



The MARYLAND
HEALTH CARE COMMISSION

*Health Information Exchange
Approved Policies & Resolutions*

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Health Information Exchange

PARTICIPATING ORGANIZATION ACCESS	
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Goal: The *Participating Organization*¹ Access policy aims to ensure that only authorized users have access to the minimum necessary² information through a health information exchange (HIE) that is limited to authorized purposes and relevant to their current role as defined by the participating organization. The standards for minimum necessary are established by the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Administrative Simplification Provisions.

Purpose: This policy describes an HIE's responsibilities as it relates to allowing participating organizations the ability to access information through the HIE. An HIE is responsible for ensuring that policies related to *Participating Organization Access* are implemented according to the provisions outlined in this policy.

Policy:

1. An HIE must require users to be authenticated according to the *User Authentication* policy prior to accessing protected health information (PHI) through the HIE. Proper authentication will ensure that only appropriately authorized users have access to the HIE.
2. In consultation with stakeholders, an HIE will develop and maintain an HIE Access Matrix. The HIE Access Matrix must be reviewed annually to determine if revisions are necessary to accommodate changes in technology, standards, and laws. The HIE Access Matrix must remain constant across all participating organizations.
3. An HIE will include in the HIE Access Matrix defined levels of access to the HIE that are available to appropriately authorized users for authorized purposes. The HIE Access Matrix will serve as a guide that allows participating organizations the ability to establish HIE access levels for authorized users within their organization.
4. The HIE Access Matrix must be used by the HIE to assign staff (i.e., staff of the HIE and staff of Business Associates) to the level of access that ensures that only minimum necessary access to the HIE is allowed. Staff access to PHI that is available through the HIE is permitted as long as the individual is in good standing³. Staff access to PHI will be granted for the daily operations and maintenance of the HIE.
5. An HIE must request that participating organizations identify a system administrator within their organization. An HIE will require the administrator to:

¹ A Participating Organization is any health care provider that enters into a Participation Agreement with an HIE.

² Minimum necessary refers to the least amount of information necessary to render care.

³ Staff in good standing are those that have not been terminated by the HIE for inappropriate access of the HIE as outlined in the *Suspension and Termination of User Access* policy.



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- a) Identify new and existing users within their organization to be properly registered by the organization;
 - b) Assign levels of HIE access to authorized users that appropriately correspond to their role within the organization;
 - c) Modify a user's HIE access level in the event that a change in role within the organization has occurred where they require a different level of access; and
 - d) Immediately terminate HIE access for any user that is not in good standing, which includes resignation or termination.
6. An HIE must provide technical assistance and guidance to the administrator of the participating organization in assigning access levels to appropriately authorized users. An HIE must require participating organizations and Business Associates to attest to the appropriateness of the roles assigned and the corresponding level of access.
 7. An HIE must allow users to query the HIE in accordance with the *Consumer Choice* policy. An HIE is responsible for maintaining the integrity of roles assigned, via the HIE Access Matrix, in the core infrastructure of the HIE.

Procedure:

An HIE should implement procedures that are inclusive of the following items:

HIE Access Matrix Development, Review, and Revision

1. The HIE Access Matrix should have a column for each access level and a row for each use case (e.g., electronic eligibility, clinical lab ordering/results delivery, electronic prescribing, medication history, clinical summary exchange, etc.) and corresponding associated data, including identified sensitive health information. See *Figure 1* for a generic template.
2. The HIE Access Matrix should be developed prior to the assignment of access to users and prior to allowing access to information.

User Case (UC)	Associated Data (AD)	Access Level 1	Access Level 2	Access Level 3	Access Level 4	Access Level 5
UC 1	AD 1	x	x	x	x	x
	AD 2	x	x	x	x	x
	AD 3	x	x	x	x	x
UC 2	AD 1	x	x	x	x	x
	AD 2	x	x	x	x	x
	AD 3	x	x	x	x	x
UC 3	AD 1	x	x	x	x	x
	AD 2	x	x	x	x	x
	AD 3	x	x	x	x	x
UC 4	AD 1	x	x	x	x	x
	AD 2	x	x	x	x	x
	AD 3	x	x	x	x	x
UC 5	AD 1	x	x	x	x	x
	AD 2	x	x	x	x	x
	AD 3	x	x	x	x	x

Figure 1



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Assignment and Changes HIE Access Levels

1. An HIE should provide consultation to an administrator prior to any initial identification and assignment of access levels to users, which will include at a minimum:
 - a. A detailed explanation of the HIE Access Matrix; and
 - b. Recommendations as to what levels of access will most adequately correspond with the current roles of an identified user.
2. Identified access levels for users should be operationalized within one (1) business day of receipt of the request by the HIE.
3. An HIE should require the administrator to terminate a user's access immediately in the event that the user resigns from the organization or is terminated.

Associated Policies:

1. *Audit*
2. *Consumer Choice*
3. *Enforcement*
4. *Suspension and Termination of Provider Access*
5. *Sensitive Health Information*
6. *User Authentication*
7. *User Authorization*



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USER AUTHORIZATION

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Goal: The *User Authorization policy* aims to assure the confidentiality of health information by requiring a health information exchange (HIE) to establish user access levels. Authorization levels are necessary to appropriately determine what information is available to users accessing the HIE.

Purpose: This policy describes the responsibility of an HIE to define the requirements for establishing user access, and ensuring that users are properly authenticated. Users must be authorized to access information through the HIE that is consistent with the job functions as determined by the participating organization. User authorization is critical to establishing user accountability and managing risk.

Policy:

1. An HIE must require participating organizations to quarterly audit their user accounts. These audits must review what information was accessed as compared to the care that was provided by the user.
2. An HIE must require participating organizations to validate that consumer assent has been obtained prior to querying the HIE. An HIE needs to require participating organizations to have a robust policy around assent to query consumer information through the HIE.
3. *An HIE must audit for break the glass activity and review findings with the participating organizations. As part of the review process, an HIE must investigate to determine if participating organizations are appropriately using their emergency access privileges.*
4. An HIE must require participating organizations to notify consumers on a timely basis when authorized individuals inappropriately access consumer information. Participating organizations will need to take immediate corrective action against users that violate their privileges.

Procedure:

An HIE should implement procedures that are inclusive of the following items:

1. An HIE should protect against unauthorized use by requiring participating organizations to audit their authorization records on a quarterly basis. Participating organizations should also be required to report unauthorized access, use, and disclosure to the consumer within (10) ten days of discovery.



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2. An HIE should require participating organizations to validate consumer assent to access their information through the HIE. As part of the registration process, participating organizations should be required to affirm that this process has occurred through a notation in the file of an electronic flag.
3. An HIE should require participating organizations to take appropriate corrective action against users that inappropriately access information through the HIE. Suspension and terminations should be subject to an appeal process.

Associated Policies:

1. *Audit*
2. *User Authentication*
3. *Enforcement*
4. *Notification of Breach*
5. *Participating Organization Access*



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CONSUMER CHOICE

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Goal: The *Consumer Choice* policy aims to ensure that all consumers⁴ are afforded the opportunity to control the use of their protected health information (PHI) that is available through a health information exchange (HIE). Allowing consumers the ability to control their information that can be queried is a vital component of a trusted, consumer-centric HIE. As technology continues to evolve, an HIE must explore and implement the ability for consumers to control the access of their PHI at a more granular level. This may include limiting access by categories of medical data, specific encounters, or classification of providers.

Purpose: This policy describes an HIE's responsibility as it relates to a consumer's choice in allowing their PHI to be made available through the HIE. This will enable consumers to control who has access to their electronic health information, and allow them the opportunity to choose whether and when to participate in the HIE. This policy will ensure that the PHI of consumers who choose not to participate will not be available for query through the HIE.

Policy:

1. An HIE must allow consumers the ability to opt-out⁵ of the HIE, and to reverse their opt-out decision. All consumers are considered to be a participant in the HIE until they have explicitly opted-out. An HIE must allow consumers the ability to communicate their preference through an appropriate medium of the consumer's choice. An HIE is responsible to make available patient education information designed to assist consumers to exercise an educated choice regarding participation in the HIE.
2. **An HIE must require participating organizations to inform the consumer of their right to object prior to any initial query of the consumer's PHI through the HIE, except in a medical emergency.**⁶ Participating organizations must refrain from querying the consumer's PHI through the HIE if the consumer objects.
3. An HIE must provide consumers with the option to receive confirmation of their choice to opt-out or back into the HIE. If confirmation is requested, an HIE must acknowledge on a timely basis the change in participation status through an appropriate medium of the consumer's choice. An HIE must include in the opt-out information an explanation of when the change will become effective and what information will be excluded from the HIE.

⁴ A consumer is an individual that is capable of making decisions regarding their health care as defined by existing law, or a parent/legal guardian.

⁵ Opt-out is when a consumer elects to prevent their PHI from being made available through the HIE.

⁶ Once permission to query is given it may be relied upon at future encounters.



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4. An HIE will ensure that consumer PHI is not available for query when a consumer has opted-out of the HIE. A consumer's request to opt-out must become effective not later than one (1) business day from the day that the opt-out request is received by an HIE. Consumers must be allowed to modify their participation in the HIE at any time and through various methods.
5. An HIE will maintain a Master Patient Index (MPI) that contains a minimum data set to identify consumers and their current opt-out status.
6. An HIE will maintain an audit trail that uniquely identifies a consumer's participation status for a length of time consistent with state and federal requirements. The information must be housed in a retrievable storage medium. An HIE is required to perform periodic testing to demonstrate that stored data is recoverable.
7. An HIE must provide consumers, upon request, with a report related to who has accessed their PHI through the HIE. Consumers may request and receive a report free of charge twice yearly. An HIE may charge a reasonable fee for any additional reports.

Procedure:

An HIE should implement procedures that are inclusive of the following items:

1. An HIE should allow a consumer to select their participation status related to opting-out or back into the HIE in at least six (6) ways:
 - a. Online via a secure website, which should be available 24 hours per day (except for reasonable maintenance down-time);
 - b. A toll-free number, which should be available Monday through Friday;
 - c. By mail, via a standardized form;
 - d. By fax, via a standardized form;
 - e. In person at the HIE during business hours; or
 - f. Through a willing participating organization acting on the consumers behalf.



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2. An HIE should make materials available to participating organizations to use to educate consumers about the HIE and their participation options. Participating organizations should make these materials available to consumers and discuss the materials with them at their initial visits.
3. An HIE should make changes to a consumer's participation status selection at the HIE level within (1) business day of receipt.
4. In the event that a consumer requests a change in their participation status, an HIE should confirm that the participation status was changed within three (3) business days. Consumers should be offered at least five (5) ways to receive this notification:
 - a. Online to an email specified by the consumer;
 - b. A letter to an address specified by the consumer;
 - c. A letter by fax to a fax number specified by the consumer;
 - d. A letter in person at the HIE during normal business hours;
 - e. Via a text message.
5. An HIE should establish a process to validate guardianship.
6. An HIE should offer consumers a copy of who has accessed their PHI via the HIE upon request, free of charge, twice yearly. An HIE may charge a fee for additional requests, which cannot exceed cost.

Associated Policies:

1. *Consumer Access*
2. *Consumer Access to Audit*
3. *Consumer Outreach & Education*
4. *Exceptions to Consumer Choice*
5. *Secondary Data Use*
6. *Sensitive Health Information*
7. *Suspension and Termination of Consumer Access*



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USER AUTHENTICATION	
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Goal: The *User Authentication* policy aims to protect patient information by ensuring that verification of a user's identity occurs before access is granted; preventing unauthorized users from accessing a health information exchange (HIE). User authentication is an essential component for maintaining the integrity of protected health information (PHI). The ultimate objective is to achieve two factor authentication. Stakeholders must be assured that information available through the HIE is accessed by only those individuals that have a legitimate need to access the information.

Purpose: This policy describes an HIE's responsibilities as it relates to authenticating users to the HIE. User authentication is critical to ensuring that the individual attempting to access the HIE is who they claim to be. Authentication also substantiates that the user is permitted to access information within the HIE.

Policy:

1. An HIE must authenticate users accessing the HIE on a direct basis and require participating organizations to authenticate users accessing the HIE prior to granting them access. Authentication enables an HIE to validate that users attempting to access the HIE are who they claim to be. Authentication must occur at each attempt the user tries to access the HIE.
2. An HIE will authenticate users accessing the HIE and require participating organizations to authenticate users accessing the HIE using the following matrix:

User Connectivity	Authenticating Party	Required Authentication Protocol			
		Single Factor ⁷	Single Factor w/ Two Factor Characteristics ⁸	Two Factor ⁹	Multi-Factor
Providers					
a. Direct via the HIE provider portal	HIE		✓		
b. Through an EHR system onsite of a Participating Organization	Participating Organization		✓		
c. Through an EHR system remote from a Participating Organization	Participating Organization		✓		
Consumers					
d. Direct via the HIE consumer portal	HIE				[TBD]

⁷ Single factor authentication includes a user name and strong password.

⁸ Two factor characteristics include user name and password with an additional security precaution, such as one or more security questions, device registration, etc.

⁹ Two factor authentication includes a user name, password and secret key, private key, one-time password, token, etc. (Examples include, SecurID, IronKey, PhoneFactor, and Virtual Token™ multi-factor authentication, etc.)



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3. An HIE must accept the credentials of users accessing the HIE through a third party EHR. User credentials may only be accepted by an HIE after a user has gone through appropriate registration and identity proofing procedures of the HIE.
4. An HIE will, at a minimum, follow the National Institute of Standards and Technology (NIST) Level 2 registration as outlined in the most recent version of *Special Publication 800-63: Electronic Authentication Guideline*. An HIE must also follow the registration record retention requirements for Level 2.
5. An HIE must require participating organizations to ensure that each user is assigned a unique user name and password. Individual unique user names and passwords must be established in accordance with the most recent version of the NIST, *Special Publication 800-63: Electronic Authentication Guideline*. An HIE must use the protocols established by NIST in requiring that all participating organizations adopt these standards.
6. An HIE must encrypt user authentication data stored in the HIE. An HIE is required to use industry best practices in determining the level of encryption for user authentication data. Encryption of authentication data is required to protect the data.
7. An HIE is required to periodically audit user authentication logs as part of its routine audit process. Included in the audit, an HIE must develop protocols that identify outliers for the audit of the authentication and assessment logs. Any unusual findings from the audit must be investigated and resolved in a timely manner.
8. An HIE will maintain an audit trail of user authentication logs for a length of time consistent with state and federal requirements. The information must be housed in a retrievable storage medium. An HIE is required to perform periodic testing to demonstrate that stored data is recoverable.

Procedure:

An HIE should implement procedures that are inclusive of the following items:

1. An HIE should require participating organizations to use an EHR product that complies with the NIST standards for user authentication.
2. An HIE should institute audit procedures that ensure that only appropriately authenticated users are granted access to the HIE and report any unusual findings back to the participating organizations.



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3. An HIE should require participating organizations to report any unusual findings from their authentication log audit to the HIE within seventy-two (72) hours of discovery.

Associated Policies:

1. *Audit*
2. *Authorization*
3. *Consumer Access & Authentication*
4. *Enforcement*
5. *Notification of Breach*
6. *Participating Organization Access*



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SENSITIVE HEALTH INFORMATION

Approval Date: 03-01-11

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Goal: The *Sensitive Health Information* policy aims to keep select protected health information (PHI) confidential. The sensitivity of PHI is subjective and varies depending on the specifics of an individual consumer's situation and context. This policy aims to continue to advance consumer control over specific PHI exchanged through an HIE when technology can support granular-level control. Keeping consumer-selected PHI confidential will increase consumer trust in the HIE, which is essential to the successful operation of the HIE. Federal and state laws impose heightened privacy and security requirements upon the disclosure of certain types of PHI that may be considered particularly private or sensitive to a patient. This policy aims to ensure that all entities involved in the exchange of PHI through the HIE follow Federal and Maryland law.

Purpose: In general, sensitive health information is considered to be information that carries with it unusually high risks in the event of disclosure. An HIE currently does not have the capability to selectively identify or prevent the exchange of specific PHI. This policy describes the responsibility of an HIE for reducing the risk of sensitive health information being compromised or disclosed inappropriately. It is the responsibility of an HIE to utilize its current technologies, leverage the technologies of participating organization, and explore new technologies which will increase consumer control over specific PHI exchanged through the HIE. This policy does not pertain to the reporting of conditions required by law.

Policy:

1. An HIE will require participating organizations to adhere to federal and state law when exchanging PHI through the HIE. Release of PHI that requires written consent under federal or state law can only occur through clinical messaging or point-to-point transmission. The participating organization must obtain consent consistent with current federal or state law prior to the release of PHI to an authorized recipient.
2. An HIE will require participating organizations who have the technical capability to do so to allow consumers to request that sensitive PHI be withheld from the HIE. An HIE will require participating organizations without this capability to inform consumers that they cannot selectively withhold PHI from the HIE; and provide consumers with the opportunity to opt-out of the HIE.
3. An HIE will require participating organizations to notify consumers and the HIE of an inadvertent release of sensitive PHI to the HIE after a consumer requested that it be withheld. An HIE will require the participating organization to immediately remove the specific PHI from being made available to the HIE. An HIE will investigate the event to determine what corrective action should be taken.



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4. An HIE will work with participating organizations to identify the organization in part or in whole as a provider of specific services, where the majority of information yielded is considered sensitive. These participating organizations that are not able to withhold publishing health information deemed sensitive as part of the organization's PHI will not upload information to the HIE except in cases of point-to-point messaging.

Procedure:

An HIE should implement procedures that are inclusive of the following items:

1. An HIE should annually review federal and state law and implement appropriate procedures to facilitate participating organization compliance with these laws when exchanging information through the HIE. An HIE should educate participating organizations on any changes to federal and state laws or HIE procedures that are applicable to the exchange of information through the HIE.
2. An HIE should assess participating organizations technological capabilities to identify and control sensitive PHI and provide guidance on allowing consumers to request that sensitive PHI be withheld from the HIE.
3. An HIE should encourage participating organizations to provide timely notification to established consumers in the event that their technology changes, such that they are able to allow consumers to request specific PHI be withheld from the HIE and implement this request.
4. An HIE should require participating organizations to provide timely notification to consumers and the HIE in the event that PHI was released to the HIE after requesting that it be withheld. An HIE should follow appropriate procedures to investigate the disclosure event to determine what corrective action should be taken. An HIE should provide participating organizations with guidance on restricting specific PHI, which was subsequently released without authorization, from being made available to the HIE.
5. An HIE should work with participating organizations to analyze the information they intend to make available to the HIE and current technological capabilities to segregate specific records from being make available to the HIE. An HIE should apply consistent assessment protocols when working with a participating organization to determine whether the majority of information yielded is sensitive PHI.



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6. An HIE should annually review the current feasibility of selectively identifying and controlling specific PHI through the HIE. In the event that the capabilities are implemented, an HIE should educate and inform participating organizations and consumers on changes to controlling select PHI through the HIE.

Associated Policies:

1. *Audit*
2. *Consumer Access to Audit*
3. *Consumer Choice*
4. *Data Use and Disclosures*
5. *Enforcement*
6. *Liability*
7. *Notification of Breach*
8. *Participating Organization Access*
9. *Public Health Reporting*
10. *Suspension and Termination of Provider Access*



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EMERGENCY ACCESS FOR PARTICIPATING ORGANIZATION

Approval Date: 03-01-11

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Goal: The *Emergency Access for Participating Organizations* policy aims to ensure that participating organizations have the ability to access information in an emergency situation through a health information exchange (HIE) that is essential to providing care, even in the event that a consumer has not had the opportunity to object to a query. This policy will enable participating organizations to access information for treatment that may not be available under non-emergent circumstances.

Purpose: This policy describes an HIE's responsibility for enabling participating organizations to obtain information through the HIE without prior consumer agreement. Consumer assent may not be obtainable at every encounter and the ability of participating organizations to have access to appropriate information for treatment is essential to care delivery.

Policy:

1. An HIE will allow participating organizations to access information through the HIE without consumer agreement in emergency situations if the participating organization determines that the following conditions are met:
 - a. The consumer is in immediate need of medical attention and the opportunity to secure consumer agreement would result in delay of treatment that would increase the risk to the consumer's life or health;
 - b. Information available through the HIE may be material to emergency treatment; and
 - c. The participating organization has an established policy that describes the requirements and attestation process that all of the conditions for emergency access have been met.
2. An HIE will require participating organizations to discontinue querying of the consumer record upon the completion of the emergency encounter.
3. An HIE will maintain and review audit logs of emergency access at minimum on a bi-monthly basis. Any unusual findings from the access log review must be investigated with the participating organization and resolved in a timely manner. An HIE must retain these files for a timeframe consistent with applicable state or federal law or best practices.
4. An HIE must require participating organizations to notify consumers when their information has been accessed through the HIE under this *Emergency Access Policy*. Consumers notification must occur within a reasonable time period of the discovery by the HIE.



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5. An HIE will require participating organizations to allow emergency access only to users with the appropriate access designation consistent with participating organization policy.

