applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than July 16, 2026.

A. Federal Reserve Bank of Dallas (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201–2272. Comments can also be sent electronically to *Comments.applications@dal.frb.org:*

1. *Austin Family Trust B, Jeff Austin, Jr. as trustee, both of Jacksonville, Texas; JML Trust, Mary Margaret Austin, as trustee, both of Jacksonville, Texas; and LAPA Trust, Carole Leigh Austin Mattson, as trustee, both of Georgetown, Texas;* to join the Austin/Chapman Family Control Group, a group acting in concert, to acquire voting shares of Austin Bancorp, Inc., and thereby indirectly acquire voting shares of Austin Bank, Texas National Association, both of Jacksonville, Texas.

2. *Austin Family Trust B, Jeff Austin, Jr. as trustee, both of Jacksonville, Texas;* to acquire voting shares of Capital Bancorp, Inc., Jacinto City, Texas, and thereby indirectly acquire voting shares of Capital Bank, Houston, Texas.

In addition,*JML Trust, Mary Margaret Austin, as trustee, both of Longmont, Colorado; LAPA Trust, Carole Leigh Austin Mattson, as trustee, both of Littleton, Colorado; Jessica Leigh Neill Swinnea, Chandler, Texas; and Austin Kyle Neill, Dallas, Texas;* to join the Austin/Chapman Family Control Group, a group acting in concert, to retain voting shares of Capital Bancorp, Inc., and thereby indirectly retain voting shares of Capital Bank.

3. *Austin Family Trust B, Jeff Austin, Jr. as trustee, both of Jacksonville, Texas;* to join the Austin/Chapman Family Control Group, a group acting in concert, to acquire voting shares of Athens, TX Bancshares, Inc., and thereby indirectly acquire voting shares of First State Bank, both of Athens, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–13287 Filed 6–30–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6869]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medication Guides for Prescription Drug Products

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 July 31, 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 0910–0393. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Medication Guide Requirements for Prescription Drug Product Labeling

OMB Control Number 0910–0393—Reinstatement with change

This information collection supports FDA regulations pertaining to the distribution of patient labeling, called Medication Guides, for human prescription drug and biological products used primarily on an outpatient basis, and required for products that pose a serious and significant public health concern. Agency regulations codified in part 208 (21 CFR part 208): *Medication Guides for Prescription Drug Products* set forth general requirements applicable to both content and format elements for Medication Guides, as well as provide for exemption and deferral requests. Medication Guides provide patients with important information about drug products, including the drug's approved uses, contraindications, adverse drug reactions, cautions for specific populations, and are required in accordance with applicable regulations.

To assist consumers and industry with understanding regulatory requirements applicable to, and the purpose of, Medication Guides, we have developed resources and made them available on our website at *https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#medication-guides.* Among the resources, we include the guidance document titled *Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)* (November 2011), (available at *https://www.fda.gov/media/79776/download*), as well as a discussion of the distinction between Medication Guides and Consumer Medication information. The regulations in 21 CFR part 208, the associated guidance document, and the informational resources are intended to enable patients to use medications most safely and effectively.

Included among the requirements in 21 CFR part 314 that govern applications for FDA approval to market a new drug is the submission of any Medication Guide (see 21 CFR part

314.50), as applicable under 21 CFR part 208, as well as any supplemental changes (see 21 CFR 314.70). The Agency uses the information submitted to determine whether the Medication Guide complies with applicable regulatory requirements. Information collection activities applicable to regulations in 21 CFR part 314 are currently approved in OMB control no. 0910–0001. In this request FDA is accounting for information collection burden we believe attributable to regulatory requirements 21 CFR part 208.

