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

Form #3

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OFFICE OF 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: 1

TITLE OF RULE BEING PROPOSED: All Payer Claims Database – Data Submission 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: Legal Division
1124 Smith Street
Post Office Box 50540
Charleston, West Virginia 25305-0540

LEGISLATIVE RULE TITLE: ALL PAYER CLAIMS DATABASE - DATA SUBMISSION REQUIREMENTS (TITLE 114A, SERIES 1)

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 14, 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:**

      July 14, 2011 (public comment period ended).

   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)**

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 14, 2011

Comments to Proposed Legislative Rule on All Payer Claims Database ("APCD") Submission Requirements (Series 1)

Prepared by Highmark West Virginia Inc. d/b/a Highmark Blue Cross Blue Shield West Virginia

Mr. Murphy,

Highmark West Virginia Inc. ("Highmark WV") previously submitted informal comments but a variety of our initial concerns translated into the published regulations. Representatives of Highmark WV have since had an opportunity to review the proposed legislative rules as published. As a result of that review, we have certain issues, concerns and clarification requests, as briefly described below:

1. Comments are problematic when no clear picture of the data's intended use is defined. For example, insured accounts often have members living across state lines, and carving out those members would lead to an incorrect reflection of true cost. To name another difficulty, the rule is limited to West Virginia members but does not address those who prefer to use out-of-state providers. Depending on the analysis intended, there could be inconsistencies, dilutions and duplications of data, but insurers cannot comment specifically on those obstacles based on educated guesses about the ultimate aims. Insurers have a need for clear and transparent expectations so that all roadblocks can be addressed.
2. In many cases, insurers such as Highmark WV house certain data but do not have ownership or authority to distribute; this data would consequently fall outside the rule's purview. Examples would include Highmark WV's administration of the Federal Employee Health Benefit Program (FEHBP) and, by virtue of our license with the Blue Cross Blue Shield Association, our obligation to pay claims for members not insured by Highmark WV.
3. Concerns have been brought to our attention about the treatment of information categorized as sensitive by various other state laws (e.g. substance abuse). Often information of this nature requires separate authorization from persons with medical data at stake, and obtaining those authorizations would be cumbersome if even possible.
4. The rule does not clearly define privacy and security responsibilities for APCD submissions once outside the control of payers. Security breach notification laws, HIPAA, HITECH and other such legislative initiatives would seemingly apply to the data at issue.

5. Insurers have a particular concern about FOIA implications. How can the rule reassure payers that confidential and proprietary information will not be made public via our simple act of compliance with it? Will there be a pre-disclosure process?
6. How does the approach taken by West Virginia compare to other approaches enlisted in other states? Are consistent criteria and uses being sought and will meaningful analysis among states be possible? Has West Virginia considered other, more decentralized models, such as the sentinel program underway at the Food & Drug Administration?

These comments were kept intentionally brief, as we understand you are probably in receipt of several others. However, we do not mean to downplay the importance to our organization of each. Please feel free to contact me with any questions or if further discussion is necessary. With respect to comments submitted informally by Ed Hamilton in early May, he is equally willing to discuss the issues at length.

Respectfully submitted,

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

Insurance Commissioner
Title 114A, Series 1

ATTACHMENT TO QUESTION 2(d):

Highmark West Virginia Inc. (fka Mountain State BCBS) made a number of comments, many of which are better characterized as concerns with details of the APCD project itself rather than suggestions for changes to the rule. The MOU parties respond to each as follows:

1. Highmark noted concerns with the aims of the program and the difficulties with commenting without knowing clearly the data's intended use; it also points out the possible problems with using data that excludes, for example, only West Virginia members who prefer to use out-of-state providers. The MOU parties note that the program is, like its counterparts around the nation, is intended to enable research into the real costs of medical care throughout the state through the collection of paid-claims data.

2. Highmark noted that it may house certain data that it does not own or have authority to distribute, such as data related to Highmark WV's administration of the Federal Employee Health Benefit Program (FEHBP). The MOU parties respond that even in the event a carrier is deemed a "health care payer" with respect to any such data, the rule includes a process by which a carrier can be exempted from the submission requirements – "3.2.c. The MOU parties may grant an exemption for cause to any presumed data submitter or class of presumed data submitters from all or some of the requirements of this rule"; this concept is echoed in section 5.2 as well:

   > 5.2. If a data submitter is unable to meet the terms and conditions of this rule and the submission manual due to circumstances beyond its control, a written request must be made to the MOU parties as soon as it is practicable after the data submitter has determined that an extension or waiver is required. The written request shall include the specific requirement to be extended or waived; an explanation of the cause; the methodology proposed to eliminate the necessity of the extension or waiver; and the time frame required to come into compliance. The decision of the MOU parties is not subject to further review.

