

Version	Approval Date	Owner
0.1	April 7, 2016	Privacy Officer

Clinical Data Repository Access Policy

1. Purpose

The purpose of this Policy is to establish the permissions and restrictions related to access to the Clinical Data Repository (CDR). In furtherance of the mission of HealthShare Exchange of Southeastern Pennsylvania' (HSX), HSX will provide secure access to health information Data that enables preventative and cost effective care; improves the quality of care; and facilitates the transitions of care. This access may be provided to HSX Participants and their Authorized Users such as hospitals, health care providers, health plans, health care facilities across the continuum of care and accountable care organizations to facilitate the sharing of Data in a more efficient, effective manner on behalf of the patients and members they serve and is limited to Data for patients with whom such providers have a treatment relationship and who have not opted out of the HIE and/or by accountable care organizations and payors for their subscribed members.

2. Scope

The HSX CDR is designed to store Data such as, but not limited to, lab results, radiology reports, and transcribed documents received from Data Suppliers and Data Exchangers. Such persisted Data will remain in the CDR subject to access and query by Data Viewers and Data Exchangers for Permitted Purposes contained in the Founding Member Participation Agreement (PAR) pursuant to HSX Policies and HSX approved Use Cases, as applicable and for Authorized Users of External Networks pursuant to the Clinical Data Repository Access Policy for External Networks.

CDR access/viewing limitations shall be role based and are as follows:

- **Opt out patients-** There shall be no access to Data of patients who have opted out.

- **Self Pay Patients-** There shall be no access by a health plan to the patient Data for any patient who had a self-pay encounter.
- **42 CFR Part 2 Facility Data** - All Data provided by Part 2 facilities (an entity must be federally assisted and hold itself out as providing, and provide, alcohol or drug abuse diagnosis, treatment or referral for treatment) shall be marked as confidential and shall not be viewable in the CDR without the appropriate consent obtained on behalf of the patient/member.
- **Access to confidential Data** (HIV/Aids; Sexual and Domestic Violence Related; Substance Abuse Related; Psychiatry Related; celebrity/VIP;) provided by non-42 CFR Part 2 facilities, shall be permitted with patient consent to Providers who are not acting in an emergency circumstance but only for a specified period of time. There shall be no access to confidential Data without appropriate patient consent except in accordance with the prudent layperson definition of emergency circumstance as defined by the Health Reform Act and Pennsylvania Law.
- **Emergency Access:** Emergency Department Providers and staff involved in treating a patient under an emergency medical condition and prudent layperson standard as defined by Pennsylvania law and the Health Reform Act shall have access to all patient Data maintained in the CDR including any confidential Data but excluding Data of patients who have opted out.
- **Health Plan Access** to Data shall be limited only to Data of active members of such health plans. Such access shall be controlled by the establishment of Health Plan groups in the CDR.
- **Accountable Care Organization Access** to Data shall be limited only to Data of their attributed members. Such access shall be controlled by the establishment of Accountable Care Organization groups in the CDR.
- **Physicians and Non-Physician Professional's Access** to Data shall be limited to their patients for treatment purposes. This access includes access by licensed residents and fellows.
- **Non-licensed health care workers' Access** to patient Data is limited based on their association with licensed physician and non-physician professional(s).

Minimum Necessary Data Elements: HSX may restrict the Data elements accessible to an individual Authorized User or groups or categories of Authorized Users.

3. Procedures

HSX Authorized Users

- For Participants accessing the CDR via the web-portal, HSX designates Authorized Users who are able to search patients/members based on the access controls defined in the Scope section of this Policy.
- HSX shall review the accounts for the Authorized Users on an annual basis to assess appropriate continued access to the CDR.
- Authorized Users shall be deactivated when their accounts are no longer needed or after 90 days of no use.

