

POLICIES AND PROCEDURES
TOPIC: Patient Consent - General
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I. BACKGROUND AND PURPOSE

The purpose of this policy is to describe how the Consent decision of Patients to participate or not participate in the WVHIN’s Health Information Exchange can be meaningfully exercised. The policy will also describe how that Consent decision may be subsequently changed by Patients.

II. POLICY

The WVHIN will offer all Patients a meaningful way to decide whether to participate or not participate in the Health Information Exchange that it sponsors. This Patient Consent process will be governed by an Opt-Out policy. This means that all Patients of a Data Supplier or a Full Service Participating Organization will be automatically enrolled in the WVHIN’s Health Information Exchange, and no affirmative action needs to be taken by a Patient to establish his or her Consent. A Patient shall be deemed to have given his or her Consent to participate until and unless the Patient affirmatively Opts-Out of the WVHIN’s Health Information Exchange.

To ensure that Patients are able to make an informed choice, each Patient will receive a written Patient Notice from his or her Participating Organization during the first Patient encounter after the Participating Organization enrolls in the WVHIN’s Health Information Exchange. Where possible, Patients may be provided with the Patient Notice prior to the anticipated enrollment of the Participating Organization in the Health Information Exchange. The Patient Notice will be developed and approved by the WVHIN, and will explain the function of the Health Information Exchange, the Permissible Purposes for disclosure of the Patient’s Protected Health Information to other Participating Organizations, and the potential benefits and risks of participation in the Exchange. In addition, the WVHIN will undertake other measures designed to inform Patients about the Health Information Exchange, including but not limited to publication of the written Patient Notice in a local newspaper of general circulation in each defined area that the WVHIN intends to serve.

If a Patient does not Opt-Out of the WVHIN’s Health Information Exchange, his or her Protected Health Information will generally be disclosed in response to a specific request, or Inquiry, made by a Participating Organization for a Permissible Purpose. However, a Patient’s Protected Health Information will not be disclosed in response to such an Inquiry when it

contains Sensitive Health Information for which a specific authorization is required (see Policy and Procedure Document Number 102 for the handling of Sensitive Health Information) even if a Patient does not Opt-Out.

A Patient who does not want his or her Protected Health Information to be disclosed to other Participating Organizations may Opt-Out by following the procedures below. If a Patient does Opt-Out, his or her Protected Health Information will not be disclosed through the WVHIN's Health Information Exchange for any Permissible Purpose except Public Health Reporting. A Patient who elects to Opt-Out is not eligible to establish his or her own Patient Portal on the Health Information Exchange.

A Patient may decide at any time to change his or her Consent to participate in the WVHIN.

III. PROCEDURES

A. Patient Procedures.

1. No action is needed by a Patient if he or she wishes to participate in the WVHIN. A Patient shall be deemed to have given his or her Consent to participate until and unless the Patient affirmatively Opts-Out of the WVHIN's Health Information Exchange. These alternatives shall be collectively referred to herein as the Patient's Consent decision.

2. Every Patient must receive educational information about the WVHIN's Health Information Exchange from his or her Participating Organization during his or her first encounter with that Participating Organization after it enrolls in the Exchange. This educational information must be provided in writing, and in any other format (on-line presentation, oral presentation, foreign language presentation, etc.) designed to ensure that its contents are communicated to and understood by the Patient. This educational information must consist of, at a minimum, a written Patient Notice developed and approved by the WVHIN which explains:

- (i) the function of the WVHIN's Health Information Exchange;
- (ii) the Permissible Purposes for which a Patient's Protected Health Information may be disclosed to other Participating Organizations through the Health Information Exchange;
- (iii) the types of Protected Health Information which may be disclosed to other Participating Organizations;
- (iv) the need for the Patient's specific written authorization to disclose certain categories of Sensitive Health Information;

- (v) the fact that a Patient's Personal Demographic Information will be included in a Master Patient Index maintained by the WVHIN to permanently record his or her Consent decision;
- (vi) the potential benefits and risks of participation in the Health Information Exchange; and
- (vii) the fact that a Patient's participation in the Health Information Exchange is voluntary and subject to a Patient's right to Opt-Out.

