consumers or households, 5,500; State and local government agencies, 200.

Estimated average hours per response: Private sector, 1.5; Individual consumers or households, 1.5; State and local government agencies, 1.5.

Estimated annual burden hours: Private sector, 12,900; Individual consumers or households, 16,500; State and local government agencies. 600.

General description of collection: The FR 3067 is a series of surveys used to conduct research related to the Federal Reserve System's role in the payments system, including supervisory, regulatory, fiscal, or operational responsibilities. The survey topics are time-sensitive and the questions of interest vary with the focus of the survey. Because the relevant questions may change with each survey, there is no fixed reporting form. For each survey, the Board prepares questions of specific topical interest and then determines the relevant target group to contact.

Legal authorization and confidentiality: The Board uses the information obtained through the FR 3067 to discharge its statutory responsibilities, including those under the following statutes:

- Section 609 of the Expedited Funds Availability Act; [1]
- Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act; [2]
- Sections 904 and 920 of the Electronic Fund Transfer Act; [3]
- Section 7 of the Bank Service Company Act; [4]
- Section 15 of the Check Clearing for the 21st Century Act; [5] and
- Sections 2A, 11, 11A, 13, and 16 of the Federal Reserve Act.[6]

The FR 3067 surveys are voluntary. Individual respondents may request confidential treatment in accordance with the Board's Rules Regarding Availability of Information.[7] Requests for confidential treatment of information are reviewed on a case-by-case basis. To the extent information provided on the FR 3067 is nonpublic commercial or financial information, which is both customarily and actually treated as private by the respondent, the information may be protected from disclosure pursuant to exemption 4 of the Freedom of Information Act.[8]

Board of Governors of the Federal Reserve System, September 12, 2022.

Margaret Shanks,

Deputy Secretary of the Board.

[FR Doc. 2022–19999 Filed 9–14–22; 8:45 am]

BILLING CODE 6210–01–P

[1] 12 U.S.C. 4008(c) (authorizing the Board to prescribe such regulations as it may determine appropriate to carry out its responsibility to regulate the payment system).

[2] 12 U.S.C. 5461(b) (authorizing the Board to promote uniform standards for the management of risks by systemically important financial market utilities and conduct of systemically important payment, clearing, and settlement activities by financial institutions, as well as providing an enhanced role in the supervision of risk management standards for systemically important financial market utilities and systemically important payment, clearing, and settlement activities by financial institutions).

[3] 15 U.S.C. 1693b, 1693o–2 (authorizing the Board to prescribe regulations relating to interchange fees for electronic debit transactions and require any debit card issuer or payment card network to provide the Board with such information as may be necessary to carry out its responsibility to regulate interchange fees for electronic debit transactions).

[4] 12 U.S.C. 1867 (authorizing the Board to issue such regulations and orders as may be necessary to administer and carry out the purposes of the Bank Services Company Act and prevent evasions thereof).

[5] 12 U.S.C. 5014 (authorizing the Board to prescribe such regulations as it determines necessary to implement, prevent circumvention or evasion of, or facilitate compliance with the Expedited Funds Availability Act, as amended).

[6] 12 U.S.C. 225a, 248, 248a, 342, 360, and 248–1 (*inter alia,* requiring the Board to maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates).

[7] 12 CFR 261.17.

[8] 5 U.S.C. 552(b)(4).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–379, CMS–10344, CMS–10594, CMS–10415 and CMS–1957]

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 (the 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 14, 2022.

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, you 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–10415 Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

CMS–1957 Social Security Office (SSO) Report of State Buy-In Problem

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 Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Financial Statement of Debtor; *Use:* CMS is authorized to collect the information requested on this form by sections 1124(a)(1), 1124A(a)(3), 1128, 1814, 1815, 1833(e), and 1842(r) of the Social Security Act [42 U.S.C. 1320a–3(a)(1), 1320a–7, 1395f, 1395g, 1395(l)(e), and 1395u(r)] and section 31001(1) of the Debt Collection Improvement Act [31 U.S.C. 7701(c)]. Section 1893(f) (1)) of the Social Security Act and 42 CFR 401.607 provides the authority for collection of this information. Section 42 CFR 405.607 requires that, CMS recover amounts of claims due from debtors including interest where appropriate by direct collections in lump sums or in installments. The physician/supplier may be unable to refund a large overpaid amount in a single payment. The MAC cannot recover the overpayment by recoupment if the physician/supplier does not accept assignment of future claims, or is not expected to file future claims because of going out of business, illness or death. In these unusual circumstances, the MAC has authority to approve or deny extended repayment schedules up to 12 months, or may recommend to the Centers for Medicare and Medicaid Services (CMS) to approve up to 60 months. Before the MAC takes these actions, the MAC will require full documentation of the physician's/supplier's financial situation. Thus, the physician/supplier must complete the CMS–379, Financial Statement of Debtor. *Form Number:* CMS–379 (OMB control number 0938–0270); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 500; *Number of Responses:* 500; *Total Annual Hours:* 1,000. (For policy questions regarding this collection contact Monica Thomas at 410–786–4292).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Elimination of Cost-Sharing for full benefit dual-eligible Individuals Receiving Home and Community-Based Services; *Use:* Section 1860 D–14 of the Social Security Act sets forth requirements for premium and cost-sharing subsidies for low-income beneficiaries enrolled in Medicare Part D. Based on this statute, 42 CFR 423.771, provides guidance concerning limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in Part D plans. 42 CFR 423.771 (b) establishes requirements for determining a beneficiary's eligibility for full subsidy under the Part D program. Regulations set forth in 423.780 and 423.782 outline premium and cost sharing subsidies to which full subsidy eligible are entitled under the Part D program.

