




Copy PIA (Privacy Impact Assessment)

Do you want to copy this PIA ?

Please select the user, who would be submitting the copied PIA.

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

Does this need to migrate to a Sub-Component?: No

Consolidated Parent Component

Component Name

No Records Found

General Information

| | | | |
|---------------------------|---|------------------------------|----------------|
| PIA Name: | CDC - OCIO Azure GSS - NSMBB ED3N Newborn Screening Data Warehouse - QTR3 - 2024 - CDC8414554 | PIA ID: | 8414554 |
| Name of Component: | OCIO Azure GSS | Name of ATO Boundary: | OCIO Azure GSS |

Migrated Sub-Component PIA

PIA Name

No Records Found

Sub-Component


Software Name

NSMBB ED3N Newborn Screening Data Warehouse

Original Related PIA ID

PIA Name

CDC - NSMBB ED3N - QTR2 - 2024 - CDC8205346

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|---------------------------------|---|---------------------------------------|-----------|
| Overall Status: |  | PIA Queue: | |
| Submitter: | JONES-CHANEY, Sunshine | # Days Open: | 148 |
| Submission Status: | Re-Submitted | Submit Date: | 5/21/2024 |
| Next Assessment Date: | 01/03/2028 | Expiration Date: | 1/3/2028 |
| Office: | OD | OpDiv: | CDC |
| Security Categorization: | | | |
| Legacy PIA ID: | | Make PIA available to Public?: | Yes |
| 1: | Identify the Enterprise Performance Lifecycle Phase of the system | | |
| 2: | Is this a FISMA-Reportable system? | | |
| 3: | Does the system have or is it covered by a Security Authorization to Operate (ATO)? | | |
| 4: | ATO Date or Planned ATO Date | | 7/30/2024 |

Privacy Threshold Analysis (PTA)

PTA Name

CDC - OCIO Azure GSS - NSMBB ED3N Newborn Screening Data Warehouse - QTR3 - 2024 - CDC8414545

History Log: [View History Log](#)

PTA

PTA

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| 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. | No changes |
| 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 purpose of ED3N is to serve as a secure, central, and national resource for the state newborn screening community, containing a data repository and data sharing resources for newborn screening data. ED3N collects infant and specimen level newborn screening (NBS) data to help overcome analytic challenges and harmonize testing and interpretive processes in order to reduce false positive and negative newborn screening results.

ED3N consist of three functional modules: 1) Biochemical, 2) Molecular, and 3) Clinical. Data sources for ED3N include Newborn Screening Programs/Departments of Health as well as treating/managing clinicians. This is further delineated below in each module section. All data collected is de-identified at the infant level.

1. Biochemical: Data for this module will flow from Newborn Screening Programs and include analyte values from tandem mass spectrometry and other biochemical tests, methods and instrumentation used, normalization techniques, and test cutoff values.
2. Molecular: Data for this module flow either from Newborn Screening Programs or from treating clinicians and will include variants identified through molecular analysis and the interpretation of the variants assigned by NBS programs or other diagnostic laboratories.
3. Clinical: Data for this module will flow either from Newborn Screening Programs or from treating clinicians and will include clinical information necessary for tracking final diagnoses and health outcomes for infants afflicted by an NBS condition.

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.

ED3N collects, stores, or shares the following types of information:

Newborn and parental demographic information (e.g., date of birth, time of birth, sex, birthweight, gestational age, etc.).

Specimen-specific information (e.g., date and time of collection, site of collection, etc.).

Newborn screening laboratory values and result interpretations (including all biochemical and molecular screening results)

Clinical evaluation, diagnostic, and treatment information (only for certain cases, when applicable)

Geographical information (e.g., zip code, state)

The data will be stored and maintained within NSMBB ED3N for the life of the system.

PTA - 5A:

Are user credentials used to access the system?

Yes, but the user credentials are maintained in a sep

PTA - 5B:

Please identify the type of user credentials used to access the system.