   The MOU parties believe this mechanism is sufficient to meet the concerns expressed in this regard.

3. Highmark expressed concerns about the treatment of information categorized as sensitive by various other state laws (e.g. substance abuse)

that might require separate authorizations from affected persons that would be cumbersome or even impossible. Again, the MOU parties point to the exemption provisions in section 3.2.c of the rule 5.2, as well as the privacy and security provisions of series 2 of this title, as sufficient safeguards.

4. Highmark notes that information categorized as sensitive by various other state laws (e.g. substance abuse) often requires separate authorization from persons with medical data at stake and that obtaining those authorizations would be cumbersome if even possible. The MOU parties recognize that federal and state law may require separate authorization for release of specially protected health information and responds that, as part of the process of developing the Submission Manual, areas of specially protected health information will be identified and processes developed to ensure compliance with law without requiring additional patient authorization or consent. Therefore, no changes to the proposed rule will be made.

5. Highmark notes that the proposed rule does not clearly define privacy and security responsibilities for APCD submissions once this data is outside control of payers and comments that security breach notification laws, HIPAA, HITECH and other such legislative initiatives would seemingly apply to such data. The MOU parties concurs with the application of relevant privacy and security laws and regulations to the APCD submissions and directs attention to proposed Title 114A, Series 2, in which these privacy/security concerns are addressed.

6. Highmark notes insurers' concerns about the FOIA implications of the APCD's receipt of the data and asks for reassurance that confidential and proprietary information will not be made public and whether there be a pre-disclosure process for informing insurers of FOIA requests related to such data? The MOU parties point out that the law establishing the APCD program, W. Va. Code § 33-4A-4(b), specifically exempts such data from release under FOIA. The MOU parties will be conferring with stakeholders over the next year to determine a pre-disclosure process that will be addressed amendments to Title 114A, Series 2.

7. Finally, Highmark asks how the rule's approach compares to other those in other states with respect to such areas as the following: Are consistent criteria and uses being sought? Will meaningful analysis among states be possible? Has West Virginia considered other, more decentralized models, such as the sentinel program underway at the Food & Drug Administration? In response, the MOU parties note that the underlying statute provides that they may "[a]ttempt to ensure that the requirements with respect to the reporting of data be standardized so as to minimize the expense to parties subject to similar requirements in other jurisdictions ... . §33-4A-3(a) (5). The rule also provides for standardization and for coordination with other states' efforts through consultation with the national APCD Council. Paragraph 4.1.a, for example, provides that "[s]pecifications based on existing standards for claims transactions developed and maintained by standards development organizations such as ANSI, ASC, X12N and NCPDP, and referenced by the APCD Council core data

set. Where a standard does not currently exist or is not feasible for use, a standard shall be established by the Commissioner after consultation with the APCD Council and the standing advisory board." The MOU parties will also establish advisory boards of stakeholders to provide a forum for discussion of the issues raised by Highmark as the program is developed.

Insurance Commissioner
Secretary of DHHR
Chair of Health Care Authority
Joint Legislative Rule
Title 114A, Series 1

ALL-PAYER CLAIMS DATABASE --
DATA SUBMISSION REQUIREMENTS

TITLE 114A, SERIES 1

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 database. The statute assigns to each of the MOU parties an area of primary responsibility: The Insurance Commissioner is primarily responsible for the collection of the data from insurers. WV Code 33-4A-2. This proposed rule addresses only the data-collection aspects of the program (future rules will address the other areas -- DHHR will maintain the data, and HCA will release it to other agencies, researchers, etc.). The rule provides that the more technical aspects of data reporting will be addressed in detail in a "Submission Manual" to be developed by OIC through a process that mirrors rulemaking to a large degree, e.g. opportunity for public comment.

Insurance Commissioner
Secretary of DHHR
Chair of the Health Care Authority
Joint Legislative Rule
Title 114A, Series 1

ALL-PAYER CLAIMS DATABASE --
DATA SUBMISSION REQUIREMENTS

TITLE 114A, SERIES 1

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 WV Code 33-4A-8. WV 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 (future rules will address the other areas -- DHHR will maintain the data, and HCA will release it to other agencies, researchers, etc.). WV Code 33-4A-2. This proposed rule addresses only the data collection aspects of the program, a responsibility assigned to HCA.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: All-Payer Claims Database -- Data Submission Requirements (Title 114A, Series 1)

Type of Rule: __X__ 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.

