

Copy PIA (Privacy Impact Assessment)

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Instructions


Review the following steps to complete this questionnaire:

- 1) Answer questions.** Select the appropriate answer to each question. Question specific help text may be available via the  icon. If your answer dictates an explanation, a required text box will become available for you to add further information.
- 2) Add Comments.** You may add question specific comments or attach supporting evidence for your answers by clicking on the  icon next to each question. Once you have saved the comment, the icon will change to the  icon to show that a comment has been added.
- 3) Change the Status.** You may keep the questionnaire in the "In Process" status until you are ready to submit it for review. When you have completed the assessment, change the Submission Status to "Submitted". This will route the assessment to the proper reviewer. Please note that all values list questions must be answered before submitting the questionnaire.
- 4) Save/Exit the Questionnaire.** You may use any of the four buttons at the top and bottom of the screen to save or exit the questionnaire. The button allows you to complete the questionnaire. The button allows you to save your work and close the questionnaire. The button allows you to save your work and remain in the questionnaire. The button closes the questionnaire without saving your work.

Acronyms

ATO - Authorization to Operate
CAC - Common Access Card
FISMA - Federal Information Security Management Act
ISA - Information Sharing Agreement
HHS - Department of Health and Human Services
MOU - Memorandum of Understanding
NARA - National Archives and Record Administration
OMB - Office of Management and Budget
PIA - Privacy Impact Assessment
PII - Personally Identifiable Information
POC - Point of Contact
PTA - Privacy Threshold Assessment
SORN - System of Records Notice
SSN - Social Security Number
URL - Uniform Resource Locator

General Information

PIA Name:	CDC - DARS - QTR3 - 2023 - CDC7000174	PIA ID:	2123752
Name of Component:	CDC - Drug Activity Reporting System	Name of ATO Boundary:	Drug Activity Reporting System
Overall Status:		PIA Queue:	
Submitter:		# Days Open:	375
Submission Status:	Re-Submitted	Submit Date:	9/3/2024
Next Assessment Date:	N/A	Expiration Date:	9/27/2027
Office:		OPDIV:	CDC
Security Categorization:	Moderate	OpDiv PIA ID:	CDC7000174
Legacy PIA ID:		Make PIA available to Public?:	Yes
1:	Identify the Enterprise Performance Lifecycle Phase of the system.		Operations and Maintenance
2:	Is this a FISMA-Reportable system?		Yes
3:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?		Yes
4:	ATO Date or Planned ATO Date.		2/4/2022
5:	Is the system or electronic information collection, agency or contractor operated?		Agency

PTA

PTA		
PTA - 2:	Indicate the following reason(s) for this PTA. Choose from the following options.	PIA Validation (PIA Refresh)
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	None
PTA - 3:	Is the data contained in the system owned by the agency or contractor?	Agency
PTA - 4:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions.	The Drug Activity Reporting System (DARS) is an internal inventory management and tracking system that will enable CDC's Division of Scientific Resources (DSR) Subject Matter Experts (SME's) with the ability to manage product release life cycle and product inventory, generate reports based on selected data fields and manage data/form storage associated with each product release. DARS will enable the SME's to streamline the drug release process, generate reports, provide visibility and decision support tools, and increase efficiencies.

PTA - 5:	List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.	<p>DARS maintains information on four categories of individuals.</p> <p>First, the system maintains the following information collected from select general population individuals requiring access to special requirement drugs: Name, email, phone number, Date of Birth (DOB), age, gender, pregnancy status, ethnicity, race, address and foreign travel activities.</p> <p>In addition, the system collects the following information on vaccine recipients: Name, age, sex, position, duties, indication (i.e., why they should receive the vaccine).</p> <p>Also, DARS collects information on Physician/Laboratory/Pharmacy: Point of Contact (POC) name, business address, email, fax, and phone number.</p> <p>Lastly, DARS maintains information on its internal CDC users: Name, userID, and email.</p> <p>Users access DARS using Personal Identity Verification (PIV) card, with authentication by the CDC Active Directory (AD). AD is a separate system with its own PIA.</p>
PTA - 5A:	Are user credentials used to access the system?	
PTA - 5B:	Please identify the type of user credentials used to access the system.	

