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November 20, 2008

Sallie H. Milam, Esq.
Chief Privacy Officer, WV Executive Branch
Executive Director, WVHIN
WV Health Care Authority
100 Dee Drive
Charleston, WV 25311

Re: Sensitive Information Exchange

Dear Ms. Milam:

You have asked our opinion as to whether there is support under existing West Virginia law, and for drug and alcohol treatment records under federal law, to permit health care providers to input sensitive data into the WVHIN, as well as to receive sensitive data, as the phased roll-out of the WVHIN's services develops. I understand that Phase 1 and 2 of the roll-out will be designed to support health care coordination (treatment purposes) and inquiry functionalities. I also understand that a consent process for patient/consumer participation will continue to be used when appropriate. Sensitive information for purposes of this opinion letter is protected health information (PHI) that is subject to certain specific disclosure constraints under West Virginia state laws and, in the case of drug and alcohol treatment, federal law. The short answer is yes, with additional considerations discussed below, grouped by the specific type of sensitive PHI reviewed and a separate discussion for electronic prescribing.

**Mental Health Information [West Virginia Code, Chapter 27, Article 3 "Confidentiality;"
and see 64 WV C.S.R. Title 11]**

Mental Health Information (M-PHI) which is "confidential information," may be disclosed in accord with West Virginia statutory law. Confidential information in this context is broadly defined and includes diagnosis or treatment, information transmitted by others participating in the accomplishment of objectives of diagnosis or treatment, the fact that a person is a client or patient and all opinions, advice, instructions or prescriptions and "any record or characterization of the matters" described. W.Va. Code § 27-3-1(a). Confidential information may be disclosed for treatment or internal review purposes, to staff of the mental health facility

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where the patient is being cared for or to other health professionals involved in the treatment of the patient. W.Va. Code § 27-3-1(b)(5). Recently, the Legislature added a paragraph to Article 3, "Confidentiality," to allow information to be transferred for treatment, payment, health care operations, and other permitted purposes under HIPAA, for thirty (30) days. Patient consent is not needed during this window of time as long as the provider makes a good faith effort to obtain consent from the patient or legal representative, discloses the minimum necessary for the stated purpose and provides prompt notice of disclosure to the patient or legal representative. W.Va. Code § 27-3-1(b). Confidential information may also be disclosed to protect against a clear and substantial danger of imminent injury by a patient or client to himself or another. *Id.* Any other disclosure of confidential information other than those included within the scope of paragraph (b) requires a patient's signed authorization. W.Va. Code § 27-3-2.

The WVHIN has thus far elected to utilize an opt-out approach for patient/consumer consent for its demonstration projects and its phased roll-out, when consent is considered prudent and depending on the type of service being offered.¹ Specifically, patients/consumers have participated in an opt-out consent process prior to entry of selected PHI from their providers into the network, which process appears to have been embraced by the patients who have participated in the demonstration projects, as evidenced by the small number of persons who elected to opt-out. For M-PHI then, in the context of the opt-out process, what procedures will support the WVHIN's objectives and satisfy legal constraints such that M-PHI can be entered into the WVHIN secure network (disclosure to the WVHIN) and transmitted across the network (transmission) for inquiry functionality and coordination of care activities?

As noted above, the statute specifically permits M-PHI to be disclosed to other health professionals involved in patient treatment. The proposed WVHIN services in the Phase 1 and Phase 2 rollout are to support the health care community in its delivery of patient treatment. However, the WVHIN itself is not a health professional. Rather, the WVHIN is being developed as a support service for health professionals to allow them first, to receive clinical laboratory data quickly with less risk of data being mislaid or critical numbers overlooked in the paper shuffle, and two, to more efficiently and effectively coordinate patient care and eliminate duplication of services. Thus, the WVHIN, as a support service for PHI transfer, data consolidation and PHI delivery for the purposes of patient treatment, will be an agent of the health care professional. The WVHIN is proceeding on a separate track to develop provider agreements which will memorialize the reasonable expectations of the parties to the agreement and clarify the legal relationships. The WVHIN is also exploring the best fit under federal law (HIPAA) for its relationships with health care professionals.