Each month CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration (SSA). The SSA sends a monthly file of Supplementary Security Income-eligible beneficiaries to CMS. Similarly, the State Medicaid agencies submit Medicare Modernization Act files to CMS that identify full subsidy beneficiaries. CMS deems the beneficiaries as having full subsidy and auto-assigns these beneficiaries to bench mark Part D plans. Part D plans receive premium amounts based on the monthly assessments. *Form Number:* CMS–10344 (OMB control number 0938–1127); *Frequency:* Monthly; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 51; *Number of Responses:* 612; *Total Annual Hours:* 621. (For policy questions regarding this collection contact Roland Herrera at 410–786–0668).

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Provider Network Coverage Data Collection; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111–148) was signed into law on March 23, 2010. On March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was signed into law. The two laws are collectively referred to as the Affordable Care Act (ACA). The ACA established competitive private health insurance markets called Marketplaces, or Exchanges, which gave millions of Americans and small businesses access to affordable, quality insurance options that meet certain requirements. These requirements include ensuring sufficient choice of providers and providing information to enrollees and prospective enrollees on the availability of in-network and out-of-network providers.

In the final rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (CMS–9937–P), we finalized network adequacy standards for qualified health plan (QHP) issuers, including stand-alone dental plans (SADPs) mostly focused on issuers in QHPs in the Federally-facilitated Exchanges (FFEs). This information collection notice is for two of the standards from the rule: one applying in the FFE and one applying to all QHPs. Specifically, under 45 CFR 156.230(d) and 156.230(e), we require notification requirements for enrollees in cases where a provider leaves the network and for cases where an enrollee might be seen by an out of network ancillary provider in an in-network setting. These standards will help inform consumers about his or her health plan coverage to better make cost effective choices. The Centers for Medicare and Medicaid Services (CMS) is updating an information collection request (ICR) in connection with these standards. The burden estimates for this ICR included in this package reflects the additional time and effort for QHP issuers to provide these notifications to enrollees. *Form Number:* CMS–10594 (OMB control number 0938–1302); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 374; *Number of Responses:* 374; *Total Annual Hours:* 551,276. (For policy questions regarding this collection contact Nicole Levesque at *nicole.levesque@cms.hhs.gov*).

4. *Type of Information Collection Request:* Revision of a currently approved colleciton; *Title of Information Collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery; *Use:* This collection of information is necessary to enable the

Agency to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient, and satisfying experience with the Agency's programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Collecting voluntary customer feedback is the least burdensome, most effective way for the Agency to determine whether or not its public websites are useful to and used by its customers. Generic clearance is needed to ensure that the Agency can continuously improve its websites through regular surveys developed from these pre-defined questions. Surveying the Agency websites on a regular, ongoing basis will help ensure that users have an effective, efficient, and satisfying experience on any of the websites, maximizing the impact of the information and resulting in optimum benefit for the public. The surveys will ensure that this communication channel meets customer and partner priorities, builds the Agency's brands, and contributes to the Agency's health and human services impact goals. *Form Number:* CMS–10415 (OMB control number 0938–1185); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 2,000,000; *Number of Responses:* 2,000,000; *Total Annual Hours:* 50,000. (For policy questions regarding this collection contact Aaron Lartey at 410–786–7866.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Social Security Office (SSO) Report of State Buy-In Problem; *Use:* The statutory authority for the State Buy-in program is Section 1843 of the Social Security Act, amended through 1989. Under section 1843, a State can enter into an agreement to provide Medicare protection to individuals who are members of a Buyin coverage group, as specified in the State's Buy-in agreement. The Code of Federal Regulations at 42 CFR 407.40 provides for States to enroll in Medicare and pay the premiums for all eligible members covered under a Buyin coverage group. Individuals enrolled in Medicare through the Buy-in program must be eligible for Medicare and be an eligible member of a Buy-in coverage group. The day to day operations of the State Buy-in program is accomplished through an automated data exchange process. The automated data exchange process is used to exchange Medicare and Buy-in entitlement information between the Social Security District Offices, State Medicaid Agencies and the Centers for Medicare & Medicaid Services (CMS). When problems arise that cannot be resolved though the normal data exchange process, clerical actions are required. The CMS–1957, ''SSO Report of State Buy-In Problem'' is used to report Buy-in problems cases. The CMS–1957 is the only standardized form available for communications between the aforementioned agencies for the resolution of beneficiary complaints and inquiries regarding State Buy-in eligibility. *Form Number:* CMS–1957 (OMB control number 0938–0035); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,400; *Number of Responses:* 1,400; *Total Annual Hours:* 467. (For policy questions regarding this collection contact Keith Johnson at 410–786–2262.)

Dated: September 12, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–20007 Filed 9–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2143]

Determination That Bacitracin for Injection, 10,000 Units/Vial and 50,000 Units/Vial, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that bacitracin for injection, 10,000 units/vial and 50,000 units/vial, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for bacitracin for injection.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Bacitracin for injection, 10,000 units/vial and 50,000 units/vial, is the subject of ANDA 060733 (originally NDA 6–483), held by Pharmacia and Upjohn Company (a subsidiary of Pfizer Inc.), and was initially approved on July 29, 1948. Bacitracin for injection is an antibiotic for intramuscular administration, the use of which is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible