Title 69 Series 14
Department of Health and Human Resources
Office of Drug Control Policy
COLLECTION AND EXCHANGE OF DATA RELATED TO OVERDOSES

Summary of Public Comments:
The Department notes that many comments received addressed sections of the rule that have previously received Legislative approval. While the Department did not originally propose many modifications to this rule, except those made necessary by statutory amendments passed during the 2018 Regular Legislative Session, the responses summarize all comments received and the subsequent agency action.

Section 1 – General

Comment
1.1 Scope States "....(1) the exchange of data and information with and between the Office....". Enrolled HB 2620 does not contain the word "between"; the enrolled version simply states, "with the Office".
Response
The Department has reviewed this comment and finds clarification is needed, therefore, some changes were made. The words "and between" are not found in the applicable section of W. Va. Code §16-5T-1 et seq. and the agency agrees to strike them.
Comment
What data will be exchanged? The amount of Naloxone data may be unduly burdensome and potentially prejudicial.
Response
The Department has reviewed this comment, and no changes were made. The data that mandatory reporters are to share with the ODCP is enumerated in the rule. Data that the ODCP may exchange with the entities in section 1.1. has not yet been determined.
Comment
Hospitals and licensed or certified providers of health care are included. Therefore, the specific addition of "and hospital emergency rooms and departments" is unnecessarily redundant and makes the wording of the Scope section, not fit the wording in the Enrolled HB 2620.
Response
The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute. "Hospital emergency rooms and departments" were specifically added to W. Va. Code §16-5T-4(b)(6) during the 2018 Regular Session of the Legislature through the passage of Senate Bill 272.
Comment
1.6. This paragraph does not specifically mention hospital emergency rooms and departments; therefore, in this section, wording is a match to the enrolled legislation. If it is determined that the Scope, as currently written in this proposed document, can be language that is different than the Enrolled HB 2620, the specific mention of hospital emergency rooms/departments needs to be included here as well to be consistent.

Response
The Department has reviewed this comment. Existing provisions in the rule address this issue, and therefore, no changes were made. Section 1.6. states that the proposed rule is applicable to health care providers. The definition of "Health care provider" at section 2.9. of the proposed rule includes a "hospital" which would necessarily include "hospital emergency rooms and departments." The agency will take no action regarding this comment.

Comment
1.7. Collection of data from pharmacies is not included in §16-5T-2 (c) 17. In addition, pharmacies do not collect data on treatment of overdoses.

Response
The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute. Pursuant to W. Va. Code §16-5T-4(b)(1) pharmacies are required to report the information enumerated in W. Va. Code §16-5T-4(a).

Comment
The word "storage" does not appear in the Enrolled HB 2620. While the legislation may imply this, in this section, the language should match the bill. The word "storage" can appear later in this Rule.

Response
The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute. In order to fulfill the mandates of W. Va. Code §16-5T-3(a), the ODCP shall establish and *maintain* a central repository of the information collected.

Comment
It is confusing to include pharmacies and the CSMP in this Rule. Pharmacies to not attend to or treat overdoses/poisonings so what would these entities be required to report according to this Rule based on reporting of overdoses? Current legislation and WV Board of Pharmacy rules already require pharmacies to document naloxone dispensing in the CSMP.

Response
The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute. Pharmacies are among the entities required to report pursuant to W. Va. Code §16-5T-4(b)(1). The "dispensation or provision of an opioid antagonist" is among the information that shall be reported to the ODCP pursuant to W. Va. Code §16-5T-4(a)(3). Data from the Controlled Substance Monitoring Database may be reported, but is not required.

Comment
The type of overdose data to be reported needs to be specific. Lay persons may not be forthcoming in their sharing of information.

Response
The Department has reviewed this comment, and no changes were made. The rule applies to specific professional individuals and entities, not lay persons.

Comment
The data to be reported to the ODCP is already collected by the Poison Control Center. Although it is not a mandate, there will be some duplication.

Response
The Department has reviewed this comment, and no changes were made. The rule provisions are consistent with the requirements of the statute. Reporting to the WV Poison Center is not mandated by W. Va. Code §18B-11B-1 *et seq.*

Section 2 – Definitions

Comment
2.1 "Data and Information". Data is information in a special format. "data is information that has been translated into an electronic form to allow processing and transmission". Use of the phrase "not limited to" is overly broad and risks going beyond the scope of the Rule.
Response
The Department has reviewed this comment, and no changes were made. The rule provision is consistent with the requirements of the statute. The Secretary is granted broad authority to propose rules to implement the provisions of the law. In drafting the proposed rule, the Department has attempted to identify the full extent of the differing forms of information that may be collected, now and into the future. Technological advances may make it possible to collect additional forms of data relevant to the ODCP's mission. Thus, while current technology only provides us the ability to gather data in the form of numbers, words, and images, the collection of additional forms of data, currently unknown to the Department, may be possible in the future. As written, the definition would allow the Department to avail itself of that data without having to amend the proposed rule. Finally, the inclusion of the phrase does not appear to prejudice any person or entity regulated by the proposed rule.
Comment
A definition is needed for "Data Repository". Here is where the concept that collection also includes data storage can be added.
Response
The Department has reviewed this comment. Existing provisions in the rule address this issue, and therefore, no changes were made. Ordinarily, a term that does not appear in a rule does not require a definition.
Comment
According to the Food and Drug Administration (FDA) the definition of "drug" includes biological products. The current wording in the proposed Rule is not correct as the United States Pharmacopoeia and National Formulary are combined and should not be separated in text by the Homeopathic Pharmacopoeia. Also, some reporters may only be able to report a drug class/type.
Response
The Department has reviewed this comment, and no changes were made. The definition contained in the current rule is identical to the definition of "drug" contained in the Uniform Controlled Substance Act, W. Va. Code §60A-1-101(m). The Department believes the consistency between the definition used in this rule and the Uniform Controlled Substances Act will aid in the implementation of the rule. The rule provision is consistent with the requirements of the statute.
Comment
A definition for "Illicit Drug" should be added to make it clear that novel synthetic opioids and novel synthetics are covered.

Response
The Department has reviewed this comment, and no changes were made. West Virginia law regarding the interpretation of a statute or rule focuses first on the language of the statute or rule. See Maikotter v. University of West Virginia Bd. of Trustees/West Virginia Univ., 206 W.Va. 691, 696, 527 S.E.2d 802, 807 (1999); West Virginia Human Rights Comm'n v. Garretson, 196 W.Va. at 123, 468 S.E.2d at 738. "In the absence of any definition of the intended meaning of words or terms used in a legislative enactment, they will, in the interpretation of the act, be given their common, ordinary and accepted meaning in the connection in which they are used." Syl. pt. 1, Miners in General Group v. Hix, 123 W.Va. 637, 17 S.E.2d 810 (1941), overruled on other grounds, Lee–Norse Co. v. Rutledge, 170 W.Va. 162, 291 S.E.2d 477 (1982). The Department believes the definition of the term "illicit" is clear and no definition of the term is necessary.

Comment
"Emergency response provider". Current naloxone legislation in WV requires the reporting of naloxone use by firefighters. It seems, therefore, that firefighters should be included here as these individuals are not included in this Rule otherwise.

Response
The Department has reviewed this comment. Existing provisions in the rule address this issue and, therefore, no changes were made. Some fire departments in the state are licensed emergency medical services agencies and meet the definition of "emergency response provider." Additionally, firefighters would necessarily be included by W. Va. Code §16-5T-2(c)(18) which states "and other entities" as required by the office[.]"

Comment
Definition of "health care provider" includes a mix of specific entities AND individuals which becomes confusing later in the Rule when it comes to who reports and when. For example: a pharmacist, nurse, physician only when working in a clinic or hospital?
What about a pharmacist, nurse, physician, psychologist, or other included in this definition not at work who acts as a good Samaritan outside of the workplace, who administers naloxone to a citizen not under their care? Should also include school nurses who may be called upon to attend to an overdose not in the nursing office but on school grounds or athletic field.

Response
The Department has reviewed this comment, and no changes were made in response. Section 2.9 defines "health care provider" which includes "other person[s] providing....health care *services of any kind.*

Comment
We recommend amending the rule to reduce duplicative reporting requirements from entities such as hospitals and hospital emergency rooms and departments.

Response
The Department reviewed this comment and finds clarification is needed. Although hospitals and hospital emergency rooms and departments are all considered mandatory reporters under the statute and rule, not all of the data collected will be duplicative. An individual experiencing an overdose may encounter one, some, or all of the mandatory reporters. The information they provide to the ODCP will be from their unique perspective during the overdose response experience, and will enhance the ODCP's ability to achieve its statutory purpose. The Department will, however, amend the definition of "health care provider."