PTA - 6:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual.	<p>DARS is a system that handles specific prescription drug release operations by recording which drugs are being stored, where the drugs are stored and all drug movement/transport. It includes storing drug inventories, clinic and lab information, and details about all official drug releases, including drug recipient information.</p> <p>DARS maintains information on four categories of individuals. First, the system maintains the following information collected from select general population individuals requiring access to special requirement drugs: Name, email, phone number, Date of Birth (DOB), age, gender, pregnancy status, ethnicity, race, address and foreign travel activities. In addition, the system collects the following information on vaccine recipients: Name, age, sex, position, duties, indication (i.e., why they should receive the vaccine). Also, DARS collects information on Physician/Laboratory/Pharmacy: Point of Contact (POC) name, business address, email, fax, and phone number. Lastly, DARS maintains information on its internal CDC users: Name, userID, and email.</p> <p>Information collected by the system enables SMEs to have direct access to drug release information without having to manually extract data. The information is also used to enhance reporting capabilities, and to provide better version control of protocols and associated forms. Collection of specific patient information is required about recipient before drug release. Information collected will be retained temporarily or when no longer needed for essential medical assistance.</p> <p>User credentials are also processed by DARS, which are used for user authentication.</p>
PTA - 7:	Does the system collect, maintain, use or share PII?	Yes
PTA - 7A:	Does this include Sensitive PII as defined by HHS?	Yes
PTA - 8:	Does the system include a website or online application?	Yes
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	No
PTA - 9:	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	The purpose of the website is for SMEs to have direct access to drug release information without having to manually extract data. The information is also used to enhance reporting capabilities, and to provide better version control of protocols and associated forms. Collection of specific patient information is required about recipient before drug release. Information collected will be retained temporarily or when no longer needed for essential medical assistance.
PTA - 10:	Does the website have a posted privacy notice?	No
PTA - 11:	Does the website contain links to non-federal government websites external to HHS?	No
PTA - 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	

PTA - 12:	Does the website use web measurement and customization technology?	Yes
PTA - 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	Session Cookies - Does Not Collect PII
PTA - 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA - 13A:	Does the website collect PII from children under the age thirteen?	
PTA - 13B:	Is there a unique privacy policy for the website and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 14:	Does the system have a mobile application?	No
PTA - 14A:	Is the mobile application HHS developed and managed or a third-party application?	
PTA - 15:	Describe the purpose of the mobile application, who has access to it, and how users access it. Please address each element in your response.	
PTA - 16:	Does the mobile application/ have a privacy notice?	
PTA - 17:	Does the mobile application contain links to non-federal government websites external to HHS?	
PTA - 17A:	Is a disclaimer notice provided to users that follow external links to resources not owned or operated by HHS?	
PTA - 18:	Does the mobile application use measurement and customization technology?	
PTA - 18A:	Describe the type(s) of measurement and customization technologies or techniques in use and what information is collected.	
PTA - 19:	Does the mobile application have any information or pages directed at children under the age of thirteen?	
PTA - 19A:	Does the mobile application collect PII from children under the age thirteen?	
PTA - 19B:	Is there a unique privacy policy for the mobile application and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 20:	Is there a third-party website or application (TPWA) associated with the system?	No
PTA - 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

PIA

PIA

PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Name Email Address Phone numbers Foreign Activities Date of Birth Mailing Address User Credentials Other - Free text Field - Race, Ethnicity, Gender, Pregnancy Status.
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PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Business Partners/Contacts (Federal, state, local agencies) Employees/ HHS Direct Contractors Members of the public Vendors/Suppliers/Third-Party Contractors (Contractors other than HHS Direct Contractors)
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system.	Below 50
PIA - 4:	For what primary purpose is the PII used?	PII is required to accurately identify recipient of prescribed drug(s) being supplied.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	HHS Credentialed users are identified by name and userID for access to the system.
PIA - 6:	Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID.	Not Applicable. SSN are not collected or used.
PIA - 6A:	Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID.	Not Applicable. SSN are not collected or used.
PIA - 7:	Identify legal authorities governing information use and disclosure specific to the system and program.	Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) 42 USC 243: General grant of authority for cooperation From Title 42-THE PUBLIC HEALTH AND WELFARECHAPTER 6A-PUBLIC HEALTH SERVICE SUBCHAPTER II-GENERAL POWERS AND DUTIES Part B-Federal-State Cooperation
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	Yes
PIA - 8A:	Please specify which PII data elements are used to retrieve records.	User's Name & User ID
PIA - 8B:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	System of Records, 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems, HHS/ CDC/NCID."
PIA - 9:	Identify the sources of PII in the system.	Government Sources Within the OPDIV State/Local/Tribal
PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA - 10A:	Provide the information collection approval number.	
PIA - 10B:	Identify the OMB information collection approval number expiration date.	4/30/2023