In light of the above, it is our opinion that West Virginia law at present could support M-PHI disclosure to the WVHIN and transmission for treatment-related purposes as long as the opt-out process includes specific information to the patient/consumer that their M-PHI may move,

¹ However, for purposes of pushing clinical data from laboratory to provider (Phase 1 of the roll-out), no patient consent is implicated. In the case of HIV-test results from a WV laboratory, a notice must be attached. See discussion under HIV-AIDS section of this letter.

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that is, be subject to disclosure to the WVHIN and transmission across the WVHIN for treatment-related purposes unless the patient chooses to opt-out of the network.

The process for disclosure of M-PHI by state-operated mental health facilities is set forth in the West Virginia Code of State Rules Title 64, Series 59. These rules are applicable only to state-operated mental health facilities and may lead the WVHIN to explore with the Department of Health and Human Resources the development of a protocol or recommended rule amendment before state-operated mental health facilities can fully participate in the WVHIN's services. The Rule distinguishes between "confidential information" § 64-59-11.2 and "disclosure of [clinical] records." 64 W.Va. C.S.R. 59-11.5 and *see generally*, §11.4. Per these rules, confidential information may be disclosed for treatment purposes without a signed patient authorization. §59-11.2.1.e. Confidential information is defined in accord with the state law, discussed above. However, a patient/client is to "be informed upon the commencement of any contact with medical or behavioral health professionals that their rights to confidentiality are limited in the ways set forth in this rule." §59-11.2.2. In other words, it would seem that the opt-out process with a specific discussion with the patient that M-PHI may be shared among providers would satisfy this prong of the rule; however, disclosure of "records" is treated separately and includes a distinct consent component.

Clinical records includes all pre-admission data, post-admission data and discharge records, physical and emotional diagnoses, medication history, consents, etc. *See* 64 W.Va. CSR § 59-11.4.2. While section 11.5 incorporates the treatment disclosures found in section 11.2, the rule also states that disclosure to "persons or agencies which require the information in order to provide continuing service to the client; and...insurers or other third-party payers... require the consent of the client/patient or designee and the consent of the secretary of the Department of Health and Human Resources." § 59-11.5.1.e. Consent is defined as a written and signed authorization, with a copy provided to the patient. 64 W.Va. C.S.R. § 11.3; § 27-3-2.

Accordingly, as the WVHIN is not a health care provider its definition, for the purposes of this rule, would seem to be included in the "persons or agencies which require the information to provide continuing service." § 11.5.1.e. If this is the appropriate designation for the WVHIN for the state operated mental health facilities rule, then a signed patient consent and consent from the Secretary of the Department of Health and Human Resources are necessary for disclosure to the WVHIN for this subset of M-PHI. Therefore, where M-PHI originates may play a role as to when this information can be disclosed to the WHIN through the use of the opt-out process.

Finally, Article 3 of the mental health statute is silent as to whether consent is needed for necessary disclosures for payment and health care operations (ancillary functions), other than the recent legislative addition of a thirty day window for in-patient mental health facilities for HIPAA-permitted disclosures. § 27-3-1(b). Accordingly, one would have to find that treatment-related disclosures incorporates these ancillary functions to find that confidential mental health information can be disclosed and transmitted for ancillary functions without a written authorization; that is, that the opt-out consent process would be sufficient. This is a murky area

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particularly since the statute acknowledges these ancillary functions, distinct from treatment, may be disclosed without consent but subject to certain requirements for a thirty day period. As these ancillary functions are not critical for the phase one and two stages of the WVHIN roll-out, it may well be that experience and law will clarify what is needed to permit this data to flow through the WVHIN. Also, it is foreseeable, that at least for payment purposes, a contractual authorization will exist separately from the WVHIN that will cover this disclosure and transmission; that is, the health insurance contract or governmental insurer will require the patient's consent, as a condition of coverage, for electronic transmission of data for payment/reimbursement purposes.

HIV/AIDS – The AIDS-Related Medical Testing and Confidentiality Act [W.Va. Code § § 16-3C-1--9]

HIV-related test results are confidential and subject to disclosure requirements under this Act. HIV-related tests are defined to include "a test for the HIV antibody or antigen or any future valid test..." W.Va. Code § 16-3C-1(j); *see generally*, W.Va. Code § 16-3C-2. The confidentiality extended under Article 3C applies specifically to HIV-related tests, the subject of the test and the test results, W.Va. Code §16-3C-3(a). The statute is commonly perceived as one protecting all HIV-related information; however to date we find no West Virginia case which construes the statute as affording such a broad blanket of heightened confidentiality. Accordingly, it is reasonable to apply the statute as written to conclude that a patient's self disclosure of HIV/AIDS is only entitled to the same protections and permitted disclosures as all other PHI.

