

## **North Carolina Health Information Exchange Privacy and Security Policies**

### **Introduction**

The North Carolina Health Information Exchange (the “NC HIE”) is a not-for-profit organization that has established an electronic, statewide network (the “HIE Network”) to facilitate the exchange of health information among health care providers, health plans and other health industry stakeholders. The goal of the NC HIE is to assist health care organizations in improving the quality and controlling the cost of health care services through enhanced access to medical information and other clinical support.

The NC HIE is committed to health information exchange that is secure and private. Accordingly, the NC HIE has adopted these Privacy and Security Policies (“Policies”), which govern the use, disclosure and maintenance of health information available through the HIE Network. All individuals and entities that have access to health information through, or otherwise utilize, the HIE Network must agree to abide by these Policies.

These Policies are not designed to supersede any applicable state or federal laws or regulations, all of which continue to apply to any activities subject to these Policies. These Policies may be amended from time to time by the NC HIE Board of Directors.

These Policies are effective as of June 1, 2011.

## SECTION 1: DEFINITIONS

- 1.1 **Authorized User** means an employee or independent contractor of a Participant, or a credentialed member of a Participant's medical or other professional staff, who meets the criteria set forth in Section *[insert Authorization Section]* of the Policies and has been authorized by the Participant to be a user of the NC HIE Network.
- 1.2 **Business Associate** has the meaning ascribed to this term in 45 C.F.R. § 160.103.
- 1.3 **Business Associate Contract** means the written agreement required by 45 C.F.R. §§ 164.502(e) containing the terms set forth in 45 C.F.R. § 164.504(e).
- 1.4 **Covered Entity** has the meaning ascribed to this term in 45 C.F.R. § 160.103.
- 1.5 **De-identified Data** means information that does not identify an Individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an Individual.
- 1.6 **Designated IRB** means one or more institutional review boards or privacy boards constituted in accordance with 45 C.F.R. § 164.512(i)(1) that have been designated by the NC HIE Board of Directors to review and approve requests by researchers for access to Protected Health Information available through the HIE Network for Research.
- 1.7 **Disclose** or **Disclosure** means the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information.
- 1.8 **Emergency Medical Condition** means a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in (i) placing an Individual's health in serious jeopardy (ii) serious impairment to an Individual's bodily functions or (iii) serious dysfunction of any bodily organ or part of an Individual.
- 1.9 **Health Care Operations** means any of the following:
- 1.9.1 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.
- 1.9.2 Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, Health Plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.

- 1.9.3** Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of 45 C.F.R. § 164.514(g) are met, if applicable.
- 1.9.4** Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs.
- 1.9.5** Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies.
- 1.9.6** Business management and general administrative activities of the entity, including, but not limited to (i) management activities relating to implementation of and compliance with the requirements of HIPAA, (ii) customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that Protected Health Information is not disclosed to such policy holder, plan sponsor, or customer, (iii) resolution of internal grievances, (iv) the sale, transfer, merger, or consolidation of all or part of a Covered Entity with another Covered Entity, or an entity that following such activity will become a Covered Entity and due diligence related to such activity, and (v) consistent with the applicable requirements of 45 C.F.R. § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the Covered Entity.
- 1.10** **Health Plan** has the meaning ascribed to this term in 45 C.F.R. § 160.103.
- 1.11** **HIE Network** means the voluntary, statewide electronic health information exchange network overseen and administered by the NC HIE.
- 1.12** **HIPAA** means the Health Insurance Portability and Accountability Act of 1996, as amended, and the implementing regulations at 45 C.F.R. Parts 160-164.
- 1.13** **Individual** means the person who is the subject of Protected Health Information.
- 1.14** **NC HIE** means the nonprofit corporation selected by the Governor of North Carolina to serve as the sub-recipient of grant funds from or as the State-designated entity named by the State pursuant to Section 3013 of the federal Health Information Technology for Economic and Clinical Health Act of 2009.
- 1.15** **Opt Out** means the affirmative decision of an Individual or his or her Personal Representative to disallow the Individual's Protected Health Information maintained by or on behalf of one or more specific Participants from being disclosed to other Participants through the HIE Network.
- 1.16** **Opt Out Form** means the written or electronic document that records the decision by an Individual or his or her Personal Representative to Opt Out.

- 1.17 Opt Out Revocation Form** means the written or electronic document that records the decision by an Individual or his or her Personal Representative to revoke his or her decision to Opt Out.
- 1.18 Participant** means a Covered Entity, a Provider that is not a Covered Entity, a Business Associate of a Covered Entity or the North Carolina Division of Public Health that has entered into a Participation Agreement with the NC HIE or a Qualified Organization.
- 1.19 Participation Agreement** means the written agreement entered into by a Participant with the NC HIE or a Qualified Organization governing the Participant's use of the NC HIE Network.1/30/2012
- 1.20 Payment** means:
- 1.20.1** Subject to Section 1.20.2, the activities undertaken by: (i) a Health Plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or (ii) a health care provider or Health Plan to obtain or provide reimbursement for the provision of health care.
- 1.20.2** The activities in Section 1.20.1 must relate to the Individual to whom health care is provided and include, but are not limited to: (i) determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims; (ii) risk adjusting amounts due based on enrollee health status and demographic characteristics; (iii) billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing; (iv) review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; (v) utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and (vi) disclosure to consumer reporting agencies of any of the following Protected Health Information relating to collection of premiums or reimbursement: (A) name and address; (B) date of birth; (C) social security number; (D) payment history; (E) account number; and (F) name and address of the health care provider and/or Health Plan.
- 1.21 Personal Representative** is a person who is permitted to act on behalf of an Individual with respect to the Individual's Protected Health Information pursuant to 45 C.F.R. § 164.502(g).
- 1.22 Policies** means these North Carolina Health Information Exchange Privacy and Security Policies.
- 1.23 Protected Health Information** means information, including demographic information, collected from an Individual that: (1) is created or received by a health care provider, Health Plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an Individual; the provision of health care to an Individual; or the past, present, or future payment for the provision of health care to an Individual; and (i) that identifies the Individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the Individual. Notwithstanding the foregoing, Protected Health Information excludes (A) education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. §

1232g; (B) records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and (C) employment records held by a Covered Entity in its role as employer.

- 1.24 Provider** means (i) an entity such as a hospital, nursing home, home health agency, adult care home, mental health facility or professional corporation legally authorized to provide health care services in North Carolina, (ii) a health care professional referenced in N.C. General Statutes § 90-21.11 or a resident or student acting under the supervision of such a professional, (iii) a local health department as defined in N.C. General Statutes § 130A.-2 or (iv) mental health, developmental disabilities, and substance abuse facilities as referenced in N.C. General Statutes § 122C-3.
- 1.25 Psychotherapy Notes** means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the Individual’s medical record. Psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the Treatment plan, symptoms, prognosis, and progress to date.
- 1.26 Public Health** means the activities described in 45 C.F.R. § 164.512(b).
- 1.27 Public Health Authority** means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.
- 1.28 Qualified Organization** means an entity that has been designated by the Board of Directors of the NC HIE to contract with Participants on the NC HIE’s behalf to facilitate the participation of such Participants in the HIE Network.
- 1.29 Required by Law** means a mandate contained in law that compels an entity to make a use or Disclosure of Protected Health Information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
- 1.30 Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- 1.31 Substance Abuse Treatment Records** means the records of federally assisted drug or alcohol abuse treatment facilities and programs that are subject to protection under 42 C.F.R. Part 2.
- 1.32 Treatment** means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of

health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

- 1.33 Workforce** means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for an entity, is under the direct control of such entity, whether or not they are paid by such entity.

## SECTION 2: ELIGIBLE PARTICIPANTS

- 2.1 Restrictions on Use of HIE Network.** Except as specified in Sections 2.7, 6, 11 and 13, the NC HIE may permit only Participants and their Authorized Users to access or Disclose Protected Health Information through the HIE Network.
- 2.2 Covered Entities and Other Providers.** The following persons or entities are eligible to be Participants:
- 2.2.1** Any Covered Entity.
  - 2.2.2** Any Provider that is not a Covered Entity.
  - 2.2.3** Business Associates that are approved by the NC HIE under Section 2.3.
- 2.3 Business Associates.** A Business Associate of a Covered Entity is not eligible to be a Participant unless each of the following requirements is satisfied:
- 2.3.1** One or more Covered Entities that are Participants must notify the NC HIE in writing that the Business Associate has a compelling need to access or Disclose Protected Health Information through the HIE Network in order to effectively perform functions for the Covered Entity that fall within the scope of a Business Associate Contract between the Covered Entity and the Business Associate.
  - 2.3.2** The NC HIE determines, in its sole discretion, that the Business Associate has a compelling need to access or Disclose Protected Health Information through the HIE Network. A compelling need shall exist only if (i) the Business Associate is performing care coordination, care management, utilization review, quality improvement or other similar services designed to improve the quality or control the cost of health care services and (ii) the inability to use the NC HIE would serve as a substantial impediment to the effective performance of such services.
  - 2.3.3** The Business Associate provides evidence to the NC HIE that it maintains an office or facility in the United States and is authorized to do business in the State of North Carolina.
  - 2.3.4** The NC HIE determines, in its sole discretion, that the Business Associate has the capacity and commitment to maintain the privacy and security of Protected Health Information.
  - 2.3.5** The Business Associate satisfies any other eligibility criteria adopted by the NC HIE in its sole discretion.
- 2.4 Contractual Obligations.** Each Participant must enter into a Participation Agreement and Business Associate Contract with the NC HIE or a Qualified Organization prior to obtaining authorization to access or Disclose Protected Health Information through the HIE Network.

**2.5 Affiliates.** Entities that control one another or are under common control may elect to participate in the HIE Network as a single Participant or multiple Participants. One entity controls another entity if the first entity has the power to appoint a majority of the members of the second entity's governing body.

