

Michigan Office of Administrative Hearings and Rules
611 West Ottawa Street; 2nd Floor, Ottawa Building
Lansing, MI 48933
Phone: (517) 335-8658 FAX: (517) 335-9512

**AGENCY REPORT TO THE
JOINT COMMITTEE ON ADMINISTRATIVE RULES (JCAR)**

Under the Administrative Procedures Act (APA), 1969 PA 306, the agency that has the statutory authority to promulgate the rules must complete and submit this form electronically to the Michigan Office of Administrative Hearings and Rules (MOAHR) at o'berryd@michigan.gov.

1. Agency Information:

Agency name:	Health and Human Services
Division/Bureau/Office:	Bureau of Epidemiology and Population Health
Name, title, phone number, and e-mail of person completing this form:	Mary E Brennan, MDHHS Regulatory Affairs Officer, 517-284-4850, brennanm@michigan.gov
Name of Departmental Regulatory Affairs Officer reviewing this form:	Mary E Brennan

2. Rule Set Information:

MOAHR assigned rule set number:	2018-074 HS
Title of proposed rule set:	Reporting of Poisonings Due to the Use of Prescription or Illicit Drugs

3. Purpose for the proposed rules and background:

With the dramatic increase in the rise of overdoses and deaths caused by prescription medications and illicit “street” drugs, tracking the information is difficult as there is no requirement that health professionals and health facilities report this information. Without the information, the State is unable to proportionately leverage resources to each county to combat the overdoses/death epidemic occurring in this State.

With the increase in the popularity and continual addition of new synthetic opioid “street” drugs and associated increase in overdoses and associated deaths, the Department needs to collect the data from health professionals and health facilities quickly to assess critical needs of counties and their population and provide appropriate health warnings, rehabilitation, and preventative care for Michigan citizens. As the impact of the opioid crisis evolves, the Department of Health and Human Services needs to understand the use of other drugs in the population.

4. Summary of proposed rules:

The proposed rules would require, when requested by MDHHS, facilities and health care professionals as defined in the rules, to provide data regarding overdoses of prescription or illicit drugs, whether or not they result in death. The rules identify the data required, the timeframes, and confidentiality standards associated with that data.

5. List names of newspapers in which the notice of public hearing was published and publication dates (attach copies of affidavits from each newspaper as proof of publication).

Marquette Mining Journal-Publication Date: February 18, 2019; Oakland Press-Publication Date: February 20, 2019 , Battle Creek Enquirer-Publication Date: February 19, 2019

6. Date of publication of rules and notice of public hearing in *Michigan Register*:

March 1, 2019

7. Time, date, location, and duration of public hearing:

Tuesday, March 12, 2019. MDHHS South Grand Building, 333 S. Grand Ave., Rooms 1K and 1L, Lansing, MI 48909. 1:00 p.m. to 3:30 p.m.

8. Provide the link the agency used to post the regulatory impact statement and cost-benefit analysis on its website:

https://www.michigan.gov/mdhhs/0,5885,7-339-73970_7701_7869---,00.html

9. List of the name and title of agency representative(s) attending public hearing:

Sarah Lyon Callo, State Epidemiologist and MDHHS Director of Epidemiology and Population Health; Matthew Buck, State Administrative Assistant to Ms. Lyon Callo; Jared Welehodsky, MDHHS Department Analyst, Policy, Planning and Legislative Services

10. Persons submitting comments of support:

Ms. Paige Fults, Ms. Amanda Kogowoski

11. Persons submitting comments of opposition:

Dr. Joyce L. deJong, D.O.