Procedure:

An HIE should implement procedures that are inclusive of the following items:

1. An HIE should establish a policy that describes the conditions for emergency access to the HIE by a user and a procedure for capturing that access was gained during an emergency situation. This process should include an attestation from the user that the circumstances delineated in this policy exist prior to a query of the information through the HIE.
2. An HIE should require participating organizations to discontinue querying of the consumer record upon the completion of the emergency encounter. Participating organizations should be required to audit emergency access and compare to discharge dates and times.
3. An HIE should maintain audit logs of emergency access which include, at minimum, the following:
 - a. The identity of the consumer of the record that was accessed;
 - b. The identity of the user accessing the record;
 - c. The name of the participating organization;
 - d. The attestation that the emergent situation existed;
 - e. The date and time the emergency access was granted to the user; and
 - f. The date and time the emergency access was terminated.
4. An HIE should establish a method to notify consumers when their information has been accessed under the *Emergency Access Policy* through one of the following mediums:
 - a. Online to an email specified by the consumer; or
 - b. A letter to an address specified by the consumer; or
 - c. A letter by fax to a fax number specified by the consumer.



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EMERGENCY ACCESS FOR PARTICIPATING ORGANIZATION

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Associated Policies:

1. *Consumer Access*
2. *Consumer Access to Audit*
3. *Consumer Choice*
4. *Consumer Outreach & Education*
5. *Participating Organization Access*
6. *Sensitive Health Information*



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PROPOSED RESOLUTION FOR INCREASED PATIENT CONTROL

Approval Date: 01-11-11

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Resolved: In order to achieve a means for patient control beyond what the current technical solution allows, the Policy Board recommends that MHCC direct the state-designated HIE to explore reasonable alternatives to implement the following, including the costs and benefits of implementation. CRISP will report back to the Policy Board by September 2011 on the following items:

1. The ability to implement patient consent directives regarding publication and access to PHI, including limiting access to specified categories of medical data, to records of specified medical encounters, to records of specified providers or classifications of providers, and limitations of access to specified purposes, including emergency-only access.
2. The ability to prevent the automatic uploading of PHI to an edge device when a consumer opts out of the exchange, except for the limited data set required to record the opted out status of the patient.



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PROPOSED RESOLUTION FOR QUERY IMPLEMENTATION

Approval Date: 03-01-11

Scheduled Review Date: 03-01-12

Rational

At an increasing rate, providers are requesting permission to query the state designated health information exchange (HIE). Over the last year, the Policy Board has finalized and submitted four policies to the Maryland Health Care Commission (MHCC) for approval. The pace of policy development has been extremely thoughtful with each policy requiring a great deal of deliberation by the Policy Board. The value of the statewide HIE to providers is primarily the ability to query the HIE. In the absence of a full set of policies recommended by the Policy Board, the HIE has been operating under state and federal laws. The HIE query function needs to be activated as soon as possible so that providers can begin to use the data and residents can begin receiving the associated benefits; further delay could jeopardize the ongoing viability of the project. Making the current data available as the Policy Board continues to develop thoughtful policies will ensure the growth and sustainability of the statewide HIE.

Be It Resolved

The Policy Board recommends that the MHCC continue the advancement of the HIE by allowing the state designated HIE to enable participating organizations to query the statewide HIE under the following conditions:

1. The deployment of the query function will operate within the context of the policies approved by the Policy Board, i.e., *Participating Organization Access, User Authorizations, User Authentication, and Consumer Choice*. As the Policy Board approves additional policies, these will be incorporated into each participating organization's agreement with the state designated HIE. The state designated HIE will require all participating organizations to execute the participation agreement as a condition of participation.
2. The deployment of the query function will operate under all applicable state and federal laws and regulations, including but not limited to the *Health Insurance Portability and Accountability Act of 1996*, including provisions of the *Health Information Technology for Economic and Clinical Health Act*, and the *Maryland Confidentiality of Medical Records Act*.
3. The state designated HIE will require participating organizations' adherence to existing laws, regulations, and policies adopted by the MHCC in their participation agreement. The participation agreement must ensure that participating organization agree and understood that certain violations of law or policy will result in termination of access to the statewide HIE.
4. The state designated HIE will provide updates on the progress of query deployment as part of their routine updates to the Policy Board. Included in the update should be the organization names and total queries, implementation activities underway, and near term plans for the HIE functionality, additions, and participants.



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Health Information Exchange

SUSPENSION AND REINSTATEMENT OF ACCESS

Approval Date: 04-12-11

Scheduled Review Date: 04-12-12

Goal: The *Suspension and Reinstatement of Access* policy aims to allow a health information exchange (HIE)¹⁰ to work in coordination with participating organizations to suspend and reinstate users from accessing the HIE. This policy seeks to ensure that only organizations and their users who are in good standing are able to access information through the HIE.

Purpose: This policy describes an HIE's responsibility as it relates to the suspension and reinstatement of access to the HIE for participating organizations and its users. This policy will enable an HIE to suspend and reinstate a participating organizations' access and/or users' access as well as require participating organizations to notify the HIE to suspend and request the reinstatement of a user's access to the HIE.

Policy:

1. An HIE must inform participating organizations of the circumstances that can result in a participating organization or user suspension and reinstatement. At a minimum, this must include inappropriately accessing, using, or disclosing protected health information, consistent with state and federal laws and regulations and Maryland HIE policies.
2. An investigation must be conducted by the HIE if there is reason to believe a participating organization or its user may have inappropriately accessed, used, or disclosed protected health information obtained through the HIE. The HIE may immediately suspend a user or participating organization prior to actions under this policy to avoid serious harm related to privacy and security or other provision of applicable law. An HIE must require participating organizations to notify the HIE of a user suspension by the participating organization.
3. An HIE must suspend participating organizations' or users' access to the HIE immediately once the HIE has made a decision to suspend a participating organization and/or user. An HIE must indefinitely suspend a participating organization effective on the date an agreement is terminated by the participating organization. An HIE is required to provide notification to participating organizations and users that are suspended.
4. An HIE must inform participating organizations of the process for reinstating access privileges for a participating organization or user that has been suspended. An HIE is required to provide notification upon reinstatement of access privileges to participating organizations and users and include any conditions regarding accessing the HIE.
5. An HIE must have reasonable procedures for suspension and reinstatement, including a right to appeal. An HIE must require participating organizations to have reasonable procedures for suspension and reinstatement of their users, including a right to appeal.

¹⁰ A health information exchange is an infrastructure that provides organizational and technical capabilities for the exchange of protected health information electronically among entities not under common ownership.



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6. An HIE must inform participating organizations that the HIE will provide immediate oral notification to the Maryland Health Care Commission (MHCC) of suspensions and reinstatements. The MHCC will receive timely written notification of final suspensions and reinstatements. An HIE must inform participating organization that final suspension and reinstatement information is not considered confidential by the HIE and the MHCC.
7. An HIE must require participating organizations to implement a reasonable and scalable appropriate use policy to ensure users are appropriately accessing, using, and disclosing protected health information.

Procedure:

An HIE should implement procedures that are inclusive of the following items:

1. Prior to initiating any agreement with a participating organization an HIE should provide notification, detailing at minimum:
 - a. The circumstances that can result in a participating organization and user suspension and reinstatement;
 - b. Procedures for suspension and reinstatement, including a right to appeal;
 - c. That the HIE will notify the MHCC of all suspensions and reinstatements; and
 - d. That final suspension and reinstatement information is not considered confidential by the HIE and the MHCC.
2. An HIE should provide notice of a suspension that details the reason(s) why a participating organization or user has been suspended, any corrective action requirements and timeframes, including mitigation of harm and future actions to be taken by the HIE in the event corrections are not made.
3. When a participating organization or user is suspended from accessing the HIE, an HIE should reinstate the participating organization's or user's access to the HIE when appropriate and timely corrections are made and verified by the HIE.
4. An HIE should determine if any reinstated user's or participating organization's access privileges should be modified to ensure the privacy and security of the HIE. These modifications should be applied and notification should be provided to the user or participating organization detailing the modification implemented.



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5. An HIE should suspend a participating organization's and a user's access to the HIE when it is determined that a violation has occurred and appropriate and timely corrections have not been made.
6. An HIE should provide detailed notification to the MHCC of suspensions or reinstatements within one (1) business day.
7. An HIE should verify that participating organizations have implemented a reasonable appropriate use policy and procedures pertaining to suspension and reinstatement, including a right to appeal. An HIE should encourage participating organizations to require each user to attest to the terms and conditions of the appropriate use policy.

Associated Policies:

1. **Complaints**
2. *Enforcement*
3. *Notification of Breach*
4. *Participating Organization Access*



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Health Information Exchange

CONSUMER ACCESS

Approval Date: 05-24-10

Scheduled Review Date: 05-24-12

Goal: The *Consumer Access* policy aims to ensure that consumers¹¹ are afforded the opportunity to access their protected health information (PHI) that is available through a health information exchange¹² (HIE).

Purpose: This policy describes an HIE's responsibility as it relates to facilitating and enabling consumers' ability to gain access to their information that is available through an HIE. This will allow a mechanism for consumers to view their information, identify inaccurate information, and monitor access. Allowing consumers the ability to access their information is a vital component of a trusted, consumer-centric HIE.

Policy:

1. An HIE will enable consumers to gain access to their information by, at a minimum, providing metadata¹³ about their information that is available through an HIE and provide information about how to gain access to their information either through a single point of contact or through the participating organizations that house the information.
2. An HIE will facilitate the correction of any perceived inaccurate information that is available through the HIE.
3. An HIE must allow consumers to request information related to the access of their PHI through the HIE. Consumers must be provided information relative to the PHI accessed, including the participating organization or individual that accessed their PHI, when the PHI was accessed, and what was accessed.
4. An HIE will provide one or more mechanisms that will allow consumers to communicate to the HIE any perceived inappropriate access of their PHI through the HIE. Any report submitted to an HIE regarding perceived inappropriate access of PHI must be acknowledged, investigated, and resolved in a timely manner with communication back to the consumer.

Procedure:

An HIE should implement procedures that are inclusive of the following:

¹¹ A consumer is an individual or someone authorized to make decisions on their behalf.

¹² A health information exchange is an infrastructure that provides organizational and technical capabilities for the exchange of protected health information electronically among entities not under common ownership.

¹³ Metadata is any structured data used to aid the identification, description and location of networked electronic resources.



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CONSUMER ACCESS

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Scheduled Review Date: 05-24-12

1. An HIE should provide the following information as it relates to the consumer's PHI: the source of the information, the date the information was created, and data type.
2. Upon the receipt of a report from a consumer of perceived inaccurate information that is being made available to the HIE, an HIE should provide information to the consumer regarding correction of perceived inaccurate information in accordance with HIPAA.
3. An HIE should make best efforts, in so far as feasible, to notify participating organizations or individual users that have accessed incorrect PHI that has subsequently been corrected.
4. An HIE should immediately acknowledge the receipt of a report from a consumer of any perceived inappropriate access of their information through the HIE. An HIE will begin an investigation of this report within two (2) business days and communicate to the reporting consumer of the findings and resolution.

Associated Policies:

1. *Consumer Access to Audit*
2. *Consumer Choice*
3. *Consumer Outreach and Education*
4. *Consumer Verification*
5. *Data Use and Disclosure*
6. *Consumer Portals & Health Record Banks*
7. *Participating Organization Access*
8. *Sensitive Health Information*
9. *Suspension and Termination of Consumer Access*



The MARYLAND HEALTH CARE COMMISSION

Health Information Exchange

CONSUMER OUTREACH, EDUCATION & ENGAGEMENT

Approval Date: 05-24-10

Scheduled Review Date: 05-24-12

Goal: The *Consumer Outreach, Education, and Engagement* policy aims to ensure that consumers¹⁴ are provided with accurate and current information about a health information exchange's (HIE) capabilities, benefits, and risks in order to make informed decisions about their health information and health. This policy also aims to ensure that consumers are engaged as full participants in partnership with an HIE, which will enable them to express their concerns and influence HIE services. Outreach, education and engagement is the responsibility of all stakeholders involved in an HIE.

Purpose: This policy describes the nature and breadth of consumer outreach, education and engagement responsibilities of an HIE in coordination with its participating organizations. An HIE is responsible for proactively educating consumers about their rights and responsibilities as they relate to the HIE and providing channels for bi-directional communications, feedback, and input. Engaging consumers as participants in partnership with an HIE is essential to a trusted consumer-centric HIE.

Policy:

1. An HIE must establish a consumer outreach, education and engagement strategy and implementation plan that incorporates the core message and/or content established by the Maryland Health Care Commission (MHCC) in consultation with stakeholders. The core content will include a general overview of the fundamentals of health information technology, including electronic health records and electronic health information exchange; health information privacy and security laws; and benefits and risks of automating and exchanging health information as compared to paper-based health information.
2. An HIE's outreach, education and engagement strategy must include, at a minimum, the following content: what information can be exchanged through the HIE; what information is maintained by the HIE; what access consumers and others have to their information being exchanged through the HIE; their rights and responsibilities regarding the protection, use, and correction of their information; how they may exercise these rights; the implications of disclosing or not disclosing their medical information through the HIE; rights and responsibilities of organizations participating in an HIE, and an HIE's policies and procedures.
3. An HIE will develop outreach, education and engagement materials that are balanced, culturally sensitive, language appropriate, current, and include plain language that is easily understood by the consumer populations served.

¹⁴ A consumer is an individual or someone authorized to make decisions on their behalf.



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4. An HIE must seek broad consumer input and engage a variety of consumer representation¹⁵ through a range of feedback and communication methods. Consumer input must be sought in the continued development of outreach, education, engagement and services including, HIE implementation, relevant ongoing development, new or changed policies, and HIE improvements.
5. An HIE must conduct consumer outreach, education and engagement through a variety of communication channels to allow access by consumers, including those hard-to-reach populations. An HIE must facilitate the outreach, education and engagement efforts of participating organizations, the provider community, and community based consumer organizations that provide health-related information and assistance. Outreach, education and engagement efforts must include tailored assistance to stakeholder organizations to support effective engagement of consumers, particularly hard-to-reach populations.