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| 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>These types of information are collected because they are necessary data elements that can affect newborn screening risk assessment and are required in order to meet the goals of ED3N.</p> <p>Infant Demographics (date of birth, time of birth, sex, birthweight, gestational age, etc.). These demographics will be used to incorporate into the risk assessment algorithms as they are known to influence some of the analytes for newborn screening and used to look at timeliness of screening.</p> <p>Parental Demographics (race, ethnicity, education, age, etc.). These are used to assess gaps and disparities in the screening process as they pertain to SES and race/ethnicity.</p> <p>Specimen Information (age of infant at time of collection, time of collection, collection source, etc.). These are needed as they are known to influence the analytes tested for newborn screening and to assess timeliness of screening.</p> <p>Molecular Results (instrument used, sequencing methodology, regions analyzed, single gene variant data). This module, built around molecular results, is to assist programs in the incorporation of molecular technology into newborn screening. These assist in the bioinformatics and variant classification and are needed to understand genotype/phenotype relationships.</p> <p>Biochemical Results (instrument used, state screening cutoffs and algorithms, biochemical analyte values, daily mean of median of analytes). This module is for biochemical data. This data is incorporated into the system to both enhance risk assessment using biochemical analytes and to compare across programs and existing practices.</p> <p>Follow-up/Clinical/Diagnostic Information (age at diagnosis, age at treatment, diagnostic biochemical analyte values, diagnostic single gene variant data, etc.). This data is needed to understand the outcome of screening and whether screen positive results are true or false positives. This data is also incorporated into the risk assessment algorithms and used to assess timeliness of the newborn screening system.</p> <p>Program Information (one screen vs. two screen states, years started testing for the disorder, combinations seen by the state, etc.). This data provides a basis for understanding differences across NBS programs and serve as comparators for various analytic and screening performance outcomes.</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 |

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| 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 to serve as a national data repository, a data sharing resource and provide data-driven decision-making tools, correlations, and resources about newborn screening data, for states' newborn screening communities in the detection of disease risk in newborns. |
| PTA - 10: | Does the website have a posted privacy notice? | Yes |
| 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 website 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

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| PIA - 1: | Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share. | Date of Birth Other - Free text Field - Medical Information - Single sex, birthweight, gestational age, |
| PIA - 2: | Indicate the categories of individuals about whom PII is collected, maintained or shared. | Patients Members of the public |
| PIA - 3: | Indicate the approximate number of individuals whose PII is maintained in the system. | Above 2000 |
| PIA - 4: | For what primary purpose is the PII used? | The primary purpose of the PII is to aid in state Newborn Screening program's ability to interpret their screening results in the context of demographic and clinical information and to link subsequent clinical information to the same patient. |
| PIA - 5: | Describe any secondary uses for which the PII will be used (e.g. testing, training or research). | Secondary uses of the PII can include assessing trends and exploring new markers or algorithms that may improve newborn screening result interpretation and understanding. |
| PIA - 6: | Describe the function of the SSN and/or Taxpayer ID. | Not applicable |
| PIA - 6A: | Cite the legal authority to use the SSN. | Not applicable |
| PIA - 7: | Identify legal authorities, governing information use and disclosure specific to the system and program. | Executive Order 12862 directs Federal agencies to provide service to public that matches or exceeds the best service available in the private sector. |
| PIA - 8: | Are records in the system retrieved by one or more PII data elements? | No |
| PIA - 8A: | Please specify which PII data elements are used to retrieve records. | |
| 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. | |
| PIA - 9: | Identify the sources of PII in the system. | Government Sources State/Local/Tribal Non-Government Sources Private Sector |
| PIA - 10: | Is there an Office of Management and Budget (OMB) information collection approval number? | Yes |
| PIA - 10A: | Provide the information collection approval number. | OMB Control No: 0920-1391 ICR Reference No: 202211-0920-010 |
| PIA - 10B: | Identify the OMB information collection approval number expiration date. | 4/30/2026 |