Participant Authorized Users

- HSX Participants shall designate Authorized Users in accordance with their policies related to access to electronic medical records and consistent with HSX access controls defined in the Scope section of this policy.
- **Reason for Search** –For access to patient Data, Authorized Users shall select from the following default CDR search reasons:
 - Use and disclosure for audit of accounting of disclosures
 - Use and disclosure for administrative user
 - Use and disclosure for specialized government functions
 - Use and disclosure for judicial and administrative proceedings
 - Use and disclosure for law enforcement purposes
 - Use and disclosure by the covered entity to defend itself in legal action
 - Use and disclosure for patient consent
 - Use and disclosure for treatment
 - Use and disclosure for urgent patient activity liaison
 - Use and disclosure for health plan quality reporting
- **HSX Authorized Users** shall, at a minimum, be able to search on the following patient information:
 - First name
 - Last name
 - Date of birth
 - Gender
 - or
 - Member ID or Medical Record number

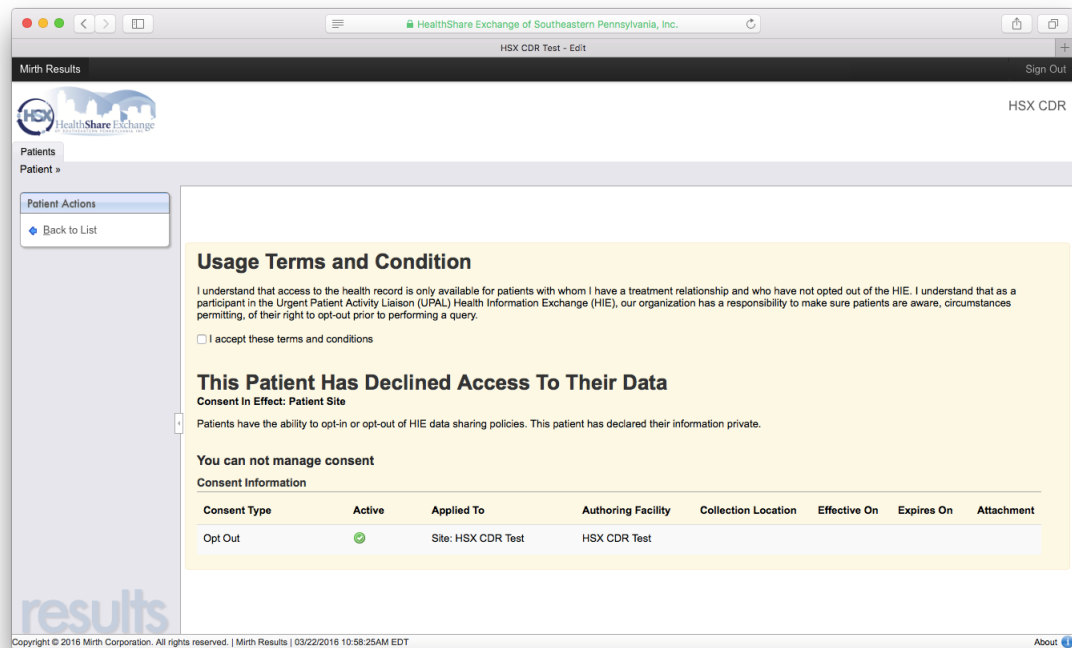
- The search will display any patient record that contains these minimal search elements.

Name	Date of Birth	Gender	Last Name
thame	12/12/1900	Male	thame

Patient health information will be available only to the Authorized User who has accepted the Search and Treatment Attestation.

- Treatment Attestation** is required when HSX Authorized Users access the CDR on behalf of a member or patient. Authorized Users shall attest as follows when querying or viewing Data in the CDR:
 - I understand that access to the health Data is only available for patients with whom I have a treatment relationship and who have not opted out of the HIE and/or for members who are subscribed to my ACO or health plan.
- Opt-Out** – Access to the HSX CDR is subject to the HSX Opt-Out and Opt-Back-In Policy. No Data of a patient shall be available in the case of a patient/member who has chosen to opt-out in accordance with such Policy.