It is difficult to project the costs of the project prior to the design and feasibility analysis required as part of the rule development, however, budget estimates from other states operating or developing databases range from $500,000 to $1,500,000. The size of the population and the analytic services provided impact the overall operating costs.

The state has been awarded a federal State Health Access Program (SHAP) grant which will be utilized to capitalize the APCD. The state matching requirement of the grant is 20% or $100,000 to $300,000 of the estimates provided above. Ongoing operations are to be funded by user fees, penalties and other available funding sources of the MOU agencies.

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		100,000	100,000
Current Expenses	0	0	0
Repairs & Alterations	0	0	0
Assets	0	0	0
Equipment	0	0	0
Other	0	0	400,000
2. Estimated Total Revenues	0	0	0

3. Explanation of above estimates (including long-range effect):
Please include any increase or decrease in fees in your estimated total revenues.

See #1 "Fiscal Note Summary," no fees until data has been collected (FY 2013 at earliest) and users pay for use of it, bulk of "other" is for IT support and operations as program develops and purchases are put out for bids, etc. It is envisioned that vendors will provide majority of services under an ED's oversight

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 #1 "Fiscal Note Summary"

Date: 7-25-11

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

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 1
ALL-PAYER CLAIMS DATABASE -- DATA SUBMISSION REQUIREMENTS

Sections.

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 1
ALL-PAYER CLAIMS DATABASE -- DATA SUBMISSION REQUIREMENTS

§114A-1-1. General.

1.1. Scope. -- The purpose of this rule is to implement the provisions of W. Va. Code §33-4A-*1 et seq.* providing for the establishment of an all-payer claims database.

1.2. Authority. -- W. Va. Code §33-4A-8.

1.3. Filing Date. --

1.4. Effective Date. --

§114A-1-2. Definitions.

As used in this title:

2.1. "All-payer claims database" or "APCD" means the program established pursuant to W. Va. Code §33-4A-1 *et seq.* for the collection, management and release of medical claims data submitted by health care payers.

2.2. "Accredited Standards Committee (ASC) X12" means the standards development organization accredited by the American National Standards Institute (ANSI) that develops and maintains electronic data interchange (EDI) standards and related documents for national and global markets, including standards for insurance claims transactions, or any successor organization.

2.3. "American National Standards Institute" or "ANSI" means the nonprofit membership organization that acts as an administrator and coordinator of the United States private sector voluntary standardization system consisting of public agencies and private organizations.

2.4. "APCD Council" means the collaborative effort convened and coordinated by the Institute for Health Policy and Practice (IHPP) at the University of New Hampshire (UNH) and the National Association of Health Data Organizations (NAHDO) that is focused on improving the development and deployment of state-based all-payer claims database programs, including the development of a core data set for use by such programs.

2.5. "Chair" means the chairperson of the West Virginia Health Care Authority.

2.6. "Commissioner" means the West Virginia Insurance Commissioner.

2.7. "Data" means information consisting of, or derived directly from, member eligibility files, medical claims files and pharmacy claims files.

2.8. "Data set" means a collection of individual data records and data elements, whether in electronic or manual files.

2.9. "Data submitter" means a health care payer that the Commissioner has determined is subject to the submission and reporting requirements of this rule for a given calendar year because it meets the threshold of having paid or administered the payment of health insurance claims in this state for policies for 500 or more covered lives in the prior calendar year and has not been exempted for cause from such requirements by the MOU parties.

2.10. "Data processor" means any entity that performs data collection and data management functions pursuant to a contract with the MOU parties.

2.11. "Health care payer" means any insurer or health maintenance organization licensed in this state that pays medical benefits pursuant to a policy, certificate or contract of health; any state and federal government payers of such benefits; or any third-party administrator that administers a self-funded health insurance plan. For the purposes of this rule, "health care payer" does not include workers' compensation payers.

2.12. "Health care provider" or "provider" means any physician, hospital or other person or organization that is licensed or otherwise authorized in this state to furnish health care services.

2.13. "Medical claims file" means a data file composed of service level remittance information for all non-denied adjudicated claims for each billed service including, but not limited to member demographics; provider information; charge/payment information; and clinical diagnosis/procedure codes. The term includes data related to behavioral, mental health, or substance abuse treatment.

2.14. "Member" means a subscriber and the spouse, dependent or other persons covered by the subscriber's policy.

2.15. "Member Eligibility file" means a data file that contains demographic information for each individual member eligible for medical or pharmacy benefits for one or more days of coverage at any time during the reporting period.

2.16. "MOU parties" means, collectively, the Secretary, Insurance Commissioner and Chair.