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12. Identify any changes made to the proposed rules based on comments received during the public comment period:

	Name & Organization	Comments Made at Public Hearing	Written Comments	Agency Rationale for Change	Rule Number & Citation Changed
1.	Health Care Association of Michigan, Michigan Council of Nurse Practitioners, Michigan Health & Hospital Association, Michigan Osteopathic Association, Michigan State Medical Society		"The definition of 'poisoning' is vague. Poisoning uses the term 'morbid condition' without giving the definition of morbid in the rules."	Current language: (h) "Poisoning" means a morbid condition, including death, produced by a poison. MDHHS agrees that the definition needs to be expanded to provide for a clearer definition of "morbid condition."	R 325.76(h): "Poisoning" means any morbid condition, including death, that is related to, characterized by, affected by, induced by, or a product of a poison as defined in subrule (g). "
2.	Ms. Paige Fults, Michigan Health and Hospital Association (MHA), on behalf of MHA, Michigan Council of Nurse Practitioners, Michigan Osteopathic Association, Michigan State Medical Society	"We would request that a formal definition of "drug overdose" be included in the rules, if possible. [... W]ithout this clear definition, facilities and health care providers raise the fact that they didn't know if it was related and what you wanted reported		Current Language: 1) Health professionals and health facilities shall provide reports when requested by the department or local health department. The department or local health department shall notify health professionals and health facilities when reports	R 325.77(1): Health professionals and health facilities shall provide reports when requested by the department or local health

		<p>had to do with medication toxicity, medication side effects, poly pharmacy, or sedation due to opioid use."</p>		<p>of prescription or illicit drug poisonings shall be submitted. Both of the following apply:</p> <p>(a) Reports shall be made within 5 working days following request by the department or local health department.</p> <p>(b) Reports shall be provided to the department or local health department that makes the request.</p> <p>The Department does agree that reporters would need a clear understanding of what type of poisonings (i.e., poisonings resulting from exposure to particular substances) and under which conditions (i.e., context of poisoning event) should be reported to the Department in order to fulfill the intent of this ruleset. For this reason, the Department will publish specific requests on at least an annual basis, under the authority granted by the Public Health Code (PA 368 of 1978) and this ruleset, detailing which substance poisonings should be reported and when (see</p>	<p>department for routine public health surveillance and/or investigation of specific events. The department or local health department shall notify health professionals and health facilities when reports of prescription or illicit drug poisonings shall be submitted. Both of the following apply:</p> <p>(a) Reports shall be made within 5 working days following request by the department or local health department.</p> <p>(b) Reports shall be provided to the department or local health department that</p>
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				<p>above: item #1). The intent of this rule set is to identify events of public health concern and necessitating a public health response. The intent is that the request could come in two ways: a routine surveillance data request, utilizing existing data feeds to identify emerging trends; or, through a Specific Event Investigation Request in the case of a suspected outbreak of poisonings. This is the logic that will applied to determine whether a particular poison should be included in the published requests.</p>	<p>makes the request.</p>
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13. Date report completed:

<u>5-28-2019</u>

The Mining Journal

Upper Michigan's Largest Daily Newspaper

249 W. Washington St., P.O. Box 430, Marquette, Michigan 49855. Phone (906)228-2500. Fax (906)228-3273.

AFFIDAVIT OF PUBLICATION

STATE OF MICHIGAN

AFFIDAVIT OF PUBLICATION

For the County of **MARQUETTE**

In the matter of: Notice of Public Hearing
Michigan Department of Health and Human Services
Bureau of Epidemiology and Population Health
Rules for Reporting Poisonings Due to the Use of Prescription or Illicit Drugs
March 12, 2019

Size: 2 x 9

State of **MICHIGAN**, County of Marquette ss.

JAMES A. REEVS


being duly sworn, says that he is

PUBLISHER

of **THE MINING JOURNAL**

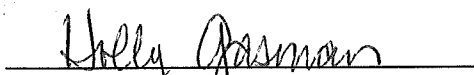
a newspaper published and circulated in said county and otherwise qualified according to Supreme Court Rule; that annexed hereto is a printed copy of a notice which was published in said newspaper on the following date, or dates, to-wit

February 18, 2019



JAMES A. REEVS

Subscribed and sworn to before me this 18th day of February 2019.



HOLLY GASMAN
Notary Public for MARQUETTE County, Michigan
Acting in the County of Marquette
My commission expires: May 25, 2025

AFFIDAVIT OF PUBLICATION

**BATTLE CREEK ENQUIRER NEWSPAPER
77 MICHIGAN AVE E.
BATTLE CREEK, MICHIGAN**

State of Michigan, County of Livingston} ss

IN THE MATTER OF REPORTING OF POISONINGS


MI DEPT OF HEALTH & HUMAN SERV

Being duly sworn, says that he/she is authorized by the publisher of The Battle Creek Enquirer to swear that a certain notice, a copy of which is annexed here to, was published in the following publication: The Battle Creek Enquirer.

1. Published in the English language for the dissemination of general and/or legal news, and
2. Has a bonfide list of paying customers or has been published at least once a week in the same community without interruption for at least 2 years, and
3. Has been established, published and circulated at least once a week without Interruption for at least one (1) year in the community where the publication is to occur.

The The Battle Creek Enquirer 02/19/2019

Ad# LJ-0100403696



Scott Feneley

SUBSCRIBED AND SWORN TO BEFORE ME THIS 13th
DAY of MARCH, 2019

GINA ANNE HUFF
NOTARY PUBLIC - STATE OF MICHIGAN
COUNTY OF LIVINGSTON
My Commission Expires March 9, 2023



Acting in the County of Livingston

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AFFIDAVIT OF PUBLICATION

2125 Butterfield Dr, Suite 102N • Troy MI 48084

MI DEPT OF HEALTH & HUMAN SERVICES
333 S GRAND AVE-3RD FLOOR

LANSING, MI 48909
Attention: Mary E. Brennan

STATE OF MICHIGAN,
COUNTY OF OAKLAND

The undersigned Cyndy Slater Cyndy Slater, being duly sworn the he/she is the principal clerk of Royal Oak Tribune, Oakland Press, theoaklandpress.com, theoaklandpress.com2, published in the English language for the dissemination of local or transmitted news and intelligence of a general character, which are duly qualified newspapers, and the annexed hereto is a copy of certain order, notice, publication or advertisement of:

MI DEPT OF HEALTH & HUMAN SERVICES

Published in the following edition(s):

Oakland Press	02/20/19
theoaklandpress.com	02/20/19
theoaklandpress.com2	02/20/19
Royal Oak Tribune	02/20/19

*All
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**NOTICE OF PUBLIC HEARING
MICHIGAN DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Bureau of Epidemiology and Population Health
Rules for Reporting of Poisonings Due to the
Use of Prescription or Illicit Drugs
Rule Set 2018-074 HS

The Michigan Department of Health and Human Services will hold a public hearing to receive public comments on the permanent rules to replace the current emergency rules entitled Reporting of Poisonings Due to the Use of Prescription or Illicit Drugs.

Tuesday, March 12, 2019

1:00 P.M. to 4 P.M.

MDHHS South Grand Building-Rooms 1K and L

333 S. Grand Avenue

Lansing, Michigan 48909

Email: MDHHS-AdminRules@michigan.gov

The general purpose of these rules addresses the need for statistical data to combat the dramatic increase in the rise of overdoses and deaths caused by prescription medications and illicit "street" drugs. Tracking the information is difficult as there is no requirement that health professionals and health facilities report this information. Without the information, the State is unable to proportionately leverage resources to each county to combat the overdoses/death epidemic occurring in this State.

By authority conferred on the Department of Health and Human Services by section 8 of 1978 PA 312; sections 2221, 2226, 2233, 5111 of 1978 PA 368; Executive Reorganization Order No. 2015-1; and section 48 of 1969 PA 306, being MCL 325.78, MCL 333.2221, MCL 333.2226, MCL 333.2233, MCL 333.5111, MCL 400.227, and MCL 24.248. These rules will take effect 30 days after filing with the Secretary of State. The rules (Rule Set 2018-071 HS) are published on the Michigan Government web site at <http://www.michigan.gov/orr> and in the Michigan Register in the March 1, 2019 issue. Copies of the draft rules may also be obtained by mail or electronic transmission at the following address:

**Department of Health and Human Services
Attn: Sarah Lyon-Callo
333 South Grand Avenue, 3rd Floor
Lansing, MI 48909
Telephone: 517-284-4924
E-mail: MDHHS-AdminRules@michigan.gov**

Comments on the rules may be made in person at the hearing or by mail or electronic mail until Friday, March 15, 2019.

