(m)(6)(A)(i) of the FD&C Act, provides that a HUD approved under an HDE is eligible to be sold for profit if the device meets certain criteria: The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or the device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients, or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) provides that the Secretary of Health and Human Services (the Secretary) will assign an annual distribution number (ADN) for devices that meet the eligibility criteria to be permitted to be sold for profit. The ADN is defined as the number of devices ''reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States,'' and therefore shall be based on the following information in a HDE application: the number of devices reasonably necessary to treat such individuals.

Section 520(m)(6)(A)(iii) provides that an HDE holder immediately notify the agency if the number of devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) provides that an HDE holder may petition to modify the ADN if additional information arises.

The FDA issued guidance entitled ''*Humanitarian Device Exemption (HDE) Program* (September 2019) (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf*), which addresses commonly asked questions about HDEs and HUDs, including FDA actions on HDE applications, post-approval requirements, and special considerations for devices marketed under the HDE Program. The guidance document reflects changes in the HDE Program resulting from statutory amendments made by the 21st Century Cures Act (Cures Act) and explains the criteria FDA considers to determine if ''probable benefit'' has been demonstrated as part of the Agency's decision-making process regarding marketing authorization for a HUD. This guidance document also reflects amendments made to the HDE provision of the FD&C Act by the FDA Reauthorization Act of 2017 (FDARA).

Section 402(j)(5)(B) (42 U.S.C. 282(j)(5)(b)) of the Public Health Service Act (PHS Act), requires a certification to accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 354, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met. Relevant regulations are found in 21 CFR parts 814, subpart H (humanitarian use devices—HUDs), and discussed in FDA's notice of implementation of the certification on December 12, 2007 (72 FR 70599). Certification is made via form FDA 3674, ''Certification of Compliance (*https://www.fda.gov/media/134964/download*)—Under 42 U.S.C. 282(j)(5)(B), with Requirements of *ClinicalTrials.gov* Data Bank.''

HUDs are subject to the general restriction that no profit may be made on their use. For HUDs labeled for use in certain populations, FDA exempts a certain number of these devices each year from the prohibition on profit. This number is known as the annual distribution number (ADN). The information gathered by this collection enables FDA to set this number. Failure to collect this information would prevent FDA from assigning an ADN.

The information is submitted to FDA as an ''eCopy'' via FDA's Center for Devices and Radiological Health (CDRH) Customer Collaboration Portal (*https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal*). Instructions and information regarding eCopy submission are available on FDA's website at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-medical-device-submissions* and in the FDA guidance document, ''eCopy Program for Medical Device Submissions'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions*).

In the **Federal Register** of August 7, 2025 (90 FR 38151) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

| Activity/21 CFR Part/Form | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| **Humanitarian Use Devices; 21 CFR Part 814** | | | | | |
| Request for HUD designation—814.102 | 23 | 1 | 23 | 40 | 920 |
| Certification of Compliance (form FDA 3674) [2] | 4 | 1 | 4 | .75 (45 minutes) | 3 |
| HDE Application—814.104 | 3 | 1 | 3 | 328 | 984 |
| HDE Amendments and resubmitted HDEs—814.106 | 3 | 3 | 9 | 50 | 450 |
| HDE Supplements—814.108 | 30 | 1 | 30 | 80 | 2,400 |
| Procedures for review of an HDE, including a request for withdrawal—814.116. | 1 | 1 | 1 | 1 | 1 |
| Notification of withdrawal of institutional review board approval—814.124(b). | 1 | 1 | 1 | 2 | 2 |
| Periodic reports—814.126(b)(1) | 36 | 4 | 144 | 120 | 17,280 |
| Total | | | | | 22,040 |
| **Information to Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements** | | | | | |
| Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act. | 1 | 1 | 1 | 100 | 100 |
| Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act. | 1 | 1 | 1 | 50 | 50 |
| Request for Determination of Eligibility Criteria—613(b) of FDASIA. | 1 | 1 | 1 | 10 | 10 |
| ADN Notification—520(m)(6)(A)(iii) of the FD&C Act | 1 | 1 | 1 | 100 | 100 |
| ADN Modification—520(m)(6)(C) of the FD&C Act | 1 | 1 | 1 | 100 | 100 |
| Total | | | | | 360 |
| Reporting Total | | | | | 22,400 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Form FDA 3674 is approved under OMB Control No. 0910–0120. This ICR includes burden only for HUD submissions.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity/21 CFR Part | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| **Humanitarian Use Devices; 21 CFR Part 814** | | | | | |
| HDE Records—814.126(b)(2) | 81 | 1 | 81 | 2 | 162 |

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Activity/21 CFR Section | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| **Humanitarian Use Devices; 21 CFR Part 814** | | | | | |
| Notification of emergency use—814.124(a) | 22 | 1 | 22 | 1 | 22 |

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

Our estimated burden for the information collection reflects an overall decrease of 321 hours and a corresponding decrease of 63 responses. The total hour burden for this information collection is estimated to be 22,584 hours. In a nonmaterial/non-substantive change request (83–C), approved 3/24/2023, we consolidated the information collection activity previously approved under OMB control number 0910–0661 into this information collection. This includes information collection associated with the annual distribution number reporting requirements related to pediatric patients and pediatric populations under section 613 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), which amended section 520(m) of the FD&C Act. The consolidation also included FDA guidance entitled ''Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers'' (HDE guidance) (July 2010, updated September 2019) (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf*). The guidance does not affect the

estimated burden estimates in this extension.

**Lowell M. Zeta,**

*Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2025–N–4942]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Standards Quality Act Requirements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Mammography Quality Standards Act.

**DATES:** Either electronic or written comments on the collection of information must be submitted by February 9, 2026.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 9, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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–2025–N–4942 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Standards Quality Act Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**FOR FURTHER INFORMATION CONTACT:** Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the 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, including each proposed extension of an existing 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