HIV-related tests and results (HIV-tests) may be disclosed to licensed medical personnel or appropriate health care personnel treating the patient when knowledge of the HIV-tests "is necessary or useful to provide appropriate care or treatment, in an appropriate manner." W.Va. Code § 16-3C-3(a)(5); *see also*, W.Va. Code § 16-3C-3(a)(4), HIV-test information may be disclosed to "a funeral director or an authorized agent or employee of a health facility or health care provider if the...facility...is authorized to obtain the test results, the agent or employee provides patient care...and the agent or employee has a need to know such information." The personnel are required to "maintain the confidentiality of such test results." *Id.* Health care provider is defined to include the provision of "health care services of any kind." W.Va. Code § 16-3C-1(l).

Disclosures made to providers {and certain other permitted recipients} are to contain a specific written notice which states that the information is disclosed from records whose confidentiality is protected by state law. State law prohibits the recipient from making further disclosure without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. A general authorization will not suffice. W.Va. Code § 16-3C-3(c).

The HIV-tests Act has related rules clarifying confidentiality. *See*, W.Va. C.S.R. Title 64,

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Series 64. Any laboratory performing an HIV-related test in West Virginia shall have the statement of confidentiality in W. Va. Code § 16-3C-3(c) appear on the report form or as an attachment to the report form returned to the health care provider or facility. 64 W.Va. C.S.R. § 64-9.1. An agent or employee of a health facility or health care provider has a need to know HIV test results under the provisions of W. Va. Code §16-3C-3(a)(4) when the information is medically necessary to protect the individual from a significant risk of transmission or will have an impact on the treatment modality. 64 W.Va. C.S.R. § 64-9.4. Finally, no person who obtains information protected by the provisions of W. Va. Code §16-3C-1 et seq. and this rule may convey the protected information to any other person except in strict compliance with W. Va. Code §16-3C-1 et seq. and the rule. Unauthorized disclosure will subject the person to all penalties available. 64 W.Va. C.S.R. § 64-9.1.

In light of the above, it is our opinion that West Virginia law at present could support HIV-tests disclosure to the WVHIN and transmission for treatment-related purposes as long as the opt-out process includes specific information to the patient/consumer that their HIV-tests may move, that is, be subject to disclosure to the WVHIN and transmission across the WVHIN for treatment-related purposes unless the patient chooses to opt-out. Note however, that a positive HIV test report, or the diagnosis of AIDS related complex, or the diagnosis of the AIDS syndrome or disease, may not constitute a basis upon which to deny the individual so diagnosed, access to quality health care: Provided, that this subsection does not apply to insurance. W.Va. Code § 16-3C-6(a). The anti-discrimination clause suggests that the WVHIN will need to consider whether providing a patient/consumer the option to decline to participate in the WVHIN is sufficient to satisfy the anti-discrimination clause.

There are three significant caveats to utilizing the opt-out approach for HIV-test results: first, disclosure to health care personnel is limited to that which is "necessary or useful to provide appropriate care," W.Va. Code § 16-3C-3(a)(5); therefore, it may be that some method to document provider attestation as to necessity or usefulness will need to be developed. Second, the HIV-tests data when generated in West Virginia should be accompanied with the statutory notice governing re-disclosures before the data is "returned to the health care provider or facility." 64 W.Va. C.S. R. § 64-9.1. Third, a Provider-WVHIN agreement should be in place which clarifies the relationship between the providers and the WVHIN so as to demonstrate the "agency" relationship. W.Va. Code § 16-3C-3(a)(4).

Finally, while the statute is limited to confidentiality for HIV-tests, the WVHIN may consider whether it wants to expand the opt-out process to include information about how all other HIV/AIDS data (other than HIV-tests) will be treated in the same, secure manner as all other PHI.