The following will appear when an Authorized User conducts a patient search for a patient opted out of the HSX Network:



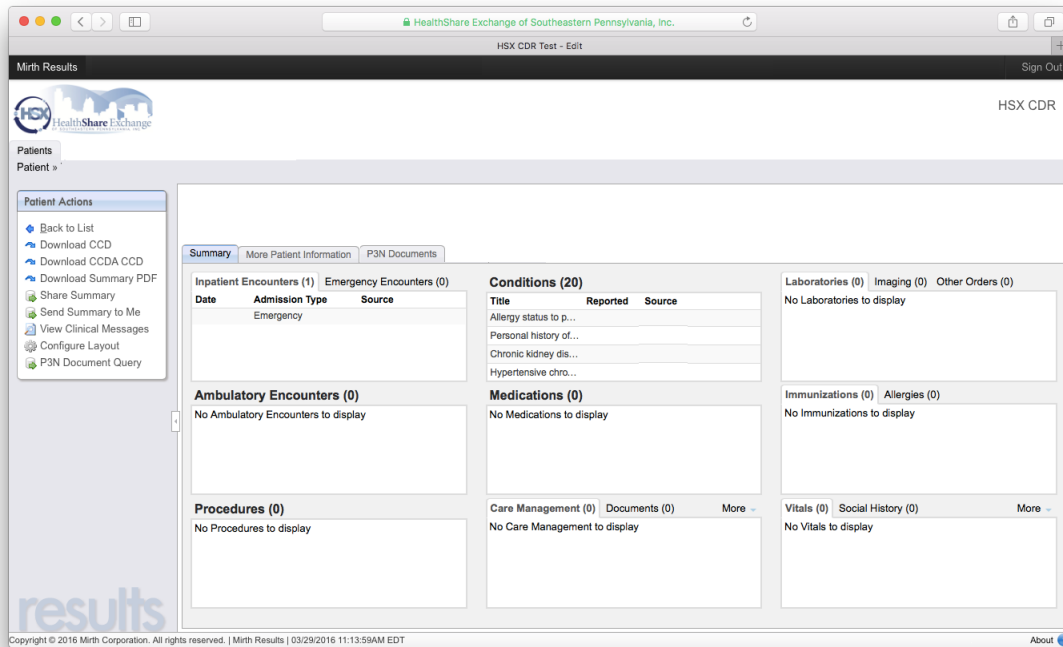
The screenshot shows a web browser window with the address bar displaying "HealthShare Exchange of Southeastern Pennsylvania, Inc.". The page title is "Mirth Results" and the user is logged in as "HSX CDR". The page layout includes a sidebar with "Patients" and "Patient Actions" (Back to List). The main content area displays a "Usage Terms and Condition" section with a checkbox for "I accept these terms and conditions". Below this, a yellow banner states "This Patient Has Declined Access To Their Data" with the note "Consent In Effect: Patient Site". A message indicates that patients can opt-in or opt-out of HIE data sharing policies, and this patient has declared their information private. A section titled "You can not manage consent" contains a table with consent information.

Consent Type	Active	Applied To	Authoring Facility	Collection Location	Effective On	Expires On	Attachment
Opt Out	☒	Site: HSX CDR Test	HSX CDR Test				

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Data Accessed Upon Successful Search

Upon a successful search, an Authorized User shall have access to patient/member Data.



- HSX CDR Authorized User reviews patient Data as represented in the CDR.
- HSX CDR Authorized User may obtain Data as needed through an export in a structured data format. For treatment purposes, this could be a longitudinal clinical record of the patient/member. HSX may configure who has the ability to export data from the CDR.
- HSX CDR user exits and logs off CDR.

Access to Confidential Data

As outlined in the Scope section, under certain circumstances Authorized Users shall have access to confidential Data.

- Access to confidential Data is limited to HSX Authorized Users.
- Due to technological restrictions, Participant Authorized Users would not have access to confidential Data.
- If an HSX Authorized User queries a patient record that contains confidential Data, a notification that the record contains confidential Data shall appear.