**2.6 Qualified Organizations.**

**2.6.1** The NC HIE may enter into agreements with Qualified Organizations under which Covered Entities and other Providers that have entered into a Participation Agreement with the Qualified Organization are eligible to be Participants. The agreement between the NC HIE and the Qualified Organization must authorize the NC HIE or its designees to conduct off-site and on-site audits of the Qualified Organization and its Participants to evaluate compliance with the Policies and any contractual obligations imposed by the NC HIE on the Qualified Organization. Such agreement must also require the Qualified Organization to abide by the Policies.

**2.6.2** The form of a Qualified Organization's Participation Agreement must be approved by the NC HIE.

**2.6.3** The NC HIE must enter into a Business Associate Contract with each Qualified Organization.

**2.7 Arrangements With Out-of-State Exchanges.**

**2.7.1** The NC HIE may enter into agreements with statewide, regional or local electronic health information exchanges operating outside the State of North Carolina under which Covered Entities or other health care providers participating in the exchange are granted the right to use the HIE Network.

**2.7.2** The NC HIE may enter into such agreements with only those out-of-state exchanges that are deemed by the NC HIE to maintain and enforce adequate privacy and security safeguards and policies. The NC HIE and the entity operating the out-of-state exchange must also enter into a Business Associate Contract.

**2.7.3** Entities operating out-of-state exchanges must agree to (i) abide by the Policies and (ii) require any Covered Entities or other health care providers that gain access to the HIE Network through the exchange to abide by the Policies, except as expressly set forth otherwise in the agreement between the exchange and the NC HIE. For example, application of the Policies may be waived by the NC HIE if the out-of-state exchange imposes more stringent requirements on its participants or a provision of the Policies is designed to comply with a North Carolina law to which an out-of-state entity is not subject.

**2.7.4** Out-of-state exchanges must authorize the NC HIE or its designees to conduct off-site and on-site audits of the exchange and its participants designed to evaluate compliance with the Policies and any contractual obligations imposed by the NC HIE on the exchange.

**2.7.5** The NC HIE is not required to directly enter into a Participation Agreement or Business Associate Contract with any Covered Entity or other health care provider that gains access to the HIE Network through an out-of-state exchange under this Section 2.7.

### **SECTION 3: ACCESS TO PROTECTED HEALTH INFORMATION FOR TREATMENT, PAYMENT AND HEALTH CARE OPERATIONS**

- 3.1 Purposes for Access.** Except as specified in Sections 11 and 13, Authorized Users may access Protected Health Information through the HIE Network only to carry out Treatment, Payment or Health Care Operations.
- 3.2 Need for Relationship With Individual.** An Authorized User may access an Individual's Protected Health Information through the HIE Network to carry out Treatment, Payment or Health Care Operations only in the following circumstances:
  - 3.2.1** The Authorized User has obtained access to the HIE Network through a Participant that is a Provider and the Provider has a Treatment relationship with the Individual.
  - 3.2.2** The Authorized User has obtained access to the HIE Network through a Participant that is a Health Plan and the Individual is receiving or has received health benefits from the Health Plan.

## SECTION 4: MINIMUM NECESSARY REQUIREMENT

- 4.1 Obligations of Authorized Users.** Subject to Section 4.2, Authorized Users must make reasonable efforts to access and use only the minimum amount of Protected Health Information available through the HIE Network that is necessary to carry out the authorized purpose for which such Protected Health Information is accessed or used.
- 4.2 Treatment Exception.** The obligations set forth in this Section 4 do not apply to the access to or use of Protected Health Information by a Provider for Treatment.
- 4.3 Reliance on Access Requests.** A Participant making a Disclosure of Protected Health Information through the HIE Network may rely on compliance with this Section 4 by Participants accessing Protected Health Information through the HIE Network. A Participant making such a Disclosure is not required to take any additional steps to restrict the availability of its own Protected Health Information through the HIE Network, except as expressly required by other provisions of the Policies or applicable law.
- 4.4 Minimum Necessary Policies and Criteria.** Each Participant must establish protocols designed to limit the amount of Protected Health Information accessed by its Authorized Users for recurring and routine purposes to the amount necessary to carry out the authorized purpose. Each Participant must establish criteria governing the amount of Protected Health Information accessed by its Authorized Users for other purposes that are designed to limit such access to the amount of Protected Health Information necessary to carry out the authorized purpose.
- 4.5 Record Searches.** When searching any master patient index, record locator service or other similar system made available by the NC HIE to locate records about an Individual through the HIE Network, an Authorized User must follow any search guidelines established by the NC HIE and make reasonable efforts to minimize instances in which the Protected Health Information of the wrong Individual is inadvertently accessed by the Authorized User.

## SECTION 5: EMERGENCY ACCESS

- 5.1 Standards for Emergency Access.** Authorized Users may access Protected Health Information maintained by Participants about an Individual who has exercised his or her right to Opt Out of Disclosures by such Participants if all of the following requirements are satisfied:
- 5.1.1** The reasonably apparent circumstances indicate to the Authorized User that (i) the Individual has an Emergency Medical Condition; (ii) a meaningful discussion with the Individual or his or her Personal Representative about whether to rescind a previous decision to Opt Out is impractical due to the nature of the Individual's Emergency Medical Condition; and (iii) information available through the HIE Network could assist in the diagnosis or Treatment of the Individual's Emergency Medical Condition.
  - 5.1.2** The Authorized User obtains access to the HIE Network through a Provider that is treating or diagnosing the Individual's Emergency Medical Condition.
  - 5.1.3** The Authorized User is involved in providing or arranging for the diagnosis or Treatment of the Individual's Emergency Medical Condition.
- 5.2 Attestation.** The NC HIE shall ensure that the Protected Health Information of Individuals who have exercised their right to Opt Out is not accessible to Authorized Users under this Section 5 unless the Authorized User seeking such access provides an attestation electronically through the HIE Network at the time he or she requests access stating that all of the conditions specified in Section 5.1 are satisfied. All such attestations shall be stored electronically by the NC HIE for a period of at least six years.
- 5.3 Termination of Emergency Access.** Authorized Users shall cease emergency access of an Individual's Protected Health Information under this Section 5 promptly upon (i) stabilization of the Individual's Emergency Medical Condition or (ii) a request by the Individual or his or her Personal Representative to cease such access.
- 5.4 Audit Trail.** The NC HIE shall conduct periodic audits to evaluate whether Authorized Users are engaging in emergency access of Protected Health Information through the HIE Network in accordance with this Section 5. The NC HIE may delegate the responsibility for conducting such audits to Participants, Qualified Organizations or other parties if (i) the NC HIE approves the audit protocols used by the Participant, Qualified Organization or other party for each audit and (ii) the results of each audit are provided in writing to the NC HIE. All audit findings must be maintained by the NC HIE for a period of six years.

## SECTION 6: ACCESS RIGHTS OF NC HIE WORKFORCE

- 6.1 Authorized Purposes.** The NC HIE may authorize its own Workforce to access Protected Health Information through the HIE Network only to the extent consistent with the terms of the NC HIE's Business Associate Contracts with Participants and only for one or more of the following purposes:
- 6.1.1 To facilitate the Disclosure of Protected Health Information to Participants or for Research or Public Health purposes as permitted by the Policies.
  - 6.1.2 To process or otherwise implement Opt Out requests.
  - 6.1.3 To perform patient identity or patient records maintenance.
  - 6.1.4 To create De-identified Data in accordance with Section 10.
  - 6.1.5 To conduct or assist in the performance of audits permitted or required by the Policies, including audits of Emergency Access required by Section 5.
  - 6.1.6 To perform data analysis on behalf of and at the request of one or more Participants, to the extent consistent with HIPAA and the Policies.
  - 6.1.7 To evaluate the performance of or develop recommendations for improving the operation of the HIE Network.
  - 6.1.8 To conduct technical system support and maintenance on the HIE Network.
  - 6.1.9 To engage in any other activities reasonably related to the operation of the HIE Network. that are authorized by the NC HIE Board of Directors and are consistent with applicable law.
- 6.2 Role-Based Access.** The NC HIE shall establish role-based access standards reasonably designed to enable each Workforce member to access only such Protected Health Information that is necessary for the performance of his or her authorized activities. These standards shall ensure that NC HIE Workforce members access and use only the minimum necessary amount of Protected Health Information reasonably required to carry out the authorized purpose.
- 6.3 Training.** No NC HIE Workforce member may access Protected Health Information through the HIE Network unless the Workforce member has received training regarding the Policies and acknowledged in writing the receipt thereof.
- 6.4 Discipline for Non-Compliance.** The NC HIE shall discipline Workforce members who violate the Policies or engage in any other unauthorized or inappropriate behavior that undermines the privacy or security of Protected Health Information available through the HIE Network. Depending on the circumstances, disciplinary measures may include verbal and written warnings, retraining, demotion, suspension or termination of employment.

- 6.5 Reporting and Non-Retaliation.** The NC HIE shall require all Workforce members to report any actual or suspected violation of the Policies of which they become aware. No Workforce member may be subject to retaliation of any kind for reporting a violation in good faith.
- 6.6 Business Associates.** The NC HIE may authorize its own Business Associates to access Protected Health Information for a purpose that is consistent with Section 6.1, provided the NC HIE has entered into a Business Associate Contract with the Business Associate. Such Business Associates may include, but are not limited to, Qualified Organizations.

## **SECTION 7: OPT OUT RIGHTS**

**7.1 Right of Individuals to Opt Out.** An Individual may elect to Opt Out at any time. An Individual may Opt Out of having the NC HIE Disclose (i) the Individual's Protected Health Information obtained through the HIE Network from all Participants or (ii) the Individual's Protected Health Information obtained through the HIE Network from those Participants the Individual lists on the Opt Out Form. A Personal Representative may Opt Out on behalf of an Individual.

**7.2 Use of Opt Out Form.** The NC HIE shall develop an Opt Out Form to facilitate an individual's decision to Opt Out. The Opt Out Form may be amended by the NC HIE from time to time with the approval of the NC HIE Board of Directors.

### **7.3 Contents of Opt Out Form.**

#### **7.3.1 The Opt Out Form shall include the following information:**

- a. A notice that Participants are authorized to Disclose an Individual's Protected Health Information through the HIE Network unless and until the Individual elects to Opt Out by completing and submitting the Opt Out Form.
- b. A notice that an Individual's decision to Opt Out will not prevent Participants from Disclosing an Individual's Protected Health Information through the HIE Network for Public Health or Research purposes.
- c. A notice that an Individual's decision to Opt Out will not affect the Individual's right to receive health care services or benefits from Participants.
- d. **An explanation of:**
  - i. The purpose and basic functions of the HIE Network.
  - ii. The types of Protected Health Information that are exchanged through the HIE Network.
  - iii. The types of Participants that may Disclose and access Protected Health Information through the HIE Network.
  - iv. The purposes for which Protected Health Information is exchanged through the HIE Network.
  - v. **The effect of a decision to Opt Out on Providers' access to Protected Health Information to treat an Emergency Medical Condition.**
  - vi. How to submit an Opt Out Form.
  - vii. Where to obtain additional information about the HIE Network.

**7.3.2** The Opt Out Form shall contain the following elements:

- a. A field in which the Individual may specify the Participants that are being restricted from Disclosing the Individual's Protected Health Information through the HIE Network.
- b. A field in which the Individual may indicate that he or she is electing to prohibit all Participants from Disclosing his or her Protected Health Information through the HIE Network.

**7.3.3** The Opt Out Form shall include the demographic information determined by the NC HIE Board to be necessary for accurate matching of Individuals in the HIE Network.

#### **7.4 Processing of Opt Out Requests by NC HIE.**

**7.4.1** The NC HIE shall post the Opt Out Form prominently on its website. The NC HIE shall permit Individuals or their Personal Representatives to complete and submit the Opt Out Form by mail or electronically through such website.

**7.4.2** The NC HIE shall operate a toll-free telephone line to receive calls from Individuals about Opt Out requests. A log of all calls on the telephone line shall be maintained by the NC HIE for a period of six years. Upon request, NC HIE staff receiving such calls shall assist Individuals in completing Opt Out Forms. If a paper Opt Out Form is completed by NC HIE staff over the telephone, the NC HIE shall mail the Opt Out Form to the Individual for his or her signature. The Individual shall be required to mail the signed Opt Out Form to the NC HIE.

**7.4.3** Upon receipt of an Opt Out Form through its website or by mail, the NC HIE shall transmit a letter confirming the Individual's decision to Opt Out to the mailing address provided in the Opt Out Form. The letter shall direct the Individual to contact the NC HIE if the Opt Out Form was submitted in error or if the Individual would like to revoke his or her decision to Opt Out. The NC HIE shall maintain records of all Opt Outs for six years.

**7.4.4** The NC HIE shall prepare an educational brochure explaining the purpose of the HIE Network and the nature of its activities. The brochure shall include an Opt Out Form as a tear-off page or in another format deemed appropriate by the NC HIE. The brochure shall indicate how the Opt Out Form may be submitted to the NC HIE and will include the NC HIE's toll-free telephone number. The NC HIE shall distribute sufficient copies of the brochure to all Participants.

#### **7.5 Distribution of Opt Out Forms by Participants.**

**7.5.1** All Provider Participants that provide face-to-face Treatment to Individuals shall make the brochure prepared by the NC HIE under Section 7.4.4 available in their offices or facilities upon request. Such Provider Participants shall offer the brochure to each Individual at the first face-to-face encounter with the Individual after the brochure becomes available. Notwithstanding the foregoing, Provider Participants that do not Disclose Protected Health Information through the HIE Network without an Individual's written authorization are not obligated to comply with this Section 7.5.1.

- 7.5.2 All Health Plan Participants shall include a copy of the brochure prepared by the NC HIE under Section 7.4.4 in their enrollment and renewal materials, if any.
- 7.5.3 Nothing in this Section 7.5 shall be construed as requiring a Participant to collect Opt Out Forms from Individuals or transmit Opt Out Forms to the NC HIE.
- 7.6 Implementation of Opt Outs.** The NC HIE shall employ technical measures to prevent the Disclosure of any Protected Health Information through the HIE Network that is subject to an Opt Out. Such measures shall be implemented within two business days of the completion of the Opt Out verification process described in this Section 7. **Notwithstanding the foregoing, the NC HIE may permit Protected Health Information subject to an Opt Out to be Disclosed through the HIE Network to provide Treatment for a Medical Emergency Condition in accordance with Section 5, for Research in accordance with Section 11 or for Public Health in accordance with Section 13.**
- 7.7 Opt Out Revocation Process.**
- 7.7.1 An Individual or his or her Personal Representative may revoke his or her decision to Opt Out at any time.
- 7.7.2 The NC HIE shall develop an Opt Out Revocation Form. The submission of an Opt Out Revocation Form in accordance with this Section 7 shall be the sole means by which an Individual may revoke his or her decision to Opt Out. No Participant shall use any other mechanism to revoke an Individual's decision to Opt Out. The Opt Out Revocation Form may be amended by the NC HIE from time to time with the approval of the NC HIE Board of Directors.
- 7.7.3 The Opt Out Revocation Form shall include the elements relating to the Individual included in Section 7.3.3 and shall be distributed and collected according to the methods set forth in Section 7.4.
- 7.8 Maintenance of Protected Health Information in HIE Network.** A Participant may maintain a copy of its Protected Health Information in a computer system operated by the NC HIE or a Qualified Organization without regard to whether an Individual has elected to Opt Out.
- 7.9 Restrictions on the Disclosure of Certain Information.** If Protected Health Information is not subject to an Opt Out, such information may be Disclosed through the NC HIE for any purpose permitted by the Policies, except that Participants shall not include Psychotherapy Notes, Substance Abuse Treatment Records, or other information that may not be Disclosed without a patient's authorization under federal law in the Protected Health Information made available through the HIE Network unless (i) the Individual or his or her Personal Representative has signed an authorization form that complies with applicable law permitting the Disclosure of such information and (ii) the information is identified in the HIE System as subject to restrictions on re-disclosure absent additional authorization.
- 7.10 Education and Awareness.** The NC HIE shall engage in public awareness activities deemed appropriate by the NC HIE to educate North Carolina residents about the NC HIE, including the right of Individuals and their Personal Representatives to Opt Out.

## **SECTION 8: RESTRICTIONS ON ACCESS BY HEALTH PLANS**

- 8.1 Acceptance of Restriction Requests by Providers.** All Providers must have a process for accepting written requests by Individuals or their Personal Representatives that Protected Health Information relating to the Individual's receipt of a particular health care item or service from the Provider not be Disclosed by the Provider to a Health Plan for Payment or Health Care Operations. Providers are obligated to grant such requests if the Individual or his or her Personal Representative agrees to pay the Provider in full for the health care items or services subject to such restriction.
- 8.2 Notifying the NC HIE of Restriction Requests.** Providers agreeing to restriction requests under Section 8.1 must notify the NC HIE of all such restrictions in a manner and time period that will enable the NC HIE to implement the restriction in accordance with 45 C.F.R. § 164.522. Notification may be provided in either of the following ways:
- 8.2.1** The Provider may electronically tag, segregate or otherwise identify the records subject to the restriction request in its electronic health record system in accordance with technical standards approved by the NC HIE designed to ensure that such records are not Disclosed to Health Plans through the HIE Network.
- 8.2.2** The Provider may notify the NC HIE of the restriction in writing or by electronic mail in accordance with procedures adopted by the NC HIE.
- 8.3 Implementation of Restrictions on Disclosures to a Health Plan.** The NC HIE shall employ technical measures to implement the restrictions transmitted by Providers under Section 8.2. These measures shall ensure that any Protected Health Information subject to a restriction is not accessible to any Health Plan through the HIE Network.

## SECTION 9: ACCOUNTINGS OF DISCLOSURES

- 9.1 Tracking of Disclosures by the NC HIE.** The NC HIE shall ensure that the HIE Network has the capacity to track all Disclosures of each Participant's Protected Health Information made through the HIE Network. Disclosures shall be tracked in accordance with the following standards:
- 9.1.1** If the Disclosure is from one Participant to another Participant for Treatment, Payment or Health Care Operations, a record of the Disclosure must be maintained by the NC HIE for three years from the date of the Disclosure. The information tracked for each such Disclosure shall be sufficient to enable a Participant to provide an accounting to the Individual that complies with HIPAA.
- 9.1.2** If the Disclosure is from the NC HIE to another party for Public Health, Research or any other purpose permitted by the Policies, a record of the Disclosure must be maintained by the NC HIE for six years from the date of the Disclosure. The information tracked for each such Disclosure shall include:
- a. The date of the Disclosure;
  - b. The name of the entity or person who received the Protected Health Information and, if known, the address of such entity or person;
  - c. A brief description of the Protected Health Information disclosed; and
  - d. A brief statement of the purpose of the Disclosure that reasonably informs the Individual of the basis for the Disclosure.
- 9.1.3** If the NC HIE Discloses the Protected Health Information of 50 or more Individuals for Research, the information tracked shall be sufficient to enable a Participant to provide an accounting to the Individual that includes:
- a. The name of the protocol or other Research activity.
  - b. A description, in plain language, of the Research protocol or other Research activity, including the purpose of the Research and the criteria for selecting particular records.
  - c. A brief description of the type of Protected Health Information that was Disclosed.
  - d. The date or period of time during which such Disclosures occurred, or may have occurred, including the date of the last such Disclosure during the accounting period.
  - e. The name, address, and telephone number of the entity that sponsored the Research and of the researcher to whom the information was Disclosed.

- f. A statement that the Protected Health Information of the Individual may or may not have been Disclosed for a particular protocol or other Research activity.

## 9.2 Requests for Accountings by Participants.

- 9.2.1 A Participant may request that the NC HIE provide the Participant with an accounting of Disclosures of an Individual's Protected Health Information made through the HIE Network to enable the Participant to respond to a request for an accounting by the Individual or his or her Personal Representative under HIPAA. Participants must make such requests in accordance with procedures and utilizing forms adopted by the NC HIE.
  - 9.2.2 The NC HIE shall be obligated to provide an accounting of those Disclosures made through the HIE Network within the following time periods:
    - a. If the Disclosure is from one Participant to another Participant for Treatment, Payment or Health Care Operations, the accounting must include at least those Disclosures made during the three year period immediately preceding the date of the Individual's request.
    - b. If the Disclosure is from the NC HIE to another party for Public Health, Research or any other purpose permitted by the Policies, the accounting must include at least those Disclosures made during the six year period immediately preceding the date of the Individual's request.
  - 9.2.3 The NC HIE shall respond to all requests for accountings by Participants within 30 days of the NC HIE's receipt of the request. The NC HIE's response shall include, for each Disclosure for which an accounting must be provided, all of the information the NC HIE is obligated to track under Section 9.1.
- 9.4. **9.3 Accounting Requests by Individual.** Upon the receipt of accounting requests from individuals or their Personal Representatives, the NCHIE shall forward the request to all Participants whose Protected Health Information is subject to the request and notify the Individual or Personal Representative that such Participants will be preparing a response. In those cases where Individuals or Personal Representatives prefer not to receive a response from the Participants, the NCHIE Management will establish guidelines under which Individuals or Personal Representatives can request accounting information directly from the NCHIE. **Exemption from Accounting Requirement.** The NC HIE shall not be responsible for tracking or providing Participants with an accounting of any Disclosures exempt from the HIPAA accounting requirement under 45 C.F.R. § 164.528 (a)(ii)-(ix).

## SECTION 10: DE-IDENTIFIED DATA

- 10.1 Creation of De-Identified Data.** The NC HIE, through its Workforce or Business Associates, may access Protected Health Information through the HIE Network to create De-Identified Data in accordance with this Section 10.
- 10.2 Standards for De-Identification.** Data will be deemed De-identified Data only if one of the following standards is satisfied:
- 10.2.1** A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and rendering information not individually identifiable determines that the that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information. The methods and results of the analysis that justify such determination must be documented.
- 10.2.2** The following identifiers are removed from the data:
- a. Names;
  - b. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census (1) the geographic units formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
  - c. All elements of dates (except year) for dates directly related to the individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
  - d. Telephone numbers;
  - e. Fax numbers;
  - f. Electronic mail addresses;
  - g. Social security numbers;
  - h. Medical record numbers;
  - i. Health plan beneficiary numbers;
  - j. Account numbers;
  - k. Certificate/license numbers;

- l. Vehicle identifiers and serial numbers, including license plate numbers;
- m. Device identifiers and serial numbers;
- n. Web Universal Resource Locators;
- o. Internet Protocol address numbers;
- p. Biometric identifiers, including finger and voice prints;
- q. Full face photographic images and any comparable images; and
- r. Any other unique identifying number, characteristic, or code, except as permitted for re-identification purposes provided certain conditions are met, as set forth under HIPAA.

**10.2.3** Notwithstanding Sections 10.2.1 and 10.2.2, information will not be deemed De-identified Data if the NC HIE has actual knowledge that the information could be used, alone or in combination with other information, to identify an Individual who is a subject of the information.

**10.3 Re-identification.** The NC HIE Board of Directors shall develop guidelines that specify when the NC HIE will assign a code or employ other means of record identification to allow De-identified Data to be re-identified in the event appropriate for clinical or other valid purposes. If such a code is assigned or other means of record identification is established:

**10.3.1** The code or other means of record identification must not be derived from or related to information about the Individual and may not otherwise be capable of being translated so as to identify the Individual; and

**10.3.2** The NC HIE may not use or disclose the code or other means of record identification for any other purpose, and may not disclose the mechanism for re-identification.

**10.4 Uses of De-identified Data.** The NC HIE may use or make available to other parties De-identified Data for any purpose approved by the NC HIE Board of Directors. The NC HIE Board of Directors may authorize the NC HIE to charge a fee to Participants or other parties requesting De-identified Data to the extent consistent with applicable law. No Participant shall have the right to restrict the NC HIE's use or transmission of De-identified Data.

## SECTION 11: ACCESS TO DATA FOR RESEARCH

- 11.1 Requirements for Disclosure for Research.** The NC HIE may Disclose Protected Health Information to appropriately qualified researchers for Research if one of the following requirements is satisfied:
- 11.1.1** All Individuals whose Protected Health Information is being Disclosed have signed a written authorization for the Disclosure that complies with HIPAA.
  - 11.1.2** The Research has been approved by a Designated IRB, which has waived the requirement of obtaining Individuals' authorization for the Disclosure in accordance with 45 C.F.R. § 512(i)(2).
  - 11.1.3** The Protected Health Information is limited to that of decedents, the deaths of the relevant Individuals have been documented by the researcher requesting the information and the researcher represents to the NC HIE in writing that the information is necessary for Research.
  - 11.1.4** The Protected Health Information requested constitutes a limited data set, as defined at 45 C.F.R. § 164.514(e), and a data use agreement, as described under 45 C.F.R. § 164.514(e), has been executed by the researcher and the NC HIE.
- 11.2 Appointment of Designated IRB.** The NC HIE shall enter into a written agreement with each Designated IRB to carry out the functions contemplated by this Section 11. Such agreement shall ensure that the Designated IRB performs its obligations in accordance with 45 C.F.R. §164.512(i).
- 11.3 Minimum Necessary.** Except for Research carried out pursuant to Section 11.11.1, the NC HIE shall Disclose only the minimum necessary Protected Health Information for the permitted Research purpose.
- 11.4 Verification.** The NC HIE shall verify the identity and authority of any researcher requesting access to Protected Health Information for Research prior to Disclosing such information to the researcher.
- 11.5 Accounting.** The NC HIE shall maintain a record of all Disclosures for Research in accordance with Section 9.1.2 of the Policies.
- 11.6 Fees.** The NC HIE may charge fees to researchers seeking access to Protected Health Information available through the HIE Network, provided that such fees must be reasonably related to the costs incurred by the NC HIE in connection with reviewing and complying with the Research request, including but not limited to, the cost of review by a Designated IRB.

## **SECTION 12: RESPONDING TO SUBPOENAS AND DISCOVERY REQUESTS**

- 12.1 Disclosures In Response to Court Orders.** The NC HIE may Disclose Protected Health Information in its possession in response to a court order provided the NC HIE Discloses only the Protected Health Information expressly authorized by such order.
- 12.2 Disclosures in Response to Subpoenas and Discovery Requests.**
- 12.2.1** Subject to Section 12.3, the NC HIE may Disclose Protected Health Information in its possession in response to a subpoena, discovery request or other lawful process that is not accompanied by an order of a court only if the subpoena, discovery request or other lawful process is accompanied by a written authorization from the Individual who is the subject of the requested Protected Health Information.
- 12.2.2** The NC HIE shall respond to subpoenas, discovery requests or other lawful processes that do not satisfy the requirements of Section 12.1 or 12.2.1 by transmitting a written objection to the party requesting the Protected Health Information setting forth the need for either a court order or a written authorization from the Individual in connection with such request.
- 12.3 Opportunity for Participants to Resist Request.** The NC HIE shall notify all Participants whose Protected Health Information is subject to a potential Disclosure under Section 12.2 of the NC HIE's intention to make the Disclosure no less than five days prior to the anticipated date of the Disclosure. The NC HIE shall not Disclose any Participant's Protected Health Information if (i) the Participant notifies the NC HIE within such five-day period of the Participant's intention to move to quash the subpoena or otherwise resist the request and (ii) the Participant takes such action within the time period necessary to prevent the NC HIE from failing to comply with any legal duty to which it is subject. The NC HIE shall not make any Disclosure under this Section 12 to the extent any request for Protected Health Information is withdrawn by the requesting party or rejected by a court or administrative tribunal in response to an objection by a Participant.
- 12.4 No Obligation to Search Participant Records.** Under this Section 12, the NC HIE shall Disclose only those records under its custody and control. The NC HIE shall not Disclose any records the NC HIE may be capable of obtaining by conducting searches through the HIE Network of the records maintained by Participants or Qualified Organizations in their own record systems.
- 12.5 Consultation With Counsel.** The NC HIE shall consult with its counsel regarding its authority to Disclose Protected Health Information under this Section 12 prior to making any such Disclosure.
- 12.6 Minimum Necessary.** The NC HIE shall Disclose only the minimum necessary Protected Health Information in response to requests covered by this Section 12.
- 12.7 Verification of Identity.** The NC HIE shall verify the identity and authority of the requesting party prior to Disclosing Protected Health Information under this Section 12.
- 12.8 Accounting of Disclosures.** The NC HIE shall maintain a record of Disclosures made under this Section 12 in accordance with Section 9.1.2 of the Policies.

## SECTION 13: ACCESS TO DATA BY GOVERNMENT AGENCIES

- 13.1 Disclosures Required by Law.** The NC HIE may Disclose Protected Health Information to a government agency or its representatives or agents when the Disclosure is Required by Law. Nothing in this Section 13.1 shall be construed as obligating the NC HIE to Disclose Protected Health Information to a government agency on behalf of a Participant when the Participant, rather than the NC HIE, is Required by Law to make the Disclosure.
- 13.2 Disclosures for Public Health Purposes.** The NC HIE may Disclose Protected Health Information to Public Health Authorities for Public Health purposes. The NC HIE Board of Directors shall approve the general types of Public Health purposes for which Protected Health Information may be Disclosed under this Section 13.2.
- 13.3 Minimum Necessary.** The NC HIE shall Disclose only the minimum necessary Protected Health Information for the purposes specified in Section 13.1 or 13.2. The NC HIE may rely on a public health official's or other government official's determination that the information requested represents the minimum necessary for the requested purpose.
- 13.4 Verification.** The NC HIE shall verify the identity and authority of the representative or agent of the government agency making the request prior to Disclosing Protected Health Information for the purposes specified in Section 13.1 or 13.2.
- 13.5 Accounting of Disclosures.** The NC HIE shall maintain a record of Disclosures made under Section 13.1 or 13.2 in accordance with Section 9.1.2 of the Policies.
- 13.6 Participant Notification.** Except as restricted by applicable law, the NC HIE shall promptly notify Participants whose Protected Health Information has been Disclosed by the NC HIE under Section 13.1.
- 13.7 Other Disclosures Not Permissible.** The NC HIE shall not Disclose Protected Health Information to government agencies or their representatives or agents for any purpose not permitted by this Section 13 or another provision of the Policies.