The public hearing will be conducted in compliance with the 1990 Americans with Disabilities Act, in accessible buildings with handicap parking available. Anyone needing assistance to take part in the hearing due to disability may call 269-337-3744 to make arrangements.

Published February 20, 2019

RULES FOR REPORTING OF POISONINGS
DUE TO THE USE OF PRESCRIPTION OR
ILLICIT DRUGS, PUBLIC HEARING

March 12, 2019

Prepared by

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STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BUREAU OF EPIDEMIOLOGY AND POPULATION HEALTH

PUBLIC HEARING
RULES FOR REPORTING OF POISONINGS DUE TO THE USE OF PRESCRIPTION
OR ILLICIT DRUGS

333 South Grand Avenue, Lansing, Michigan

Tuesday, March 12, 2019, 1:00 p.m.

PANEL: SARAH LYON-CALLO
MATTHEW BUCK
JARED WELEHODSKY
MARY BRENNAN

RECORDED BY: Marcy A. Klingshirn, CER 6924
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6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

TABLE OF CONTENTS

PAGE

Opening Statement by Ms. Lyon-Callo.	3
Statement by Ms. Paige Fults	7
Statement by Ms. Amanda Kogowski	12

1 Lansing, Michigan

2 Tuesday, March 12, 2019 - 1:02 p.m.

3 MS. LYON-CALLO: Good afternoon, everyone. Thank
4 you for coming. It is now 1:02 p.m. on Tuesday, March 12th,
5 2019. My name is Sarah Lyon-Callo and I'm the state
6 epidemiologist and director for the Department of Health and
7 Human Services, Bureau of Epidemiology and Population
8 Health. I'd like to introduce Mr. Matthew Buck. He is my
9 state assistant administrator within the Bureau, as well as
10 Jared Welehodsky. Can you share your title?

11 MR. WELEHODSKY: I work in the Policy Planning
12 Division at MDHHS.

13 MS. BRENNAN: Good afternoon. I'm Mary Brennan.
14 I'm the DHHS Regulatory Affairs officer, and my only purpose
15 here is to make everyone here behave.

16 MS. LYON-CALLO: Okay. So we are on the record
17 for the public hearing for the administrative rules
18 involving reporting of poisonings due to the use of
19 prescription or illicit drugs. So we have a brief
20 presentation today regarding these draft rules.

21 As you know, nationally there have been more than
22 400,000 deaths from opioid overdose between 1999 and 2017.
23 There are basically three waves during this epidemic, the
24 most recent being due to illicit Fentanyl use. Michigan has
25 followed the national trends depicted in this slide.

1 Unfortunately, we expect there to be new drugs involved in
2 epidemic of overdose, whether it be fatal or nonfatal
3 overdoses, and that these drugs will continue to change over
4 time.

5 Surveillance of drug poisoning in Michigan is
6 currently somewhat limited. We are able to look at data on
7 fatal drug poisonings through use of death certificates and
8 using some federal dollars, we're able to conduct some
9 extractions of medical examiner records. Our understanding
10 of nonfatal drug poisonings is through the use of syndromic
11 surveillance or chief complaint data, and through the use of
12 a purchase data set from the Michigan Health and Hospital
13 Association, their inpatient and outpatient discharge data.

14 These are both very important and valuable data
15 sources, however, each have their own limitations. Our
16 syndromic or chief complaint data are quickly available, but
17 are relatively incomplete and at times nonspecific. The
18 inpatient and outpatient discharge data are a very rich data
19 set and we've used these for retrospective surveillance and
20 evaluation purposes, but they are not timely enough for
21 rapid response.