Procedures:

1. An HIE should regularly engage consumers and solicit feedback on outreach, education and engagement strategies and general HIE implementation and enhancements through recognized valid methods that will capture the diversity of views and recommendations. An HIE should ensure consumer representation within their governance structure, such as establishing a consumer advisory committee.
2. An HIE should explicitly state within their agreement with a participating organization the responsibilities of the participating organization as it relates to consumer outreach, education and engagement. An HIE should make outreach, educational and engagement materials and resources available, including:
 - a. Sample draft language to include in their notice of privacy practice; and
 - b. Access to electronic and printable educational resources to interested stakeholders as needed.
3. An HIE should develop outreach, education and engagement strategies and materials that:
 - a. Include core content established by the MHCC in consultation with stakeholders;
 - b. Include all relevant information, maintaining a balance when presenting points of view on the subject matter, including the risks and benefits of HIE;

¹⁵ Consumer representation includes, but is not limited to, individuals that represent consumer advocacy organizations and online consumer advocates that are independent of care delivery or payment organizations.



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- c. Foster informed participation of the consumer;
 - d. Are both engaging and understandable, minimize the use of technical terms, clearly defines any technical terms that are used, and that reaches the varying levels of education, understanding, and interest across the consumer audience;
 - e. Use text and illustrations that is culturally sensitive, language appropriate, and recognizes user diversity including ethnicity, age, race, and gender; and
 - f. Include content that is accurate for the timeframe the materials are to be used and notes any time limitations.
4. An HIE should implement outreach, education and engagement strategies that use multiple communication channels, which may include social media, newspaper announcements, mailings, community based meetings, toll-free consumer support phone lines, DVDs, online video sources, and translation and interpretation services.
 5. An HIE should implement outreach, education and engagement strategies that target all consumers receiving health care in Maryland, including hard-to-reach populations. This can be accomplished by building relationships with community organizations that regularly interact with hard-to-reach populations.¹⁶

Associated Policies:

1. *Consumer Access*
2. *Consumer Access to Audit*
3. *Consumer Choice*
4. *Participating Organization Access*
5. *Sensitive Health Information*
6. *Suspension and Termination of Consumer Access*

¹⁶ Hard-to-reach population include but are not limited to the elderly and individuals with disabilities, mental illness, or special needs and their caregivers; those with low literacy, limited English proficiency, and limited technology resources; low income populations; children in states custody; the incarcerated; those living in rural areas; and those populations where sensitive health information may be of significant concern.



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AUDIT OF ACCESS, USE AND DISCLOSURE

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Goal: The *Audit* policy aims to ensure that health information exchanges (HIEs) establish audit policies and procedures that will promote transparency and compliance with access, use, and disclosure requirements. Audit activities will facilitate compliance and help preserve the integrity of HIEs and the privacy and security of individuals' protected health information (PHI).

Purpose: The *Audit* policy requires HIEs to monitor compliance with all applicable laws and internal HIE policies. Periodic and ad hoc audits provide HIEs the ability to monitor compliance with access, use, and disclosure requirements. HIEs will take appropriate action if a violation is identified.

Policy:

1. An HIE shall develop policies and procedures for periodic and ad hoc audits that are sufficient to detect patterns of inappropriate access, use, and disclosure.
2. An HIE shall conduct periodic audits that are objective, proactive, and systematic; in accordance with generally accepted industry practices.
3. An HIE shall conduct ad hoc audits when a possible violation is identified.
4. An HIE must notify the participating organization or other authorized users and take appropriate steps to remediate the situation when an audit shows evidence of a violation.
5. An HIE will make a summary report of audit results available to the public, at least annually.
6. An HIE will provide an updated summary report of audit results and supporting documentation and/or conduct an ad hoc audit upon the request of the Maryland Health Care Commission (MHCC).
7. An HIE will, when appropriate, use audit findings to: 1) educate and train participating organizations or other authorized users and 2) evaluate and potentially implement new control measures to ensure proper use and access of the HIE by participating organizations.

Procedure:

An HIE should implement procedures that are inclusive of the following:

1. An HIE should record at least the below information as part of their periodic and ad hoc audits. These records should be stored centrally at the HIE level for an amount of time consistent with the *Health Insurance Portability and Accountability Act of 2009*. This information must remain unalterable so that anyone, regardless of participation or access role, cannot change or tamper with the content of the data in the audit logs:



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- a. The identity of the consumer of the PHI that was accessed;
 - b. The consumer's participation status at the time of access;
 - c. The identity of the user accessing the PHI;
 - d. The identity of the participating organization the user is affiliated with;
 - e. The date and time of access;
 - f. The source and type of the PHI;
 - g. The date and time the PHI was made available to the HIE;
 - h. The date the user was registered to the HIE; and
 - i. The user's access level at the time of access.
2. An HIE should maintain a record of access attempts to the HIE. The record should contain, at a minimum, the following: date, time, and source or entity, if possible, attempting to access the HIE, and number of attempts. An HIE should continually monitor access attempts and use the record to identify and remediate any unauthorized access by implementing appropriate controls.
3. **An HIE should conduct periodic audits at least annually and should review audit results to ensure compliance with applicable laws. Any unusual findings should be investigated in a timely manner. Any findings of inappropriate access, use, or disclosure will be addressed pursuant to state and federal law and the HIE's agreement with the participating organization. At a minimum, breaches of security of information, including but not limited to the following should be reviewed during this process:**
- a. Only authenticated users, or users whose credentials have been accepted by the HIE, obtain access to the HIE;
 - b. Authorized users access PHI through the HIE specific only to their level of access;
 - c. Authorized users are not accessing PHI through the HIE, of consumers that have opted out;
 - d. **Applicable requirements were met when PHI was accessed through the HIE during an emergency access procedure;** and
 - e. Inappropriate use or disclosure by HIE staff.



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4. An HIE should allow participant organizations access to audit records that include records involving that participating organization. The records shall include the name and access level of each user who accessed PHI, the name of the consumer whose PHI was accessed, the date and time of access, and the type of PHI that was accessed. Routine requests for records should be responded to within ten (10) business days of receipt of request. During an enforcement situation, requests for records should be responded to more quickly in accordance with the *Enforcement* policy.
5. **An HIE should make annual audit results available to the public by posting them on its website within thirty (30) days of completion of the audit. The audit result should measure at least the following:**
 - a. The number of times patient data was accessed.
 - b. The number of unique patients whose data was accessed;
 - c. The number of individual users who accessed the HIE;
 - d. The number of authorized HIE users;
 - e. The number of participating organizations whose users accessed the HIE;
 - f. **The number of accesses that were of an emergency access nature;**
 - g. The number of breaches identified by the audit and the nature of each breach;
 - h. The number of times in which PHI of a consumer who was opted out was accessed through the HIE; and
 - i. Actions taken as a result of the audits to improve the privacy, safety, reliability, utility, security, and integrity of the HIE while supporting compliance with all laws.
6. Upon request by the MHCC, an HIE should provide either an updated summary report of audit results and supporting documentation or conduct an ad hoc audit and provide the results of such within the timeframe specified within the request.



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Associated Policies:

1. *User Authorization*
2. *User Authentication*
3. *Consumer Access to Audit*
4. *Consumer Choice*
5. *Data Use and Disclosure*
6. *Enforcement*
7. *Emergency Access for Participating Organizations*
8. *Notification of Breach*
9. *Participating Organization Access*
10. *Suspension and Reinstatement of Access*



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SECONDARY DATA USE

Approval Date: 09-27-11

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Goal: The *Secondary Data Use* policy aims to facilitate legitimate secondary use of data available from a health information exchange (HIE) where the use promotes improvement in consumer health, public health, or performance of the health care delivery system. This policy also aims to ensure that each entity utilizing data or information available from an HIE for secondary use follows appropriate data safeguards.

