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 423.1976(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.

II. Provisions of the Notice—Annual AIC Adjustments

A. AIC Adjustment Formula and AIC Adjustments

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.

	CY 2015	CY 2016	CY 2017	CY 2018	CY 2019
ALJ Hearing	$150	$150	$160	$160	$160
Judicial Review	1,460	1,500	1,560	1,600	1,630

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]

BILLING CODE 4120–01–P

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 not 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,

CMS Privacy Advisor, Division of Security, Privacy Policy and Governance, Information Security and Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services.

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, I–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 send the Hub responses 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 uses published in the System of Records Notices (SORNs) cited below:

A. CMS System of Records:

• CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR 6591 (Feb. 14, 2018). Routine use 3 supports CMS's disclosures to USCIS.

B. USCIS System of Records:

• DHS/USCIS–004 Systematic Alien Verification for Entitlements Program, 81 FR 78619 (Nov. 8, 2016). Routine use H permits USCIS' disclosures to CMS.

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BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6526]

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:

Electronic Submissions

Submit electronic comments 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.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit 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, 10001 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, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *drugtrackandtrace@fda.hhs.gov.*