22 These draft rules are intended to fill this gap.
23 The rules would allow the Department to gather information
24 on drug poisonings for medical practitioners, so it'd enable
25 us to have more timely analyses for our local communities

1 and provide us the ability to investigate outbreaks of drug
2 poisonings.

3 I want to be clear that these rules do not require
4 health care practitioners to immediately report to the
5 department upon their passage. What these rules do is allow
6 MDHHS to ask for information, but also requires the
7 department to create a mechanism for coordinating collection
8 of that data and sharing of that data with local public
9 health and others in order to minimize reporting burden. I
10 also wanted to point out that the rules -- that under the
11 rules, submitted reports are not FOIAable.

12 So how would we implement these rules? Using
13 federal grant dollars, MDHHS is building a surveillance
14 module for routine reporting. We're leveraging an existing
15 data system we use for communicable disease reporting and
16 existing flow of admission discharge transfer HL7 messages.
17 Therefore, we expect the burden of collection of nonfatal
18 poisonings to be minimized for this reason.

19 So as an overview, at the request of MDHHS, a
20 health care professional and facility would submit reports
21 of prescription and/or illicit drug poisonings. The rules
22 permit MDHS to request reporting elements such as those
23 which relate to evidence of drug poisoning, for example,
24 diagnoses codes, as well as patient information and
25 demographics, reporting provider, health care facility

1 and/or laboratory findings. And, again, the rule permits
2 MDHHS to further investigate referrals of drug poisonings.

3 So one example of use of the rule would be that
4 MDHHS would set up a standing request for health care
5 providers to submit referrals to the department. This would
6 be MDHS mining existing ADT messages for indicators of drug
7 poisonings or overdoses, health care providers could
8 regularly conduct quality assurance on submitted referrals,
9 and health care providers that do not participate in regular
10 transmission of ADT messages would have an ability to
11 manually submit all referrals to MDHHS as they do now for
12 communicable disease.

13 Another example would be if the department had
14 identified a potential outbreak or hot spot of drug
15 poisoning activities. The department or its local health
16 department partner could conduct active outreach to the
17 health care providers to investigate this outbreak. This
18 could include outreach to individuals or their
19 representatives, outreach to health care providers and/or
20 facilities, completion of case report forms, or record
21 abstraction. So very similar to how we investigate
22 communicable disease outbreaks today.

23 I wanted to provide some -- just the references
24 that we used in this presentation. And then just briefly
25 state that formal questions and comments must be filed -- on

1 these rules must be filed between March 12th, today, and
2 March 15th, 2019. Questions and comments may be filed at
3 today's hearing by mail or by electronic mail. If they're
4 filed by mail, they must be postmarked by 3/15/19 at the
5 latest. And you can send those comments via mail to myself
6 or the e-mail address there is MDHHS-
7 AdminRules@Michigan.gov. So thank you very much for your
8 attention and interest. If you would like your appearance
9 today to be documented, please use the public hearing
10 sign-in sheet in the back of the room. I think you all did
11 that. And if at this time if you'd like to make a comment
12 regarding the proposed rule changes, please come forward and
13 introduce yourself. Please spell your name for the recorder
14 and provide your comments for the record.

15 PAIGE FULTS

16 MS. PAIGE FULTS: Hi. Thank you guys so much for
17 the opportunity to speak today. My name is Paige Fults. I
18 am the director of Advocacy here at the Michigan Health and
19 Hospital Association.

20 REPORTER: Can you spell your name, please?

21 MS. PAIGE FULTS: Paige is P-a-i-g-e. My last
22 name is Fults, F-u-l-t-s.

23 Today, in addition to representing the MHA, I'm
24 actually also representing the Michigan Council of Nurse
25 Practitioners, the Michigan Osteopathic Association, and the

Page 7

1 Michigan Medical -- the Michigan State Medical Society. Our
2 formal written remarks will be e-mailed by Friday's deadline
3 to make sure everything that we go over has a little bit
4 more of a detailed component to it.

