



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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7/30/2021 2:38:48 PM

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-SERIES: 114A-01

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: 114A-01 All-Payer Claims Database - Data Submission Requirements

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 33-4A-8

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

To effectuate the provisions of this article, the secretary and commissioner may propose joint rules for legislative approval in accordance with the provisions of 29A-3-1 et seq. of this code as necessary to implement this article.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/30/2021

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/30/2021

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

n/a

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

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.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Amendments reflect changes to the rule's authorizing statute made in SB 390 in 2021.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

n/a

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

n/a

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

n/a

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2021 Increase/Decrease (use "-")	2022 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			0
Personal Services			0
Current Expenses			0
Repairs and Alterations			0
Assets			0
Other			0
2. Estimated Total Revenues			0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

n/a

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 114A
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. -- ~~April 20, 2012.~~

1.4. Effective Date. -- ~~July 1, 2012.~~

1.5. Sunset Provision. – This rule shall terminate and have no further force or effect on August 1, 2027.

§114A-1-2. Definitions.

As used in this ~~title~~ rule:

2.1. "All-payer claims database" or "APCD" or "Act" 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~~ common data layout 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 the data elements from enrollment and eligibility files, specified types of claims, and reference files for data elements not maintained in formats consistent with national coding standards.

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~~ for purposes of the state's all-payer claims database.

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; any workers' compensation insurer; or any third-party administrator that administers a self-funded health insurance plan.

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 the procedural rule promulgated pursuant to subsection 4.2. of this rule 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. A TPA that administers claims for an ERISA plan is not required to submit data but may voluntarily submit data.

§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~~ or pharmacy claims, or both, 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~~ or pharmacy claims, or both, on behalf of a self-funded health plan in the immediately preceding calendar year. Self-funded employer plans governed by ERISA may decide whether or not to submit their data.

3.2. The Commissioner shall maintain and publish on the Office of the Insurance Commissioner's website by April 1 of each year 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 Offices of the Insurance Commissioner 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~~ Secretary 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 ~~and~~;

3.3.c. Claims under Medicare supplemental policies.

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 8 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.

4.1. ~~The proposed~~ Secretary shall develop and maintain an APCD Submission Manual that 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, the National Association for Health Data Organizations (NAHDO), or 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~~ Secretary 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 Submission Manual has been developed, ~~Commissioner~~ the Secretary will adopt the same as a procedural rule as defined by W. Va. Code §~~29A-1-2(g)~~ 29A-1-2(h), subject to the provisions of W. Va. Code §29A-3-1 *et seq.*

§114A-1-5. Submission Requirements.

5.1. Each data submitter shall submit to the ~~Commissioner~~ Secretary or his or her designee ~~a~~ an annual completed health care claims data set, including a member eligibility file, a medical claims file, a provider 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~~ Secretary 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~~ Secretary is not subject to further review.

§114A-1-6. Vendors.

6.1. The ~~MOU parties~~ Secretary 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~~ Secretary shall establish a standing advisory board to provide input on the various functions of the APCD. Such board shall be composed 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;

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~~ or private health care research organizations, or both; and

7.1.e. The West Virginia Insurance Commissioner, the Director of the Public Employees Insurance Agency or his or her designee, the Commissioner of the Bureau for Medical Services or his or her designee, and the Director of the Children's Health Insurance Program or his or her designee.

7.2. The ~~MOU parties~~ Secretary 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~~ Secretary, 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 Secretary shall notify the Commissioner of any health plan that fails to submit data.

~~8.2.~~ 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.* or this rule by filing a petition in the Circuit Court of Kanawha County.

~~8.2.~~ 8.3. The Commissioner may deny, suspend, or revoke the license of a TPA subject to this rule 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.~~ 8.4. 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.~~ 8.5. The Commissioner may conduct an examination of any insurer or TPA subject to this rule 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. The costs of such examination may be assessed against the insurer or TPA.

~~8.5.~~ 8.6. 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.

§114A-1-9. Data Collection Privacy and Security Requirements.

9.1. Data submitters shall transmit all data to the Secretary or his or her designee using a secure method approved by DHHR.

9.2. 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 Rev.2, Guidelines for the Selection, Configuration, and use of Transport Layer Security Implementations, August 2019, NIST Special Publication 800-77 Rev.1, Guide to IPsec VPNs, June 2020, or NIST Special Publication 800-113, Guide to SSL VPNs, July 2008, or others which are Federal Information Processing Standards 140-3, March 2019, validated, all as amended or superseded.

§114A-1-10. Data Retention and Initial Use and Disclosure Privacy and Security Requirements.

10.1. 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.

10.2. The Secretary shall assess the completeness and quality of data submitters' submissions in order to determine compliance with established data reporting requirements and standards. The Secretary shall 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 completeness and quality assessment, all personal identifiers shall remain encrypted. Results of the completeness and quality assessments may be shared with the APCD's Advisory Board.