In the **Federal Register** of January 27, 2026 (91 FR 3511), we published a 60-day notice requesting public comment on the proposed collection of information. We received a number of comments. Some comments discussed FDA's proposed rule (RIN 0910–AH68) that issued on May 31, 2023, ''Medication Guides: Patient Medication Information (PMI),'' (88 FR 35694). While we reviewed these comments in the context of this reinstatement request, we have also added them to the rulemaking docket (FDA–2019–N–5959) for continued consideration. Other comments communicated general support for improving the content, clarity, and readability of Medication Guides, including the use of electronic delivery. Finally, some comments questioned the accuracy of FDA's burden assessment attributable to authorized dispensers who provide Medication Guides to patients. FDA is most appreciative of all public input regarding its information collection activities and as a result of these latter comments, together with a reexamination of previous submissions for OMB review and approval of ICR 0910–0393, we have significantly revised our assessment of the disclosure burden attributable to requirements established in 21 CFR part 208 for distributors and authorized dispensers of Medication Guides.

Our 60-day notice states that respondents to the information collection are sponsors of new drug applications, distributors of prescription drug products, and authorized dispensers of prescription drug products. We determined the number of respondents to the annual recordkeeping requirements based on the number of new drug sponsors whose product applications we believe are subject to the requirements in 21 CFR 208, consistent with internal Agency data and a recent preliminary regulatory impact analysis in support of rulemaking RIN 0910–AH68. We retain those estimates provided in our 60-day notice, as reflected below in table 1.

At the same time, we have adjusted our assessment of disclosure burden. Specifically, we previously calculated burden we believe attributable to requirements in 21 CFR 208.24 and applied our assessment to distributors and authorized dispensers collectively. Upon reexamination of the information collection requirements applicable to 21 CFR part 208.24, we have separated burden to align with tasks that apply to manufacturers, distributors, and authorized dispensers, respectively, as reflected below in table 2.

We estimate the burden of the collections of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR Section 208 (obtaining the PMI)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and format of a Medication Guide; § 208.20	70	1	70	320	22,400
Exemptions and deferrals; § 208.26(a)	1	1	1	4	4
Total			71		22,404

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

Noting that 5 CFR 1320.3(m) defines a recordkeeping requirement to include the reporting to the Federal government regarding such records, we have characterized the submission of Medication Guides to FDA as reporting activity required as a function of certain NDA submissions (currently approved under OMB control no. 0910–0001). Based on our evaluation of internal data, we estimate that, in the next three years, 70 holders of applications will prepare and submit one Medication Guide annually for our review. We estimate that the application holders will expend 320 hours to prepare and submit the Medication Guide. In addition, we estimate that, in the next three years, one sponsor of one of the new or supplementary applications will request an exemption under § 208.26(a) from at least some of the Medication Guide format or content requirements, annually. We assume sponsors will expend an average of 4 hours annually to prepare and submit a request for exemption.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR Section 208 (Providing the PMI for Distribution)	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure [2]	Total hours
Manufacturer ensures that Medication Guides are provided in adequate supply to authorized dispensers, or provides means to produce Medication Guide; § 208.24(b)(1) and (b)(2)	70	9,000	630,000	1.25	787,500
Distributor provides Medication Guides or means to produce to authorized dispensers § 208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Dispensing Medication Guide to patient 208.24(e)	88,736	5,705	506,238,880	.0027	1,366,845
Total			508,587,880		4,303,095

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Figures have been rounded to the nearest one, one-thousandth.

Assuming that the same 70 application holders of products requiring Medication Guides must ensure that distributors and authorized dispensers are provided with an adequate supply or means to produce the required Medication Guide, as required under 21 CFR 208.24(b)(1) and (b)(2), we calculate an average of 9,000 disclosures annually and an average of 1.25 hours per disclosure, as reflected in row 1, table2.

Similarly, assuming 12% of 1,600 distributors (191), based on figures consistent with, accounted for, and approved in OMB control number 0910–0806 (Pharmaceutical Distribution Supply Chain) will ship drug products that require a Medication Guide and must provide the Medication Guide or the means to produce it to authorized dispensers, as required under 21 CFR 208.24(c), we calculate an average of 9,000 disclosures annually and an average of 1.25 hours per disclosure, as reflected in row 2, table 2.