5 Upon review of the rules for consideration there's
6 been some confusion within the health care community of
7 whether or not these rules apply exclusively to controlled
8 substances and opioids. We respectfully request a
9 clarification on that just to better facilitate the
10 satisfaction of what is being asked in the requirements.
11 The title of the rules in the definition section seem to
12 imply to us that providers in health facilities would be
13 reporting on all accidental or intentional poisonings for
14 both controlled substances and non-controlled substances.
15 One example of this is such as insulin. If that's not the
16 case, we request the title of the rules be updated to
17 include the term "opioid" in them to help the confusion be
18 cleared with the health care community. In addition, we
19 also are hoping that a definition of "drug" and "poisoning"
20 could be updated.

21 We would request that a formal definition of "drug
22 overdose" be included in the rules, if possible. Without
23 the formal definition, the interpretation of drug overdose
24 has been interpreted by some who we ask to review the rules
25 as a continuum of care or side effects of over medication

1 that has happened. So without this clear definition,
2 facilities and health care providers raise the fact that
3 they didn't know if it was related and what you wanted
4 reported had to do with medication toxicity, medication side
5 effects, poly pharmacy, or sedation due to opioid use. Was
6 that something that was intended to be included in these
7 rules and reports or not? There also currently is not an
8 ICD-10 code for those instances and at a minimum, we
9 requestfully respected (sic) -- would ask that the drug
10 overdose definition would be included in the public health
11 code because that would help clear up some of the confusion
12 that has been created.

13 Our understanding is that the intent is to have
14 the system automated that wouldn't require health
15 professionals to enter data, use the list of ICD-10 codes,
16 or retain files for future use. And while we're extremely
17 supportive of this approach and we think it does create and
18 ensure that there's less administrative burden on both
19 facilities and providers, we would appreciate if the rules
20 would provide a little bit more clarity to address the
21 situations in which the automated data sharing, if it's
22 unavailable, could be collected from existing information
23 feeds.

24 We also respectfully request both the inclusion of
25 a state plan to provide a form that would be able to ensure

1 to capture all necessary information at the initial request
2 from the department or delay the implementation until the
3 automated data collection system is operational. And this
4 was before your presentation, so just a side note on that.
5 We also do appreciate the current flexibility that would
6 allow the reporting format to keep the option of being --
7 data being pulled for those facilities and providers who
8 have it available to them. We do understand that some
9 providers and facilities would not have the ability to have
10 the information be pulled.

11 We would also request a list of ICD diagnosis
12 codes for facilities and providers that they're expected to
13 report on. Wanted to make a quick note that it's important
14 that ICD-10 doesn't have a specific code for Fentanyl, and
15 we do think that is something you guys were interested in
16 capturing. So just be aware that our facilities and
17 providers would need an adequate way to ensure the state
18 would be able to capture Fentanyl moving through that
19 process.

20 Currently the rules specify actions required of
21 health professionals and health facilities when a report is
22 requested. However, there isn't the criteria in the actual
23 report to see when it's requested. Unlike some of the
24 frequently asked question documents that was prepared by
25 DHHS, there were two specific scenarios that were mentioned

1 and we would respectfully request that those parameters be
2 included in the rules, if possible.

3 The last request was just very technical in
4 nature. It had to do with the provision 3C, which requires
5 the reporting entity, if they are a clinical laboratory.
6 The way the statement appears we believe that it's missing
7 the term "if applicable." As currently written, the
8 language requires both logical observation identifier names
9 and codes and SnoMed. "And" is in there and underlined.
10 There is a little bit of a technical nature for us in this
11 fact because this rule is problematic since some health
12 facilities no longer use SnoMed codes and do not have
13 interfaces linking SnoMed to electronic medical records
14 anymore. So with that, we would request and urge the
15 department to replace that current language to allow that
16 reporting only if it's available for those particular health
17 care organizations and providers.

18 So thank you for your comments -- thank you for
19 allowing us to comment, and I will submit this written this
20 week with just some more detail. Thank you so much.

21 MS. LYON-CALLO: Thank you. So the person who
22 came in late, we're at the stage of the hearing where if
23 you'd like to make a comment regarding proposed rule
24 changes, you're welcome to do so at the mic. Please
25 introduce yourself and spell your name for our reporter.

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AMANDA KOGOWSKI

MS. AMANDA KOGOWSKI: Thank you for the opportunity to speak today. My name is Amanda Kogowski. I am the project manager of the System for Opioid Overdose Surveillance.

REPORTER: Can you spell your last name, please?

MS. AMANDA KOGOWSKI: Oh. K-o-g-o-w-s-k-i.

So this is a CDC funded project working to increase the timeliness of opioid overdose data across the state of Michigan. So the current standard for tracking overdoses in Michigan involves reporting that lags up to 18 months. And while such data can be useful for retrospective analysis of changes in overdoses, they are fully insufficient for informing rapid public health and law enforcement responses that are required for reducing opioid overdoses. Thus, the state of Michigan has great need to increase the timeliness of fatal and nonfatal opioid overdose reporting to move to rapid surveillance of opioid overdoses for public health and law enforcement response. Near realtime surveillance have provided currently missing basis for identifying when and where resources are currently needed. An example of this is near realtime opioid overdose surveillance will provide an empirical basis for specifying optimal naloxone distribution to community organizations and EMS workers. Another example is overdose death spike alerts

1 may provide law enforcement with timely and spatially
2 specific information about lethal illicit opioids
3 circulating.

4 We envision the most effective strategies as those
5 that rely on coordination between multiple organizations
6 such as public health, law enforcement and emergency medical
7 services that could all benefit from surveillance and that
8 does not have such a time lag. Thank you.

9 MS. LYON-CALLO: Thank you.

10 MS. BRENNAN: Ma'am, did you sign in when you came
11 in?

12 MS. AMANDA KOGOWSKI: Yeah. Thank you.

13 MS. BRENNAN: Thank you.

14 REPORTER: Do you want to go off the record while
15 we're waiting for anybody else who shows up or --

16 MS. BRENNAN: Pending further public comment, we
17 are off the record.

18 REPORTER: Thank you.

19 (Off the record)

20 MS. BRENNAN: It is 3:30 p.m. There have been no
21 testimony nor any written testimony provided. The meeting
22 or the public hearing on these rules has concluded.

23 (Proceedings concluded at 3:30 p.m.)

