

US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

09/09/2025

OPDIV:

IHS

Name:

AudioCare Pharmacy Refill IHS

PIA Unique Identifier:

P-1640937-050366

The subject of this PIA is which of the following?

Minor Application (stand-alone)

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

No

Does the system include a Website or online application available to and for the use of the general public?

No

Identify the operator.

Agency

Is this a new or existing system?

New

Does the system have Security Authorization (SA)?

No

Indicate the following reason(s) for updating this PIA.**Describe the purpose of the system.**

AudioCARE, an Artera Government Solutions Product is a Commercial-Off-The-Shelf (COTS) system that offers a suite of products comprised of telephony, text and email applications that enhance patient communications for Indian Health Service (IHS) facilities. The system is integrated with the Resource Patient Management System/Electronic Health Record (RPMS/EHR) System and the IHS facility's phone switch. The RPMS/EHR maintains its own unique PIA. The system increases the efficiency in handling routine patient requests and providing self-help tools accessible 24 hoursx7days per week for pharmacy refills, status checks, renewal requests, and medication education. AudioCARE can automatically deliver important notifications to engage with patients and provide important healthcare information while obtaining important patient's feedback during the notification, such as reminders for appointments and other emergency communications

Describe the type of information the system will collect, maintain (store), or share.

AudioCARE will collect, maintain (store), or share the following PII elements:

Name, date of birth (DOB), social security number (SSN), email address, phone#, medication and prescription data including prescription #, Refills, Exp Date, Last Fill Date, Rx Status.

Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.

The PHI / PII used by AudioCARE is either received directly from the user via telephone, or from the RPMS/EHR via internal System-to-System information sharing. All information is kept behind the IHS Firewall and on the premises, under IHS control

The system provides automated, 24 hours/7 days per week means for users to request prescription refills/renewals and other information about their prescriptions. The system can use emails/phone #s to communicate health care related messages to the patient, based on preference

Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Social Security Number
Date of Birth
Name
E-Mail Address
Phone Numbers
Medications and Prescription information relayed to the user including Rx #, Refills, Exp Date, Last Fill Date, Rx Status,
Medication information based on National Drug Code (NDC), site name

Indicate the categories of individuals about whom PII is collected, maintained or shared.

Patients

How many individuals' PII is in the system?

100,000-999,999

For what primary purpose is the PII used?

Patient Name - used to customize patient communications
SSN - Identifies the patient and retrieves prescription data from RPMS/EHR; not disclosed used internally
DOB - verifies patients when calling in to refill prescriptions/get prescription information; not disclosed and used internally
Phone Number /email- used for messaging and communications to the patient
Prescription Number- used with SSN to retrieve prescription information from RPMS/EHR; for processing refills/renewals; not disclosed and used internally

The PHI / PII used by AudioCARE is either received directly from the user via telephone, or from the RPMS/EHR via internal System-to-System information sharing.

Describe the secondary uses for which the PII will be used.

None

Identify legal authorities governing information use and disclosure specific to the system and program.

Departmental Regulations (5 U.S.C.301); Privacy Act of 1974 (5 U.S.C. 552a); Federal Records Act (44 U.S.C. 2901); Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248); Section 327A of the Public Health Service Act, as amended (42 U.S.C. 254a); Snyder Act (25 U.S.C. 13); Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.); Transfer Act of 1954 (42 U.S.C. 2001–2004); HIPAA, HITECH (and subsequent regulations); and 21st Century Cures Act, 42 CFR Part 2. Privacy Act of 1974; Report of Amended or Altered System; Medical, Health and Billing Records System. <https://www.govinfo.gov/content/pkg/FR-2010-01-12/pdf/2010-285.pdf>.

Are records on the system retrieved by one or more PII data elements?

Yes

Identify the number and title of the Privacy Act System of Records Notice (SORN) that is being use to cover the system or identify if a SORN is being developed.

SORN 9-17-0001, Medical, Health, and Billing Records Systems

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

Other

Government Sources

Identify the OMB information collection approval number and expiration date

Exempt from an OMB Information Collection Number through Public Law 114-255, the 21st Century Cures Act, Section 2035: Exemption for IHS from the Paperwork Reduction Act requirements.

Is the PII shared with other organizations?

No

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.

Indian Health Manual - Part 2, Chapter 7 - It is IHS policy to provide adequate notice of its uses and disclosures of PHI and of the individual's rights and IHS' legal duties with respect to PHI. A copy of the Notice is provided to new patients, patients whose charts are reactivated, and patients who reach legal age. The Patient Registration Office provides a copy of the current Notice to the patient. The staff member has the patient acknowledge receipt of the Notice by signing the Acknowledgment of Receipt of IHS Notice of Privacy Practices. The signed "Acknowledgement of Receipt of IHS Notice of Privacy Practices" is filed into the patient's medical record.

HS employees are notified at the time of hire that their PII will be collected and give consent as it is part of the on-boarding process.

Is the submission of PII by individuals voluntary or mandatory?

Voluntary

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.

