

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

Form #3

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WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: Secretary of DHHR; Insurance Commissioner; and Chair of the Health Care Authority

TITLE NUMBER: 114A

CITE AUTHORITY W. Va. Code §33-4A-8

AMENDMENT TO AN EXISTING RULE: YES ___ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 2

TITLE OF RULE BEING PROPOSED: All Payer Claims Database - Privacy and Security Requirements

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.



Charles O. Lorensen
Cabinet Secretary
West Virginia Department of Revenue

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 28, 2011

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: WV OFFICES OF THE INSURANCE COMMISSIONER
ATTN: Timothy Murphy - Legal Division
1124 Smith Street
Post Office Box 50540
Charleston, West Virginia 25305-0540

LEGISLATIVE RULE TITLE: All-Payer Claims Database -
Privacy and Security Requirements
(Title 114A, Series 2)

1. **Authorizing statute(s) citation:**

W. Va. Code §33-4A-8.

2. a. **Date filed in State Register with Notice of Hearing or Public Comment Period:**

June 8, 2011 (notice of public comment period).

b. **What other notice, including advertising, did you give of the hearing?**

N/A

c. **Date of Public Hearing(s) or Public Comment Period ended:**

Public comment period ended July 8, 2011.

d. **Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.**

Attached X No comments received

e. **Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)**

Sec. of DHHR; Insurance Commissioner;
Chair of the Health Care Authority
Title 114A, Series 2

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Timothy Murphy, Associate Counsel
Offices of the Insurance Commissioner
P.O. Box 50540
Charleston WV 25305
304-558-6279, Ext. 1210
304-558-1362 FAX
Timothy.Murphy@wvinsurance.gov

- g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

N/A

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

N/A

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.
- b. Date of hearing or comment period:
- c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?
- d. Attach findings and determinations and reasons:

July 8, 2011

Comments to Proposed Legislative Rule on the All-Payer Claims Database (Series 2)
Prepared by Highmark West Virginia Inc. d/b/a Highmark Blue Cross Blue Shield West Virginia

Mr. Murphy,

Representatives of Highmark West Virginia Inc. ("Highmark WV") have had an opportunity to review the proposed legislative rule and, as a result of that review, would like to clarify the government's intention with regard to Section 4.2.

The applicable text reads in part as follows (emphasis added):

4.2 The MOU parties shall only use the data to assess the completeness and quality of health care payers' submissions in order to determine compliance with established data reporting requirements and standards. For purposes of this initial use, all personal identifiers shall remain encrypted and not visible to the MOU parties.

There is an indication implicitly stated in the above-listed provision that personal identifiers are going to be further encrypted before they are shared with MOU parties, rendering individuals unidentifiable. Is it the state's intention to perform such encryption, as we suspect it is, or will this require additional levels of encryption from the submitters of data? Highmark WV does not believe it should be responsible for the additional encryption.

Please feel free to contact me with any questions or if further discussion is necessary.

Respectfully submitted,

Angela E. Havelly, J.D.
Associate Counsel
Highmark West Virginia Inc.
(304) 424-9086

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

July 11, 2011

Timothy Murphy, Associate Counsel
WV Offices of the Insurance Commissioner
Legal Division
P. O. Box 50540
Charleston WV 25305-0540

Re: Proposed All-Payer Claims Database Privacy and Security Rule, CSR 114A, §2

Dear Mr. Murphy:

Thank you for the opportunity to comment on the above-referenced proposed rule. The WV Health Care Authority has the following comments:

1. Section 3.2 of Title 114A, Series 2, should be expanded to include all relevant security standards pertinent to the encryption of data in transmission as follows: NIST Special Publication 800-77, Guide to IPsec VPNs, December 2005, NIST Special Publication 800-113, Guide to SSL VPNs, July 2008, or others which are Federal Information Processing Standards 140-2, May 2001, validated. Section 3.2 should also indicate that such transmission will ensure authenticity, as opposed to availability.
2. Section 4.2 should clarify that it applies to both use and disclosure, and that the only permitted disclosure at this time, pending promulgation of additional rules, is back to the respective data submitter, where the completeness and quality review indicates a problem with the data, and such disclosure is required to facilitate the data collection process.
3. The Brief Summary of the Rule should reflect that development of the privacy and security requirements are an area of responsibility assigned to HCA, not DHHR.
4. The Statement of Circumstances should reflect that the statute assigns primary responsibility to the HCA for the release of data and should identify that the proposed rule addresses security, in addition to privacy.
5. The Fiscal Note should reflect that the proposed rule addresses security, in addition to privacy.

Very truly yours,

Sallie Milam
WV's Chief Privacy Officer, WV Health Care Authority

100 Dee Drive • Charleston, West Virginia 25311 • 304.558.7000 • 304.558.7001/fax • 1.888.558.7002/toll free

www.hcawv.org

ATTACHMENT TO QUESTION 2(d):

I. Highmark West Virginia Inc. (formerly known as Blue Cross Blue Shield of WV), commented on section 4.2 of the proposed rule and questioned whether the required encryption of all personal identifiers will be performed by the state. Highmark stated that it “does not believe it should be responsible for the additional encryption.” It is the MOU parties’ intention to provide the encryption technology itself or through a vendor on its behalf.

II. The WV Health Care Authority made the following comments:

1) Section 3.2 of Title 114A, Series 2, should be expanded to include various relevant security standards pertinent to the encryption of data in transmission and should also indicate that such transmission will ensure authenticity, as opposed to availability. The MOU parties agree and amend the rule as follows:

3.2. Transmission of the data from each data submitter to the APCD shall be in a secure manner that prevents unauthorized access and ensures authenticity, confidentiality, and integrity. This data transmission shall be secured to the level required by the HIPAA Security and Privacy Rules, 45 CFR § 164.102 *et seq.* and shall be encrypted per NIST Special Publication 800-52, Guidelines for the Selection and use of Transport Layer Security Implementations, June 2005, NIST Special Publication 800-77, Guide to IPsec VPNs, December 2005, or NIST Special Publication 800-113, Guide to SSL VPNs, July 2008, or others which are Federal Information Processing Standards 140-2, May 2001, validated, all as amended or superseded.

2) Section 4.2 should clarify that it applies to both use and disclosure, and that the only permitted disclosure at this time, pending promulgation of additional rules, is back to the respective data submitter where the completeness and quality review indicates a problem with the data and such disclosure is required to facilitate the data collection process. The MOU parties agree and amend the rule as follows:

4.2. The MOU parties shall only use the data to assess the completeness and quality of data submitters’ submissions in order to determine compliance with established data reporting requirements and standards. The MOU parties shall only disclose data back to the respective data

submitter, where the completeness and quality review indicates a problem with the data, and such disclosure is required to facilitate the data collection process. For purposes of this initial use, all personal identifiers shall remain encrypted and not visible to the MOU parties. Results of the completeness and quality assessments may be shared with the APCD's Advisory Board.

III. Additional changes

The definitions section was changed to exclude the terms that are included in series 1 of this title. Section 2 is amended to read as follows:

§114A-2-2. Definitions.

As used in this joint legislative rule, all terms that are defined in section 1 of the Act and in series 1 of this Title have those same meanings.

2.1. "Act" means the all-payer claims database act, W. Va. Code §33-4A-1 *et seq.*

2.2. "Title" means Title 114A.

Insurance Commissioner
Secretary of DHHR
Chair of Health Care Authority
Joint Legislative Rule
Title 114A, Series 2

ALL-PAYER CLAIMS DATABASE - PRIVACY AND SECURITY REQUIREMENTS

TITLE 114A, SERIES 2

BRIEF SUMMARY OF RULE

This is a joint rule proposed pursuant to HB 2745 (RS 2011, effective June 10), which provides that the Insurance Commissioner, Secretary of DHHR and the Chair of the Health Care Authority (collectively, the "MOU parties") "shall execute" an MOU to develop an all-payer claims. The statute assigns to each of the MOU parties an area of primary responsibility: The Insurance Commissioner for the collection of the data from insurers (series 1), DHHR for the maintenance of the data and HCA for the release of data to third parties. W. Va. Code §33-4A-2. This proposed rule addresses only the privacy and security provisions of the All-Payer Claims Database Program, an area of responsibility assigned to HCA.

Insurance Commissioner
Secretary of DHHR
Chair of the Health Care Authority
Joint Legislative Rule
Title 114A, Series 2

ALL-PAYER CLAIMS DATABASE - PRIVACY AND SECURITY REQUIREMENTS

TITLE 114A, SERIES 2

STATEMENT OF CIRCUMSTANCES

HB 2745, enacted during the 2011 regular session of the Legislature, provides that the Insurance Commissioner, Secretary of DHHR and the Chair of the Health Care Authority (collectively, the "MOU parties") "shall execute" an MOU to develop an all-payer claims database and provides that these agencies may propose joint legislative rules "as are necessary to implement" the all-payer claims database program. See W. Va. Code §33-4A-8. W. Va. Code §33-4A-8 further provides that no claims data may be collected and no fees may be assessed to users of such data until rules are promulgated. The statute assigns to each of the MOU parties an area of primary responsibility; the Insurance Commissioner is primarily responsible for rules and enforcement related to the collection of the data from insurers, DHHR for maintenance of the data and HCA for privacy/security and the release of data to other agencies, researchers, etc. W. Va. Code §33-4A-2. This proposed rule addresses only the privacy and security issues involved in collecting and retaining the data.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: All-Payer Claims Database - Privacy and Security Requirements (114A-2)
 Type of Rule: X Joint Legislative Interpretive Procedural
 Agency: WV Offices of the Insurance Commissioner
 Address: Post Office Box 50540
1124 Smith Street, Greenbrooke Building
Charleston, West Virginia 25305-0540
 Phone Number: (304) 558-6279 x1210 Email: Timothy.Murphy@wvinsurance.gov

Fiscal Note Summary

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

See Fiscal Note for Title 114A, Series 1; this rule deals with privacy of the data.

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	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs & Alterations	0	0	0
Assets	0	0	0
Equipment	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

Rule Title: All-Payer Claims Database Program's Privacy and Security Rule (114A-2)

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

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

See Fiscal Note for Title 114A, Series 1; this rule deals with privacy of the data.

MEMORANDUM

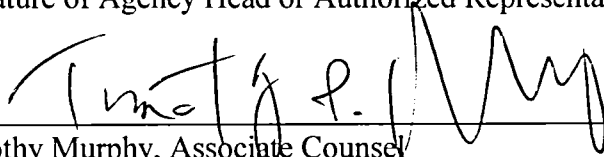
Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

See Fiscal Note for Title 114A, Series 1; this rule deals with privacy of the data.

Date: _____

7-28-11

Signature of Agency Head or Authorized Representative



Timothy Murphy, Associate Counsel
WV Offices of the Insurance Commissioner
P. O. Box 50540
Charleston WV 25305-0540
Timothy.Murphy@wvinsurance.gov

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SECRETARY OF STATE

TITLE 114A
JOINT LEGISLATIVE RULE
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN RESOURCES,
INSURANCE COMMISSIONER, AND THE CHAIR OF THE HEALTH CARE AUTHORITY

SERIES 2
ALL-PAYER CLAIMS DATABASE -- PRIVACY AND SECURITY REQUIREMENTS

§114A-2-1. General.

1.1. Scope. -- This joint legislative rule implements the privacy and security provisions of the All Payer Claims Database Program found at W. Va. Code §33-4A-1 *et seq.* as administered by the Department of Health and Human Resources, the Insurance Commissioner, and the Chair of the Health Care Authority.

1.2. Authority. -- W. Va. Code §§33-4A-4(b), (d); 33-4A-8(a) and (e).

1.3. Filing Date. -- _____, 2012

1.4. Effective Date. -- _____, 2012

§114A-2-2. Definitions.

As used in this joint legislative rule, all terms that are defined in section 1 of the Act and in series 1 of this Title have those same meanings.

2.1. "Act" means the all-payer claims database act, W. Va. Code §33-4A-1 *et seq.*

2.2. "Title" means Title 114A.

§114A-2-3. Data Collection Privacy and Security Requirements.

3.1. Data submitters shall transmit all data to the APCD or its designee over the APCD's secure electronic communications network.

3.2. Transmission of the data from each data submitter to the APCD shall be in a secure manner that prevents unauthorized access and ensures authenticity, confidentiality, and integrity. This data transmission shall be secured to the level required by the HIPAA

Security and Privacy Rules, 45 CFR § 164.102 *et seq.* and shall be encrypted per NIST Special Publication 800-52, Guidelines for the Selection and use of Transport Layer Security Implementations, June 2005, NIST Special Publication 800-77, Guide to IPsec VPNs, December 2005, or NIST Special Publication 800-113, Guide to SSL VPNs, July 2008, or others which are Federal Information Processing Standards 140-2, May 2001, validated, all as amended or superseded.

§114A-2-4. Data Retention and Initial Use and Disclosure Privacy and Security Requirements.

4.1. The APCD program shall retain the data in a secure manner that prevents unauthorized access and ensures confidentiality, integrity and availability of all data transmitted to the APCD, at the levels required by the HIPAA Security and Privacy Rules, 45 CFR § 164.102 *et seq.* and shall be encrypted per NIST Special Publication 800-111, Guide to Storage Encryption Technologies for End User Devices, November 2007, as amended or superseded.

4.2. The MOU parties shall only use the data to assess the completeness and quality of data submitters' submissions in order to determine compliance with established data reporting requirements and standards. The MOU parties shall only disclose data back to the respective data submitter, where the completeness and quality review indicates a problem with the data, and such disclosure is required to facilitate the data collection process. For purposes of this initial use, all personal identifiers shall remain encrypted and not visible to the MOU parties. Results of the completeness and quality assessments may be shared with the APCD's Advisory Board.

4.3. No additional uses or disclosures contemplated by this program shall be made until such time as the MOU parties promulgate rules specifically delineating the same.