Purpose: This policy describes an HIE's responsibility regarding disclosure of data to entities who request data for secondary use. This policy describes how consumers and participating organizations are to be informed by an HIE about disclosures of data for secondary use.

Policy:

1. An HIE must limit its use and disclosure of data to purposes of treatment and payment;¹⁷ health care operations;¹⁸ reporting to public health authorities¹ in compliance with reporting required or authorized by law; or other disclosure required by law. Any other use of data, including data without identifiers, is considered *secondary* use and requires approval by the Maryland Health Care Commission (MHCC) in consultation with the Department of Health and Mental Hygiene (DHMH).
2. An HIE must inform its participating organizations about the circumstances and procedures under which data that participating organizations make available to the HIE may be disclosed by the HIE for secondary use. An HIE must require its participating organizations to notify each consumer about secondary use of data at the time the initial opportunity to opt-out is presented and in a manner that is understandable to the consumer. The notification must include the type of consumer data that may be disclosed for secondary use, the entities that may, after review and approval, receive consumer data without prior consumer consent, and the purposes which those entities may use that information.
3. An HIE may only use or disclose data for secondary use available through the HIE with approval by the MHCC, in consultation with the DHMH. The MHCC, in consultation with the DHMH, will evaluate on a case-by-case basis and may approve requests regarding secondary use of information that is available through the HIE:

¹⁷ As defined in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.501)

¹⁸ Only for conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment; as defined in the HIPAA Privacy Rule (45 CFR 164.501)



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- a. If the requesting entity has received approval from an Institutional Review Board (IRB) and demonstrates that the outcome of the proposed use will potentially improve consumer health, improve public health, and/or improve the performance of the health care delivery system; and the applicant will have adequate safeguards to ensure confidentiality of source data, prevent re-disclosure that would identify an individual, and prevent re-release of source data; or
 - b. If the proposal for secondary use is from a public health authority for de-identified data¹; the use is for investigation, surveillance, and/or response, in performance of its lawful function(s) but not specifically required or authorized by law; and the public health authority will have adequate safeguards to ensure confidentiality of source data, prevent re-disclosure that would identify an individual, and prevent re-release of source data; or
 - c. If the requesting entity has received approval from an Institutional Review Board (IRB) and demonstrates that the outcome of the proposed use has been determined to serve a legitimate purpose consistent with the interest of the subject individuals; and the applicant will have adequate safeguards to ensure confidentiality of source data, prevent re-disclosure that would identify an individual, and prevent re-release of source data.
4. Upon advance request, the MHCC may, after consultation with DHMH, waive IRB review required under 3.(a.) or 3.(c.) on such conditions as the MHCC deems appropriate, including where data reviews and authorizations already exist. Ongoing approval of a specific secondary use consistent with these policies may be granted by the MHCC on such conditions as MHCC deems appropriate.
 5. As part of an HIE's Data Use Agreement with an entity to which it disclosed data for secondary use, there must be annual oversight by an IRB or by the HIE in cases where IRB review was not required, even if the entity is a covered entity or a business associate.¹ If an IRB or the HIE determines that the entity has failed to use or protect the data in accordance with the approved secondary use requirements, an HIE must immediately terminate the Data Use Agreement and require the entity to destroy the data previously released by the HIE.
 6. An HIE will make summary reports available to the public quarterly that provide specific information about requests for data for secondary use and the release of data for secondary purposes.



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7. An HIE must include as part of its outreach, education, and engagement strategies, in coordination with its participating organizations:
 - a. An explanation of the circumstances under which the consumer's data may be disclosed by the HIE for the purposes of secondary use without any prior patient consent; and
 - b. The process for application and approval for secondary uses of data available through the HIE.
8. An HIE may charge a requesting entity a reasonable fee to cover costs associated with its disclosures for secondary use.

Procedure:

An HIE should implement procedures that are inclusive of the following:

1. An HIE should allow entities seeking data for secondary use from the HIE to submit preliminary data request to the HIE, where the HIE can make a determination of whether the data would be released if eventually approved by an IRB and/or the MHCC, in consultation with DHMH.
2. An HIE should explicitly state within their agreement with a participating organization the circumstances and procedures under which data that participating organizations make available to the HIE may be disclosed by the HIE for secondary use.
3. All secondary data use requests to the HIE should include the name of the entity requesting the data, name and role of principle investigator and any co-investigators, data elements requested, details about the purpose of the study and study protocol, the start and end date of the study, and a description of how the request meets the requirements of this policy.
4. An HIE should specify in their Data Use Agreement the length of time that the data released by the HIE may be retained during the approved use; when the data must be destroyed upon completion of the approved secondary use; the process for annual oversight by IRB or by the HIE, including any audit or periodic reporting requirements; and action steps the HIE will require of the entity if the entity has failed to use or protect the data in accordance with the approved secondary use requirements.



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5. An HIE should post summary reports in a prominent place on the HIE's website. Summary reports should include at a minimum the number of requests, the approval or denial status of those requests, the name of the requestor, the purpose for which the information was being requested, whether the request includes any financial compensation to the HIE, the outcomes of requests for secondary use of data made available through the HIE, and any termination of secondary data use by the HIE. All approved requests for secondary use of data, with a short description of each of the projects, should be included in the summary report. Unless exempted by DHMH and MHCC as part of the approval process, the results of the project should be summarized upon completion.
6. An HIE should facilitate the education efforts of its participating organizations to notify each consumer about secondary use of data.
7. An HIE should equally apply any fees it charges to entities it discloses data to for secondary use, which is reflective of the effort required to prepare and release the data of the request.

Associated Policies:

1. *Consumer Choice*
2. *Consumer Outreach, Education & Engagement*
3. *Enforcement*
4. *Data Use and Disclosure*
5. *Participating Organization Access*
6. *Sensitive Health Information*
7. *Suspension and Reinstatement of Access*
8. *User Authorization*



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PRIMARY DATA USE AND DISCLOSURE

Approval Date: 04-05-12

Scheduled Review Date: 04-05-13

Goal: The *Primary Data Use and Disclosure* policy aims to ensure that a health information exchange (HIE) and participating organizations appropriately use and disclose protected health information (PHI) consistent with applicable laws and regulations. These protocols related to how information can be used and disclosed are intended to build trust among stakeholders.

Purpose: This policy describes an HIE's responsibility as it relates to appropriate uses and disclosure of information accessed through the HIE. Establishing requirements around data use and disclosure for primary purposes is critical to sharing data electronically. An HIE has a role in guarding against the inappropriate use and disclosure of information available through the HIE.