2.17. "National Council for Prescription Drug Programs" or "NCPDP" means the standards development organization accredited by the American National Standards Institute (ANSI) that develops and maintains national standards for pharmacy payers and providers, including standards for the pharmacy claim transaction, or any successor organization.

2.18. "Personal identifiers" means information relating to an individual member or insured that identifies, or can be used to identify, locate or contact a particular individual member or insured.

2.19. "Pharmacy claims file" means a data file containing service level remittance information from all non-denied adjudicated claims for each prescription including, but not limited to member demographics; provider information; charge/payment information; and national drug codes.

2.20. "Secretary" means the Secretary of the West Virginia Department of Health and Human Resources.

2.21. "Standards Development Organization" or "SDO" means an entity accredited by the American National Standards Institute (ANSI), such as ASC X-12, National Council for Prescription Drug Programs (NCPDP) and Health Level Seven (HL-7), that is responsible for maintaining the structure and control elements of transactions, or any of its successors.

2.22. "Submission Manual" or "Manual" means that document approved by the Commissioner, including amendments adopted by the Commissioner subsequent to its initial adoption, and published on the West Virginia Offices of the Insurance Commissioner's ("OIC") website that sets forth the required data file format, data elements, code tables, edit specifications, thresholds required for a submission to be deemed complete, methods for submitting data, submission schedules, and other information associated with the data submitters' submission and reporting duties.

2.23. "TPA" means a third-party administrator licensed by the Commissioner under W. Va. Code §33-46-12 or §33-46-14 or registered with the Commissioner under W. Va. Code §33-46-13.

§114A-1-3. Determination of Health Care Payers Subject to Submission and Reporting Requirements; Exemptions.

3.1. Presumptive data submitters:

3.1.a. Any health care payer is presumed to be a data submitter for any calendar year if it issued a policy, certificate or contract under which it paid medical and/or pharmacy claims to a provider in this state in the immediately preceding calendar year; and

3.1.b. Any TPA is presumed to be a data submitter for any calendar year if it administered the payment of medical and/or pharmacy claims on behalf of a self-funded health plan in the immediately preceding calendar year.

3.2. The Commissioner shall maintain and publish on the OIC website a list of data submitters and the periods with respect to which each must report and submit data in accordance with this rule.

3.2.a. The Commissioner shall exclude from the list presumptive data submitters that, as reflected in OIC records or as otherwise determined by the Commissioner, did not pay or administer the payment of medical claims for 500 or more persons in the preceding calendar year.

3.2.b. Any entity that believes it should not be included on the list for any given year, on the ground that it did not meet the relevant 500-life threshold or that it is not a health care payer covered by this rule, may dispute the Commissioner's determination in accordance with the procedure set forth in W. Va. Code §33-2-13.

3.2.c. The MOU parties may grant an exemption for cause to any presumed data submitter or class of presumed data submitters from all or some of the requirements of this rule. Cause for an exemption includes but is not limited to the increased cost or difficulty in complying with the submission requirements or the marginal value of the data that would be reported by the exempt payers.

3.2.d. Payers of benefits under Medicare supplemental policies are categorically exempt from submitting data associated with claims made under such policies until such time as data is being obtained by the APCD from Medicare and the Commissioner includes such payers on the list provided for in subsection 3.2 of this section.

3.3. Data related to the following claims and benefits are not subject to this rule:

3.3.a. Claims under policies providing coverage for only accident, disability or a combination of both; liability insurance or coverage issued as a supplement to liability insurance; credit only insurance; coverage for on-site clinics; similar insurance where medical benefits are secondary or incidental to other insurance benefits;

3.3.b. The following benefits if provided under a separate policy or certificate: Limited scope dental or vision; long-term care, nursing home care, home health care, community-based care, or any combination thereof; coverage for only a specified disease or illness; or hospital indemnity or other fixed indemnity insurance.

3.4. Any data submitter that has contracted to have its reporting and submission duties under this rule fulfilled by another person (including a TPA that administers that payer's claims) remains responsible for compliance with this rule regardless of the terms of any such contractual arrangement, and such data submitter remains subject to the investigation and enforcement provisions of section 7 of this rule notwithstanding that suspected or demonstrated noncompliance is attributable to the fault of such other person with which the data submitter has an arrangement for submission and reporting.

§114A-1-4. Development of Submission Manual; Amendments.

4.1. The proposed Manual shall include, at a minimum, the following:

4.1.a. Specifications based on existing standards for claims transactions developed and maintained by standards development organizations such as ANSI, ASC, X12N and NCPDP, and referenced by the APCD Council core data set. Where a standard does not currently exist or is not feasible for use, a standard shall be established by the Commissioner after consultation with the APCD Council and the standing advisory board.