The screenshot shows the HSX HealthShare Exchange web application interface. A yellow 'Confidential Data Notice' overlay is present, stating: 'This patient has confidential data you do not have access to view.' Below the notice is a button labeled 'Unlock Confidential Data'. The main interface displays a patient's medical record with various tabs and sections:

- Patient Actions:** Back to List, Download CCD, Download CCDA CCD, Download Summary PDF, Share Summary, Send Summary to Me, View Clinical Messages, Configure Layout, Unlock Confidential Data.
- Summary:** Inpatient Encounters (0), Emergency Encounters (6), Ambulatory Encounters (1).
- Conditions (5):** Tobacco use, Anogenital (vener...), K62.5, Cough.
- Procedures (0):**
- Medications (0):**
- Laboratories (0):**
- Imaging (0):**
- Other Orders (0):**
- Allergies (0):**
- Immunizations (0):**
- Vitals (0):**
- Social History (0):**

- Based on the limitations defined in the Scope section, if the Authorized User is able to access the confidential Data, the Authorized User shall select the reasons for unlocking the confidential Data and the confidential Data shall be viewable.

The 'Unlock Confidential Data' dialog box contains the following text and options:

Note: This record contains information which may or may not include confidential healthcare information that is specifically protected under State and/or Federal law. Because of the potentially confidential nature of this information, access is limited.

Select the level of confidential data to unlock:

- ☐ Restricted Data
- ☐ Restricted and Very Restricted Data

Please indicate your reasons for accessing this information:

- ☐ I am treating this patient in an emergency situation that poses an immediate threat to the patient's health and requires immediate medical intervention.
- ☐ I have obtained a written authorization to view confidential health information from the patient and will submit this authorization to the HIE within 7 days.
- ☐ I need confidential information for treatment purposes.

Buttons: Save, Cancel

Service Availability and Support

HSX or its designees will provide 24/7 availability and support when the CDR is available in production. To make support requests, contact HSX Support as follows:
Phone: 855-479-7372 (855-HSX-SEPA)

4. Enforcement

HSX's Chief Information Security Officer will work with HSX Participants in identifying specific Authorized Users and will manage access to the HSX Network and CDR accordingly.

In accordance with the HSX Audit and Monitoring Policy, HSX will monitor access/viewing to Data to ensure that it is in accordance with the purpose and scope defined above. Any Participants' and/or Authorized Users failure to adhere to HSX's applicable Policies including the Data Misuse Policy will be subject to corrective actions that may include, but not be limited to, re-education, training, suspension of service until the Participant is able to comply with applicable Policies, and/or termination of access.

HSX shall maintain audit logs in accordance with the HSX *Compliance Policy* for (7) seven years of access information

5. References

Regulatory References:

- HIPAA Regulatory Reference: HIPAA § 164.502 (a)
- Pa. Code § 9.672 (c)
- Confidentiality of HIV-Related Information Act 35 P. S. § 7607 (Act 148)
- <http://archive.samhsa.gov/healthPrivacy/docs/EHR-FAQs.pdf>
- <http://www.paehealth.org/certification>
- Pennsylvania eHealth Information Technology Act; P.L. 1042, No. 121
- 28 Pa. Code § 103.22(b); 28 Pa Code. § 115.27; 28 Pa. Code §563.9.
- 29 CFR 2590.717-2719A 4 (i) (Patient Protections)
- **"Participant"** as defined in the HSX Founding Member Participation Agreement means, in general, a person or entity that has entered into a binding agreement with HSX setting forth the terms and conditions of access to and use of the HSX Network after such person or entity is approved as an authorized Participant of HSX.

6. Definitions

For a complete list of definitions, refer to the *Glossary*.

Policy Owner	HSX Chief Privacy Officer	Contact	Don.Reed@healthshareexchange.org
Approved By	Senior Management Team	Approval Date	04/01/2016
Approved By	Executive Committee	Approval Date	04/07/2016
Date Policy In Effect	04/07/2016	Version #	1.0
Original Issue Date	04/07/2016	Last Review Date	October 23, 2023 December 5, 2022 September 29, 2021 September 21, 2020 April 7, 2016
Related Documents	Audit and Monitoring Policy Clinical Data Repository Access for External Networks Credentialing Policy Data Misuse Policy Opt Out and Opt Back In Policy Compliance Policy HSX Founding Member Participation Agreement HSX Use Case Governance Urgent Patient Activity Liaison Use Case		