

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10556]

Agency Information Collection Activities: Proposed Collection; Comment Request**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).**ACTION:** Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 24, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By *regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier: ____/OMB Control Number: ____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT:
William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10556 Medical Necessity and Contract Amendments Under Mental Health Parity

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Necessity and Contract Amendments Under Mental Health Parity; *Use:* Upon request, regulated entities must provide a medical necessity disclosure. Receiving this information will enable potential and current enrollees to make more educated decisions given the choices available to them through their plans and may result in better treatment of their mental health or substance use disorder (MH/SUD) conditions. States use the information collected and reported as part of their contracting process with managed care entities, as

well as their compliance oversight role. In states where a Medicaid Managed Care Organization (MCO) is responsible for providing the full scope of medical/surgical and MH/SUD services to beneficiaries, the state will review the parity analysis provided by the MCO to confirm that the MCO benefits are compliant. CMS uses the information collected and reported in an oversight role of State Medicaid managed care programs. *Form Number:* CMS-10556 (OMB control number: 0938-1280); *Frequency:* Once and occasionally; *Affected Public:* Individuals and households, the Private sector, and State, Local, or Tribal Governments; *Number of Respondents:* 71,104,769; *Total Annual Responses:* 426,628; *Total Annual Hours:* 71,294. (For policy questions regarding this collection contact Matthew Rodriguez at 303-844-4724.)

William N. Parham, III,
Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025-18649 Filed 9-24-25; 8:45 am]

BILLING CODE 4120-01-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2025-N-0195]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Production, Storage, and Transportation of Shell Eggs (Preventing Salmonella Enteritidis)

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 October 27, 2025.

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 0910-0660. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Lansdown St., North Bethesda, MD 20852, 301-796-8867, *PRASstaff@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.

Production, Storage, and Transportation of Shell Eggs (Preventing *Salmonella Enteritidis* (SE))—21 CFR 118.10 and 118.11

OMB Control Number 0910-0660—Extension

This information collection supports Agency regulations in part 118 (21 CFR part 118), Production, Storage, and Transportation of Shell Eggs, and Form FDA 3733, Shell Egg Producer Registration Form. The Public Health Service Act (PHS Act) (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce such regulations as “are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State” (section 361(a) of the PHS Act (42 U.S.C. 264(a))). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21

U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under part 118, shell egg producers are required to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation. Shell egg producers also are required to maintain records concerning their compliance with part 118 and to register with FDA. As described in more detail about each information collection provision of part 118, each farm site with 3,000 or more egg-laying hens that sells raw shell eggs, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all of their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Section 118.10 of FDA's regulations requires recordkeeping for all measures a farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are compiled and retained at each farm site and examined there periodically by FDA inspectors. Section 118.10 also requires each farm site with 3,000 or more egg-laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan. Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 (21 CFR 118.11) of FDA's regulations requires that each farm covered by § 118.1(a) register with FDA using Form FDA 3733. The term “Form FDA 3733” refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at <https://>

www.access.fda.gov. We strongly encourage electronic registration because it is faster and more convenient. The system accepts electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer receives confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations also are accepted. Form FDA 3733 is available for download for registration by mail, Fax or CD-ROM. More information is available at our website at <https://www.fda.gov/food/registration-food-facilities-and-other-submissions/shell-egg-producer-registration> and <https://www.fda.gov/food/shell-egg-producer-registration/shell-egg-producer-registration-registrationcancellation-paper-mail-or-fax-or-cd-rom>.

Recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for us to be able to determine compliance. Information provided under these regulations helps us to quickly notify the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support our enforcement activities.

Description of Respondents:

Respondents to this information collection include farm sites with 3,000 or more egg-laying hens that sell raw eggs, other than directly to the consumer.

In the **Federal Register** of June 27, 2025 (90 FR 27614), 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 RECORDKEEPING BURDEN¹

Activity; 21 CFR section	Number of record-keepers ²	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Refrigeration Records; § 118.10(a)(3)(iv)	2,600	52	135,200	0.5 (30 minutes)	67,600
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (positive) ³ .	343	52	17,836	0.5 (30 minutes)	8,918
Egg Testing; § 118.10(a)(3)(vii)	331	7	2,317	8.3	19,231
Environmental Testing; § 118.10(a)(3)(v) ³	6,308	23	145,084	0.25 (15 minutes)	36,271
Testing, Diversion, and Treatment Records; § 118.10(a)(3)(v) through (viii) (negative) ³ .	5,965	1	5,965	0.5 (30 minutes)	2,983
Prevention Plan Review and Modifications; § 118.10(a)(4).	331	1	331	10	3,310
Chick and Pullet Procurement Records; § 118.10(a)(2).	4,731	1	4,731	0.5 (30 minutes)	2,366

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

Activity; 21 CFR section	Number of record-keepers ²	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Rodent and Other Pest Control; § 118.10(a)(3)(ii), and Biosecurity Records; § 118.10(a)(3)(i).	9,462	52	492,024	0.5 (30 minutes)	246,012
Prevention Plan Design; § 118.10(a)(1)	350	1	350	20	7,000
Cleaning and Disinfection Records; § 118.10(a)(3)(iii).	331	1	331	0.5 (30 minutes)	166
Total	393,857

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

² Some records are kept on a by-farm basis and others are kept on a by-house basis.

³ Calculations include requirements for pullet and layer houses.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity; 21 CFR section	Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Registrations or Updates; § 118.11 ...	FDA 3733 ²	350	1	350	2.3	805
Cancellations; § 118.11	FDA 3733	30	1	30	1	30
Total	835

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

² The term “Form FDA 3733” refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at <http://www.access.fda.gov> per § 118.11(b)(1).

Our estimates for the recordkeeping burden and the reporting burden are based on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-18617 Filed 9-24-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0350]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

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 October 27, 2025.

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 0910-0732. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, 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.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0732—Extension

This information collection supports FDA regulations. Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act provides FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. FDA has the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))). In accordance with that authority, FDA issued a rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (81 FR 28974, May 10, 2016). The definition of the term “tobacco product” in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) products that contain nicotine from any source. As a result, non-