4.1.b. Reporting requirements related to submission of adjustment records, capitated service claims, co-insurance/co-payments, coordination of benefit claims, denied claims and exclusions.

4.1.c. File format, data elements and mapping locators, and code value sources to be submitted for each required file; and file transmission procedures, file testing, and run-out period;

4.1.d. A data submission schedule; and

4.1.e. Data quality standards, including but not limited to thresholds for determining the completeness and accuracy of a submitted file; and procedures for notifying data submitters of file rejections; procedures and timelines for correcting or resubmitting files that do not meet quality standards.

4.2. After a proposed Manual has been developed:

4.2.a. The Commissioner shall file it with the Secretary of State for publication in the state register for 30 days, with a request for public comment.

4.2.b. After the comment period set forth in subdivision a of this subsection, the Commissioner may, after consideration of any comments or suggestions received, revise the proposed Manual and publish it on the OIC website for at least 30 days before such Manual is made effective.

4.3. *Amendments*. Subsequent amendments to the Manual are subject to the procedure set forth in subsection 4.2 of this rule for adoption of the initial version of the Manual.

4.4. Except as provided in this rule, order or other directive issued by the Commissioner, each data submitter shall submit data in the form and manner set forth in the applicable version of the submission manual and at such times set forth in the applicable submission schedules.

§114A-1-5. Submission Requirements.

5.1. Each data submitter shall submit to the Commissioner or his or her designee a completed health care claims data set, including a member eligibility file, a medical claims file, and a pharmacy claims file for all members who are West Virginia residents, in accordance with the requirements set forth in the submission manual.

5.2. If a data submitter is unable to meet the terms and conditions of this rule and the submission manual due to circumstances beyond its control, a written request must be made to the MOU parties as soon as it is practicable after the data submitter has determined that an extension or waiver is required. The written request shall include the specific requirement to be extended or waived; an explanation of the cause; the methodology proposed to eliminate the necessity of the extension or waiver; and the time frame required to come into compliance. The decision of the MOU parties is not subject to further review.

114A-1-6. Vendors.

6.1. The MOU parties may enter into an agreement(s) with one or more data processors. The agreement shall provide that the third party designee shall be strictly prohibited from collecting, releasing or using data or information obtained in its capacity as a collector and processor of the data for any purposes other than those specifically authorized by the agreement.

§114A-1-7. Advisory Boards.

7.1. The MOU parties shall establish a standing advisory board to provide input on the various functions of the APCD. Such board shall be comosed of the following persons:

7.1.a. Two persons designated by the Commissioner to represent data submitters;

7.1.b. Two persons designated by the Chair to represent health care providers; and

7.1.c. Two persons designated by the Secretary to represent the interests of health care consumers;

7.1.d. Two persons designated by the Secretary from public and/or private health care research organizations; and

7.1.e. A representative from each of the following: PEIA, the state Medicaid office and the state Children's Health Insurance Program.

7.2. The MOU parties may appoint *ad hoc* advisory groups to study and report on various issues.

7.3. Members of the standing advisory board or an *ad hoc* advisory group shall not be compensated. Terms of membership will be determined according to the designating party, but any member may be removed at any time by the MOU party that designated such member. Any member may serve on more than one board simultaneously.

§114A-1-8. Enforcement; Examination; Penalties.

8.1. The Commissioner may, acting individually or jointly with one or both of the other MOU parties, seek to enjoin any further violation of W. Va. Code §33-4A-1 *et seq.* of this rule by filing a petition in the Circuit Court of Kanawha County.

8.2. The Commissioner may deny, suspend or revoke the license of a TPA for any violation of this rule or, in lieu of such action, impose a penalty pursuant of W. Va. Code §33-46-17(d) in a sum not to exceed $10,000.

8.3. Pursuant to the authority granted by W. Va. Code §33-2-3a, the Commissioner may conduct an investigation of any person he or she has cause to believe is violating or has violated any provision of W. Va. Code §33-4A-1 *et seq.* or this rule.

8.4. The Commissioner may conduct an examination of any insurer or TPA pursuant to W. Va. Code §33-2-9 to determine compliance with the provisions of W. Va. Code §33-4A-1 *et seq.* and this rule.

8.5. The Commissioner may, in addition to or in lieu of any other sanctions, impose a penalty on any data submitter for failure to comply with the submission requirements of this rule in an amount not to exceed $100 per day for the first two weeks of non-compliance and $500 per day thereafter, not to exceed a maximum of $25,000 per any single occurrence.