Regarding authorized dispensers, we currently assume 88,736 authorized dispensers based on informal data and reports from various pharmacy trade associations and have retained this figure. We also retain our estimated average of 5,705 patients to whom Medication Guides will be distributed annually. However, we have revised the time we attribute necessary to the task of dispensing Medication Guides to patients, as required under 21 CFR part 208.24(e). FDA originally proffered 5 seconds in its proposed rule of August 24, 1995 (60 FR 44182) inviting comment under the Paperwork Reduction Act of 1980. In our final rule on December 1, 1998 (63 FR 66378), after enactment of the Paperwork Reduction Act of 1995, FDA again estimated 5 seconds of burden for the task of dispensing a Medication Guide to a patient and invited public comment. No comments were posted to the rulemaking docket (Legacy Docket No. 93–0371; RIN 0910–AA37) regarding the 5-second estimate.

Upon further review, we find that in 2008 FDA revised its original estimate from 5 seconds to 3 minutes based on a public comment that the estimate had remained unchanged since 1998, ''while the program continue[d] to expand in an unchecked manner,'' (emphasis added), and that FDA's estimate failed to consider ''realities pharmacists face in complying with the program'' (emphasis added). See Docket No. FDA–2008–N–0162. We are now adjusting that estimate to 10 seconds noting the following:

- As required by the PRA of 1995, FDA has confined its estimate of burden attributable to that we believe is required by 21 CFR 208.24(e), which entails the task of dispensing the Medication Guide. Effort that may be attributable to counseling patients, dispensing literature not required by 21 CFR 208.24(e), and to patients reading the Medication Guide is not included in our estimate.
- As provided for by the PRA of 1995, FDA believes that tasks that may be associated with dispensing a Medication Guide, such as counseling patients, dispensing literature not required by our regulations, and recordkeeping that may be required by other authorities such as State licensing agents and the Drug Enforcement Administration, to be usual and customary as part of the practice of pharmacy. Therefore, we estimate no burden for efforts relating to tasks that fall beyond the scope of 21 CFR part 208.
- FDA does account for various tasks that may be performed by authorized dispensers in its active collection inventory including OMB control numbers 0910–0800 (Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act); 0910–0806 (Pharmaceutical Distribution Supply Chain); and 0910–0858 (Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act); and
- FDA believes that the advent of technology has facilitated, not prolonged, the effort necessary in satisfying existing requirements under 21 CFR part 208.

Upon adjusting our estimates accordingly, the information collection reflects a decrease of 22,938,375 hours and an increase of 4,829,782 responses annually. We believe these estimates are consistent with current submission figures and the specific tasks required in 21 CFR part 208.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13346 Filed 6–30–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Rural Health Innovation and Transformation Technical Assistance

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA will provide additional award funds to the Rural Health Innovation and Transformation Technical Assistance (RHIT–TA) recipient, the University of Iowa, to provide additional technical assistance on rural value-based care-related activities and support the improvement of health care in rural areas.

FOR FURTHER INFORMATION CONTACT: Lawrencia Afagbedzi, Health Insurance Specialist, Federal Office of Rural Health Policy, HRSA at *lafagbedzi@hrsa.gov* and 301–443–3196.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: The University of Iowa.

Amount of Non-Competitive Award: One supplemental award for $150,000.

Project Period: August 1, 2023, to July 31, 2027.

Assistance Listing Number: 93.692.

Award Instrument: Cooperative Agreement Supplement for Services.

Authority: Section 711 of the Social Security Act (42 U.S.C. 912).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, state	Supplemental award amount
UB7RH25011	University of Iowa	Iowa City, IA	$150,000

Justification: This funding will provide a one-time supplement to the University of Iowa through the RHIT–TA Cooperative Agreement with a budget period of August 1, 2026, through July 31, 2027. This supplement will allow the University of Iowa to build on past and ongoing projects supported by HRSA to support health