

represent a nationwide average of consumer purchase prices, net of discounts and rebates. The contractor shall provide notification when a drug product becomes generally available and that the contract include such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. CMS has developed a National Average Drug Acquisition Cost (NADAC) for states to consider when developing reimbursement methodology. The NADAC is a pricing benchmark that is based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark is based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey is conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date. *Form Number:* CMS-10241 (OMB control number 0938-1041); *Frequency:* Monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 72,000; *Total Annual Responses:* 72,000; *Total Annual Hours:* 36,000. (For policy questions regarding this collection contact: Lisa Shochet at 410-786-5445.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Event Data From Contracted Part D Providers for Payment; *Use:* The PDE data is used in the Payment Reconciliation System to perform the annual Part D payment reconciliation, any PDE data within the Coverage Gap Phase of the Part D benefit is used for invoicing in the CGDP, and the data are part of the report provided to the Secretary of the Treasury for Section 9008.

CMS has used PDE data to create summarized dashboards and tools, including the Medicare Part D Drug Spending Dashboard & Data, the Part D Manufacturer Rebate Summary Report, and the Medicare Part D Opioid Prescribing Mapping Tool. The data are also used in the Medicare Trustees Report. Due to the market sensitive nature of PDE data, external uses of the data are subject to significant limitations. However, CMS does analyze the data on a regular basis to determine drug cost and utilization patterns in order to inform programmatic patterns and to develop informed policy in the Part D program.

The information users will be Pharmacy Benefit Managers (PBM), third party administrators and pharmacies, and the PDPs, MA-PDs, Fallbacks and other plans that offer

coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. *Form Number:* CMS-10174 (OMB control number: 0938-0982); *Frequency:* Yearly; *Affected Public:* Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 739; *Total Annual Responses:* 1,499,238,090; *Total Annual Hours:* 2,998. (For policy questions regarding this collection contact Ivan Iveljic at 410-786-3312.)

Dated: August 30, 2021.

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 re-established matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Department of Health and Human Services, Administration for Children and Families, Office of Planning, Research, and Evaluation (HHS/ACF/OPRE), is providing notice of a re-established matching program between the Department of Defense, Defense Manpower Data Center (DoD/DMDC) and State Public Assistance Agencies (SPAAs), "Verification of Continued Eligibility for Benefits Through the Public Assistance Reporting Information System (PARIS) Program." HHS/ACF/OPRE facilitates the matching program.

DATES: The deadline for comments on this notice is October 4, 2021. 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 September 30, 2021, through March 30, 2023) 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 Director, Division of Data and Improvement, HHS/ACF Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, *paris@acf.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: General questions about the matching program may be submitted to Alicia Gumbs, HHS/ACF Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201 (202) 690-8490, *paris@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a, subsection(e)(12)), 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 complies with these requirements.

Naomi Goldstein,

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

Participating Agencies

Department of Defense, Defense Manpower Data Center (DoD/DMDC) is the source agency, and each State Public Assistance Agency (SPAA) is a non-Federal agency. The Department of Health and Human Services, Administration for Children and Families, Office of Planning, Research and Evaluation (HHS/ACF/OPRE) facilitates the matching program and is not a source or recipient of data used in the matching program.

Authority for Conducting the Matching Program

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

Purpose(s)

This matching program identifies individuals receiving both Federal compensation (pay or pension benefits) and public assistance benefits under Federal benefit programs administered by the states and verifies public assistance clients' declarations of income circumstances.

Each participating State Public Assistance Agency (SPAA) will provide the Department of Defense, Defense Manpower Data Center (DMDC) with finder files containing identifying and other data about public assistance applicants or recipients (clients), which DMDC will match against DoD military and civilian pay files, military retired pay files, and survivor pay files (Office of Personnel Management (OPM) civilian retired and survivor pay files will not be used). DMDC will return matched data to the SPAA, which the SPAA will use to verify clients' continued eligibility to receive public assistance benefits under HHS' Medicaid and Temporary Assistance for Needy Families (TANF) programs and the Department of Agriculture's Supplemental Nutrition Assistance Program (SNAP) and, if ineligible, to take such action as may be authorized by law and regulation to ensure fair and equitable treatment in the delivery of benefits attributable to funds provided by the Federal Government. HHS will support each SPAA's efforts to participate in the matching program by assisting with finalizing the terms of the agreement and coordinating signatures on the agreement.

Categories of Individuals

The categories of individuals whose information is involved in the matching program are:

- Individuals who apply for or receive public assistance benefits under Federal programs administered by the states (*i.e.*, under Medicaid, TANF, and SNAP); and
- Individuals who receive compensation from the DoD (*i.e.*, military, civilian, survivor, or retirement pay or pension benefits).

Categories of Records

The categories of records involved in the matching program are public assistance client identifying information and Federal pay and pension data.

A SPAA will provide the following data elements to DMDC about each public assistance client:

- Client social security number (SSN), client last name, first name, client date of birth, address, gender, marital status, information regarding the specific public assistance benefit being received, file date, state name, state optional data, client location code, and case number.

DMDC will provide the SPAA with match results containing the following data elements about any public assistance client who is receiving compensation from DoD:

- SSN; state data; record type; file date; date of birth; last name; first name; middle name; suffix name; sex; gross pay; unit identification (ID) code (UIC); agency; pay plan; pay grade; pay step; basic salary; state residence; Federal taxable wages; Federal tax withheld; state taxable wages; state tax withheld; employee status code; payroll office number; personnel office ID; pay basic code; pay period end date (YYYYMMDD); disbursing date (YYYYMMDD); pay status; category code; total base pay all drills; marital status code; dependents quantity; off duty military code; welfare to work hire code; city; state; zip; address lines 1, 2, 3, 4, 5 and 6; mailing address effective; claim number; retired pay entitlement effective; comments 1, 2, 3 and 4; and member SSN.

System(s) of Records

The DoD data used in this matching program will be disclosed from the following system of records, as authorized by routine use 16 published March 11, 2019: DMDC 01, titled "Defense Manpower Data Center Data Base," last published in full at 84 FR 6383 (Feb. 27, 2019), and modified at 84

FR 8698 (Mar. 11, 2019) and 84 FR 15605 (Apr. 16, 2019).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0874]

Proposal To Refuse To Approve a New Drug Application for ITCA 650 (Exenatide in DUROS Device); Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Director of the Center for Drug Evaluation and Research (Center Director) at the Food and Drug Administration (FDA or Agency) is proposing to refuse to approve a new drug application (NDA) submitted by Intarcia Therapeutics, Inc. (Intarcia), for ITCA 650 (exenatide in DUROS device) in its present form. This notice summarizes the grounds for the Center Director's proposal and offers Intarcia an opportunity to request a hearing on the matter.

DATES: Submit either electronic or written requests for a hearing by October 4, 2021; submit data, information, and analyses in support of the hearing and any other comments by November 1, 2021.

ADDRESSES: You may submit hearing requests, documents in support of the hearing, and any other comments as follows. Please note that late, untimely filed requests and documents will not be considered. Electronic requests for a hearing must be submitted on or before October 4, 2021; electronic documents in support of the hearing and any other comments must be submitted on or before November 1, 2021. The <https://www.regulations.gov> electronic filing system will accept hearing requests until 11:59 p.m. Eastern Time at the end of October 4, 2021, and will accept documents in support of the hearing and any other comments until 11:59 p.m. Eastern Time at the end of November 1, 2021. Documents received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before these dates.

Electronic Submissions

Submit electronic comments in the following way: