

Northern Berkshire eHealth Collaborative

Policy: Consent to Release Information to the eHealth Summary

Approved by: The Northern Berkshire eHealth Steering Committee

Date: July 11, 2006

Description:

In order to satisfy applicable Massachusetts regulatory requirements surrounding disclosure of certain classes of clinical information, this policy outlines the procedures, documents and technology solutions that will be used in this regard.

Coded (tagged) elements will be developed for the following lists in the master files (dictionaries) within the eClinicalWorks system. These tagged elements will determine the information that will become part of the shared medical records, the 'eHealth Summary'. The intent is to provide the appropriate levels of consent for disclosure, while still maintaining a robust set of clinical content in the eHealth Summary with the goal creating the opportunity for as high quality of care possible in the community. This list is derived from the Contents of the eHealth Summary from the Northern Berkshire eHealth Steering Committee documents;

- Medications
- Laboratory Results
- Radiology Results
- Family History – Certain Elements
- Medical History – Certain Elements
- Diagnoses (ICD-9)
- Procedures (CPT / HCPCS)
 - o Medical
 - o Surgical

The following levels of data element 'tagging' will be used to delineate the type of consent required for 'disclosure' based on our interpretation of the Massachusetts law.

Level 0 (zero): These data elements do not flow to the eHealth Summary. These may have been added to a dictionary or list 'on the fly' by a clinician and requires clinical review for determination if appropriate for the eHealth Summary and assignment of the appropriate consent level (see below). This is the default tagging if a data element is

added ‘on the fly’ by a clinician, since the element must be reviewed before it can be determined what level of consent is required to release the element.

Note: Tagged elements can be listed (in the eCW software) with a separate font or color in the pick list, so that it is clear to clinicians which elements flow to the eHealth Summary.

Blank (Not a tagged data element): These do flow to the eHealth Summary with a blanket (opt-in) consent signed by the patient. Generally, these include those data elements **not** considered ‘highly sensitive’ by state law plus those data elements considered ‘OK to flow to the eHealth Summary’ with the blanket consent.

Categories of data elements included: All except those specified below (in Level 1), including; Mental Health, Infectious & Venereal Disease, Abortion, Child abuse, Domestic Abuse/Sexual Assault, Mammography, Research involving controlled substances, Alcohol & Drug Abuse.

Implications: For these elements to be available in the eHealth Summary we must have a general consent with a disclaimer to the patient (either on the consent form or in supporting literature), indicating the categories of ‘sensitive’ elements. Once signed, the consent form will be scanned and kept as a part of the patient’s permanent record (eHealth Summary). This level represents the base level of consent for all patients in the Community.

Additional consideration: For this level of consent it will be incumbent on our clinical staff to be aware of the general categories of conditions considered ‘sensitive.’ Although providers are not legally required to re-affirm patients’ consent in the event of a new diagnosis (including of ‘sensitive’ conditions listed above), providers are encouraged to use their discretion about what is appropriate for patients. Education and guidance will be provided to our clinical staff concerning this process.

Level 1 (one) – Includes those data elements tagged as OK to flow to the eHealth Summary, **ONLY** with per-event consent from the patient at the time of occurrence.

Categories of elements: HIV/AIDS and Genetic Testing Results for Screening Purposes

Implications: For these elements to be submitted to the eHealth Summary, the community must have a mechanism for real-time consent from the patient at the time of occurrence. This will involve a pop-up window that the provider would ask the patient to sign, for consent to release information to the eHealth Summary that includes any of Level 1 elements. If a patient does not consent to disclose these elements, then the item (test or result) will not flow to the eHealth Summary. This per event consent will **not** affect any

other consent the patient may have provided with respect to the general consent described above.

Implications:

- 1) As results return to the ordering provider, from the laboratory information system, they will be ‘matched’ to the EHR’s dictionary of terms (lab tests in this case) and if the corresponding test in the eCW data dictionary is tagged as a Level 1 element, the result will not automatically flow to the eHealth Summary, but rather it will be ‘quarantined’ in the ordering physician’s inbox awaiting a signed consent from the patient. As counseling occurs between the provider and the patient, or at a convenient point in time, the provider will ask the patient for consent to release these elements to the eHealth Summary. If consent is denied by the patient, the item will then be removed from the inbox and it will not flow to the eHealth Summary. The result(s) will be available in the physician’s private EHR records only from that point forward, for this occurrence of the test & results.

Level 1 Elements Specific Policies

- 1) We will ‘interpret’ the legislative meaning of ‘HIV Results’ to be slightly broader than just the test result itself. We may include specific medications that are only used for positive HIV patients. We may also include in this definition, the elements of the Problem List (for example) that specifically identify a person with HIV or for any diagnosis codes and other elements that specifically identify this condition. Other ‘related’ problems or conditions that do not explicitly disclose the results of an HIV test will not be considered in this category. A clinical review committee, representing the community, will make the determinations regarding the elements to be considered ‘HIV specific’ or ‘Genetic Tests’.
- 2) The category ‘Genetic Testing Results’ is very broad and tagging as Level 1 will occur for all ‘Tests’ associated with Genetic Testing of any kind to require per occurrence consent to disclose by the patient. Each ‘Test’ associated with the category “Genetic Test”, requires a separate consent to disclose the results. We will, therefore be required to prompt the provider, and they will subsequently be required to ask the patient for consent to disclose these results for each occurrence of the tests & results.
 - a. Technical Requirement: There may be several elements tagged as Level 1 in the encounter for the patient, including Problems, Medications, Diagnoses, Tests, etc., which are ‘related’ to HIV or Genetic Tests. When consent is given it is for the HIV or Genetic Test result so we will need the ability to ‘link’ or ‘relate’ the other Level 1 data elements to the ‘Test’ that requires the consent so that when consent is given it will trigger the release of the other ‘related’ elements, in addition to the test result itself. Before closing the office note, the eCW system should ‘loop’ through all Level 1 Tests that are ordered for the encounter, then prompt the provider to ‘link’, via a checkbox method, the other (non-Tests) Level 1 elements indicated in the encounter documentation. These may include; Problems, Medications, Diagnoses, etc., that are ‘related’ to the test, so when the consent to disclose to the eHealth Summary is given, the test results as well as the ‘related’ level 1 data elements can be released to the electronic community record (eHealth Summary).

Global Policies & Procedures

- 1) All 'results', reports or other tagged elements, whether they are laboratory, radiological or other types must pass through the ordering or covering physician's inbox for review, prior to being 'disclosed' to the eHealth Summary. Once the physician reviews the result and 'signs' them then they can be disclosed to the eHealth Summary, assuming the appropriate levels of consent have been met.
 - a. Technical Requirement: It must be possible to 'match' a lab result returning to the EHR from the LIS to its corresponding entry in the eCW data dictionary for the identification of all Level 0 and Level 1 Tests and other results as applicable. Once identified, these results, and their 'related' Level 1 data elements (see Level 1 above), must be able to be 'quarantined' in the ordering physician inbox for later consent to disclose by the patient.
 - b. Technical Requirement: The patient's signature for consent to release Level 1 elements must be kept with the encounter record indefinitely for proof of consent to disclose, with the corresponding date, location and time the consent was given.

- 2) We will periodically refresh the global consent for all patients every 24 months. We will not seek re-consent of patients that are not scheduled for an appointment with the practice. As patients are seen, after the 24-month period we will trigger a reminder for re-consent at the registration desk.
 - a. Technical Requirement: The system must track the last date of 'global consent' and 'trigger re-consent to be required by the next appointment after the 24 month interval has expired.