

Regional Offices to assess Sponsoring organizations' compliance with Medicare program requirements. If outliers or other data anomalies are detected, MOEG requires audited organizations to provide impact analyses to better understand and report the scope of the noncompliance. These MA and Part D organizations then receive their audit results, are required to implement corrective actions, and to demonstrate correction of all conditions cited in the final audit report by undergoing a validation audit. If the validation audit demonstrates substantial correction of the conditions, MOEG will communicate its decision to close the audit in a letter to the MA and Part D organization. Any new or isolated issues of non-compliance that remain will be referred to the CMS Account Manager for follow-up. Regional Offices will work in collaboration with MOEG and other divisions within CMS for resolution. *Form Number:* CMS-10717 (OMB control number: 0938-New); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 190; *Total Annual Responses:* 179; *Total Annual Hours:* 36,082. (For policy questions regarding this collection contact Kellie Simons at 410-786-0886.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment; *Use:* The Exchanges, which became operational on January 1, 2014, enhanced competition in the health insurance market, expanded access to affordable health insurance for millions of Americans, and provided consumers with a place to easily compare and shop for health insurance coverage. The reporting requirements and data collection in Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment (CMS-2334-F) address: (1) Standards related to notices, (2) procedures for the verification of enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan; and (3) other eligibility and enrollment provisions to provide detail necessary for state implementation. The submission seeks

OMB approval of the information collection requirements associated with selected provisions in 45 CFR parts 155, 156 and 157. *Form Number:* CMS-10468 (OMB control number: 0938-1207); *Frequency:* Annually; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 1,522; *Total Annual Responses:* 9,533; *Total Annual Hours:* 103,710. (For policy questions regarding this collection contact Anne Pesto at 410-786-3492.)

3. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Plus Choice Program Requirements Referenced in 42 CFR 422.000-422.700; *Use:* The information collection requirements are mandated by 42 CFR part 422. Section 4001 of the Balanced Budget Act of 1997 (BBA) added sections 1851 through 1859 to the Social Security Act to establish the Managed Care program. The Medicare, Medicaid, and SCHIP Benefits Improvement Act and Protection Act of 2000, Public Law 106-554 added requirements to the Managed Care program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) created the Medicare Advantage program.

A major goal of the Medicare Advantage program is to provide ease of access for Original Medicare beneficiaries who wish to enroll in a Medicare Advantage program. Certain populations of beneficiaries such as the dually eligible population (those beneficiaries enrolled in both Medicaid and Medicare) have grown since the program was created and these populations require more flexibilities.

MA organizations (formerly M+C organizations) and potential MA organizations (applicants) use the information collected based on the regulations at 42 CFR part 422 to comply with the application requirements and the MA contract requirements. CMS uses the information collected based on the regulations at 42 CFR part 422 to approve contract applications, monitor compliance with contract requirements, make proper payment to MA organizations, determine compliance with the new prescription drug benefit requirements established by the MMA, and to ensure that correct information is disclosed to Medicare beneficiaries, both potential enrollees and enrollees.

Information supplied by organizations is used to determine eligibility for contracting with CMS, for determining compliance with contract requirements, and for calculating proper payment to

the organizations. Information supplied by Medicare beneficiaries is used to determine eligibility to enroll in the M+C organization and to determine proper payment to the organization that enrolled the beneficiary. Separate OMB approval was sought for each form as required.

The information collection request also incorporates the new minimum criteria for dual eligible special needs plans (D-SNPs) to integrate Medicare and Medicaid benefits detailed in Section 50311(b) of the Bipartisan Budget Act of 2018 and set forth in in Final rule (CMS-4185-F, RIN 0938-AT59) for CY2020 and 2021. The integration requirements improve care coordination, quality of care, and beneficiary satisfaction while reducing administrative burden. *Form Number:* CMS-R-267 (OMB control number: 0938-0753); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 6,727,508; *Total Annual Responses:* 6,750,814; *Total Annual Hours:* 1,848,180. (For policy questions regarding this collection contact Marna Metcalf Akbar at 410-786-8251.)

Dated: May 29, 2020.

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; Matching Program

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), Office of Planning, Research and Evaluation (OPRE), is providing notice of a re-established matching program between the Department of Veterans Affairs (VA) and State Public Assistance Agencies (SPAAs) participating in the Public Assistance Reporting Information System (PARIS) Program. The matching program provides the SPAAs with VA compensation and pension data on a periodic basis to use in determining

public assistance applicants' and recipients' eligibility for certain public assistance benefits. HHS/ACF/OPRE facilitates the matching program, and the Department of Defense (DoD), Defense Manpower Data Center (DMDC) conducts the matches of SPAA and VA data and provides associated support.

DATES: The deadline for comments on this notice is July 6, 2020. 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 August 30, 2020, through February 28, 2022) and within 3 months of expiration may be renewed for 1 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 written comments on this notice, by mail or email, to the PARIS Project Officer, Division of Data and Improvement, HHS/ACF Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20024, paris@acf.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

General questions about the matching program may be submitted to Joshua Williams, PARIS Project Officer, Division of Data and Improvement, HHS/ACF Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20024, paris@acf.hhs.gov.

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. Obtain approval of a Computer Matching Agreement, prepared in accordance with the Privacy Act, by the Data Integrity Board of each federal agency that is a source or recipient of data used in the matching program. 5 U.S.C. 522a(o)(1), (u)(3)(A), and (u)(4).
2. Provide adequate advance notice of the matching program, including a copy of the agreement, to Congress and the Office of Management and Budget (OMB). 5 U.S.C. 552a(o)(2)(A)(i) and (r).

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

4. Make the Computer Matching Agreement available to the public. 5 U.S.C. 552a(o)(2)(A)(ii).

5. 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).

6. 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).

7. Provide an annual report of the matching program activities to Congress and OMB, and make the report available to the public. 5 U.S.C. 552a(u)(3)(D).

This matching program meets these requirements.

Naomi Goldstein,

Deputy Assistant Secretary for Planning, Research and Evaluation, ACF.

Participating Agencies

VA is the source agency, and SPAAs are non-federal agencies.

Authority for Conducting the Matching Program

Sections 402, 1137, and 1903(r) of the Social Security Act (42 U.S.C. secs. 602(a), 1320b-7, and 1396b(r)).

Purpose(s)

The matching program will provide participating SPAAs with VA compensation and pension data on a periodic basis to use in determining public assistance applicants' and recipients' eligibility for benefits under Medicaid, Temporary Assistance for Needy Families (TANF), Supplemental Nutrition Assistance Program (SNAP), and general assistance programs, and to use in helping relevant veterans to better understand similar benefits available through the VA, which may be better alternatives. The matching program helps ensure fair and equitable treatment in the delivery of benefits attributable to funds provided by the Federal Government.

Categories of Individuals

The categories of individuals involved in the matching program are:

- Individuals applying for, or receiving, Medicaid, TANF, SNAP, and/or general assistance benefits (public assistance clients); and
- Individuals receiving VA pay or pension benefits.

Categories of Records

The categories of records used in the matching program are identifying information and compensation and pension data.

On an approximately quarterly basis, VA will provide DoD/DMDC with a file containing VA benefit record data about all individual VA benefit and compensation recipients, and each SPAA will provide DoD/DMDC with a non-federal file containing identifying information, including Social Security Numbers (SSNs) about public assistance clients. DoD/DMDC will compare the SSNs in each SPAA file to the VA file and will provide the SPAA with match results containing the following data elements (as applicable) about each public assistance client whose SSN matches the SSN of an individual receiving VA compensation or pension benefits:

VA File Number; Veteran/Beneficiary/ Apportionee SSN and SSN Verification Indicator; Payee Type Code; Award Type, Award Line Type, and Award Status Codes; Gender Code; Last Name/ First Name/Middle Name; Beneficiary Birth Date; Veteran/Spouse Aid and Attendance Code; Station Number; Spouse; Minor Child; School Child; Helpless Child; Parent; Combined Degree; Entitlement Type Code; Change Reason; Suspense Reason; Last Paid Date; Effective Date; Gross Amount; Net Award Amount; Payment Amount; Frequency Pay Type Code; Income for VA Purposes Amount; Beneficiary/ Spouse Annual Amounts (for Wages, Insurance, Interest, Social Security, Civil Service Retirement, Military, Railroad Retirement Board, Black Lung, and Rest); Beneficiary/Spouse Rest of Exclusion Amount; Medical Expense/ Education Expense/Last Expense/ Hardship Amounts; Receivable/ Receivable Amount; Monthly Deductions/Deduction Amount; Proceeds/Proceeds Amount; Address Type Indicator; Address Name/ Fiduciary; Address Fiduciary Type; Address Name Beneficiary; Corporate Format Address (Address Lines One, Two, and Three, City Name, State Name, ZIP Code Prefix and Suffix, Country Type Name, Foreign Postal Code, Province Name, Territory Name, Military Postal Type, Military Post Office); and Benefits Delivery Network Treasury Address and ZIP Code Prefix.

System(s) of Records

The VA data used in this matching program will be disclosed from the following system of records, as authorized by routine use 35: "Compensation, Pension, Education,

and Vocational Rehabilitation and Employment Records—VA (58VA21/22/28),” 84 FR 4138 (Feb. 14, 2019).
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by August 3, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-2007-D-0369 for “Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.” 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.govinfo.gov/content/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 the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillendale Building, 4th Floor, 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 draft guidance documents.

FOR FURTHER INFORMATION CONTACT: Mara Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4709C, Silver Spring, MD 20993-0002, 301-796-0683.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA’s website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal**