



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Health And Human Resources TITLE-SERIES: 69-14

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

RULE NAME: Collection and Exchange of Data Related to Overdoses

CITE STATUTORY AUTHORITY: W. Va. Code §16-5T-5

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 07/21/2018 4:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

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PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

This rule establishes requirements to facilitate the exchange of data and information with and between the Office of Drug Control Policy, the Department of Health and Human Resources and its Bureaus, the Department of Military Affairs and Public Safety, the Department of Administration, the Administrator of Courts, the Poison Control Center, and the Board of Pharmacy

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

Statement of Circumstances:

This rule must be modified pursuant to the Governors Bill (SB 272) that amended W. Va. Code §16-5T-4 during the 2018 Regular Session by adding hospital emergency rooms and departments to the list of mandatory reporters of suspected or reported overdose data.

Identification of Proposed Amendments:

The amended list of mandatory reporters appears in sections 1.1., 1.7., and 2.11. of the rule. The rule also has been renumbered to correct a numbering error.

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

This rule modification will have no fiscal impact on the costs and revenues of state government.

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

n/a

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2018 Increase/Decrease (use "-")	2019 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 and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

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

This rule modification will have no fiscal impact.

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

Yes

Heather J Mcdaniel -- 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 69
LEGISLATIVE RULE
OFFICE OF DRUG CONTROL POLICY
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 14
COLLECTION AND EXCHANGE OF DATA RELATED TO OVERDOSES

§69-14-1. General.

1.1. Scope. -- This rule establishes requirements to facilitate (1) the exchange of data and information with and between the Office of Drug Control Policy, the Department of Health and Human Resources and its Bureaus, the Department of Military Affairs and Public Safety, the Department of Administration, the Administrator of Courts, the Poison Control Center, and the Board of Pharmacy; and (2) the reporting of suspected or reported overdoses by law enforcement agencies, including prosecuting attorneys, state, county, and local police departments, health care providers, emergency response providers, pharmacies, ~~and~~ medical examiners, and hospital emergency rooms and departments.

1.2. Authority. -- W. Va. Code §16-5T-5.

1.3. Filing Date. -- ~~April 13, 2018.~~

1.4. Effective Date. -- ~~March 22, 2018.~~

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect on ~~March 22, 2023.~~

1.6. Applicability. -- This rule applies to the Office of Drug Control Policy, the Department of Health and Human Resources and its Bureaus, the Department of Military Affairs and Public Safety, the Department of Administration, the Administrator of Courts, the Poison Control Center, the Board of Pharmacy, law enforcement agencies, health care providers, emergency response providers, pharmacies, and medical examiners.

1.7. Background. -- The West Virginia Drug Control Policy Act (hereinafter referred to as “the Act”), enacted during the 2017 regular Legislative Session, creates the Office of Drug Control Policy (ODCP) within the Department of Health and Human Resources, under the direction of the Secretary and supervision of the State Health Officer. The ODCP is charged with creating a state drug control policy in coordination with the bureaus of the department and other state agencies. This policy must include all programs which are related to the prevention, treatment, and reduction of alcohol abuse, substance use disorder, and the use of tobacco.

The ODCP is required to (1) develop and implement a program to collect and store data from pharmacies, law enforcement agencies, emergency medical services, health care facilities, ~~and the Office of the Chief Medical Examiner~~ medical examiners, and hospital emergency rooms and departments on fatal and nonfatal overdoses caused by abuse and misuse of prescription and illicit drugs; (2) develop and implement a program that requires the collection and storage of data from law enforcement agencies,

emergency medical services, health care facilities, the Office of the Chief Medical Examiner, and other entities as required by the Office of Drug Control Policy on the dispensing and use of an opioid antagonist; and (3) facilitate the collection and storage of data and issues.

Finally, the ODCP is authorized to exchange necessary data and information with the bureaus within the department, the Department of Military Affairs and Public Safety, the Department of Administration, the Administrator of Courts, the Poison Control Center, and the Board of Pharmacy. This data and information may include, but is not limited to, data from the Controlled Substance Monitoring Program; the all-payer claims database; the criminal offender record information database; and the court activity record information.

1.8. Purpose. -- The purpose of this rule is to prescribe requirements for the collection of data and issues on fatal and nonfatal overdoses, caused by abuse and misuse of prescription and illicit drugs, and the exchange of data and information with and between the Department of Health and Human Resources, the Department of Military Affairs and Public Safety, the Department of Administration, the Administrator of Courts, the Poison Control Center, and the Board of Pharmacy. The data and information may include, but is not limited to, data from the Controlled Substance Monitoring Program; the all-payer claims database; the criminal offender record information database; and the court activity record information.

Additionally, this rule contains requirements for pharmacies operating in the state; health care providers; medical examiners; law enforcement agencies, including prosecuting attorneys, state, county, and local police departments; and emergency response providers, to report all overdoses or suspected overdoses to the department no more frequently than on a quarterly basis.

§69-14-2. Definitions.

2.1. "Data and information" means a collection of numbers, characters, images or other outputs from devices to convert physical quantities into symbols or images. Data includes, but is not limited to, numbers, words, and images. Data is typically further processed by a human or entered into a computer (input), stored and processed there, or transmitted (output) to another human, computer or other system to create information.

2.2. "Data Request" means an inquiry from a participant for data or information collected by, housed, or maintained within the ODCP that requires compilation or aggregation by the ODCP staff.

~~2.4.2.3.~~ "Department" means the West Virginia Department of Health and Human Resources.

~~2.5.2.4.~~ "Director" means the Director of the Office of Drug Control Policy.

~~2.6.2.5.~~ "Disclosure" means the release, transfer, provision, access to, or divulging in any other manner of information outside the ODCP.

~~2.7.2.6.~~ "Drug" means:

~~2.7.a.2.6.1.~~ Substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

~~2.7.b.2.6.2.~~ Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

~~2.7.c.2.6.3.~~ Substances (other than food) intended to affect the structure or any function of the body of man or animals; and

~~2.7.d.2.6.4.~~ Substances intended for use as components of any article specified in subdivisions a, b, or c, of this subsection. It does not include devices or their components, parts, or accessories.

~~2.8.2.7.~~ "Emergency response provider" means any authority, person, corporation, partnership or other entity, public or private, that owns or operates a licensed emergency medical services agency providing emergency medical service in this state.

~~2.9.2.8.~~ "Health care facility" means a facility licensed, certified, or authorized by law, established to administer and provide health care services, and which is commonly known by a wide variety of titles, including, but not limited to, hospitals, medical centers, ambulatory health care facilities, physicians' offices and clinics.

~~2.10.2.9.~~ "Health care provider" means a person, partnership, corporation, facility, hospital, or institution licensed, certified, or authorized by law to provide professional health care service in this state to an individual during this individual's medical, remedial, or behavioral health care, treatment, or confinement, and includes, but is not limited to, any licensed physician, dentist, nurse, physician's assistant, paramedic, psychologist, or other person providing medical, dental, nursing, psychological, or other health care services of any kind.

~~2.11.2.10.~~ "Law enforcement agency" means any duly authorized state, county, or municipal organization employing one or more persons whose responsibility is the enforcement of laws of the state or any county or municipality. "Law enforcement agency" does not include the Public Service Commission, nor any resort area district.

~~2.12.2.11.~~ "Mandatory reporter" means a pharmacy, health care provider, medical examiner, law enforcement agency, prosecuting attorney, ~~and emergency response provider, and hospital emergency rooms and departments.~~

~~2.13.2.12.~~ "Medical Examiner" means an individual appointed pursuant to W. Va. Code §§61-12-1 *et seq.* to perform death investigations and to establish the cause and manner of death. The term "medical examiner" includes any person designated by the medical examiner to perform any duties required by W. Va. Code §§16-19-1 *et seq.*

~~2.14.2.13.~~ "ODCP" means the Office of Drug Control Policy within the department.