Payment and health care operations purposes for disclosure are not distinctly addressed in the Act. Arguably therefore, one could find that a specific consent is needed. However, as discussed above in the mental health section, payment and health care operations purposes are ancillary to the delivery of health care. Based on current law, it is unclear to this writer whether identifying those ancillary functions as treatment-related, and providers then advising patients/consumers during the opt-out process that treatment-related disclosures will include

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these ancillary functions will be found to constitute sufficient notice and consent. Again, as noted above, it may well be that at least for payment purposes, a written authorization will exist separately from the WVHIN opt-out process that will solve the problem; that is, the health insurance contract or governmental insurer will require the patient's consent, as a condition of coverage, for electronic transmission of data for payment purposes.

Social Workers and Counselors [W.Va. Code §§ 30-30-12; 30-31-13]

Social workers and counselors who acquire confidential client information cannot disclose that information to anyone else without a patient authorization except in certain narrow situations usually involving the courts. Treatment is not a recognized exception under the law. Accordingly, the client will have to consent before the information is transmitted to a health care provider. Once consented to and disclosed to the health care provider, the information fits (in most cases) into the definition of M-PHI and may be handled as discussed above in the M-PHI section. If not M-PHI, then the information is treated as PHI. As this information can be highly sensitive, it may be prudent in the opt-out process to include information about re-disclosures related to treatment including that upon a patient/consumer's consent to the disclosure of information from a social worker/counselor to a health care provider that information becomes part of the patient's PHI that may subsequently be disclosed and transmitted to other health care providers.

Drug and Alcohol Treatments SAMHSA Rules [42C.F.R. Part 2]

Any "federally-assisted" drug and alcohol treatment provider is required to comply with the drug and alcohol treatment confidentiality rules (Part 2) as well as the HIPAA Privacy Rule. Under Part 2, disclosures for treatment purposes without written authorization are specifically limited to medical emergencies where there is a need to know for the purposes of treating a condition which poses an immediate threat to the health of an individual and requires immediate medical intervention. However, the HIPAA Privacy Rule permits disclosures for treatment, payment and health care operations without consent. It would seem that the more restrictive disclosure rules under Part 2 would govern. However, at least one Substance Abuse and Mental Health Services Administration (SAMHSA) document suggests that if the patient has written notice that disclosures may include treatment, payment and health care operations (TPO), these TPO disclosures may be made without written consent to qualified service organizations or business associates who provide services to the program's treatment, payment or health care operations.² Since this is a federal matter, a uniform approach to what notice, consent and attestation is needed to transmit and disclose TPO information across the networks among all participating networks is obviously preferable. I am advised that various agencies are studying

² U.S. SAMHSA, "The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs." (2004). On the web: www.hipaa.samhsa.gov/Part2othrchanges.htm

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this issue.

One additional point to consider: Part 2 contains a notice requirement which is to accompany records disclosed upon obtaining a patient's written consent; to wit:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 C.F.R. Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. 42 C.F.R. § 2.32.

Given that the current federal rules governing substance and alcohol abuse records from federally-assisted facilities are in conflict and that a uniform solution across participating networks would be best, the WVHIN needs to decide how it wants to handle this information in the interim.

Electronic Prescribing (W. Va. Senate Bill 1001, effective June 18, 2007, codified primarily at W. Va. Code § 30-5-1b and § 30-5-12c; "Regulation of Electronic Prescribing," filed by the W. Va. Board of Pharmacy, Aug. 29, 2008 to be codified at 15 W. Va. C.S.R. 1)

Electronic prescribing (E-prescribing) is specifically permitted under West Virginia law with the passage of Senate Bill 1001. S.B. 1001 requires that the electronic transmission be "in a manner consistent with [all] applicable federal law." The Statute specifically references HIPAA, Medicare Prescription Drug Act of 2003, Controlled Substances Act of 1970, Drug Abuse Prevention Act, and the Comprehensive Alcohol Abuse and Treatment Act of 1970. In addition to these referenced statutes, Medicare has finalized its e-prescribing rule, 42 CFR 423, and the Department of Justice, Drug Enforcement Administration, has received comments on its proposed rule, 73 Fed. Reg. 36722 (June 27, 2008), for electronic prescriptions for controlled substances.