The patient may choose to not use the automated telephone prescription refill/renewal/information system

Per the policy provided in the Indian Health Manual Part 2 Chapter 7 Section 22, "Under the HIPAA Privacy Rule, patients have the right to request restriction(s) of the use and/or disclosure of their PHI to carry out treatment; payment and health care operations; inpatient hospital directory; and disclosures to relatives, family members, personal representatives, close friends, health care givers, and any other person involved in the patient's care or payment who is identified by the patient. The

IHS is not required to agree to the request. However, a patient still may object to the disclosure of information for the inpatient hospital directory and to relatives, friends, and others involved in patient care under 45 CFR 164.510(b). See Section 2-7.19, "Procedure for the Uses and Disclosures of Protected Health Information for Involvement in the Patient's Care and for Notification Purposes."

The initial collection of PII occurs at the various healthcare facilities at the point of registration and is required to determine eligibility for services. All patients at all facilities are provided with a Notice of Privacy Practices. They are also offered Form IHS-810, "Authorization for Use or Disclosure of Protected Health Information". By completing and signing this document, patients may consent to or decline sharing of their protected health information with external entities outside the I/T/U ecosystem through the 4DH and eHealth Exchange.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

If this were to occur, the patient would be notified of upcoming change via written notice or phone call.

It is IHS policy to provide adequate notice of its uses and disclosures of PHI/PII and of the individual's rights and IHS' legal duties with respect to PHI/PII. The IHS prominently and clearly displays the Notice (2-7.18) in every facility (<http://www.hipaa.ihs.gov/>). A copy of the Notice is also provided to new patients, patients whose charts are reactivated, and patients who reach legal age. The Patient Registration Office or other appropriate department provides a copy of the current Notice to the patient. The patient acknowledges receipt of the Notice by signing the Acknowledgment of Receipt of IHS Notice of Privacy Practices. An IHS staff member signs and dates the Acknowledgement form and files the signed "Acknowledgement of Receipt of IHS Notice of Privacy Practices" into the patient's medical record. No less than every three years, IHS provides notification of the availability of the Notice and how to obtain the Notice. If the Notice is revised by a material change, the revised Notice must be posted in clear and prominent locations in every facility and on its web site, on or after the effective date of the revision. The revised Notice will be posted on the IHS website within the 60 days of a material revision. The revised Notice is also given to all patients who come into a facility after the effective date of the revision and is available upon request on or after the effective date of the revision. Additionally, IHS provides the revised notice to all eligible patients registered in the patient registration system within 60 days of the revision of the Notice. Any individual, whether or not a patient, has the right to request and receive a copy of the Notice at any time, except an inmate. Inmates have no rights to the Notice (45 CFR § 164.520 (a)(3)). IHS employees are notified at the time of hire that their PII will be collected and give consent as it is part of the on-boarding process

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.

Complaints are addressed to the Service Unit Chief, Executive Officer or (his or her) designee for investigation. Complaints are documented, maintained, and filed, and include a brief explanation of resolution, if any. Note: Complaints may also be filed directly with the Secretary, DHHS.

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

Periodic reviews are performed to ensure compliance with privacy regulations, including Privacy Act, HIPPA and Government Act of 2002, at various time-frames based on area.

Patient registration reviews patient data periodically to ensure patient data contained in RPMS/EHR remains accurate

Identify who will have access to the PII in the system and the reason why they require access.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

Indian Health Manual, Part 8, Chapter 21 - Access Control The Information Technology Access Control (ITAC) supervisors are responsible for submitting appropriate access requests for IHS system users on their team and for reviewing their team members' access. The System Administrator then grants the most restrictive access privileges needed to perform job related roles and responsibilities.

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

Appropriate access is granted to the system based on predefined roles and job descriptions, and administrative access is limited to authorized employees based on current roles, with the most limited access required assigned

Identify training and awareness provided to personnel (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.

Role-based training, IHS Rules of Behavior agreements, and Information System Security and Privacy Awareness training courses are required to be completed annually by all IHS users.

Describe training system users receive (above and beyond general security and privacy awareness training).

In person orientation and competency on the system; as well as annual HIPAA training

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.

If server is replaced, the information would be given to IHS IT to destroy. Patient information does not leave site. This is covered under IHS's NARA Records Retention schedule DAA-0513-2014-0003-0003

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

Administrative Controls: All technical personnel who access IT systems which contain protected information have met background investigation criteria for Public Trust positions. All personnel have taken mandatory security and privacy training classes and annual refreshers. Administrative personnel accessing these systems use privileged and separate accounts for administrative access.

Technical Controls: IHS firewalls, IT governance on site. Access controls lists and event logs are maintained and monitored to detect unauthorized, suspicious or malicious activity. Access lists are restricted to approved IT technical personnel. Two factor authentication must be used for access. File integrity and auditing software are employed on hardware.

Physical Controls: The IT hardware used to host protected information is located in a secured IHS facility. The facility is only open to authorized personnel whose access is monitored by locking doors with badge readers for both ingress and egress. Each discrete ingress and egress event is logged. The facility is under 24-hour surveillance by facilities security for security and environmental hazards."