PIA - 10C:	Explain why an OMB information collection approval number is not required.	N/A. Information is not collected pursuant to the Paperwork Reduction Act (PRA): OMB Control Numbers are used for data collections subject to the Paperwork Reduction Act (PRA). PRA does not apply to data collections from government Agencies or instrumentalities or employees of the United States in their official capacities or Information from individuals under treatment or clinical examination in connection with research to prevent a clinical disorder. Information/data collected for DARS is only from government sources; data is not collected from the public. Additionally, information required for user account creation, such as email address, username, password, and geographic location do not require PRA approval. Therefore, the PRA does not apply and the requirement to obtain an OMB collection approval number is N/A.
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 11A:	Identify with whom the PII is shared or disclosed.	
PIA - 11B:	Please provide the purpose(s) for the disclosures described in PIA - 11A.	
PIA - 11C:	List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	
PIA - 11D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 12A:	If PII submission is mandatory, provide the specific legal requirement that requires individuals to provide information or face potential civil or criminal penalties.	
PIA - 13:	Describe the method for notifying individuals that their information will be collected and how they can opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.	Individuals may choose not to participate by refusing to sign the consent form. However, the CDC does not collect information from individuals, so therefore, individuals would need to opt out with the administering Physician at the time of collection.
PIA - 14:	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained.	PII data are collected by CDC from the administering physician and are reviewed by the relevant CDC staff, in support of (and if/as needed for) regulatory requirements, patient care, and public health activities. If a major system change substantially affected the disclosure or use of the PII maintained in the system, CDC would notify the pertinent administering physicians so they could take appropriate action to notify the affected individuals.

<p>PIA - 15:</p>	<p>Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.</p>	<p>The CDC Drug Service provides administering physicians with a product-specific Consent Form that describes the use of the collected information. The Consent Form also provides contact information (including telephone numbers) for pertinent CDC offices (e.g., CDC's Human Research Protection Office) for individuals who have questions or concerns.</p> <p>Individuals who would like to file a complaint would be instructed to contact CDC's Human Research Protection Office at 1-800-584-8814, reasonably identify the record, and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.</p> <p>Person having complaints, concerns, or questions about Drug Activity Reporting System (DARS) privacy practices can send these inquiries via email, phone, or postal mail. General public communications are directed to CDC's Human Research Protection Office or their designee, for internal review, and then are forwarded to CDC's Senior Official for Privacy, as necessary to review concerns and respond to resolve the individual's inquiry.</p>
<p>PIA - 16:</p>	<p>Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not.</p>	<p>The system has validation and integrity rules in place. Subject Matter Experts conduct at a minimum annual reviews and thereafter periodic (monthly/quarterly) review of drug release protocols, inventory management, procurement and accountability. All the contents including PII are assessed for accuracy, relevance and improvement to process.</p>
<p>PIA - 17:</p>	<p>Identify who will have access to the PII in the system.</p>	<p>Users Administrators Contractors</p>
<p>PIA - 17A:</p>	<p>Select the type of contractor.</p>	<p>HHS/OpDiv Direct Contractors</p>
<p>PIA - 17B:</p>	<p>Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?</p>	<p>Yes</p>
<p>PIA - 18:</p>	<p>Provide the reason why each of the groups identified in PIA - 17 needs access to PII.</p>	<p>Users: Data Entry</p> <p>Administrators: Maintenance (Patches, updates) and compliance to integrity, accountability and confidentiality is maintained.</p> <p>Contractors: CDC/HHS Credentialed contractors manage the database and trouble shoot the application.</p>

PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	<p>The Business Steward limits access to the least possible number of people necessary to access PII data for conducting official responsibilities through specific Role-based requirements. If the individual's manager determines that access to the system is required for the individual to perform their regular duties, they will make a request to the system administrator who will establish an account for the user to access the system. Access to PII is strictly enforce by setting up user profile on the Principle of Least Privilege and a Need-to-Know standard. Individuals can only see selected functions and information that are necessary for its valid purpose based on their user profile.</p> <p>System Administrators in coordination with Business Steward will assign designated personnel for read/write to data fields and Subject Matter Experts to analyze transactional user's access, monitor process and protocols used, control asset inventory.</p> <p>The HHS credentialed employee PII data is identified as non-Sensitive Internal Business information (Identified by name and CDC issued UserID) and limited to authorized Administrators and Subject Matter Experts.</p>
PIA - 20:	Describe the technical methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.	Least privilege, Role Based Access methods are used to allow those with access to PII to only access the minimum amount of information necessary to perform their job. The system administrator is responsible for setting up the user access to the system based on the CDC user ID and the permissions assigned to it.
PIA - 21:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.	All CDC personnel are required to complete annual Security and Privacy Awareness Training.
PIA - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	All CDC employees who have access to PII/sensitive information are required to complete HHS/CDC Role based training.
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	Records are maintained in accordance with General Records Schedule (GRS) and comply with CDC Records Control Schedule (RCS). In accordance with GRS 5.2, final reports are created to document programmatic decisions, policies, and other related issues and are maintained permanently (CDC RCS, B-321, 2&4). Other input/output records and system data that may be required for follow-up are disposed of after 10 years. Disposal methods include erasing computer tapes, burning or shredding paper materials or transferring records to the Federal Records Center when no longer needed for evaluation and analysis. In addition, electronic media is subject to zero-wipe pass (electronic destruction) methodology.

PIA - 24:

Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.

Administrative controls: Completion of training requirements; risk analyses performed annually; branch management reviewing access requests and granting minimal amount of access.

Technical controls: Users are authenticated and data secured using operating system and server security, administered by the local system administrator. PII data is encrypted at rest and in transits with access restricted to specific authorized users as required by HHS and CDC policy.

Physical- The server is housed on CDC property with gate guards at the entrances to the property, individual user access credentials are required for each non-public building , floor, and office. Closed Circuit TV is also used by the internal security guards to check for and grant access to authorized individuals.

Review & Comments

Privacy Analyst Review

OpDiv Privacy Analyst Review Status:	Approved	Privacy Analyst Review Date:	9/3/2024
Privacy Analyst Comments:	OpDiv Analyst: Joshua Mosios (Contractor)	Privacy Analyst Days Open:	

SOP Review

SOP Review Status:	Approved	SOP Signature:	
SOP Comments:	Approved on behalf of Beverly Walker	SOP Review Date:	9/17/2024
		SOP Days Open:	14

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	Agency Privacy Analyst Review Date:	9/20/2024
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 9/20/2024 There are minor comment for the next iteration of the PTA. Other than that this PIA is ready for SAOP review and approval.	Agency Privacy Analyst Days Open:	3

SAOP Review

SAOP Review Status:	Approved	SAOP Signature:	Archer Signature_Bridget Guenther.docx
SAOP Comments:	On the next iteration of the PTA update the following PTA-1: Provide a POC the person we would go to if w PTA-5A and PTA-5B: Please provide a response.	SAOP Review Date:	9/27/2024
		SAOP Days Open:	7

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 10A	Data Feed Service, piafrmcdc	8/16/2024	This OMB number is for ebola and is expired.	
PIA - 10B	Data Feed Service, piafrmcdc	8/16/2024	Speak to your PRA rep about whether an OMB number is even required for this system (based on what I'm reading and without knowing more, it would appear not to)	
PIA - 1	BLAND, CRYSTAL	9/20/2024	<p>On the next iteration of the PTA update the following:</p> <p>PTA-1: Provide a POC the person we would go to if we had questions about the system.</p> <p>PTA-5A and PTA-5B: Please provide a response.</p>	

Admin Section

Is OpDiv Privacy Analyst Approved ?:	1	Is OpDiv Privacy Analyst Return ? :	0
Is Agency Privacy Analyst Approve ?:	1	Is SOP Return ?:	0
Is SAOP Approved?:	1	Is Agency Privacy Analyst Return ?:	0
Total Approved:	4	Is SAOP Return ?:	0
Total Approval Required:	4	Total Return:	0

Miscellaneous Fields

Last Updated:	9/27/2024 8:01 PM	History Log:	View History Log
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