Comment
A prosecuting attorney would never be called on to attend to or treat an overdose so what are they mandatorily reporting?
Response
The Department has reviewed this comment, and no changes were made in response. The rule provision is consistent with the requirements of the statute.
Comment
Unless a specific definition of "drug misuse" is provided, mandatory reporting of drug misuse will result in an excessive burden being placed on mandatory reporters and participants, and an excess number of unwanted cases in the Office of Drug Control Policy database.
Response
The Department has reviewed this comment, and no changes were made. W. Va. Code §16-5T-2(c)(17) requires the collection of data on fatal and non-fatal drug overdoses caused by the abuse and *misuse* of prescription and illicit drugs. The term "misuse" is given its common, ordinary and accepted meaning in the connection in which it is used.
Comment
In the definition of "opioid antagonist" use of the words "in the brain" will provide what is wanted while excluding what is not meant to be included here. Use of the term "opiate" would exclude use to reverse drugs like hydrocodone, oxycodone, fentanyl, etc. which are opioids. Use the term "opioid" here to cover all.
Response
The Department has reviewed this comment and finds clarification is needed, therefore, some changes will be made.
Comment
Similarly, in the definition of "opioid" include the words "in the brain" to exclude methylnaltrexone.
Response
The Department has reviewed this comment and finds clarification is needed, therefore, some changes will be made.
Comment
The definition of "overdose" is overly broad and is not limited to opioids.
Response
The Department has reviewed this comment, and no changes were made in response. The ODCP has a broad mandate and is not limited to opioid drug policy. The provisions of W. Va. Code §16-5T-4 do not limit the collection of data to opioid overdoses. W. Va. Code §16-5T-2(c)(17) requires the collection of data on fatal and non-fatal drug overdoses caused by the abuse and misuse of prescription and illicit drugs.
Comment
This Rule does not cover information that a pharmacy would have to report. A pharmacy does not attend to or treat an overdose. Reporting of dispensing or provision of naloxone is not addressed.
Response
The Department has reviewed this comment and finds clarification is needed, therefore, some changes will be made.
Comment
For hospitalized patients, this list in 2.23.11 of effects can be extremely long as effects from complications (e.g., aspiration pneumonitis) are also included.

Response
The Department has reviewed this comment, and no changes were made. The current rule provision is neither ambiguous nor likely to result in an inappropriate application of the rule.
Comment
2.23.12 needs to read "Whether an opioid antagonist was administered for a suspected or confirmed opioid overdose".
Response
The Department has reviewed this comment, and no changes were made. The current rule provision is neither ambiguous nor likely to result in an inappropriate application of the rule.
Comment
2.23.13.c. needs to clarify that by response you mean therapeutic response (return of respirations or level of consciousness) and adverse naloxone reactions (vomiting, agitation, violent behavior).
Response
The Department has reviewed this comment, and no changes were made. The current rule provision is neither ambiguous nor likely to result in an inappropriate application of the rule.

Section 4 – Exchange of Data and Information

Comment
For continuity of operations, and because requests may require varying points of view to come to the best decision, perhaps a Panel can be used to evaluate requests. I would suggest including a representative of accredited Institutional Review Boards (e.g., CAMC, Marshall University) to ensure legal determination of public health versus research data requests.
Response
The Department has reviewed this comment, and no changes were made. W. Va. Code §16-5T-2(c)(17), (c)(18) and (d) authorize the ODCP to exchange necessary data and information with specified governmental agencies.
Comment
To further purposes and goals, deidentified data would need to be shared with the public.
Response
The Department has reviewed this comment, and no changes were made. The provision is consistent with applicable state and federal laws such as HIPAA.
Comment
HB 2620 says "[t]he ODCP may exchange necessary data..., but section 4.4.1. of the rule states the "Participants will provide overdose information..." The rule cannot say will if the statute says may.
Response
The Department has reviewed this comment, and no changes were made. The rule provision is consistent with the requirements of the statute. The ODCP may exchange data with the participants pursuant to W. Va. Code 16-5T-2(d). However, the mandatory reporters are required to provide overdose information to the ODCP pursuant to W. Va. Code §16-5T-4.
Comment
Participation in this program "shall be designed to minimize inconvenience to all entities...." But making participants go back through several years of data is not convenient.

Response
The Department has reviewed this comment, and finds clarification is needed, and therefore some changes were made.
Comment
Nothing in the rule says how the ODCP will utilize the data.
Response
The enacting statute sets forth the ODCP's duties in W. Va. Code §16-5T-2(c). The ODCP is mandated to develop and implement programs for the collection of overdose data. The exchange of data and information with specified state governmental agencies is discretionary, but the collection of data in the furtherance of the ODCP's mission is not.

Dellinger, Cynthia H

From: Acree, Lindsay S <lindsayacree@ucwv.edu>
Sent: Saturday, July 21, 2018 3:50 PM
To: Dellinger, Cynthia H
Subject: 69-14 comments

Department of Health and Human Resources
Office of Drug Control Policy
Cindy Dellinger
cynthia.h.dellinger@wv.gov

Dear Ms. Delinger:

This letter is to provide comment in regards to Rule 69-14 proposed on 6/21/18. Please see the bullet points below.

Disclaimer: The opinions and statements below are my opinion and statements alone. These statements to not reflect the opinions of the University, Faculty, Staff, Students, or Administration of the University.

In 69-14-1.1, the rule states that there is a requirement to facilitate the exchange of data with the Board of Pharmacy. Which data specifically will be exchanged? For example, if naloxone data is shared, you will receive many reports of naloxone dispensed but only a portion of those reports will be related to persons that are at risk of an overdose. A large percentage of those that fill or receive Naloxone are not persons that use these substances and are therefore not at risk of an overdose. If these patients are contacted by someone regarding their Naloxone or prescriptions for opioids, this may cause patients to no longer trust his/her health care providers. In addition, this adds to stigma associated with the use of Naloxone. The reporting of Naloxone to the board of pharmacy (Naloxone is not a controlled substance but is reported to the BOP) may add to prejudice and issues when patients are filling opioid prescriptions.

69-14-1.1, 1.8 discusses the reporting of documented or suspected overdoses. Recommend to be more specific as to the types of overdose data that should be reported (opioid, methamphetamine, acetaminophen, etc.). I have concerns with lay person reporting because often they do not know or do not wish to share the names of the person in which Naloxone was used. This may also hinder people in the position to save others from obtaining Naloxone.

69-14-1.7 indicates that the reporting will be the Office of Drug Control Policy, however, the Poison Control Center already collects this data. Currently, it is not mandated to report to Poison Control but we may have duplication of data if some agencies are reporting to both the Poison Control Center and the ODCP.

Lindsay Acree, PharmD, AE-C
University of Charleston School of Pharmacy

WEST VIRGINIA HOSPITAL ASSOCIATION

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July 17, 2018

Cindy Dellinger
One Davis Square, Suite 100 East
Charleston, WV 25301

Dear Mrs. Dellinger:

Re: LEGISLATIVE RULE 69CSR14, DEPARTMENT OF HEALTH AND HUMAN RESOURSES RULE FOR THE COLLECTION AND EXCHANGE OF DATA RELATED TO OVERDOSES

On behalf of the West Virginia Hospital Association and its 63 member hospitals and health systems, we respectfully submit this letter to provide public comments in response to the above referenced **Legislative Rule 69CSR14, Collection and Exchange of Data Related to Overdoses.**

§69-14-2. Definitions.

2.9. "Health care provider"- A "health care provider" is included as a "mandatory reporter" per the definition found at 2.11. This rule is amending the definition of "mandatory reporter" to include "hospital emergency rooms and departments". However, "hospital" is already included in the definition of a "health care provider". Therefore, as drafted, both a "hospital" and a "hospital emergency room and department" are "mandatory reporter(s)". We would recommend amending the definition of "health care provider" to prevent duplicate reporting requirements for both a "hospital" and a "hospital emergency room and department".

Generally, we recommend amending this rule to include efforts to reduce duplicate reporting by mandatory reporters. Subsection 3.1 requires "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" to report. Mandatory reporters include health care providers (physician, nurse, physician's assistant, paramedic, etc.), and hospital emergency rooms and departments. If an individual overdoses, and that individual is treated and then transported by paramedics to the emergency department, the following individuals would be required to submit the same report: Paramedic, emergency response provider, the health care provider at the emergency department, and the emergency department.

Additionally, we recommend developing an efficient electronic submission option for mandatory reporters to utilize. Currently, the only option for submission is to either email or mail the completed form from the ODCP website. This is a very inefficient, time consuming reporting burden for mandatory reporters, especially in the emergency department setting.

If you have any questions or concerns, please contact me at (304) 353-9720.

Sincerely,

Brandon Hatfield
General Counsel

WEST VIRGINIA POISON CENTER

STATEWIDE POISON EMERGENCY SERVICES

Statewide: 1-800-222-1222

Administration:
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Robert C. Byrd Health Sciences Center of West Virginia University, Charleston Division, 3110 MacCorkle Ave. S.E., Charleston, WV 25304

TO: Cindy Dellinger
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FR: Dr. Elizabeth J. Scharman, Pharm.D., DABAT, BCPS, FAACT
Director, WV Poison Center
Clinical Toxicologist, Board Certified
Board Certified Pharmacotherapy Specialist

DATE: July 10, 2018

RE: Public Comment; Title-Series: 69-14; Collection and Exchange of Data Related to Overdoses

There will be a fiscal impact on participants in order to enable their data systems to report data as described. As participants receive state support, there is a fiscal impact for the state. Until there is more specific information on the required software and nature of data transmission, the extent of the fiscal impact cannot be determined.

Additional Comments:

Page 1 1.1 Scope

States "....(1) the exchange of data and information with and between the Office....". Enrolled HB 2620 does not contain the word "between"; the enrolled version simply states "with the Office".

In 2.9 of the document out for comment, hospitals and licensed or certified providers of health care are included. Therefore, the specific addition of "and hospital emergency rooms and departments" is unnecessarily redundant and makes the wording of the Scope section, not fit the wording in the Enrolled HB 2620.

If this wording is to be kept, the terms "emergency room" and emergency department" refer to the same thing so, to cover all terminology bases, would suggest "emergency room/department". As written, "and" implies that they are different.

Page 1 1.6 Applicability

This paragraph does not specifically mention hospital emergency rooms and departments; therefore, in this section, wording is a match to the enrolled legislation. If it is determined that the Scope, as currently written in this proposed document, can be language that is different than the Enrolled HB 2620, the specific mention of hospital emergency rooms/departments needs to be included here as well to be consistent.

WEST VIRGINIA POISON CENTER

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Page 1 1.7 Background

2nd paragraph

Collection of data from pharmacies is not included in §16-51-2 (c) 17. In addition, pharmacies do not collect data on treatment of overdoses.

The addition of emergency departments/rooms is not needed as they are included under the definition of health care facilities.

The word "storage" does not appear in the Enrolled HB 2620. While the legislation may imply this, in this section, the language should match the bill. The word "storage" can appear later in this Rule.

Page 2 1.8 Purpose

The Controlled Substance Monitoring Program (CSMP) and WV Board of Pharmacy are mentioned here. While this makes sense as the wording matches the Enrolled HB 4620, nothing in the proposed Rule document mentions the reporting of naloxone dispensing, or the reporting to the data repository information, of the number of opioid prescriptions written/dispensed.

If the current document does not cover these items, it is confusing to include pharmacies and the CSMP in this Rule. Pharmacies to not attend to or treat overdoses/poisonings so what would these entities be required to report according to this Rule based on reporting of overdoses? Current legislation and WV Board of Pharmacy rules already require pharmacies to document naloxone dispensing in the CSMP.

Pages 2-4 Definitions

2.1 "Data and Information". Data is information in a special format. "data is information that has been translated into an electronic form to allow processing and transmission". Use of the phrase "not limited to" is overly broad and risks going beyond the scope of the Rule.

- A definition is needed for "Data Repository". Here is where the concept that collection also includes data storage can be added.

2.6 "Drug", 2.6.1-4

According to the Food and Drug Administration (FDA) – verbatim:

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.

- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition

If the intent is to mirror this definition in the Rule, then the information contained in the last bullet (regarding biological products) needs to be included. Clarification of the first bullet, if desired, is more correctly written as:

"A substance recognized by the United States Pharmacopoeia and National Formulary (USP-NF), the Homeopathic Pharmacopoeia, or other official pharmacopoeia or formulary."

The current wording in the proposed Rule is not correct as the United States Pharmacopoeia and National Formulary are combined and should not be separated in text by the Homeopathic Pharmacopoeia.

(Not a comment but an FYI: Under the Dietary Supplement Health and Education Act of 1994, "dietary supplements are deemed to be food, *except for purposes of the drug definition*". https://oig.hhs.gov/oei/reports/oei-01-01-00120.pdf and are therefore included in the USP-NF. Mandatory reporters will need to be aware of this as they are sold to consumers as "not being a drug".)

By using the FDA verbatim for the 2nd bullet, it is unnecessary to add human or animal as it covers both.

- A definition for "illicit Drug" is missing. The Enrolled HB2620 requests data on "overdoses caused by abuse and misuse of prescription and illicit drugs". §16-5T-2 (c) 17.

  Recommendation: "An illicit drug is defined as an illegal drug including drugs prohibited by international law."

  Adding this definition, and reference to illicit drugs, to the Rule will make it clear that novel synthetic opioids and novel synthetics are covered.

2.7 "Emergency response provider". Current naloxone legislation in WV requires the reporting of naloxone use by firefighters. It seems, therefore, that firefighters should be included here as these individuals are not included in this Rule otherwise. Allowed as §16-5T-2 (c) 18 says "and other entities" as required by the office".

2.9 "Health care provider"

If the desire is to specifically mention emergency departments/rooms, then this is where this can be done without changed the wording of the Enrolled HB2620 repeated in the Background, Scope, and Applicability sections of this Rule

Should also include school nurses who may be called upon to attend to an overdose not in the nursing office but on school grounds or athletic field.

Included in this definition is a mix of specific entities AND individuals. This merging of entities and individual in one definition becomes confusing later in the Rule when it comes to who reports and when. For example: a pharmacist, nurse, physician only when working in a clinic or hospital? What about a pharmacist, nurse, physician, psychologist, or other included in this definition not at work who acts as a good Samaritan outside of the workplace, who administers naloxone to a citizen not under their care?

2.11 "Mandatory reporter"

Comments included in 2.9 above.

A prosecuting attorney would never be called on to attend to or treat an overdose so what are they mandatorily reporting?

Excludes firefighters (an initial responder) required by naloxone legislation (WV SB 431) to report naloxone administrations. In the experience of the WV Poison Center, firefighters more commonly report naloxone administrations compared with law enforcement officers.

- A definition for Drug Misuse is missing (see §16-ST-2 (c) 17; Enrolled HB2620 requests data on "overdoses caused by abuse and misuse of prescription and illicit drugs".

Unless a specific definition is provided, mandatory reporting of drug misuse will result in an excessive burden being placed on mandatory reporters and participants, and an excess number of unwanted cases in the Office of Drug Control Policy database, as all cases of prescription misuse will be required to be reported. For example, misuse of prescription drugs (which can cause poisonings and harm) include:

Accepting a medication from a friend (including antibiotics, steroid creams)
Poisoning from taking a dose at the wrong time
Taking a leftover drug for a similar condition after the original prescription period (e.g., using leftover steroid cream, a prescription cold medicine, or antibiotic)

Listed below are published definitions of drug misuse.

"An exposure resulting from the intentional improper or incorrect use of a substance for reasons other than the pursuit of a psychotropic effect"

American Association of Poison Control Centers (AAPCC) National Poison Data System (NPDS)
http://www.aapcc.org/data-system/npds-elements/

"Prescription drug misuse and abuse is the intentional or unintentional use of medication without a prescription, in a way other than prescribed, or for the experience or feeling it causes."

Substance Abuse and Mental Health Services Administration (SAMHSA)
https://www.samhsa.gov/topics/prescription-drug-misuse-abuse

"Q: What is misuse and abuse of prescription drugs?
A: When a person takes a legal prescription medication for a purpose other than the reason it was prescribed, or when that person takes a drug not prescribed to him or her, that is misuse of a drug. Misuse can include taking a drug in a manner or at a dose that was not recommended by a health care professional.

This can happen when the person hopes to get a bigger or faster therapeutic response from medications such as sleeping or weight loss pills. It can also happen when the person wants to "get high," which is an example of prescription drug abuse.

Q: What's the difference between misuse and abuse?

A: It mostly has to do with the individual's intentions or motivations."

Food and Drug Administration
https://www.fda.gov/forconsumers/consumerupdates/ucm220112.htm

Recommendation for definition of Drug Misuse for the purposes of this Rule:

"Drug misuse is defined, for the purpose of this Rule, as taking an originally legally prescribed, scheduled drug for the purposes of a mind altering or euphoric effect or for the self-treatment of pain or withdrawal in a manner that is 1) not consistent with the name of the person the prescription was written for, 2) not in the quantity stated in prescription label instructions, or 3) use beyond the original, specific medical condition the drug was prescribed for.

2.14 "Opioid antagonist" definition.

Recommend "A drug which acts as an opioid receptor antagonist, blocking the opioid receptor in the brain, thereby preventing this receptor from responding to the presence of an opioid".

Use of the words "in the brain" will provide what is wanted while excluding what is not meant to be include here (methylnaltrexone bromide used to treat opioid-induced constipation which has no activity in the brain and no ability to block analgesic and CNS effects via the opioid receptor)

Use of the term "opiate" (third to last work in the sentence) would exclude use to reverse drugs like hydrocodone, oxycodone, fentanyl, etc. which are opioids. Use the term "opioid" here to cover all.

2.15 "Opioid"

More accurate: "means any substance, as the parent compound or a metabolite, whose primary mechanism of action is via attachment to opioid receptors in the brain and whose opioid receptor activity is reversed by an opioid antagonist.

Again, include the word (the brain) to exclude methylnaltrexone.

As dextromethorphan is an N-methyl-D-aspartate receptor (NMDA) receptor antagonist, the additional wording meant to exclude this drug is not necessary. It does not have clinical activity related to the opioid receptor.

2.16 "Overdose"

Enrolled HB 2620 speaks to reporting of both prescription and illicit drugs abuse and use of naloxone. The current definition reads like what is wanted is any overdose that could be an opioid overdose.

If this is indeed the intent of this overdose definition, the problem with the current wording is that the opioid toxidrome (toxidrome means a cluster of signs/symptoms associated with a type of overdose; for opioids = miosis, respiratory depression, depressed consciousness) is not specific for an opioid overdose.

In addition, a drug screen does NOT confirm an opioid overdose. It only says that an opioid was used sometime in the past. To include this is to encourage the ordering of unnecessary and costly urine drug screens and to add a include multiple non-opioid overdoses (and non-substance abuse overdoses) into the proposed data repository

In the intent is not limited to opioid overdoses, but is meant to cover all substance abuse overdoses, the current definition includes a very long list of signs/symptoms that would cover multiple medications that are not controlled substances and not used for mind-altering purposes. With the definition as written, data on accidental exposures in children, suicide attempts by non-drugs of abuse, and medication errors by all drugs (including non-drugs of abuse), both in and outside of hospitals, would be included. This will be a huge burden on reporters and participants if this definition is left as is. In addition, the database will no longer suit what I believe to be the intent of the database.

As an overall comment on this Rule, it is not clear if the focus of this Rule is on the opioid epidemic or if the intent is to monitor all overdoses/poisonings of all drugs (non-prescription, prescription, biologically based, illicit, novel synthetic not yet scheduled) being used for mood altering/abuse effects. If more than opioid overdoses are wanted, then the definition needs to carefully exclude overdoses that are not caused by attempts to change mood or to use a cross-tolerant drug to self-treat opioid withdrawal.

It may be better to change the term to be defined to "Opioid Overdose" or "Drug of Abuse/Illicit Drug Overdose". – depending on what is intended for this Rule.

Recommendation: If what is wanted is only opioid overdoses then this Rule needs to be clear on that. If opioid only then recommend:

Presence of respiratory depression or loss of consciousness reversed by naloxone OR the presence of respiratory depression reversed with naloxone WITH clear evidence at the scene of recent opioid use (e.g., freshly used needles, empty containers/packages or suspected opioids) OR opioid paraphernalia.

An overdose is defined as: too much of or a toxic or lethal amount of a drug. Overdoses may be accidental or intentional. Taking more than the recommended amount of a drug is an overdose. (For example, taking 3 Tylenol instead of 2 for a bad headache is technically an overdose.) Therefore, to consider when writing the definition:

Do you want reports of naloxone administered to patients inadvertently receiving unintentional therapeutic overdoses of opioids while in a health care facility/hospital? These cases are beyond the scope of the opioid epidemic but will be included in the rule if not excluded.

The current definition, if left as is, also used "opiates" in the last sentence; this will exclude a (+) finding of oxycodone, buprenorphine, methadone, and other synthetic/semi-synthetic opioids on a screen.

2.19 "Pharmacy"

This Rule does not cover information that a pharmacy would have to report. A pharmacy does not attend to or treat an overdose. Reporting of dispensing or provision of naloxone is not addressed in the particular Rule; section 2.23 and 3.1 (it is addressed in Enrolled HB 2620

If the data repository mentioned in this Rule will include naloxone dispensing data (naloxone dispensing reporting covered in WV naloxone legislation, not Enrolled HB 2620), then wording needs to be added to this Rule to cover that specific type of data to be collected.

If this section is kept, Enrolled HB 2620 says "Pharmacies operating in the state" §16-5T-4 (b) (1). While I agree with what is written, this language does not mirror the Enrolled HB 4620 thereby going beyond what HB 4620 allows.

2.21 "Prosecuting attorney"

This Rule outlines reportable information requirements. Prosecuting attorneys to not attend to or treat overdoses. Unsure the purpose of including in this particular Rule (other items not pertinent to this Rule are found in Enrolled HB 2620 and not included in this document so it can be left out).

Page 5 2.23

As stated above, the definition of overdose, for purposes of this document, need to be better defined; otherwise, the requirements which follow will be burdensome to collect and the data will not meet the intent of the Enrolled HB 2620

Page 5 2.23.10

With the exception of the National Poison Data System (NPDS) which can enter specific drug information into a reportable field (capable of exporting as a series of numbers for translation) other databases can only report drug class information (for some not all drugs). In addition, many times, drug class or type is the only identification that can be made (not the specific drug). Therefore, this needs to say "Drug or drug class/type suspected of causing the overdose."

Page 5 2.23.11

For hospitalized patients, this list is effects can be extremely long as effects from complications (e.g., aspiration pneumonitis) are also included. Again, this list looks like what is wanted is only opioid overdoses; however, this is not how the enrolled legislation or the scope of this Rule currently read.

Page 5 2.23.12

This needs to read "Whether an opioid antagonist was administered for a suspected or confirmed opioid overdose". (Naloxone has other, non-labeled uses AND the definition of overdose currently used is not specific for opioids.)

Page 5 2.23.13.c.

Need to clarify that by response you mean therapeutic response (return of respirations or level of consciousness) and adverse naloxone reactions (vomiting, agitation, violent behavior).

Page 6, §69-14-4

4.1 It states "ODCP may disclose". However, later on page 7, 4.5.2.b. (Functions of the ODCP Director) states that the ODCP Director is responsible for "Coordinating with the department's privacy office to determine whether a request is valid and the information may be released under applicable law."

It is stated that "The ODCP shall have sole discretion to determine what constitutes a legitimate purpose relating to public health".

For continuity of operations, and because requests may require varying points of view to come to the best decision, perhaps a Panel can be used to evaluate requests. I would suggest including a representative of accredited Institutional Review Boards (e.g., CAMC, Marshall University) to ensure legal determination of public health versus research data requests.

Page 7, §69-14-4

4.2 "Participants may use and disclose data and information in furtherance of the purposes and goals of participants relevant....." However, the concluding sentence which follows says: "The participant agrees not to use or further disclose data and information other than as authorized by law." The last sentence appears to say that the first sentence cannot be accomplished.

Which "law" is being referred to? To further purposes and goals, deidentified data would need to be shared with the public.

4.4.1

Enrolled HB 4620 states "..the ODCP <u>may</u> exchange necessary data..). 4.4.1 states "Participants <u>will</u>..."

While participants may be willing to share data, the Rule cannot say "will" while the legislation states "may".

This comment is not meant to imply that the WV Poison Center is not in favor of the ability to share data. It is just that the wording in the Rule is not allowed by enrolled legislation.

Enrolled HB 2620, §69-5T-3 (b) states "..shall be designed to minimize inconvenience to all entities maintaining possession of the relevant information...". This is not met by requiring the review of 16 years of electronic data equally approximately 320,000 exposure records from the WV Poison Center.

Again, the WV Poison Center will work with the ODCP on this project; however, discussions on how best to do this require further discussion.

Last sentence "The participants acknowledge that...." I understand the intent of this statement, however, this type of language is better place in data use agreements rather than a rule.

Nothing in this Rule states how the ODCP may utilize this data or how the participant data will be credited to the participant agency on any/all publications resulting from ODCP release of data. Participants will need to ensure that data presentation from the ODCP accurately reflects what the data does and does not mean for a specific database type.