(410) 786–3211 or *lauren.dulay@cms.hhs.gov*).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–18448 Filed 9–23–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10749, CMS–855O, CMS–10328, CMS–10148 and CMS–10572]

Agency Information Collection Activities: Submission for OMB Review; 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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by October 24, 2025.

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.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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 Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment.

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* National Plan and Provider Enumeration System (NPPES) Supplemental Data Collection; *Use:* The adoption by the Secretary of HHS of the standard unique health identifier for health care providers is a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The unique identifier is to be used on standard transactions and may be used for other lawful purposes in the health care system. The CMS Final Rule published on January 23, 2004 adopts the National Provider Identifier (NPI) as the standard unique health identifier for health care providers. Health care providers that are covered entities under HIPAA must apply for and use NPIs in standard transactions. The law requires that data collection standards for these measures be used, to the extent that it is practical, in all national population health surveys. It applies to self-reported optional information only. The law also requires any data standards published by HHS to comply with standards created by the Office of Management and Budget (OMB).

The web based optional data fields can be seen in Appendix A1: Data Collected for the Office of Minority and Appendix A2: Data collected for the 21st Century Cures Act, interoperability. The standards apply to population health surveys sponsored by HHS, where respondents either self-report information or a knowledgeable person responds for all members of a household. HHS is implementing these data standards in all new surveys. *Form Number:* CMS–10749 (OMB control number: 0938–1427); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 545,648; Total *Annual Responses:* 545,648; *Total Annual Hours:* 92,760. (For policy questions regarding this collection contact Nora Simmons at 410–786–1981.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Registration Application; *Use:* Various sections of the Social Security Act (Act), the United States Code (U.S.C.), Internal Revenue Service Code (Code) and the Code of Federal Regulations (CFR) require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before allowing payment. The principal function of the CMS–855O is to gather information from a physician or other eligible professional to help CMS determine whether he or she meets certain qualifications to enroll in the Medicare program for the sole purpose of ordering or certifying certain Medicare items or services. The CMS–855O allows a physician or other eligible professional to enroll in Medicare without approval for billing privileges.

The collection and verification of this information protects our beneficiaries from illegitimate providers/suppliers. These procedures also protect the Medicare Trust Funds against fraud. The CMS–855O gathers information that allow Medicare contractors to ensure that the physician or eligible professional is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, or excluded from any other Federal agency or program. Furthermore, the data collected also ensures that the applicant has the necessary credentials to order and certify health care services. This is the

sole instrument implemented for this purpose. *Form Number:* CMS–855O (OMB control number 0938–1135); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits), State, Local, or Tribal Governments; *Number of Respondents:* 2,250; *Number of Responses:* 2,250; *Total Annual Hours:* 1,125. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Self-Referral Disclosure Protocol; *Use:* Section 6409 of the ACA requires the Secretary to establish a voluntary self-disclosure process that allows providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. The SRDP is a voluntary self-disclosure process that allows providers of services and suppliers to disclose actual or potential violations of section 1877 of the Act. For purposes of the SRDP, a person submitting a disclosure to the SRDP will be referred to as a ''disclosing party.'' CMS analyzes the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition.

Specifically, under the proposal a physician practice disclosing group practice noncompliance will submit an SRDP form consisting of the following components: (1) the SRDP Disclosure Form, (2) a single Group Practice Information Form covering all the physicians in the practice who made prohibited referrals to the practice, and (3) a Financial Analysis Worksheet. All other entities will continue to submit disclosures using the SRDP Disclosure Form, separate Physician Information Forms for each physician covered in the self-disclosure, and a Financial Analysis Worksheet. *Form Number:* CMS–10328 (OMB control number: 0938–1106); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 4,950. (For policy questions regarding this collection contact Caitlin Bailey at 410–786–9768.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification (Non-Privacy/Security) Complaint Form; *Use:* The Secretary of Health and Human Services (HHS), hereafter known as ''The Secretary,'' codified 45 CFR parts 160 and 164 Administrative Simplification provisions that apply to the enforcement of the Health Insurance Portability and Accountability Act of 1996 Public Law 104–191 (HIPAA). The provisions address rules relating to the investigation of non-compliance of the HIPAA Administrative Simplification code sets, unique identifiers, operating rules, and transactions. 45 CFR 160.306, Complaints to the Secretary, provides for investigations of covered entities by the Secretary. Further, it outlines the procedures and requirements for filing a complaint against a covered entity.

Anyone can file a complaint if he or she suspects a potential violation. Persons believing that a covered entity is not utilizing the adopted Administrative Simplification provisions of HIPAA are voluntarily requested to file a complaint with CMS via the Administrative Simplification Enforcement and Testing Tool (ASETT) online system, by mail, or by sending an email to the HIPAA mailbox at *hipaacomplaint@cms.hhs.gov.* Information provided on the standard form will be used during the investigation process to validate non-compliance of HIPAA Administrative Simplification provisions.

This standard form collects identifying and contact information of the complainant, as well as the identifying and contact information of the filed against entity (FAE). This information enables CMS to respond to the complainant and gather more information if necessary, and to contact the FAE to discuss the complaint and CMS' findings. *Form Number:* CMS–10148 (OMB control number: 0938–0948); *Frequency:* Occasionally; *Affected Public:* Private sector, Business or Not-for-profit institutions, State, Local, or Tribal Governments, Federal Government, Not-for-profits institutions; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 400. (For policy questions regarding this collection contact Kevin Stewart at 410–786–6149).

5. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Transparency in Coverage Reporting by Qualified Health Plan Issuers; *Use:* Sections 1311(e)(3)(A)–(C) of the ACA, as implemented at 45 CFR 155.1040(a)–(c) and 156.220, establish standards for qualified health plan (QHP) issuers to submit specific information related to transparency in coverage. QHP issuers are required to post and make data related to transparency in coverage available to the public in plain language and submit this data to the Department of Health and Human Services (HHS), the Exchange, and the state insurance commissioner. Section 2715A of the Public Health Service (PHS) Act as added by the ACA largely extends the transparency provisions set forth in section 1311(e)(3) to non-grandfathered group health plans and health insurance issuers offering group and individual health insurance coverage. *Form Number:* CMS–10572 (OMB control number: 0938–1310); *Frequency:* Annually; *Affected Public:* Private Sector, Business, and Not-for Profits; *Number of Respondents:* 400; *Number of Response* s: 400; *Total Annual Hours:* 22,000. (For questions regarding this collection, contact Jack Reeves at 301–492–5152.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–18506 Filed 9–23–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–2025–N–3346]

Elite Laboratories, Inc., et al.; Withdrawal of Approval of 72 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 72 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of October 23, 2025.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing.