

**WEST VIRGINIA  
SECRETARY OF STATE  
NATALIE E. TENNANT  
ADMINISTRATIVE LAW DIVISION**

Form #2

Do Not Mark In This Box

FILED

2011 DEC 12 PM 3: 54

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE**

AGENCY: West Virginia Health Care Authority/West Virginia Health Information Network TITLE NUMBER: 65

RULE TYPE: Legislative CITE AUTHORITY: WV Code 16-29G-7 & WV Code 16-29B-8(a)(1)

AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: N/A

TITLE OF RULE BEING AMENDED: N/A

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 28

TITLE OF RULE BEING PROPOSED: West Virginia Health Information Network Rule

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON January 11, 2012 AT 5:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

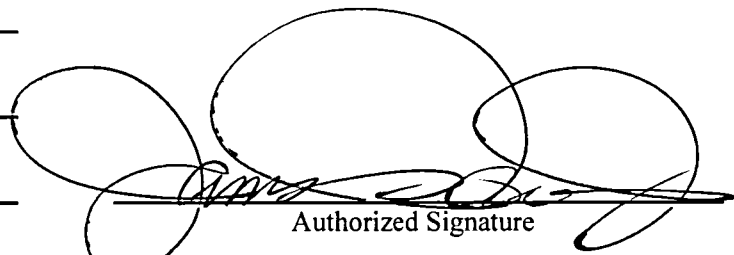
Joe E. Richards, CFO

West Virginia Health Information Network

100 Dee Drive

Charleston, West Virginia 25311-1600

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.



Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Earl Ray Tomblin  
Governor



James L. Pitrolo, Jr.  
Chairman

Michael J. Lewis, M.D., Ph.D., Secretary  
West Virginia Department of  
Health and Human Resources

Board Members  
Sonia D. Chambers  
Marilyn G. White

December 12, 2011

The Honorable Natalie Tennant  
Secretary of State  
State Capitol Complex  
Charleston, West Virginia 25305

Attention: Judy Cooper

Re: Proposed Legislative Rule, West Virginia Health  
Information Network Rule (65 CSR 28) Summary

Dear Ms. Tennant:

The West Virginia Health Care Authority is please to submit the attached proposed rule on behalf of the West Virginia Health Information Network. The proposed rule will facilitate the continued receipt of federal grant funds for the development, the implementation and the operations of the West Virginia's health information exchange.

Once implemented, the proposed Legislative Rule will be dispositive of the rights, privileges and interests of all West Virginians who participate in the health information exchange. Should you have any questions concerning our proposed rule, please contact me at your earliest convenience.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Pitrolo, Jr.", written over a large, stylized, circular flourish.

James L. Pitrolo, Jr.  
Chairman

JLP:jr

Enclosures



---

## West Virginia Health Information Network Summary Statement

---

The proposed *West Virginia Health Information Network Rule (65 CSR 28)* is necessary to preserve a \$7,819,000 *American Recovery and Reinvestment Act of 2009* (ARRA) Grant and to provide for the rights, privileges and interests of those participating in the West Virginia Health Information Network (WVHIN). The WVHIN was created by the West Virginia Legislature under the oversight of the Health Care Authority (HCA) " ...to promote the design, implementation, operation and maintenance of a fully interoperable statewide network to facilitate public and private use of health care information in the state." (*WV Code §16-29G-1*). The West Virginia Department of Health and Human Resources (WVDHHR) applied for and received a \$7,819,000 ARRA Grant for the planning, the development and the implementation of the aforementioned health information network. The ARRA Grant funds are allocated to Personnel, Fringe Benefits, Travel, Supplies, Contractual and Other. All costs are considered Direct Costs. The West Virginia Legislature has also appropriated \$3,500,000 to further facilitate the project. HCA has also allocated \$7,000,000 to further facilitate the project. The total costs to plan, to develop and to implement the project is estimated at \$18,319,000. The proposed Legislative Rule will have little, if any, financial impact on state government's costs or revenues. The costs to develop and to implement the aforementioned rules will be within the ordinary cost of doing business. There are no additional revenues proposed with the implementation of these rules. Furthermore, the implementation of these proposed rules will reduce greatly the potential for having the aforementioned federal funds expire, thereby placing a greater economic burden on the State of West Virginia to participate in the National Health Information Exchange.

The ARRA Grant is a four year (February 8, 2010—February 7, 2014) grant that cannot be renewed or extended. (The ARRA Grant years are from February 8—February 7.) The ARRA Grant requires state matching funds allocated as follows: First and Second Years 10:1; Third Year 7:1; and Fourth Year 3:1. Please note that ARRA Grant matching calculations are based on the Federal Fiscal Year (October 1—September 30 each year.) The aforementioned legislative appropriation and the Health Care Authority's allocation are more than sufficient to meet the ARRA Grant matching requirements.



Michael J. Lewis, M.D., Ph.D., Secretary  
West Virginia Department of  
Health and Human Resources

Board Members  
Sonia D. Chambers  
Marilyn G. White

## NOTICE OF PUBLIC COMMENT PERIOD

### Proposed Legislative Rule Title 65 Legislative Rule, Health Care Authority

The West Virginia Health Care Authority has scheduled a public comment period to receive comments on the following proposed Legislative Rule, West Virginia Health Information Network Rule, Title 65 CSR 28.

Written comments may be submitted to Joe E. Richards, Chief Financial Officer at the West Virginia Health Information Network, 100 Dee Drive, Charleston, West Virginia 25311. All written comments must be received no later than 5:00 p.m. **January 11, 2012.**

APPENDIX B

**FISCAL NOTE FOR PROPOSED RULES**

Rule Title: West Virginia Health Information Network Rule (65CSR28)

Type of Rule:  Legislative  Interpretive  Procedural

Agency: West Virginia Health Care Authority & West Virginia Health Information Network

Address: 100 Dee Drive  
Charleston, West Virginia 25311-1600

Phone Number: 304-558-7000 Email: info@wvhin.org

**Fiscal Note Summary**

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

The proposed West Virginia Health Information Network Rule (65 CSR 28) is necessary to preserve a \$7,819,000 American Recovery and Reinvestment Act of 2009 (ARRA) Grant and to provide for the rights, privileges and interests of those participating in the West Virginia Health Information Network (WVHIN). The WVHIN was created by the West Virginia Legislature under the oversight of the Health Care Authority (HCA) "...to promote the design, implementation, operation and maintenance of a fully interoperable statewide network to facilitate public and private use of health care information in the state." (WV Code §16-29G-1). The West Virginia Legislature has also appropriated \$3,500,000 to further facilitate the project. HCA has also allocated \$7,000,000 to further facilitate the project. The total costs to plan, to develop and to implement the project is estimated at \$18,319,000. The proposed Legislative Rule will have little, if any, financial impact on state government's costs or revenues.

**Fiscal Note Detail**

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "--")	Next Increase/Decrease (use "--")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: West Virginia Health Information Network Rule, 65 CSR 28

Rule Title:

West Virginia Health Information Network Rule (65CSR28)

**3. Explanation of above estimates (including long-range effect):**

Please include any increase or decrease in fees in your estimated total revenues.

There is no short-term or long-term economic effect with implementation of the aforementioned Legislative Rules. There are no fees associated with this proposed Legislative Rule.

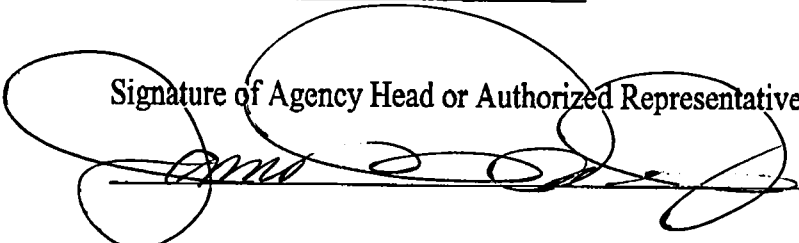
**MEMORANDUM**

Please identify any areas of vagueness, technical defects, reasons the proposed rule would not have a fiscal impact, and/or any special issues not captured elsewhere on this form.

There are no areas of vagueness, technical defects or other reasons why this proposed rule would have a fiscal impact. There are no special issues related to this proposed rule.

Date: December 12, 2011

Signature of Agency Head or Authorized Representative



**TITLE 65  
LEGISLATIVE RULE  
HEALTH CARE AUTHORITY**

**SERIES 28  
WEST VIRGINIA HEALTH INFORMATION NETWORK RULE**

**FILED**  
2011 DEC 12 PM 3:55  
OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**§65-28-1. General.**

1.1. Scope -- This legislative rule establishes the standards for the development, implementation, and operation of the West Virginia Health Information Network (WVHIN) as an interoperable statewide network for health information exchange.

1.2. Authority -- W. Va. Code §§16-29G-7 and 16-29B-8(a)(1).

1.3. Filing Date -- \_\_\_\_\_, 2012.

1.4. Effective Date -- \_\_\_\_\_, 2012.

1.5. Construction -- This legislative rule shall be liberally construed to comply with any and all applicable federal and state laws designed to ensure the privacy and security of health information.

**§65-28-2. Definitions.**

2.1. Authentication Information -- means the method of authentication assigned to each authorized user of the WVHIN by his or her participating organization in accordance with minimum WVHIN requirements. Authentication may be based upon information known only by and unique to an authorized user, such as a password and username. If required by the WVHIN, a second authentication factor may be imposed that is based upon something that an authorized user has, such as a smart card or token, or something unique to the authorized user, such as an electronic signature or fingerprint.

2.2. Authorized User -- means a member of the workforce of a participating organization who has been designated by that participating organization to access the WVHIN's health information exchange pursuant to the concept of role-based access control. An authorized user may also be a patient who has registered a personal health record on the WVHIN or, if made available by the WVHIN to patients, who has been approved for direct access to his or her PHI by a cooperating participating organization; a member of the WVHIN's workforce; or a member of the workforce of a business associate of the WVHIN.

2.3. Business Associate -- means a person or entity that performs a function, activity, or service to a health care provider, health plan, health care clearinghouse, or another business associate involving the disclosure of protected health information or personal demographic information to the business associate. The WVHIN is a business associate to each of its participating organizations. Subcontractors and vendors to the WVHIN may be business associates of the WVHIN. A business associate shall have the same meaning as such term is defined in 42 C.F.R. Part 160, as may be amended.

2.4. Business Associate Agreement -- means a contract between a covered entity under HIPAA and a business associate, or between a pair of business associates, which obligates the business associate to maintain the privacy and security of protected health information in accordance with the requirements of 42 C.F.R. Part 164, as may be amended.

2.5. Breach -- means the acquisition, access, use, or disclosure of a patient's unsecured protected health information by an unauthorized person or entity in a manner not permitted under the HIPAA privacy rules, and in a manner that otherwise satisfies all other requirements imposed by the rules governing breach notification for unsecured protected health information in 42 C.F.R. Part 164, as may be amended.

2.6. Clinical Messaging -- means the exchange of protected health information from one participating organization to another through the WVHIN in the form of test results or other clinical information. Test results can be generated by clinical laboratories, imaging providers, and other like providers. Other clinical information may consist of discharge summaries, consultation reports, and patient referral data. For purposes of the WVHIN's health information exchange, clinical messaging is a point-to-point transaction.

2.7. Covered Entity -- means a health care provider, a practitioner licensed under the provisions of Chapter 30 of the West Virginia Code or some equivalent law of another state, a health care clearinghouse, or a health plan that transmits any protected health information in electronic form. A covered entity shall have the same meaning as such term is defined in 42 C.F.R. Part 160, as may be amended.

2.8. Deidentify or Deidentification -- means the process of rendering protected health information into a form that does not identify a patient, and there is no reasonable basis to believe that the information can be used to identify a patient. In order to deidentify protected health information properly, the requirements of 45 C.F.R. Part 164, as may be amended, shall be fully satisfied.

2.9. Designated Record Set -- means any grouping of medical or billing records maintained by a covered entity and used to make treatment or payment decisions about a patient. A designated record set shall have the same meaning as such term is defined in 42 C.F.R. Part 164, Subpart E, as may be amended.

2.10. Drug or Alcohol Abuse Information -- means information related to the treatment and care of a patient suffering from alcohol or drug abuse, or both, including any information that would specifically identify a patient as receiving drug or alcohol abuse treatment and care. Drug or alcohol abuse information shall have the same meaning as the term "drug or alcohol abuse patient records" is defined in 42 C.F.R. Part 2, as may be amended. Drug or alcohol abuse information, for purposes of this rule, shall arise only in connection with care and treatment provided in a federally assisted program as defined in 42 C.F.R. Part 2, as may be amended.

2.11. Emergency Treatment -- means a condition which poses an immediate threat to the health of a patient (for example, death or serious impairment to one or more bodily systems, organs, or parts), and which requires immediate medical intervention.

2.12. Encryption -- means a technology or methodology approved by the United States Secretary of Health and Human Services that can render protected health information unusable, unreadable, or indecipherable to unauthorized individuals or entities.

2.13. E-Prescribing -- means the transmission, using electronic media, of prescription or prescription-related information between a licensed practitioner and a pharmacy, pharmacy benefit manager, or health plan, including any communication related to that prescription.

2.14. Health Care Clearinghouse -- means any entity, including a billing service, repricing

company, or other similar organization that processes health information in a nonstandard format into standard data elements or a standard transaction, or vice versa. Health care clearinghouse shall have the same meaning as such term is defined in 42 C.F.R. Part 160, as may be amended.

2.15. Health Care Provider – means a provider of medical or health services, and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. Health care provider shall have the same meaning as such term is defined in 42 C.F.R. Part 160, as may be amended.

2.16. Health Plan – means an individual or group plan that provides, or pays the cost of, medical or health services. Health plan shall have the same meaning as such term is defined in 42 C.F.R. Part 160, as may be amended.

2.17. Health Care Operations – means any of those activities identified by federal regulations at 42 C.F.R. Part 164, as may be amended, including but not limited to, quality assessment and improvement activities, case management and care coordination, reviewing the competence of licensed practitioners, underwriting, and business planning and management activities.

2.18. Health Information Exchange -- means a system for the electronic transfer of protected health information between participating organizations for a permissible purpose based upon the requirements of federal and state law. A health information exchange shall seek to achieve interoperability between and among its participating organizations.

2.19. HIPAA -- means the Health Insurance Portability and Accountability Act of 1996, as may be amended, and its implementing rules promulgated in 42 C.F.R. Parts 160, 162, and 164, as may be amended.

2.20. HIPAA Privacy Rules -- means those privacy rules described in 42 C.F.R. Part 164, Subpart E, as modified and enlarged by the Health Information Technology for Economic and Clinical Health (HITECH) Act and any other subsequent amendments.

2.21. HIPAA Security Rules – means those security rules described in 42 C.F.R. Part 164, Subpart C, as modified and enlarged by the HITECH Act and any other subsequent amendments.

2.22. HITECH Act -- means the Health Information Technology for Economic and Clinical Health Act of 2009, as may be amended, and its implementing rules promulgated at 42 C.F.R. Parts 160, 162, and 164, as may be amended.

2.23. Inquiry -- means a request directed by a participating organization to the WVHIN for the disclosure of a patient's protected health information for a permissible purpose. Inquiry involves the potential exchange of PHI between multiple participating organizations.

2.24. Licensed Practitioner -- means an individual licensed to provide health care items or services by a West Virginia board identified in Chapter 30 of the West Virginia Code, as may be amended, or by an equivalent board of another state.

2.25. Master Patient Index – means the index wherein personal demographic information of patients is securely maintained by the WVHIN to record their decision to opt-out of the health information exchange. For those patients who have not elected to opt-out, the master patient index shall be used to match such patients with any inquiries seeking the exchange of PHI for a permissible purpose. The WVHIN shall maintain personal demographic information regarding all potential patients in this

master patient index, even if the decision is made to opt-out, in order to minimize the possibility of improperly matching patients.

2.26. **Mental Health Information** -- means any information obtained in the course of treatment or evaluation of any patient suffering from a mental or behavioral disorder, including but not limited to, diagnosis and treatment information, and any information that would specifically identify a patient as receiving mental health services. Mental health information shall have the same meaning as the term “confidential information” is defined in West Virginia Code Chapter 27, Article 3, as may be amended.

2.27. **Minimum Necessary** -- means that when requesting, using, or disclosing protected health information for a permissible purpose other than treatment or emergency treatment, a covered entity or a business associate shall limit protected health information to the minimum amount needed to accomplish the intended purpose of the request, use, or disclosure. Minimum necessary shall have the same meaning as such term is defined in 42 C.F.R. Part 164, Subpart E, as may be amended.

2.28. **Out-Of-Pocket Goods and Services** -- means any goods and services for which the participating organization has been paid out-of-pocket in full by the patient, and the patient has requested the participating organization to restrict the disclosure of said goods and services to an insurance company, group health plan, or other third party payor for payment or health care operations. Out-of-pocket goods and services shall have the same meaning as such term is defined in the HITECH act, as may be amended.

2.29. **Opt-Out** -- means a process under which any patient who does not want to consent to the use and disclosure of his/her protected health information with other participating organizations pursuant to the WVHIN’s health information exchange may affirmatively express his/her decision not to participate.

2.30. **Participating Organization** -- means any health care provider, licensed practitioner, public health agency, health care clearinghouse, health plan, or other organization approved by the WVHIN that establishes a contractual relationship with the WVHIN in accordance with the standard participating organization agreement. A participating organization shall be a covered entity under HIPAA, a public health agency, or shall have a business associate agreement with a covered entity. Multiple covered entities operating as a single organized health care arrangement under 42 C.F.R. Part 160, as may be amended, may constitute a single participating organization upon approval of the WVHIN.

2.31. **Patient** – means the individual whose personal demographic information or protected health information is subject to electronic storage and transfer by the health information exchange.

2.32. **Patient Notice** -- means a written notice prepared and approved by the WVHIN, and supplied to its participating organizations for distribution to patients. The patient notice shall be provided to all patients during their first visit or encounter with a participating organization after it enrolls in the WVHIN, and where possible, before the date of anticipated enrollment. This patient notice shall explain the function of the WVHIN; the permissible purposes for which a patient's protected health information may be shared with other participating organizations through the WVHIN; the types of protected health information which may be shared with other participating organizations; the need for the patient's consent to share certain categories of sensitive health information; the potential benefits and risks of participation in the WVHIN; and the fact that a patient’s participation in the WVHIN is voluntary and subject to a patient’s right to opt-out.

2.33. **Payment** -- means any activity undertaken to obtain or provide reimbursement for the provision of health care items or services to a patient. Payment also includes activities arising out of

billing and collection, obtaining premiums for health plan coverage, determining eligibility for coverage, coordinating benefits with other health plans, performing health plan risk adjustment, reviewing medical necessity, providing precertification or preauthorization of services, and other similar transactions. Payment shall have the same meaning as such term is defined in 42 C.F.R. Part 164, as may be amended.

2.34. Personal Demographic Information -- means information which may be used to individually identify a patient, but which excludes any and all clinical or health-related information. Personal demographic information may include, but not be limited to, the patient's name, address, Social Security number, date of birth, telephone number, and driver's license number.

2.35. Personal Health Record or PHR -- means a health record that is registered by a patient with the WVHIN on his or her own behalf, and that utilizes an online platform sponsored by another organization. This personal health record may be developed by gathering and consolidating protected health information from many sources, including participating organizations of the WVHIN's health information exchange.

2.36. Protected Health Information or PHI -- means any information that relates to the past, present, or future physical or mental health or condition of a patient, the provision of health care items or services to the patient, and the past, present, or future payment for the provision of health care items or services to a patient. Protected health information also must personally identify a patient or provide a reasonable basis to believe that the information can be used to identify a patient. Protected health information shall have the same meaning as such term is defined in 42 C.F.R. Part 160, as may be amended.

2.37. Public Health Reporting -- means the exchange of protected health information through the WVHIN to a federal or state agency for the reporting and surveillance of specified health conditions as required by law, and for the reporting of immunization data. Such reporting shall contain the minimum amount of protected health information or personal demographic information as is required by law.

2.38. Psychotherapy Notes -- means notes recorded by a mental health care provider documenting or analyzing the contents of a conversation by a patient during a private, group, or family counseling session, and that are separated from the rest of the patient's medical record. Psychotherapy notes shall have the same meaning as such term is defined in 42 C.F.R. Part 164, as may be amended.

2.39. Sensitive Health Information -- means the subset of protected health information involving drug or alcohol abuse information, mental health information, psychotherapy notes, out-of-pocket goods and services, any PHI subject to a disclosure restriction requested by a patient and agreed to by a participating organization, or any other goods and services subject to heightened privacy and confidentiality requirements under federal and state laws or regulations and specifically approved by the WVHIN.

2.40. Site Administrator -- means an authorized user of the WVHIN who is a member of the workforce of a participating organization, who may grant and terminate authorized user status, and who may perform other administrative functions within or on behalf of his or her participating organization.

2.41. Treatment -- means the provision of health care items or services to a patient, including direct patient care as well as consultation, coordination, management, or patient referral between or from one participating organization to another. Treatment shall have the same meaning as such term is defined in 42 C.F.R. Part 164, as may be amended. Unless stated otherwise, treatment shall be limited to the provision of health care items or services to the patient who is the subject of the information (except in the case of mother/infant).

2.42. Unsecured Protected Health Information or Unsecured PHI -- means protected health information that has not been rendered unusable, unreadable, or indecipherable by unauthorized individuals or entities through the use of encryption or other federally-approved technology. Unsecured protected health information shall have the same meaning as such term is defined in 42 C.F.R. Part 164, as may be amended.

2.43. West Virginia Health Information Network or WVHIN -- means the public-private partnership created by West Virginia Code Chapter 29G, as may be amended, and which has as one of its purposes to develop an interoperable health information exchange in West Virginia.

2.44. Workforce – means employees, contractors, volunteers, trainees, or other persons whose conduct, in the performance of work for a participating organization, is under the direct control of such participating organization, whether or not they are paid by the participating organization. Workforce shall have the same meaning as such term is defined in 42 C.F.R. Part 160, as may be amended.

**§65-28-3. The Health Information Exchange.**

3.1. The WVHIN is authorized to establish an interoperable statewide network for the disclosure and use of PHI by and between participating organizations to improve the efficiency, quality, and integration of health care delivery, and to improve health care outcomes, all of which shall be deemed to be in the best interests of patients pursuant to West Virginia Code Chapter 16, article 29G, Section 8. PHI may be disclosed and used through the health information exchange unless and until the patient has expressed an affirmative choice to opt-out.

3.2. The WVHIN shall maintain the privacy and security of the health information exchange in accordance with all applicable federal and state laws and regulations, including but not limited to, HIPAA, the HIPAA privacy rules, the HIPAA security rules, and the HITECH act. This privacy and security shall apply not only to PHI being exchanged through the WVHIN, but shall also apply to any PHI maintained by the WVHIN in its master patient index or otherwise.

3.3. There shall be two types of PHI transactions recognized by the WVHIN:

3.3.a. One type shall involve the submission of an inquiry by one participating organization seeking the disclosure of available PHI on a particular patient from all other participating organizations, such as an inquiry for treatment purposes; and

3.3.b. The other type shall involve the point-to-point disclosure of PHI between two (2) participating organizations, such as in payment, clinical messaging, or public health reporting.

3.4. Both an inquiry and a point-to-point transaction submitted by a participating organization shall designate a permissible purpose for which PHI may be disclosed and used.

3.5. Under no circumstances shall PHI be sold to third parties by the WVHIN for marketing or other commercial purposes without the prior written consent or authorization of the affected patient.

**§65-28-4. Permissible Purposes for Health Information Exchange.**

4.1. The placement of appropriate limits upon health information exchange shall minimize the potential for misuse or abuse of PHI, thereby enhancing patient and participating organization confidence in the health information exchange process. Accordingly, the permissible purposes for which PHI may be

disclosed and used through the WVHIN shall be limited by the WVHIN. Permissible purposes may include treatment, emergency treatment, payment, health care operations, or any other purpose specifically authorized by federal and state laws or regulations and approved by the WVHIN.

4.2. Absent a permissible purpose, no exchange of PHI through the WVHIN's health information exchange shall be authorized.

4.3. A participating organization may submit an inquiry to the WVHIN for the PHI of a patient for a permissible purpose if it has a relationship to the patient sufficient to justify the permissible purpose. For example, a participating organization may submit an inquiry for treatment purposes when the participating organization is actually involved in the treatment of the patient. The WVHIN shall implement a master patient index and a record locator function to identify which participating organizations possess PHI responsive to an inquiry.

4.4. A participating organization may submit a point-to-point transaction for a permissible purpose if it has a relationship to the patient sufficient to justify the permissible purpose. For example, a participating organization treating a patient may order and receive the patient's laboratory tests results in the form of a clinical message from another participating organization. An inquiry shall not be submitted for point-to-point transactions. Rather, these transactions are limited to the disclosure and use of PHI by and between two (2) distinct participating organizations for the permissible purpose indicated.

#### **§65-28-5. Patient Opt-Out.**

5.1. Patients shall be provided with a reasonable and meaningful opportunity as set forth in this rule to make an informed choice about whether their PHI may be disclosed and used in the WVHIN's health information exchange.

5.2. Any patient who does not want to consent to the disclosure and use of his or her PHI in the health information exchange may elect to opt-out. No affirmative action by the patient is necessary when a patient consents to his or her participation in the WVHIN's health information exchange.

5.3. To ensure that patients are able to make an informed choice, each patient shall be provided with educational information by 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 such educational information prior to the enrollment of the participating organization in the WVHIN's health information exchange. This educational information shall be provided in writing, and if necessary, in any other format (on-line presentation, verbal counseling, foreign language presentation, etc.) designed to ensure that its contents are communicated to and understood by the patient.

5.4. This educational information shall consist of, at a minimum, a written patient notice developed by the WVHIN which explains in plain language:

5.4.a. The function of the WVHIN's health information exchange;

5.4.b. The permissible purposes for which a patient's PHI may be disclosed to and used by other participating organizations through the health information exchange;

5.4.c. The types of PHI which may be disclosed to other participating organizations;

5.4.d. The need for the patient's specific written consent or authorization to disclose

certain categories of sensitive health information;

5.4.e. The fact that a patient's personal demographic data shall be included in a master patient index maintained by the WVHIN to permanently record his or her consent decision;

5.4.f. The potential benefits and risks of participation in the WVHIN; and

5.4.g. The fact that a patient's participation in the WVHIN is voluntary and subject to a patient's right to opt-out.

5.5. The written patient notice may be provided to the patient as an addendum to a 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.

5.6. In addition to the written patient notice, the WVHIN shall also undertake the following efforts to educate and publicly notify patients of the existence and operation of its health information exchange:

5.6.a. The WVHIN shall publish its written patient notice and a list of all then current participating organizations during the first week of January, April, July, and October of each year in the State Register.

5.6.b. The WVHIN shall publish its written patient notice 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 defined area that the WVHIN intends to serve, as well as the expected date of implementation in each defined area. This Class III-0 legal advertisement shall be published at least thirty (30) days prior to the date upon which the WVHIN's health information exchange becomes operational in the defined area;

5.6.c. The WVHIN shall 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;

5.6.d. The WVHIN shall include the written patient notice, as well as other educational information designed to inform patients about the health information exchange and their right to opt-out, on its internet website. At this website, the WVHIN may include the capability for a patient to opt-out of the health information exchange. ; and

5.6.e. The WVHIN shall encourage prospective participating organizations 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 public areas of its facility.

5.7. A patient shall be considered an active participant in the health information exchange until and unless he or she opts-out. A patient becomes an active participant for all purposes after the enrollment of his or her participating organization in the WVHIN's health information exchange.

5.8. A patient may opt-out of the health information exchange during a patient encounter with a participating organization, or if available on the WVHIN website, by registering his or her decision to opt-out on-line.

5.9. A patient's decision to opt-out shall be communicated immediately to and permanently recorded in a master patient index maintained by the WVHIN. The WVHIN shall maintain personal demographic information regarding all potential patients in this master patient index, even if the decision is made to opt-out, in order to minimize the possibility of improperly matching patients.

5.10. A patient may elect to opt-out of the health information exchange at any time, even after having been already a participant. However, any exchange of PHI that may have occurred prior to a patient's decision to opt-out shall not be reversed.

5.11. For a patient who has opted-out, no PHI shall be disclosed through the WVHIN's health information exchange except for public health reporting to a state or federal agency.

5.12. A patient may revoke his or her decision to opt-out of the health information exchange at any time by completing a revocation form developed and approved by the WVHIN. A patient's election to revoke his or her decision to opt-out may be accomplished either during a patient encounter at a participating organization, or if available, on-line at a website maintained by the WVHIN.

**§65-28-6. Patient Rights.**

6.1. The WVHIN shall develop, implement, and operate its health information exchange in a manner that is both transparent and patient-centered, including the following:

6.1.a. All of the WVHIN's forms and educational materials shall be written in plain language;

6.1.b. All of the WVHIN's forms and educational materials shall be made readily accessible to patients free of charge either electronically, or at the request of the consumer, in paper format; and

6.1.c. All meetings of the WVHIN's board of directors shall be conducted in compliance with the West Virginia Open Governmental Proceedings Act in W. Va. Code Chapter 6, Article 9A.

6.2. A participating organization shall not deny care to any patient solely because he or she elects to opt-out of the health information exchange.

6.3. A patient shall have a right of access to his or her PHI consistent with the requirements of the HIPAA privacy rules, the HITECH act, and W. Va. Code § 16-29-1 *et seq.* Participating organizations are the originators of such PHI, and maintain the designated record sets in which the PHI resides. Accordingly, the participating organization whose designated record set is subject to a request for access by a patient shall be responsible for evaluating and responding to any such request. The WVHIN shall direct the patient to present any such request for access to the applicable participating organization for processing.

6.3.a. The participating organization shall be solely responsible for making all determinations regarding the grant or denial of the patient's request for access.

6.3.b. If such access is granted, the participating organization shall be responsible for providing such access from its own designated record set.

6.4. A patient shall have a right to amend his or her PHI consistent with the requirements of the HIPAA privacy rules and the HITECH act. Participating organizations are the originators of such PHI, and maintain the designated record sets in which the PHI resides. Accordingly, the participating organization whose PHI is subject to a request for amendment by a patient shall be responsible for evaluating, responding to, approving, or disapproving any such request. The WVHIN shall direct the patient to present any such request for amendment to the applicable participating organization for processing.

6.4.a. The participating organization shall be solely responsible for making all determinations regarding the grant or denial of the patient's requested amendment, and for ultimately providing for the amendment within its own designated record set; and

6.4.b. Any amendment agreed to by the participating organization shall be made available to the WVHIN for the purposes of the health information exchange.

6.5. A patient shall have a right to an accounting of disclosures of his or her PHI consistent with the requirements of the HIPAA privacy rules and the HITECH act. The WVHIN shall track electronically all disclosures made through its health information exchange.

6.5.a. If a request for an accounting of disclosures is received by the WVHIN from a patient or participating organization, the WVHIN shall prepare such an accounting from its health information exchange consistent with the requirements of the HIPAA privacy rules and the HITECH act, and deliver said accounting to the applicable participating organization.

6.5.b. The participating organization shall be responsible for delivering the WVHIN's accounting of disclosures, along with the participating organization's own accounting of disclosures, to the patient.

6.6. A patient shall have the right to request a restriction on the disclosure of any PHI for the permissible purposes of payment and health care operations relating to goods or services for which a patient has paid a participating organization out-of-pocket, in full, in accordance with the requirements of the HITECH act. In addition, a patient may request other disclosure restrictions upon the use and disclosure of his or her PHI subject to the agreement of the patient's participating organization in accordance with the HIPAA privacy rules. The WVHIN shall comply with any and all such restrictions by accepting a participating organization's classification of any such PHI as sensitive health information pursuant to Section 7 of this rule.

6.6.a. The participating organization shall be responsible for identifying, classifying, segregating, and blocking any PHI relating to out-of-pocket goods and services as sensitive health information; and

6.6.b. Any other restriction on the disclosure of PHI requested by a patient and agreed to by a participating organization shall likewise be identified, classified, segregated, and blocked by the participating organization as sensitive health information.

6.7. A patient shall have the right to be notified of a breach of his or her unsecured PHI consistent with the requirements of the HITECH act and W. Va. Code Chapter 46A, Article 2A. The WVHIN shall comply fully with its notification obligations under the foregoing federal and state laws.

6.8. The WVHIN shall affiliate with at least one vendor of a personal health record product. That affiliation shall permit a patient to access his or her personal health record directly through the

WVHIN. If a patient registers a personal health record with the WVHIN, that personal health record may contain PHI made available from participating organizations or other sources. Each participating organization shall process a patient's request to transfer his or her PHI from the participating organization's designated record set to the patient's personal health record in the same manner as any other request for access by the patient.

**§65-28-7. Sensitive Health Information.**

7.1. Federal and state laws impose heightened privacy and confidentiality requirements upon the disclosure and use of certain types of PHI that may be considered particularly private or sensitive to a patient. The categories of sensitive health information may include:

7.1.a. Drug or alcohol abuse information;

7.1.b. Mental health information;

7.1.c. Psychotherapy notes;

7.1.d. Out-of-pocket goods and services or other forms of PHI that are subject to a disclosure restriction that has been requested by a patient and agreed to by the participating organization; and

7.1.f. Any other goods and services subject to heightened privacy and confidentiality requirements under federal and state laws or regulations and specifically approved by the WVHIN.

7.2. The WVHIN shall provide a capability by which participating organizations may identify, classify, segregate, and block the routine disclosure of sensitive health information through the health information exchange. Each participating organization shall be solely responsible for identifying, classifying, segregating, and blocking the disclosure of sensitive health information contained in its designated record sets through the health information exchange.

7.3. The WVHIN may develop written standards or forms by which patients may specifically consent to or authorize the disclosure of their sensitive health information consistent with all legal requirements.

7.4. If an executed specific consent or authorization is required in order to disclose or use sensitive health information, the WVHIN shall a procedure by which sensitive health information may be disclosed only in a manner that complies with such consent or authorization.

7.5. A patient may revoke his or her specific consent or authorization to disclose sensitive health information at any time. However, any exchange of sensitive health information that occurred prior to revocation shall not be reversed.

**§65-28-8. Participating Organizations.**

8.1. In order to request and receive a patient's PHI through the WVHIN's health information exchange, it is necessary to first become a participating organization. The WVHIN shall make that privilege available to any health care provider, licensed practitioner, public health agency, health care clearinghouse, health plan, or other organization approved by the WVHIN that establishes a contractual relationship in accordance with a standard participation agreement developed and approved by the WVHIN.

8.2. During the course of its development and implementation, the WVHIN shall establish a plan for statewide coverage that is consistent with its available resources and the readiness of prospective participating organizations to connect to the health information exchange.

8.2.a. To evaluate the readiness of prospective participating organizations to connect to the WVHIN, the WVHIN shall prepare and publish interoperability guidelines that shall be met in order to become a participating organization.

8.2.b. The WVHIN's interoperability guidelines shall be based upon national and industry health data and security standards regarding interoperability between and among participating organizations.

8.2.c. The WVHIN's interoperability guidelines shall be designed reasonably to ensure that PHI made available through the health information exchange is complete, accurate, and current.

8.3. Upon enrollment in the WVHIN, a participating organization shall promptly enable the WVHIN to access personal demographic information and protected health information about all of its patients, and to include these patients in the WVHIN's master patient index, subject to each patient's right to opt-out of the health information exchange.

8.4. A participating organization shall thereafter promptly transmit to the WVHIN any known changes to its patients' personal demographic information to maintain the accuracy of the master patient index.

8.5. The WVHIN may in its discretion grant participating organization status to health care providers or licensed practitioners that cannot comply with the WVHIN's interoperability guidelines in order to provide such health care providers or licensed practitioners with access to the PHI of their patients maintained by other participating organizations for a permissible purpose.

8.6. A participating organization shall strictly control access to the WVHIN's health information exchange by its workforce through an organized system of approving and designating authorized users.

8.7. Each participating organization shall be solely responsible for identifying, classifying, segregating, and blocking the disclosure of sensitive health information contained in its designated record sets through the WVHIN's health information exchange.

8.8. A participating organization may disclose and use PHI as part of the health information exchange only in manner that is consistent with the following:

8.8.a. HIPAA, the HIPAA privacy rules, the HIPAA security rules, the HITECH act, and any other applicable federal law or regulation;

8.8.b. Any applicable West Virginia law or legislative rule, including but not limited to, this legislative rule promulgated at title 65, series 28; and

8.8.c. the WVHIN-approved participation agreement.

8.9. Each participating organization shall designate a site administrator from its workforce to be the primary point of contact with the WVHIN, and to perform various administrative functions,

including but not limited to, granting and terminating authorized user status to members of its workforce.

8.10. A participating organization shall promptly report any malfunction, misuse, or breach involving the health information exchange to the WVHIN, or its designee, for investigation and remediation.

**§65-28-9. Authorized Users.**

9.1. The WVHIN and each participating organization shall designate authorized users based upon job roles fulfilled by individuals in their respective workforces. Each participating organization shall be responsible for establishing this role-based access system to limit access within an organization to those workforce members with a need to know.

9.2. Each participating organization shall designate, maintain, and certify their official lists of authorized users to the WVHIN. A workforce member may be designated as an authorized user only if that member requires access to PHI in the WVHIN's health information exchange in order to perform his or her job responsibilities within the participating organization.

9.3. A workforce member who is not designated as an authorized user shall not be allowed to access the WVHIN for any purpose.

9.4. Each participating organization shall provide training for its authorized users before they may access the health information exchange. This training program shall include a review of the functionality of the health information exchange, as well as a review of all rules, policies, and procedures promulgated by the WVHIN.

9.5. Each participating organization shall be responsible for maintaining a current list of its authorized users. This requires that changes in employment status as well as other workforce changes, including termination of authorized user status, shall be communicated immediately and electronically to the WVHIN by the participating organization's site administrator.

9.6. A participating organization shall be wholly responsible for maintaining an appropriate and current list of its authorized users.

9.7. The WVHIN shall require any of its subcontractors and vendors that qualify as a business associate under HIPAA and the HITECH act to also designate, maintain, and certify their list of authorized users in accordance with the role-based access concept.

9.8. A patient may seek approval from the WVHIN for authorized user status in either of the following circumstances:

9.8.a. The patient registers his or her personal health record with the WVHIN's health information exchange; or

9.8.b. If the WVHIN offers a direct access alternative to a patient's designated record set maintained by a participating organization, the patient is approved for direct access by cooperating participating organizations.

9.9. The WVHIN may temporarily suspend or permanently revoke an individual's status as an authorized user of the WVHIN for any of the following reasons:

- 9.9.a. Violation of the WVHIN's legislative rule;
- 9.9.b. Violation of any federal or state law or regulation;
- 9.9.c. Fraudulent activity;
- 9.9.d. Prolonged inactivity on the health information exchange system; or
- 9.9.e. Any other good cause.

**§65-28-10. User Authentication.**

10.1. To optimize the privacy and security of its health information exchange, the WVHIN shall ensure that an authorized user's identity is properly authenticated each time the exchange is accessed. The WVHIN shall establish a system by which each participating organization shall implement minimum requirements for authentication information unique to each authorized user in accordance with industry standards and specifications.

10.2. The WVHIN and the participating organizations shall place strict controls upon the use of such authentication information. Authentication information shall not be shared with any other individual besides the authorized user to whom the authentication information is assigned.

10.3. Any loss or misuse of an authorized user's authentication information shall be immediately reported to the WVHIN, and if applicable, to the participating organization.

10.3.a. The WVHIN and the participating organization's site administrator shall be authorized to lock out the affected authorized user from accessing the health information exchange; and

10.3.b. This lock out shall be terminated only after an authorized user's identity is verified, and new authentication information has been approved for the authorized user in question.

**§65-28-11. Minimum Necessary.**

11.1 The HIPAA privacy rules apply a "minimum necessary" standard to many types of disclosures and uses of PHI. This standard essentially means that a covered entity or business associate shall make reasonable efforts to limit the disclosure and use of PHI to the minimum necessary to accomplish the purpose of the proposed disclosure and use.

11.1.a. The minimum necessary rule is subject to certain exceptions:

11.1.a.1. The minimum necessary rule shall not apply to any disclosures and uses of PHI for the permissible purposes of treatment or emergency treatment;

11.1.a.2. The minimum necessary rule shall not apply to disclosures and uses of PHI pursuant to a signed consent or authorization by the patient; and

11.1.a.3. The minimum necessary rule shall not apply to disclosures of PHI pursuant to a patient's request for access to his or her own PHI.

11.2. The WVHIN shall not apply the minimum necessary rule to any of the above exceptions under its health information exchange.

11.3. Participating organizations shall limit their inquiry for PHI under the WVHIN to the minimum necessary when required under the HIPAA privacy rules.

11.4. The WVHIN shall rely upon the reasoned judgment and representations of a participating organization seeking access to PHI as compliant with the minimum necessary standard under HIPAA privacy rules.

11.5. The WVHIN may develop standard protocols or data fields which are designed to disclose only the minimum necessary amount of PHI to accomplish a permissible purpose. For example, only those data fields required by federal or West Virginia law to comply with a public health reporting requirement may be employed by the WVHIN to accomplish this reporting. The WVHIN may investigate other permissible purposes for which standard protocols or data fields designed to disclose only the minimum necessary amount of PHI may be developed.

**§65-28-12. Business Associates; De-Identification of PHI.**

12.1. Under the HITECH act, the WVHIN's operation of a health information exchange qualifies it as a business associate of its various participating organizations. Accordingly, the WVHIN shall enter into a valid and binding business associate agreement with each participating organization. The business associate agreement shall comply with any and all of the requirements of HIPAA and the HITECH act.

12.2. To the extent that the WVHIN utilizes subcontractors and vendors to assist it with the development, implementation, and operation of the health information network, and said subcontractors and vendors fall within the definition of a business associate under HIPAA and the HITECH act, then the WVHIN shall enter into a valid and binding business associate agreement with each subcontractor or vendor. The business associate agreement shall comply with all of the requirements of HIPAA and the HITECH act.

12.3. The HIPAA privacy rules identify the means by which PHI may be deidentified. To be considered as deidentified, the remaining data shall not identify a patient, and there shall be no reasonable basis to believe that the information can be used to identify a patient. The WVHIN may deidentify PHI, and may disclose or use such deidentified data for any public health or research purpose approved by the WVHIN board.

**§65-28-13. Security Safeguards.**

13.1. The WVHIN shall develop and implement appropriate administrative, physical, and technical safeguards designed to protect the privacy and security of any PHI and personal demographic information that it receives, creates, discloses, or uses under its health information exchange.

13.2. At a minimum, these security safeguards shall comply with the requirements set forth in the HIPAA security rules codified at 45 C.F.R. §§ 164.306, 164.308, 164.310, 164.312, and 164.316.

13.3. Prior to developing these security safeguards, the WVHIN shall undertake a comprehensive assessment and analysis of the potential risks and vulnerabilities of its health information exchange.

13.4. The WVHIN's development and implementation of security safeguards shall remain consistent over time with new developments and changes. Accordingly, the intent of the WVHIN is that

the safeguards required by the HIPAA security rules are minimum safeguards. When necessary or appropriate, these safeguards may be amended, modified, or enhanced to keep pace with evolving technologies, new industry standards, and legal requirements that may become applicable in the future.

**§65-28-14. Complaint Procedure.**

14.1. Any patient, authorized user, or participating organization may file a written complaint with the WVHIN concerning any aspect of its operations. All complaints shall be in writing and shall identify the individual responsible for making the complaint.

14.1.a. The WVHIN shall develop and approve a complaint form which includes, at a minimum, the following items:

- 14.1.a.1. The name, address, and phone number of the individual making the complaint;
- 14.1.a.2. The date of the complaint;
- 14.1.a.3. The date that an adverse event occurred; and
- 14.1.a.4. A description of the adverse event.

14.2. The WVHIN shall designate a person responsible for receiving, investigating, and responding to complaints. This complaint procedure shall be prominently featured on the website maintained by the WVHIN, along with the name and address of the person designated by the WVHIN to handle complaints.

14.3. The WVHIN shall acknowledge receipt of a complaint, investigate it, and make every effort to resolve the complaint within a reasonable time frame, which in most cases shall not exceed thirty (30) days.

14.4. The WVHIN shall notify the complaining individual of the WVHIN's resolution or other response to the complaint in writing. This resolution or response shall include information about how the individual may forward the complaint to the Executive Director of the West Virginia Health Care Authority if it has not been resolved to the satisfaction of the complaining individual.

14.5. The WVHIN shall periodically analyze all filed complaints to determine if persistent or recurrent problems exist with the health information exchange system or its operation.

**§65-28-15. Pilot Demonstration Projects.**

The WVHIN shall be authorized to develop, implement, and operate one or more pilot demonstration projects in designated communities of the state to acclimatize participating organizations to the health information exchange environment, and to evaluate the efficiency and effectiveness of its health information exchange system. The WVHIN shall coordinate its pilot demonstration project(s) with diverse components of the health care delivery system in the communities chosen. The pilot demonstration project(s) shall be developed, implemented, and operated in full compliance with these legislative rules.