3. Identical educational information about the WVHIN's Health Information Exchange will be available to Patients on-line at a website maintained by the WVHIN.

4. The identity of each Patient receiving the Patient Notice must be verified and authenticated by the Participating Organization, including the accuracy of all Personal Demographic Information of that Patient.

5. A Patient may Opt-Out of participation in the Health Information Exchange through his or her Participating Organization. If available on the WVHIN's website, the Patient may Opt-Out by registering his or her Opt-Out decision on-line.

6. A Patient may Opt-Out of the Health Information Exchange during a visit or encounter with his or her Participating Organization. The ability of a Patient to Opt-Out of the Health Information Exchange must be made available by both Full Service and Data User Participating Organizations.

7. Prior to Opting-Out, a Patient must first be presented with a copy of the WVHIN's Patient Notice, either in paper form or electronically.

8. After a Patient's identity has been verified by the Participating Organization, and after the Patient has been presented with a copy of the Patient Notice, then a Patient may Opt-Out of participation in the Health Information Exchange by executing a standard Opt-Out form developed and approved by the WVHIN to document the Patient's Opt-Out decision. This standard Opt-Out form will be provided by the Participating Organization, and may be a paper form signed by the Patient manually, or an electronic form signed by the Patient electronically.

9. Alternatively, if available, a Patient may Opt-Out of the Health Information Exchange through an on-line electronic process available to Patients at a website maintained by the WVHIN. This on-line process will be designed by the WVHIN to elicit sufficient Personal Demographic Information from the Patient to verify his or her identity. This Patient verification process must use methods and technology that ensure proper Patient verification.

10. If available, the WVHIN's electronic on-line process must also include the same educational information that is made available to Patients by their Participating Organizations, including the written Patient Notice developed and approved by the WVHIN. Prior to Opting-

Out on-line, a Patient must acknowledge electronically that he or she has been presented with and understands the Patient Notice.

11. A Patient may choose to Opt-Out at any time, even after having already been enrolled in the Health Information Exchange. However, any exchange of Protected Health Information that may have occurred prior to a Patient's decision to Opt-Out will not be reversed.

12. A Patient may revoke his or her decision to Opt-Out of the Health Information Exchange by completing a paper or electronic Revocation form from his or her Participating Organization, or if available, by completing an electronic Revocation form on-line at a website maintained by the WVHIN. This must be a standard Revocation form developed and approved by the WVHIN.

13. Once the Revocation form has been executed by the Patient and communicated to the WVHIN, he or she will be enrolled in the Health Information Exchange from that date forward.

14. A parent or legal guardian may express the Consent decision of a minor child under the age of 18 to Opt-Out of the Health Information Exchange only through his or her Participating Organization. If necessary, a parent or legal guardian must present the Participating Organization with a legal guardianship paper, a child custody court order, or other legal authority to act on behalf of a child.

15. In the absence of an expression of Consent by a parent or legal guardian on behalf of a minor child under the age of 18, or in the case of a minor child affirmatively seeking to exercise his or her own Consent decision, a Licensed Practitioner at a Participating Organization may determine after personal examination that the child is a "mature minor" capable of making a meaningful decision as to his or her participation in the Health Information Exchange. If the minor is found to be mature by a Licensed Practitioner, the decision of the mature minor to Opt-Out of the Health Information Exchange will be respected. A minor is legally presumed to be capable of making his or her own Consent decision when seeking treatment for substance abuse, birth control, prenatal care, or a sexually transmitted disease.

16. Upon reaching the age of majority, a Patient whose Consent decision was previously expressed by his or her parent or legal guardian will be given the opportunity to exercise his or her own Consent decision in accordance with the procedures outlined in paragraphs 1 through 13 above.

17. A Patient who elects to Opt-Out is not eligible to establish his or her own Patient Portal on the Health Information Exchange.

B. Participating Organization Procedures.

1. Each Participating Organization must provide every Patient with educational information about its participation in the WVHIN's Health Information Exchange during the Patient's first visit or encounter with that Participating Organization after it enrolls in the

Exchange. This educational information must be provided in writing, and in any other format (on-line presentation, oral presentation, foreign language presentation, etc.) designed to ensure that its contents are communicated to and understood by the Patient. This educational information must consist of, at a minimum, a written Patient Notice developed and approved by the WVHIN which explains:

- (i) the function of the WVHIN's Health Information Exchange;
- (ii) the Permissible Purposes for which a Patient's Protected Health Information may be disclosed to other Participating Organizations through the Health Information Exchange;
- (iii) the types of Protected Health Information which may be disclosed to other Participating Organizations;
- (iv) the need for the Patient's specific written authorization to disclose certain categories of Sensitive Health Information;
- (v) the fact that the Patient's Personal Demographic Information will be included in a Master Patient Index maintained by the WVHIN to permanently record his or her Consent decision;
- (vi) the potential benefits and risks of participation in the Health Information Exchange; and
- (vii) the fact that a Patient's participation in the Health Information Exchange is voluntary and subject to a Patient's right to Opt-Out.

2. This written Patient Notice may be provided to the Patient as an addendum to the Participating Organization's Notice of Privacy Practices. The Participating Organization is encouraged to record the delivery of the Patient Notice in the Patient's medical record.

3. The Participating Organization shall also include a copy of the written Patient Notice on its own internet website (if any), and shall display an educational poster distributed by the WVHIN in a public area of the Participating Organization's facility.

4. Where possible, the WVHIN encourages prospective Participating Organizations to provide Patients with educational information, including the Patient Notice, prior to their enrollment in the WVHIN's Health Information Exchange. The WVHIN further encourages prospective Participating Organizations, prior to actual enrollment, to include the written Patient Notice on their own internet websites (if any), and to display the educational poster distributed by the WVHIN in public areas.

5. The identity of each Patient receiving the Patient Notice must be verified and authenticated by the Participating Organization, including the accuracy of all Personal Demographic Information of that Patient.

6. If the Patient asks questions about the WVHIN, the Participating Organization must verbally counsel the Patient about the contents of the Patient Notice. The goal of such counseling will be to educate the Patient about the potential benefits and risks of participation in the Health Information Exchange, while at the same time, to fully respect the individual Consent decision expressed by the Patient.

7. Once a Patient has been provided with a copy of the Patient Notice by a Participating Organization, it is not necessary for that same Participating Organization to repeat the process.

8. If a Patient elects to Opt-Out of the Health Information Exchange, and the Patient's identity has been verified by the Participating Organization, the Participating Organization will require the Patient to document his or her decision to Opt-Out by utilizing the standard Opt-Out form developed and approved by the WVHIN. This standard Opt-Out form may be a paper form signed by the Patient manually, or an electronic form signed by the Patient electronically. A paper or electronic copy of this Opt-Out form will be kept and permanently maintained by the Participating Organization in the Patient's medical record.

9. A Participating Organization must allow a Patient to Opt-Out at any time, even after having already been enrolled in the Health Information Exchange. However, any exchange of Protected Health Information that may have occurred prior to a Patient's decision to Opt-Out will not be reversed.

10. If requested, a Participating Organization will assist the Patient in revoking his or her decision to Opt-Out of the Health Information Exchange. The Participating Organization will supply the Patient with the standard Revocation form developed and approved by the WVHIN. This form may be in either paper or electronic form. The Participating Organization must permanently retain a paper or electronic copy of the signed Revocation form in the Patient's medical record.

11. Once the Revocation form has been executed by the Patient and communicated to the WVHIN, he or she will be enrolled in the Health Information Exchange from that date forward.

12. The Participating Organization will comply with the Consent decision made by a parent or legal guardian for his or her minor child to Opt-Out of the Health Information Exchange. If necessary, the Participating Organization will verify and authenticate the authority of the parent or legal guardian to act on behalf of the child by first reviewing a legal guardianship paper, a child custody court order, or other legal authority.

13. A Licensed Practitioner working at a Participating Organization, in the absence of an expression of Consent by a parent or legal guardian on behalf of a minor child under the age of 18, or in the case of a minor child affirmatively seeking to exercise his or her own Consent election, may determine after personal examination that the child is a "mature minor" capable of making a meaningful decision as to his or her Consent to participate in the Health Information

Exchange. If the minor is found to be mature by a Licensed Practitioner, the decision of the mature minor to Opt-Out of the Health Information Exchange will be respected.

14. A minor is legally presumed to be capable of making his or her own Consent decision when seeking treatment for substance abuse, birth control, prenatal care, or a sexually transmitted disease.

15. Upon reaching the age of majority, a Patient whose Consent decision was previously expressed by his or her parent or legal guardian will be given the opportunity to exercise his or her own Consent decision in accordance with the procedures outlined in paragraphs 1 through 11 above.

16. Upon enrollment in the Health Information Exchange, a Full Service Participating Organization will electronically supply or otherwise make available to the WVHIN Personal Demographic Information and Protected Health Information about all of its Patients so that other Participating Organizations may access their Protected Health Information for a Permissible Purpose in accordance with the WVHIN's policies and procedures.

17. All decisions made by Patients to Opt-Out of the Health Information Exchange will be immediately and electronically communicated by the Participating Organization to the WVHIN by recording such decision in the WVHIN's Health Information Exchange. This will ensure compliance with each Patient's decision to Opt-Out. It is not necessary for the Opt-Out form itself to be sent to the WVHIN. For purposes of this Policy and Procedure, the term "immediately" shall mean within the same business day.

18. A Participating Organization will not deny care to any Patient solely because he or she elects to Opt-Out of the Health Information Exchange.

19. Although not technically a Participating Organization, a Data Supplier approved by the WVHIN will electronically supply or otherwise make available to the WVHIN Personal Demographic Information and Protected Health Information about all of its Patients so that other Participating Organizations may access their Protected Health Information for a Permissible Purpose in accordance with the WVHIN's policies and procedures.

C. WVHIN Procedures.

1. The WVHIN will provide outreach, educational information, and where requested, technical assistance to Patients and Participating Organizations to promote a consistent implementation of the Consent procedures outlined above. At a minimum, the WVHIN's educational information must include a written Patient Notice developed and approved by the WVHIN which explains:

- (i) the function of the WVHIN's Health Information Exchange;

- (ii) the Permissible Purposes for which a Patient's Protected Health Information may be disclosed to other Participating Organizations through the Health Information Exchange;
- (iii) the types of Protected Health Information which may be disclosed to other Participating Organizations;
- (iv) the need for the Patient's specific written authorization to disclose certain categories of Sensitive Health Information;
- (v) the fact that the Patient's Personal Demographic Information will be included in a Master Patient Index maintained by the WVHIN to permanently record his or her Consent decision;
- (vi) the potential benefits and risks of participation in the Health Information Exchange; and
- (vii) the fact that a Patient's participation in the Health Information Exchange is voluntary and subject to a Patient's right to Opt-Out.

2. The WVHIN will also ensure that this written Patient Notice is published in the form of a Class III-0 legal advertisement in at least one qualified newspaper of general circulation, as defined by W. Va. Code Chapter 59, Article 3, in each area that the WVHIN intends to serve, as well as the expected date of implementation in each such area. This Class III-0 legal advertisement will be published at least thirty (30) days prior to the date upon which the WVHIN's Health Information Exchange becomes functional in the defined area.

3. The WVHIN will prepare and distribute educational posters for display by its Participating Organizations in public areas that are designed to inform Patients about the Health Information Exchange and their right to Opt-Out of the Exchange.

4. The WVHIN will include the written Patient Notice, as well as other information designed to inform Patients about the Health Information Exchange and their right to Opt-Out, on its internet website.

5. The WVHIN will encourage prospective Participating Organizations, prior to their actual enrollment, to begin the distribution of the written Patient Notice at each of its Patient encounters, to include the written Patient Notice on its own internet website, and to display the WVHIN's educational posters in a public area of its facility.

6. The WVHIN will develop and provide its Participating Organizations with master copies of all standard Opt-Out forms, Revocation forms, Patient Notices, and educational posters for purposes of duplication and distribution. In addition, the WVHIN will include all of these forms on-line on its website.

7. The WVHIN may make an electronic process available to Patients on-line at its website to enable Patients to Opt-Out of participation in the WVHIN's Health Information Exchange. If available, this on-line process will be designed by the WVHIN to elicit sufficient Personal Demographic Information from the Patient to verify his or her identity. This verification process must use methods and technology that ensure proper Patient verification.

8. If available, the electronic on-line process must also include the same educational information that is made available to Patients by their Participating Organizations, including the written Patient Notice developed and approved by the WVHIN. Prior to Opting-Out on-line, a Patient must acknowledge electronically that he or she has been presented with and understands the Patient Notice.

9. A Patient's election to Opt-Out either through a Participating Organization, or if available, on-line at the WVHIN's website, will be immediately communicated to the WVHIN. The WVHIN will record the Patient's decision to Opt-Out in its Master Patient Index.

10. A Patient may revoke his or her decision to Opt-Out of the Health Information Exchange at any time by completing a paper or electronic Revocation form from his or her Participating Organization, or if available, by completing an electronic Revocation form on-line at the WVHIN's website. This must be a standard Revocation form developed and approved by the WVHIN.

11. Once the Revocation form has been executed by the Patient and communicated to the WVHIN, he or she will be enrolled in the Health Information Exchange from that date forward.

12. Upon enrollment in the WVHIN, a Full Service Participating Organization will electronically supply or otherwise make available to the WVHIN Personal Demographic Information and Protected Health Information about all of its Patients. Although not technically a Participating Organization, a Data Supplier approved by the WVHIN will also electronically supply or otherwise make available to the WVHIN Personal Demographic Information and Protected Health Information about all of its Patients. The WVHIN will electronically maintain Personal Demographic Information about all Patients of Full Service Participating Organizations and Data Suppliers in a Master Patient Index in order to record and maintain each Patient's Consent decision. In addition, the WVHIN will utilize this Personal Demographic Information to enable other Participating Organizations to access the Protected Health Information of Patients for a Permissible Purpose in accordance with the WVHIN's policies and procedures.

13. All decisions made by Patients to Opt-Out of the Health Information Exchange will be electronically recorded in the WVHIN's Health Information Exchange by a Participating Organization to ensure compliance with each Patient's decision to Opt-Out.

14. For a Patient who has not Opted-Out of the Health Information Exchange, the WVHIN will generally share all or some of a Patient's Protected Health Information in response to an Inquiry from a Participating Organization for a Permissible Purpose.

15. A Patient's Protected Health Information will not be disclosed in response to an Inquiry when it contains Sensitive Health Information for which a specific written authorization is required (see Policy and Procedure Document Number 102 for the handling of Sensitive Health Information).

16. For a Patient who has Opted-Out of the Health Information Exchange, the WVHIN will ensure that no Protected Health Information will be disclosed except for the Permissible Purpose of Public Health Reporting. Instead, the Participating Organization that submitted the Inquiry will receive a message that the Patient has Opted-Out of the WVHIN's Health Information Exchange.

17. The WVHIN may Deidentify Protected Health Information, and may use or disclose such Deidentified data for any public health or research purpose approved by the WVHIN board.

18. The WVHIN may make DIRECT secure messaging available to its Participating Organizations. DIRECT secure messaging is a distinct service made available by the WVHIN separate from its Health Information Exchange, and is not subject to the Opt-Out rules contained in this Policy and Procedure on Patient Consent – General.