~~2.15.2.14.~~ "Opioid antagonist" means a particular drug that is a competitive antagonist that binds to the opioid receptors with higher affinity than agonists but does not activate the receptors, effectively blocking the receptor, preventing the human body from making use of opiates and endorphins.

~~2.16.2.15.~~ "Opioid" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-

sustaining liability. It does not include, unless specifically designated as controlled under W. Va. Code § 60A-2-201, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does not include its racemic and levorotatory forms.

~~2.17~~2.16. “Overdose” means a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of a drug, or another substance with which a drug was combined, or that a layperson would reasonably believe to be a drug. This would include an overdose that requires medical assistance, clinical suspicion for drug overdose (respiratory depression, unconsciousness, altered mental status) and either a toxicology screen positive for opiates or negative toxicology screen without other conditions to explain the clinical condition.

~~2.18~~2.17. “Overdose information” means data and information collected, maintained, or used by participants related to overdoses.

~~2.19~~2.18. “Participants” means the Office of Drug Control Policy, the Department of Health and Human Resources and its bureaus, the Department of Military Affairs and Public Safety, the Department of Administration, the Administrator of Courts, the Poison Control Center, and the Board of Pharmacy.

~~2.20~~2.19. “Pharmacy” means any drugstore, apothecary, or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and pharmacist care is provided outside this state where drugs are dispensed and pharmacist care is provided to residents of this state.

~~2.21~~2.20. “Personally identifiable information” or “PII” means all information that identifies, or can be used to identify, locate, contact, or impersonate a particular individual. PII also includes protected health information (PHI) as that term is defined in subsection 2.23. PII is contained in public and non-public records. Examples may include, but are not limited to, a specific individual’s first name (or initial) and last name (current or former); geographical address; electronic address (including an e-mail address); personal cellular phone number; telephone number or fax number dedicated to contacting the individual at his or her physical place of residence; social security account number; biometric identifiers, including but not limited to, fingerprints, palm prints, facial recognition, full-face image and iris scans; driver identification number; birth date; birth, adoption, or death certificate numbers; physical description; genetic information; medical, disability, or employment records, including salary information; and criminal records and history. When connected with one or more of the items of information specified above, PII includes any other information concerning an individual that, if disclosed, identifies or can be used to identify a specific individual physically or electronically.

~~2.22~~2.21. “Prosecuting attorney” means a prosecuting attorney, assistant prosecuting attorney, or duly appointed special prosecuting attorney.

~~2.23~~2.22. “Protected health information” or “PHI” is a subset of PII and means, with regard to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities (see 45 C.F.R. § 106.103), individually identifiable health information, including demographic information, whether oral or recorded in any form or medium that relates to an individual’s health, health care services and supplies, or payment for services or supplies, and which identifies the individual or could reasonably be used to identify the individual. This includes information that relates to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual including, but not limited to, preventive, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, as well as

counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status of an individual or that affects the structure or function of the body, such that the health information is linked to the individual.

2.24-2.23. “Reportable information” means the following information related to a mandatory reporter’s response to a suspected or reported overdose:

2.24.a-2.23.1. Name;

2.24.b-2.23.2. Date of birth;

2.24.c-2.23.3. Date and time of the response;

2.24.d-2.23.4. Location of response;

2.24.e-2.23.5. Gender of person suffering from an overdose;

2.24.f-2.23.6. Race and ethnicity, if known;

2.24.g-2.23.7. Whether the person is a smoker, if known;

2.24.h-2.23.8. Estimated or actual age of a person suffering from an overdose;

2.24.i-2.23.9. Whether the overdose occurred in the presence of a child;

2.24.j-2.23.10. Drug suspected of causing the overdose;

2.24.k-2.23.11. Observations of the physical condition of the person suffering from an overdose, including, but not limited to, pale, clammy skin; very infrequent or no breathing; deep snoring or gurgling; no response to stimuli; slow heart beat or pulse; or blue lips or fingertips;

2.24.l-2.23.12. Whether an opioid antagonist was administered;

2.24.m-2.23.13. If an opioid antagonist was administered, the following information:

2.24.m.1-2.23.13.a. The doses of opioid antagonist administered;

2.24.m.2-2.23.13.b. Whether the method of administration was auto injector or nasal spray;

2.24.m.3-2.23.13.c. The response to the opioid antagonist; and

2.24.m.4-2.23.13.d. Disposition, including whether the person who was administered the opioid antagonist stayed in the same location; jail; emergency medical services transport; absconded; or death.

2.24.n-2.23.14. Reporter’s name;

2.24.o-2.23.15. Reporter’s incident or case number; and

2.24.p-2.23.16. Such other data as the director may prescribe.

~~2.25-2.24~~ "Reporting dates" means the four calendar dates on which quarterly reports are due.

~~2.25-a-2.24.17~~. For the period January 1 through March 31, the reporting date is April 30.

~~2.25-b-2.24.18~~. For the period April 1 through June 30, the reporting date is July 31.

~~2.25-c-2.24.19~~. For the period July 1 through September 30, the reporting date is October 31.

~~2.25-d-2.24.20~~. For the period October 1 through December 31, the reporting date is January 31.

~~2.26-2.25~~. "System" means software, portal, platform, or other electronic medium controlled or utilized by the ODCP through which or by which participants exchange data and information under this rule. For purposes of this definition, it does not matter whether the ODCP controls or utilizes the software, portal, platform, or other medium through ownership, lease, license, or otherwise.

§69-14-3. Overdose Reporting.

3.1. A mandatory reporter who attends or treats, or who is requested to attend or treat, an overdose, or the administrator, or other person in charge of a health care facility in which an overdose is attended or treated or in which the attention or treatment is requested, shall report the case via a secured Web site, encrypted email, secure facsimile, or on forms approved by the department.

3.2. Reports regarding an overdose shall include reportable information and be submitted on or before each of the quarterly reporting dates. In the event a reporting date falls on a weekend, the report may be transmitted or postmarked the following business day.

3.3. Reports must be submitted in accordance with state and federal security guidelines surrounding the transmission of confidential data. Reports may be submitted by one of the following methods:

3.3.1. To a secure Web site that will be provided on the ODCP Web site prior to the first reporting date; or

3.3.2. Encrypted email, secure facsimile, or U.S. Mail on forms prescribed by the director.

3.4. The mandatory reporter making the report shall provide the reportable information concerning the person attended or treated or for whom treatment was sought.

3.5. All overdose reports submitted pursuant to this rule shall be handled in accordance with all applicable state and federal statutes and regulations pertaining to confidentiality of health care information.

§69-14-4. Exchange of Data and Information.

4.1. *Permitted Uses and Disclosures.* The ODCP may disclose data for legitimate purposes relating to public health to participants. The ODCP shall have the sole discretion to determine what constitutes a legitimate purpose relating to public health.

4.2. Participants may use and disclose data and information in furtherance of the purposes and goals of participants relevant to the development and implementation of best practices and evidence-based

substance use disorder prevention, cessation, treatment, and recovery programs, and youth tobacco access, smoking cessation and prevention when necessary for their proper management, administration, or execution of their legal responsibilities and privileges established herein. The participants agree not to use or further disclose data and information other than as authorized by law.

4.3. Data and information maintained by the ODCP may not be disclosed for commercial purposes.

4.4. Overdose Information Maintained by Participants.

4.4.1. Participants will provide overdose information dating as far back as the information is generally accessible in electronic format and is maintained on each participant's system. The specific data elements that will be exchanged are the demographic and health information being requested from the originating participant's system. The participants are not responsible for the absence of overdose information in a participant's records and are only obligated to provide such information as they currently possess. The participants acknowledge that the overdose information provided is drawn from numerous sources and the overdose information provided may not include an entire record.

4.4.2. Participants shall provide overdose information to the ODCP in a timely manner.

4.4.3. Participants will reasonably determine that information disclosed is accurate and complete. If a participant becomes aware of any material inaccuracies in its own overdose information or system, it agrees to communicate such inaccuracy to the ODCP as soon as reasonably possible.

4.5. Access to Data and Information by Participants.

4.5.1. All data requests for data and information housed and maintained by the ODCP shall be submitted to the director in a form and manner as the director may prescribe, including electronic submission.

4.5.2. *Functions of the Director.* The director is responsible for overseeing the process from receipt of a data request to the release of the data to the requestor. Specific responsibilities include:

4.5.2.a. Reviewing each data request and identifying the information being requested;

4.5.2.b. Coordinating with the department's privacy officer to determine whether a request is valid and the information may be released under applicable law;

4.5.2.c. Routing the request to the appropriate person or data analyst for completion, and following up as necessary to ensure accurate and timely completion of the request;

4.5.2.d. Communicating with the requestor as necessary; and

4.5.2.e. Maintaining accurate records of the requests.

4.5.3. Prior to receiving any data, the director may require participants to execute a data use agreement, in the form and manner as the director may prescribe.

4.6. *Ownership.* Disclosure of data under this rule does not change the ownership of such information under state and federal law. This rule does not grant to a participant any rights in the system or any of the technology used to create, operate, enhance or maintain the system of another participant.

4.7. Privacy and Security Safeguards.

4.7.1. If the data to be provided constitutes or includes PII or PHI, then only the minimum amount of PII or PHI necessary to accomplish the purposes for which the data is requested may be used or disclosed.

4.7.2. Participants shall establish procedures to prevent the disclosure of data that may contain indirectly identifying information.

4.7.3. Participants will use administrative, technical, and physical safeguards to protect the confidentiality, integrity, and availability of data it receives and to prevent the use or disclosure of any data received other than as permitted or required by federal or state law and by this rule. To that end, participants shall:

4.7.3.a. Provide for identification and authentication of authorized users;

4.7.3.b. Provide access authorization;

4.7.3.c. Guard against unauthorized access to data; and

4.7.3.d. Provide security audit controls and documentation.

4.7.4. A participant shall apply sanctions against any person, subject to the participant's policies and procedures, who fails to comply with such policies and procedures. The type and severity of sanctions applied shall be in accordance with the participant's policies and procedures. Participants shall make employees, agents, and contractors aware that certain violations may result in notification by a participant to law enforcement officials as well as regulatory, accreditation, and licensure organizations, if applicable.

4.7.5. A participant may, at its discretion, deny access to any person it has reason to believe accessed, used or disclosed data, other than as permitted under this rule.

4.7.6. Participants are also required to comply with the privacy and security provisions established by the state of West Virginia and are not required to adhere to the law or rules of or applicable to any other participant.

4.8. Breach of Privacy and Security Safeguards.

4.8.1. Breach of a material provision of the privacy and security safeguards contained in this section by a participant may be grounds for the director to discontinue the participant's access to data and information. Upon becoming aware of such a material breach, the director may do one or more of the following:

4.8.1.a. Provide an opportunity for the participant who has committed a material breach of the privacy and security safeguard contained in this section to cure the violation within 30 days, and if the

participant does not cure or end the violation within the time specified by the director, terminate the authority of the participant to access data and information;

4.8.1.b. Demand assurances from the participant that remedial actions will be taken to remedy the circumstances that gave rise to the violation within a time frame set by, or approved by, the director; and

4.8.1.c. Terminate the authority to access data and information.

4.8.2. A participant who is the subject of sanctions contained in subdivision 4.8.a., may request a hearing.

4.8.2.a. A request for a hearing must be made within 90 days of the date of the director's notification of a sanction contained in subdivision 4.8.a.;

4.8.2.b. The request for hearing must be made in writing and must clearly state the reasons for the request;

4.8.2.c. Hearings will be conducted pursuant to W. Va. Code R. §§64-1-1 *et seq.*