The proposed rules recently filed by the West Virginia Board of Pharmacy (to be reviewed and voted upon by the Legislature in 2009) clarify the scope and requirements for lawful E-prescribing. Proposed Rule, "Licensure and the Practice of Pharmacy," filed Aug. 29, 2008 ("Proposed Rule"). The definitions include "confidential information" which is PHI maintained by a pharmacist in the "patient record" (which is not defined) or which is communicated to the patient or communicated by the patient to the pharmacist. Proposed Rule at § 15-1-2.1.6. Unfortunately, "E-prescribing," that is the transmission of the PHI (including the prescription) from physician and other health-care providers to the pharmacy, is not included in the definition of "confidential information." This is not fatal to the analysis for WVHIN purposes but is a weakness in the rule's construction, since the "confidential information" as defined in the rule is "privileged" (not defined). Whatever that "privilege" may turn out to be, it would be advantageous to include the provider's transmission of PHI in the definition of

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confidential information. The "privileged" information can be released to "other members of the health care team" (which is not defined) when "necessary to the patient's health and well-being." *Id.*

The proposed rule also permits disclosure to "health plans" for payment (HIPAA definition employed for "health plans"), and disclosures to others including governmental agencies authorized by law to receive such "privileged information" for peer review, utilization review and as authorized by the patient or court order. Also, "appropriate disclosure may occur by the pharmacist directly or through an "electronic data intermediary." *Id.* E-prescribing is expressly defined to include prescribing by a practitioner either directly or through an "electronic data intermediary." Proposed Rule at § 15-1-2.1.18. Electronic Data Intermediary is defined as "an entity that provides the infrastructure to connect a computer system, hand-held electronic device or other electronic device used by a prescribing practitioner...to facilitate the secure transmission of: (A) an electronic prescription order; (B) a refill authorization request; (C) a communication; or (D) other patient care information. § 15-1-2.1.17. Electronic Data Intermediaries are required to "maintain the confidentiality and security of transmitted information as required by applicable federal and state laws." Proposed Rule at § 15-1-21.1.6. The WVHIN would fit the definition of electronic data intermediary.

In consideration of the statute and proposed rules as well as all other applicable state and federal laws, and our prior opinion regarding consent generally, it is our opinion that E-prescribing, may be supported by the WVHIN without the need for written patient authorization for utilizing the WVHIN. For patients with sensitive information which supports their prescriptions or is contained within their prescriptions, the consent/authorization analysis is the same as discussed above. The act of sending prescriptions with supporting PHI (when appropriate) is reasonably deemed to be a treatment purpose. *See, e.g.,* 45 CFR § 160.103, "HIPAA General Administrative Provisions" definition for "Health Care." While the West Virginia Supreme Court did not find pharmacists to be health care providers for purposes of applying the Medical Professional Liability Act (MPLA), *Phillips v. Larry's Drive-In Pharmacy, Inc.* 647 S.E.2d 920 (W.Va. 2007), we think the Court's opinion is limited to construing the MPLA and would likely not be the Court's view in relation to E-prescribing activity. Therefore, we think that the WVHIN may support E-prescribing activities without a specific patient authorization, subject to federally-imposed constraints (SAMHSA, DEA), as well as Board of Pharmacy specifically delineated protocols for scheduled drugs (proposed for Schedule II, dependency-inducing medications). It appears from the new Medicare rules and the proposed Department of Justice rules that E-prescribing schedule II medications will eventually be permitted with likely additional requirements imposed by the DEA and the West Virginia Board of Pharmacy.

Finally, it appears that information transmitted from a pharmacy or other approved medication supplier to (HIPAA-defined) health plans for payment purposes will be permitted by the rule, as drafted, without the need for specific patient authorization.

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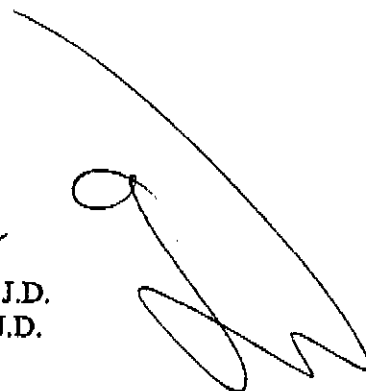
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We hope this letter is self-explanatory and will assist the WHIN as it continues to develop its services. Should you have any questions or want any further analysis of sensitive health information, please contact us.

Sincerely,

Michele

Michele Grinberg, J.D.
Alaina N. Crislip, J.D.

A large, stylized handwritten signature in black ink, likely belonging to Alaina N. Crislip, J.D., positioned to the right of the typed names.