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| PIA - 10C: | Explain why an OMB information collection approval number is not required. | OMB information collection number is provided in 10A. |
| PIA - 11: | Is the PII shared with other organizations outside the system's Operating Division? | Yes |
| PIA - 11A: | Identify with whom the PII is shared or disclosed. | Within HHS |
| PIA - 11B: | Please provide the purpose(s) for the disclosures described in PIA - 11A. | Assessing trends and exploring new markers or algorithms that may improve newborn screening result interpretation and understanding. |
| PIA - 11C: | List any agreements in place that authorize the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)). | Each state program will engage in an Information Sharing Agreement. Individual users authorized by the state program will agree to a Data Use Acknowledgment upon initial login and the initial login subsequent to a revision in the Acknowledgment, as applicable. |
| 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. | <p>Each state program and their affiliated users will only have access to the individual-level data they submitted. Aggregate data will be available to all users.</p> <p>If a disclosure is needed, any data requests beyond default access described above will require a data request form that is approved both by CDC administrators and the state programs. An additional data use agreement will be signed in these cases that outline the disclosures that will occur and permitted uses. These signed forms will be maintained for audit purposes.</p> |
| 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 individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason. | There is no method to opt out of the collection because the data is collected by the states. |
| 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. | <p>State program users will be notified on the NSMBB ED3N Landing Page when major changes have occurred to the system. An audit trail of these changes as well as versioning of NSMBB ED3N will be maintained as well.</p> <p>CDC will not have the ability to obtain consent from individuals whose PII is in the system because ED3N will not collect information from individuals. PII in the system was collected by states. Additionally, the work done in NSMBB ED3N is considered program operations, so state programs will not obtain consent on the front end when obtaining the screening information.</p> |
| PIA - 15: | 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. | Concerns should be directed to the CDC Privacy Office (privacy@cdc.gov) |

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| PIA - 16: | 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>Several data validations will be put into place to ensure data integrity upon submission. Data walkthroughs will also be implemented within the system to walk users through their data to ensure completeness and accuracy. The user will also be able to examine uploaded data to help ensure integrity and accuracy.</p> <p>A Data Governance plan and team will be set-up to set guidelines around availability and relevancy of data. This group will perform annual reviews of data use/availability as well as ensuring that only relevant data is being collected.</p> |
| PIA - 17: | Identify who will have access to the PII in the system. | <p>Users</p> <p>Administrators</p> <p>Developers</p> <p>Contractors</p> |
| PIA - 17A: | Select the type of contractor. | HHS/OpDiv Direct Contractors |
| PIA - 17B: | Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices? | Yes |
| PIA - 18: | Provide the reason why each of the groups identified in PIA - 17 needs access to PII. | <p>System Users need access to create, edit, delete, view their own records and reports.</p> <p>System Administrators need access so to create new users and assign user roles.</p> <p>Developers require access to PII in order for ongoing development of the Hub and subsequent interpretative models. In addition, access is required for developers to conduct validations and quality improvement.</p> <p>Direct contractors need access to PII in order to perform job functions such as data validation, QA/QC, and general oversight.</p> |
| PIA - 19: | Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII. | <p>System user access to PII will be determined through NSMBB policy and procedure. Per a role-based access model, access to PII is determined by contacting the system business steward via email. The system business steward verifies that the individual has a need to know and grants access. Only the approved roles of the system are allowed to access PII within the system in order to fulfill their defined role.</p> |

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| <p>PIA - 20:</p> | <p>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.</p> | <p>Role based access, access control lists, and software logic will be used to limit PII access to only the minimum amount of information necessary to perform a job.</p> <p>States - State users will only have access to PII submitted by their own state. NSMBB ED3N will have controls in place to recognize users upon login, and determined their state affiliation and the level of access to data based on their role.</p> <p>System Administrators - System administrators will have access to all PII data. NSMBB ED3N will create alerts and audit trails with user and time stamps of access to datastores/databases of PII in order to create a record of any access to this information.</p> <p>Developers, Business Analysts, etc. - Developer (etc.) users may be granted access to PII data based on need and permission from a System Administrator. NSMBB ED3N development, test, and staging environments will not contain real PII information, but may contain simulated data. Developers will spend most of their time outside of the production environment where real PII data resides.</p> |
| <p>PIA - 21:</p> | <p>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.</p> | <p>Based on the type of PII and access levels general security and privacy awareness training are required by CDC/HHS (Annual Security Awareness Training and Information Security) provides much of the training and awareness that will be required. Additional; Online data security and privacy training as it pertains to ED3N will be provided to all users. This will be modeled after current CDC-based data security and use trainings. Training will be required for access to ED3N and refresher training will be required annually.</p> |
| <p>PIA - 22:</p> | <p>Describe training system users receive (above and beyond general security and privacy awareness training).</p> | <p>All system users will be required to take training appropriate for their user role that reinforces information integrity and the importance of safeguarding PII information shared and contained in the system.</p> |
| <p>PIA - 23:</p> | <p>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).</p> | <p>Records are retained and disposed of in accordance with the CDC/ADSTR Scientific and Research Project Records, Records Control Schedule (N1-442-09-001) and GRS 4.2. Participant information is maintained as long as they have value. NSMBB will review historically collected PII to determine whether the PII is still relevant and necessary for meeting the organization 's business purpose and mission and the needs of the newborn screening community. NSMBB may consider input provided by the state submitter of the PII data in determining if a record has value or not.</p> <p>Electronic records containing PII are destroyed by securely erasing back-ups when they are no longer of value or need to ED3N.</p> |

