*uploads/2025/08/CircularA-4.pdf*), in Table 2, we have prepared an accounting statement showing the estimated total increase in costs to beneficiaries of about $770 million. As stated in section IV. of this notice, we determined the increase in cost to beneficiaries by calculating the difference between the 2026 and 2027 deductible and coinsurance amounts multiplied by the estimated change in the number of deductible and coinsurance amounts paid.

TABLE 2—ESTIMATED TRANSFERS FOR CY 2027 DEDUCTIBLE AND COINSURANCE AMOUNTS

| Category | Transfers | Period covered |
|---|---|---|
| Annualized Monetized Transfers | $770 million | 2027 |
| From Whom to Whom | Beneficiaries to Providers | |

*D. Regulatory Flexibility Act*

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration's definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year). Individuals and States are not included in the definition of a small entity. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2027 and will have an impact on the Medicare beneficiaries. As a result, we are not preparing an analysis for the RFA because the Secretary has certified that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This annual notice announces the Medicare Part A deductible and coinsurance amounts for CY 2027 and will have an impact on certain Medicare beneficiaries, but not on small entities as defined by the SBA. As a result, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has certified that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

*E. Unfunded Mandates Reform Act*

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This notice would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $193 million in any 1 year.

*F. Federalism*

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial direct effect on State or local governments, preempt State law, or otherwise have Federalism implications.

*G. Congressional Review*

This notice is subject to the Congressional Review Act and has been transmitted to the Congress and the Government Accountability Office's Comptroller General for review.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 16, 2026.

**Robert F. Kennedy, Jr.,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2026–23603 Filed 11–17–26; 4:15 pm]

**BILLING CODE 4169–69–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–3532]**

## Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Requirements for Nonclinical Laboratory Studies

**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 December 21, 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 0910–0119. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, *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.

**Good Laboratory Practice Requirements for Nonclinical Laboratory Studies**

*OMB Control Number 0910–0119—Extension*

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification, and include information collection provisions.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with GLPs. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations require that, for each nonclinical laboratory study, a final report be prepared that documents the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also require written records pertaining to: (1) personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

*Description of Respondents:* Respondents to the collection of information are sponsors of nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by FDA.

In the **Federal Register** of April 30, 2026 (91 FR 23273), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; however, they did not respond to the questions posed in 5 CFR 1320.8(d).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR part | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 58.35(b)(7); Quality assurance unit | 300 | 60.25 | 18,075 | 1 | 18,075 |
| 58.185; Reporting of nonclinical laboratory study results | 300 | 60.25 | 18,075 | 27.65 | 499,774 |
| Total | | | | | 517,849 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Part | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 58.29(b); Personnel | 300 | 20 | 6,000 | .21 (13 mins.) | 1,260 |
| 58.35(b)(1)–(6), and (c); Quality assurance unit | 300 | 270.76 | 81,228 | 3.36 | 272,926 |
| 58.63(b) and (c); Maintenance and calibration of equipment. | 300 | 60 | 18,000 | .09 (5 mins.) | 1,620 |
| 58.81(a)–(c); SOPs | 300 | 301.80 | 90,540 | .14 (8 mins.) | 12,676 |
| 58.90(c) and (g); Animal care | 300 | 62.70 | 18,810 | .13 (8 mins.) | 2,445 |
| 58.105(a) and (b); Test and control article characterization. | 300 | 5 | 1,500 | 11.8 | 17,700 |
| 58.107(d); Test and control article handling | 300 | 1 | 300 | 4.25 | 1,275 |
| 58.113(a); Mixtures of articles with carriers | 300 | 15.33 | 4,599 | 6.8 | 31,273 |
| 58.120; Protocol | 300 | 15.38 | 4,614 | 32.7 | 150,878 |
| 58.195; Retention of records | 300 | 251.50 | 75,450 | 3.9 | 294,255 |
| Total | | | | | 786,308 |

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

Based on an evaluation of the information collection, we are retaining the currently approved estimates. Our assumptions regarding the time needed for the respective activities is based on our experience with the information collection and informal communications with respondents.

**Grace R. Graham,**

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

[FR Doc. 2026–23541 Filed 11–18–26; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–3070]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Youth Tobacco Survey

**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 December 21, 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 0910–0932. 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.

**National Youth Tobacco Survey 2027–2029**

*OMB Control Number 0910–0932—Revision*

This information collection supports the development and implementation of the National Youth Tobacco Survey (NYTS), which is a key component of FDA's youth tobacco surveillance. By providing national estimates of youth tobacco use, the NYTS directly contributes to FDA's ability to effectively regulate tobacco use and prevent youth access to tobacco products in the United States. FDA's Center for Tobacco Products (CTP) was created to carry out the authorities granted under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) to educate the public about the dangers of tobacco use and to serve as a public health resource for tobacco and health information. CTP's tobacco surveillance research, including the NYTS, directly contributes to advancing the goals of Executive Order 14212: Establishing the President's Make America Healthy Again Commission, including the Make Our Children Healthy Again assessment, in three ways. First, the NYTS helps FDA CTP evaluate the effect of policies and regulations on efforts to reduce tobacco use, the leading cause of chronic disease and mortality in the United States. Second, the NYTS protects the health of children by influencing policies, regulatory action, public education campaigns, and compliance and enforcement efforts designed to decrease the likelihood of youth tobacco initiation and reduce youth tobacco use. Third, the NYTS gathers information about youth tobacco use by means of rigorous scientific methods.

The NYTS has been conducted since 1999 and serves as the gold-standard source of nationally representative estimates of youth tobacco use in the United States. In 2025, FDA assumed leadership of the NYTS from the Centers for Disease Control and Prevention (CDC). The collection was previously approved under OMB Control No. 0920–0621. The NYTS supports FDA's CTP in its efforts to reduce tobacco related disease and protect the health of children.

The survey will be conducted among a nationally representative sample of students attending public and private schools in grades 6–12. The survey will be digital, web-based, anonymous, self-administered, and will be taken on school or personal computers, tablets, or mobile devices. Information supporting the NYTS also will be collected from state-, district-, and school-level administrators and teachers. Information collected through the NYTS will be used to identify trends in youth tobacco use over time, and to inform the development of public education campaigns, policies and rules, and compliance and enforcement programs for tobacco products.

The survey will examine the following topics: use of e-cigarettes, cigarettes, cigars, smokeless tobacco (chewing tobacco, snuff, dip), hookahs, pipes, snus, nicotine pouches, other oral nicotine products, bidis, heated tobacco products, and roll-your-own cigarettes; knowledge and attitudes; media and advertising; access to tobacco products and enforcement of restrictions on access; secondhand smoke and e-cigarette aerosol exposure, and cessation.

In the **Federal Register** of May 4, 2026 (91 FR 23995), FDA published a 60-day notice requesting public comments on the proposed collection of information. Eight comments were responsive to the Paperwork Reduction Act (PRA) information collection topics solicited.

(Comment) Seven commenters expressed support for the continuation of the NYTS, with several describing it as the ''gold-standard'' and only nationally representative, school-based survey focused exclusively on youth tobacco use. Commenters emphasized the survey's value in tracking product trends, identifying emerging tobacco products, informing regulatory and enforcement actions, and supporting public health programs at the federal, state, and local levels. The State Attorneys General specifically endorsed the proposed sample size increase to maintain statistical rigor in light of declining school-based response rates.

(FDA response) FDA acknowledges and appreciates the strong support for NYTS continuation expressed across all comments. The NYTS has been administered since 1999 and has served as an essential surveillance tool for identifying trends in youth tobacco and nicotine product use, informing regulatory action, guiding public health programs, and supporting enforcement at the federal and state levels. FDA remains committed to the annual administration of the NYTS and to maintaining the scientific rigor necessary for the data to serve these functions.

(Comment) One commenter expressed support for the continuation of the NYTS and urged FDA to publish the 2025 NYTS analysis and results consistent with prior years, noting that the release of raw data without an accompanying analysis limits the