Policy:

1. An HIE must implement robust technical control measures, in accordance with then current best practices, that allow for a patient matching process that:
 - a) Maximizes the probability of identification of the correct patient record;
 - b) Minimizes the probability of inadvertently disclosing information about other patients; and
 - c) Minimizes the probability of associating a specific record with the incorrect patient.
2. An HIE must maintain an accurate representation of the original information when stored by the HIE and when disclosed to authorized users. An HIE must require participating organizations to make reasonable efforts to make available to the HIE an accurate representation of the patient data held by the participating organization.
3. An HIE and participating organizations must implement operational procedures, including technical control measures, that ensures authorized users no longer have access to the HIE after a certain time of inactivity, either during a specific log-in session or during the period of their authorization to use the HIE.
4. Participating organizations who send information to or receive information from the HIE shall enter into an agreement with the HIE that sets out the terms and conditions under which they can access and disclose information through the HIE, which shall include compliance with State regulations and applicable state and federal law. The HIE must require participating organizations to include in their data use agreement a statement that specifies requirements related to the use of the HIE by authorized users and business associates.
5. Disclosures required by law, including disclosures required by compulsory legal process, are primary uses. In responding to request for disclosures involving compulsory legal process, an HIE shall take appropriate actions to protect the patient's privacy and the provider-patient relationship in coordination with the participating organization that owns the data requested.



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PRIMARY DATA USE AND DISCLOSURE

Approval Date: 04-05-12

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Procedure:

An HIE should implement procedures that are inclusive of the following items:

1. An HIE should implement a patient matching process, which identifies the correct patient record and relevant consumer consents or participation status, in accordance with then current best practices.
2. An HIE should use best efforts to maintain and disclose to authorized users an accurate representation of the original information provided to the HIE.
3. An HIE should establish a reasonable and prudent time period not to exceed 60 minutes that requires users to re-authenticate to the HIE after a period of inactivity during a log-in session, which balances the need for care delivery with the risk of inadvertent disclosure. An HIE should require authorized users to reactivate their user account if the user has not used the HIE for a period not to exceed 90 days.
4. An HIE should require participating organizations to train new users regarding appropriate access and disclosure through the HIE consistent with the participation agreement and require authorized users to agree to the terms and conditions for access and disclosure prior to their use of the HIE. The participating organization should also periodically train their existing authorized users consistent with their HIPAA training procedures. An HIE should make available guidance to participating organizations on such training.

Associated Policies:

1. *Consumer Choice*
2. *Participating Organization Access*
3. *Public Health Reporting*
4. *Secondary Use of Data*
5. *Sensitive Health Information*
6. *Suspension and Reinstatement of Access*
7. *User Authentication*
8. *User Authorization*



The MARYLAND HEALTH CARE COMMISSION

Health Information Exchange

CONSUMER ACCESS TO AUDIT

Approval Date: 04-05-12

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Goal: The *Consumer Access to Audit* policy aims to ensure that consumers¹⁹ are afforded the opportunity to monitor the access and disclosure of their information by users of a health information exchange (HIE). This policy is intended to strengthen the process for detecting inappropriate access or disclosure and build trust in a system where data is exchanged electronically.

Purpose: This policy describes an HIE's responsibility as it relates to facilitating consumers' ability to be provided with information regarding the access and disclosure of their information through an HIE. The purpose of this policy is to allow consumers the ability to monitor the access and disclosure of their information through an HIE and report any perceived unauthorized access or disclosure.

Policy:

1. An HIE must, as part of its outreach, education, and engagement strategy, make reasonable efforts to inform consumers of their right to request an accounting of disclosures report and the process for requesting the report.
2. An HIE must provide consumers, upon request, a report identifying the patient's information disclosed by the HIE or by a business associate acting on behalf of the HIE. The report shall include the name of the individual to whom the patient's information was disclosed, the name of the individual's affiliated organization, when the information was disclosed, and what was disclosed. Included in the report must be a statement describing all disclosure of patient information for purposes of secondary use.
3. An HIE must maintain comprehensive, electronic records of information necessary to generate an accounting of disclosure report for a time period that is consistent with HIPAA requirements.²⁰
4. An HIE must verify the consumer's identity before an accounting of disclosures report is released to the consumer.
5. An HIE must acknowledge a consumer's request for an accounting of disclosures report within ten (10) business days of receipt of the request and provide the consumer with the accounting of disclosures report within thirty (30) business days of receiving a completed request.²¹ When a consumer requests additional information beyond what is provided in the accounting of disclosures report, an HIE will provide the additional information, if available, within a timely manner. If the additional information requested is not available from the HIE, an HIE must provide information to the consumer describing how to obtain such information.

¹⁹ A consumer is an individual or someone authorized to make decisions on their behalf.

²⁰ The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

²¹ A completed request is a request that has sufficient information to generate the summary accounting of disclosures report (as defined in HIPAA)



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6. An HIE shall provide consumers, upon request, with an accounting of disclosures report and a related more detailed report, if available, at no cost to the consumer at least twice every calendar year. An HIE may charge reasonable fees for any additional reports within the calendar year, at a charge that does not exceed the cost of providing the additional report(s).
7. An HIE will provide one or more mechanisms that will allow consumers to communicate to the HIE any perceived inappropriate access of their information through the HIE.

Procedure:

An HIE should implement procedures that are inclusive of the following:

1. An HIE should make clear and easily available as part of its outreach, education, and engagement strategy information about the consumer's right to request an accounting of disclosures report, the process for requesting the report, and the process for communicating to the HIE any perceived inappropriate access of their information through the HIE.
2. An HIE should provide a simple process for consumers to request an accounting of disclosures report that provides details regarding the information the consumer can receive and allows the individual to designate the time period to be reflected in the report.
3. In addition to the content of the accounting required by law²², an HIE should include in the accounting of disclosures report for each disclosure, if known:
 - a. A role description of the individual to whom the information was disclosed, including a brief patient friendly summary of the role;
 - b. The name of the participating organization that made the information available to the HIE;
 - c. The date and time the information was made available to the HIE; and
 - d. Any other information that might be helpful to the consumer.

²² As required under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Rule. Currently the CFR 164.528(b)(2) states that the content of the accounting must include: (i) The date of the disclosure; (ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person; (iii) A brief description of the protected health information disclosed; and (iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§164.502(a)(2)(ii) or 164.512, if any.



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4. In providing an accounting of disclosure report, an HIE may provide a consumer with a compilation of recurring administrative disclosures²³ to the same organization(s) or individual(s), instead of an item-by-item accounting of the disclosures. This summary should include, at the minimum, the following information:
 - a. The participating organization(s) and user(s) to whom the information was disclosed;
 - b. A description of the information disclosed;
 - c. The time span of the access; and
 - d. The number of times within the time span that the patient's information was accessed by the identified participating organization(s) and user(s).
5. An HIE should provide an accounting of disclosures report that is concise and uses plain language.
6. Consumers that present a reasonable belief to the HIE of inappropriate disclosures should be provided with an additional free report.
7. An HIE should provide a simple method for a consumer to communicate to the HIE any perceived inappropriate access of their information through the HIE. An HIE should immediately acknowledge receipt of the communication.

Associated Policies:

1. *Audit*
2. *Complaints*
3. *Consumer Choice*
4. *Consumer Outreach, Education & Engagement*
5. *Consumer Verification*
6. *Consumer Portals & Health Record Banks*
7. *Emergency Access for Participating Organizations*

²³ Administrative disclosures including health care operation and payment as defined in HIPAA



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8. *Enforcement*
9. *Primary Data Use and Disclosure*
10. *Participating Organization Access*
11. *Sensitive Health Information*
12. *Suspension and Reinstatement of Access*
13. *User Authorization*