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: CDC and state administrators will remove users from the system as they either leave their employment at the state program or transition to roles now longer requiring access. A user's role may also be changed if the user has a change of duties or moves to a different position. Administrators at the state level, with approval from CD administrators, make the determinations on who has access to the PII in the various roles of the application.

Technical: State program users can access their own state-submitted data, but not data from other state programs (except in aggregate). All users will be authenticated using two factor authentication. PII will be secured through role-based access control coupled with administrative organizational alignment.

Physical: The system is protected through restricted building access and facility level access control and identifiable data will not be stored on removable storage devices unless they are encrypted. Additional workstation/laptop/devices access controls are implemented.

Review & Comments

Privacy Analyst Review

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|---|---|-------------------------------------|-----------|
| OpDiv Privacy Analyst Review Status: | Approved | Privacy Analyst Review Date: | 5/21/2024 |
| Privacy Analyst Comments: | OpDiv Analyst: Joshua Mosios (Contractor) | Privacy Analyst Days Open: | |

SOP Review

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|---------------------------|--------------------------------------|-------------------------|--------------------|
| SOP Review Status: | Approved | SOP Signature: | JWO Signature.docx |
| SOP Comments: | Approved on behalf of Beverly Walker | SOP Review Date: | 5/22/2024 |
| | | SOP Days Open: | 1 |

Agency Privacy Analyst Review

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| Agency Privacy Analyst Review Status: | Approved | Agency Privacy Analyst Review Date: | 1/3/2025 |
| Agency Privacy Analyst Review Comments: | | Agency Privacy Analyst Days Open: | 226 |

SAOP Review

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| SAOP Review Status: | Approved | SAOP Signature: | |
| SAOP Comments: | | SAOP Review Date: | 1/3/2025 |
| | | SAOP Days Open: | 0 |

Supporting Document(s)

| Name | Size | Type | Upload Date | Downloads |
|------------------|------|------|-------------|-----------|
| No Records Found | | | | |

| Comments | | | | |
|---------------|------------------------|-----------|---|------------|
| Question Name | Submitter | Date | Comment | Attachment |
| PIA - 1 | MOSIOS, Joshua | 5/1/2024 | Please de-select "Medical Records (PHI)" as CDC is not a covered entity providing healthcare services and thus this information would not be considered "protected health information" under the Health Insurance Portability and Accountability Act (HIPAA). Instead, please write "medical information" in the free text field. Additionally, please list the collected demographic information in the free text field as well. | |
| PIA - 10C | MOSIOS, Joshua | 5/1/2024 | Note for HHS: this translated the answer from 10A for the first time. | |
| PIA - 11 | MOSIOS, Joshua | 5/1/2024 | Last PIA this system shared their PII within HHS. Is this true? If so, please make a correction. If this is no longer being done, please send a note to pia@cdc.gov explaining the change. | |
| PIA - 15 | MOSIOS, Joshua | 5/1/2024 | Please provide an external-facing (non-PII) phone number or email address for individuals to use to contact the program in the case they want to report issues related to their PII in <u>this</u> system. | |
| PIA - 11 | JONES-CHANEY, Sunshine | 5/10/2024 | In the previously approved PIA dtd 4/20/2021, no.24, the answer selected is "No". | |
| PIA - 15 | JONES-CHANEY, Sunshine | 5/10/2024 | CDC will not have the ability to obtain consent from individuals whose PII is in the system because this system ED3N does not collect information from individuals. PII in the system is collected by states. | |