Secretary) to publish changes to the AIC threshold amounts in the Federal Register (§ 405.1006(b)(2)). In order to be entitled to a hearing before an ALJ, a party to a proceeding must meet the AIC requirements at § 405.1006(b).

Similarly, a party must meet the AIC requirements at § 405.1006(c) at the time judicial review is requested for the court to have jurisdiction over the appeal (§ 405.1136(a)).

B. Medicare Part C/MA Appeals

Section 940(b)(2) of the MMA applies the AIC adjustment requirement to Medicare Part C appeals by amending section 1852(g)(5) of the Act. The implementing regulations for Medicare Part C appeals are found at 42 CFR 422, subpart M. Specifically, §§ 422.600 and 422.612 discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 422.600 grants any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsideration determination a right to an ALJ hearing as long as the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary. Section 422.612 states, in part, that any party, including the MA organization, may request judicial review if the AIC meets the threshold requirement established annually by the Secretary.

C. Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Section 1876(c)(5)(B) of the Act states that the annual adjustment to the AIC dollar amounts set forth in section 1869(b)(1)(E)(iii) of the Act applies to certain beneficiary appeals within the context of health maintenance organizations and competitive medical plans. The applicable implementing regulations for Medicare Part C appeals are set forth in 42 CFR 422, subpart M and apply to these appeals in accordance with 42 CFR 417.600(b). The Medicare Part C appeals rules also apply to health care prepayment plan appeals in accordance with 42 CFR 417.840.

D. Medicare Part D (Prescription Drug Plan) Appeals

The annually adjusted AIC threshold amounts for ALJ hearings and judicial review that apply to Medicare Parts A, B, and C appeals also apply to Medicare Part D appeals. Section 101 of the MMA added section 1860D-4(h)(1) of the Act regarding Part D appeals. This statutory provision requires a prescription drug plan sponsor to meet the requirements set forth in sections 1852(g)(4) and (g)(5) of the Act, in a similar manner as MA organizations. As noted previously, the annually adjusted AIC threshold requirement was added to section 1852(g)(5) of the Act by section 940(b)(2)(A) of the MMA. The implementing regulations for Medicare Part D appeals can be found at 42 CFR 423, subparts M and U. The regulations at § 423.562(c) prescribe that, unless the Part D appeals rules provide otherwise, the Part C appeals rules (including the annually adjusted AIC threshold amount) apply to Part D appeals to the extent they are appropriate. More specifically, §§ 423.1970 and 423.1976 of the Part D appeals rules discuss the AIC threshold amounts for ALJ hearings and judicial review. Section 423.1970(a) grants a Part D enrollee, who is dissatisfied with the independent review entity (IRE) reconsideration determination, a right to an ALJ hearing if the amount remaining in controversy after the IRE reconsideration meets the threshold amount established annually by the Secretary. Sections 423.1970(a) and (b) allow a Part D enrollee to request judicial review of an ALJ or Medicare Appeals Council decision if, in part, the AIC meets the threshold amount established annually by the Secretary.

As previously noted, section 940 of the MMA requires that the AIC threshold amounts be adjusted annually, beginning in January 2005, by the percentage increase in the medical care component of the CPI for all urban consumers (U.S. city average) from July 2003 to July of the year preceding the year involved and rounded to the nearest multiple of $10.

B. Calendar Year 2019

The AIC threshold amount for ALJ hearings will remain at $160 and the AIC threshold amount for judicial review will rise to $1,630 for CY 2019. These amounts are based on the 63.035 percent increase in the medical care component of the CPI, which was at 297.600 in July 2003 and rose to 485.193 in July 2018. The AIC threshold amount for ALJ hearings changes to $163.04 based on the 63.035 percent increase over the initial threshold amount of $100 established in 2003. In accordance with section 1869(b)(1)(E)(iii) of the Act, the adjusted threshold amounts are rounded to the nearest multiple of $10. Therefore, the CY 2019 AIC threshold amount for ALJ hearings is $160.00. The AIC threshold amount for judicial review changes to $1,630.35 based on the 63.035 percent increase over the initial threshold amount of $1,000. This amount was rounded to the nearest multiple of $10, resulting in the CY 2019 AIC threshold amount of $1,630.00 for judicial review.

C. Summary Table of Adjustments in the AIC Threshold Amounts

In the following table we list the CYs 2015 through 2019 threshold amounts.

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</table>

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Dated: August 31, 2018.

Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–20506 Filed 9–19–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Matching Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
ACTION: Notice of New Matching Program.

SUMMARY: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is providing notice of a new computer matching program between CMS and the Department of Homeland Security (DHS)/United States Citizenship and Immigration Services (USCIS), “Verification of United States Citizenship and Immigration Status Data for Eligibility Determinations.” In this matching program, DHS/USCIS provides CMS with immigrant, nonimmigrant, and naturalized or derived citizenship status information needed to make enrollment and exemption eligibility determinations as required by the Patient Protection and Affordable Care Act (ACA).

DATES: The deadline for comments on this notice is October 22, 2018. The re-established matching program will commence no sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (from approximately October 2018 to April 2020) and within 3 months of expiration may be renewed for one additional year if the parties make no change to the matching program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: Interested parties may submit comments on the new matching program to the CMS Privacy Officer by mail at: Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services, Location: N1–14–56, 7500 Security Blvd., Baltimore, MD 21244–1850, or walter.stone@cms.hhs.gov. Comments received will be available for review without redaction unless otherwise advised by the commenter at this location, by appointment, during regular business hours, Monday through Friday from 9:00 a.m. to 3:00 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact Jack Lavelle, Senior Advisor, Marketplace Eligibility and Enrollment Group, Centers for Consumer Information and Insurance Oversight, CMS, at (410) 786–0639, by email at jack.lavelle1@cms.hhs.gov, or by mail at 7501 Wisconsin Ave., Bethesda, MD 20814.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a) provides certain protections for individuals applying for and receiving federal benefits. The law governs the use of computer matching by federal agencies when records in a system of records (meaning, federal agency records about individuals retrieved by name or other personal identifier) are matched with records of other federal or non-federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual’s benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o)(2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the Federal Register as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopulos,

PARTICIPATING AGENCIES:
The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is the recipient agency, and the Department of Homeland Security (DHS), United States Citizenship and Immigration Services (USCIS) is the source agency.

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:
The statutory authority for the matching program is 42 U.S.C. 18001.

PURPOSE(S):
The matching program will provide CMS with USCIS data, including immigrant, nonimmigrant, and naturalized or derived citizenship status information from USCIS’S SAVE program and VIS system. This data will indicate whether an applicant or enrollee is lawfully present, a qualified non-citizen, a naturalized or derived citizen, and whether the five-year waiting period for many non-citizens applies and has been met. CMS and state administering entities will use the data to determine the individual’s eligibility for enrollment in a qualified health plan through a federally-facilitated exchange (FFE) and for insurance affordability programs and certificates of exemption, and to make eligibility redetermination and renewal decisions, including appeal determinations. USCIS will provide the data from USCIS’S SAVE program and VIS system about individuals whose identifying information matches identifying information that CMS submits to USCIS. CMS will make the USCIS data available to requesting state administering entities through a data services hub (Hub).

CATEGORIES OF INDIVIDUALS:
The individuals whose information will be used in the matching program are consumers who apply for any of the following eligibility determinations: eligibility to enroll in a qualified health plan through an exchange established under the ACA, eligibility for insurance affordability programs and certificates of exemption, and subsequent eligibility redeterminations and renewals, including appeal determinations.

CATEGORIES OF RECORDS:
The categories of records used in the matching program are identity and citizenship status records. The data elements are described below.

• From the CMS to USCIS. CMS will submit data elements pertaining to applicants and enrollees through SAVE to the USCIS VIS. These data elements may include the following: identification number (e.g., foreign passport number, 1–94 number, alien registration number/USCIS number); immigration document type; last name; middle initial; first name; date of birth; document expiration date (if applicable); and information contained in the comment field, such as USCIS benefit application receipt numbers, maiden names, nicknames, and additional immigration document numbers.

• From USCIS to CMS. USCIS through SAVE will follow the Hub requests that contain data from records provided to VIS and databases VIS accesses. These responses may include
the following data elements: alien registration number/USCIS number; I–94 number; last name; first name; date of birth; date of entry; status grant date, if available; and immigration status data.

**SYSTEM OF RECORDS:**

The records used in this matching program are disclosed from the following systems of records, as authorized by routine use published in the System of Records Notices (SORNs) cited below:

A. **CMS System of Records:**

B. **USCIS System of Records:**
- DHS/USCIS–004 Systematic Alien Verification for Entitlements Program, 81 FR 78619 (Nov. 8, 2016). Routine use 3 permits USCIS’ disclosures to CMS.

**Electronic Submissions**

Submit comments electronically in the following way:
- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

**Written/Paper Submissions**

Submit written/paper submissions as follows:
- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”
- Instructions: All submissions received must include the Docket No. FDA–2017–D–6526 for “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier; Guidance for Industry; Availability.”
- Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier: Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier.” This guidance specifies whether and under what circumstances packages and homogenous cases of product not labeled with a product identifier shall be grandfathered from certain requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance finalizes the draft guidance issued on November 27, 2017.

**DATES:** The announcement of the guidance is published in the Federal Register on September 20, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

Submit written comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10901 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Abha Kundi, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10901 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, drugtrackandtrace@fda.hhs.gov.