24

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Page 13

A	B			
ability 5:1 6:10 10:9	back 7:10	6:12,22	5:16	facilities 6:20 8:12
able 4:6,8 9:25	basically 3:23	communities 4:25	disease 5:15 6:12,22	9:2,19 10:7,9,12
10:18	basis 12:20,23	community 8:6,18	distribution 12:24	10:16,21 11:12
abstraction 6:21	behave 3:15	12:24	Division 3:12	facility 5:20,25
accidental 8:13	believe 11:6	complaint 4:11,16	documented 7:9	fact 9:2 11:11
actions 10:20	benefit 13:7	completion 6:20	documents 10:24	fatal 4:2,7 12:17
active 6:16	better 8:9	component 8:4	dollars 4:8 5:13	federal 4:8 5:13
activities 6:15	bit 8:3 9:20 11:10	concluded 13:22,23	draft 3:20 4:22	feeds 9:23
actual 10:22	Brennan 1:12 3:13	conduct 4:8 6:8,16	drug 4:5,7,10,24 5:1	Fentanyl 3:24 10:14
addition 7:23 8:18	3:13 13:10,13,16	confusion 8:6,17	5:21,23 6:2,6,14	10:18
address 7:6 9:20	13:20	9:11	8:19,21,23 9:9	filed 6:25 7:1,2,4
adequate 10:17	brief 3:19	consideration 8:5	drugs 1:6 3:19 4:1,3	files 9:16
administrative 3:17	briefly 6:24	CONTENTS 2:1	due 1:6 3:18,24 9:5	fill 4:22
9:18	Buck 1:11 3:8	continue 4:3		findings 6:1
administrator 3:9	building 5:13	continuum 8:25	E	Firm 1:20
AdminRules@Mi...	burden 5:9,17 9:18	controlled 8:7,14	e-mail 7:6	flexibility 10:5
7:7	Bureau 1:3 3:7,9	coordinating 5:7	e-mailed 8:2	flow 5:16
admission 5:16		coordination 13:5	effective 13:4	FOIAable 5:11
ADT 6:6,10	C	Corporation 1:19	effects 8:25 9:5	followed 3:25
Advocacy 7:18	capture 10:1,18	Council 7:24	electronic 1:19 7:3	form 9:25
Affairs 3:14	capturing 10:16	create 5:7 9:17	11:13	formal 6:25 8:2,21
afternoon 3:3,13	care 5:4,20,25 6:4,7	created 9:12	elements 5:22	8:23
alerts 12:25	6:9,17,19 8:6,18	criteria 10:22	emergency 13:6	format 10:6
allow 4:23 5:5 10:6	8:25 9:2 11:17	current 10:5 11:15	empirical 12:23	forms 6:20
11:15	case 6:20 8:16	12:10	EMS 12:25	forward 7:12
allowing 11:19	CDC 12:8	currently 4:6 9:7	enable 4:24	frequently 10:24
Amanda 2:5 12:1,2	CER 1:18	10:20 11:7 12:20	enforcement 12:14	Friday's 8:2
12:3,7 13:12	certificates 4:7	12:21	12:19 13:1,6	fully 12:13
analyses 4:25	Certified 1:19	D	ensure 9:18,25	Fults 2:4 7:15,16,17
analysis 12:13	change 4:3	data 4:6,11,12,13,14	10:17	7:21,22
and/or 5:21 6:1,19	changes 7:12 11:24	4:16,18,18 5:8,8	enter 9:15	funded 12:8
anybody 13:15	12:13	5:15 9:15,21 10:3	entity 11:5	further 6:2 13:16
anymore 11:14	chief 4:11,16	10:7 12:9,12	envision 13:4	future 9:16
appearance 7:8	circulating 13:3	deadline 8:2	epidemic 3:23 4:2	
appears 11:6	clarification 8:9	death 4:7 12:25	epidemiologist 3:6	G
applicable 11:7	clarity 9:20	deaths 3:22	Epidemiology 1:3	gap 4:22
apply 8:7	clear 5:3 9:1,11	definition 8:11,19	3:7	gather 4:23
appreciate 9:19	cleared 8:18	8:21,23 9:1,10	evaluation 4:20	go 8:3 13:14
10:5	clinical 11:5	delay 10:2	evidence 5:23	Good 3:3,13
approach 9:17	code 9:8,11 10:14	demographics 5:25	examiner 4:9	Grand 1:7
asked 8:10 10:24	codes 5:24 9:15	department 1:2 3:6	example 5:23 6:3,13	grant 5:13
assistant 3:9	10:12 11:9,12	4:23 5:5,7 6:5,13	8:15 12:22,25	great 12:16
Association 4:13	collected 9:22	6:15,16 10:2	exclusively 8:7	guys 7:16 10:15
7:19,25	collection 5:7,17	11:15	existing 5:14,16 6:6	
assurance 6:8	10:3	depicted 3:25	9:22	H
attention 7:8	come 7:12	detail 11:20	expect 4:1 5:17	happened 9:1
automated 9:14,21	coming 3:4	detailed 8:4	expected 10:12	health 1:2,3 3:6,8
10:3	comment 7:11 11:19	DHHS 3:14 10:25	extractions 4:9	4:12 5:4,9,20,25
available 4:16 10:8	11:23 13:16	diagnoses 5:24	extremely 9:16	6:4,7,9,15,17,19
11:16	comments 6:25 7:2	diagnosis 10:11		7:18 8:6,12,18 9:2
Avenue 1:7	7:5,14 11:18	director 3:6 7:18	F	9:10,14 10:21,21
aware 10:16	communicable 5:15	discharge 4:13,18	F-u-l-t-s 7:22	11:11,16 12:14,19
			facilitate 8:9	13:6

<p>hearing 1:5 3:17 7:3 7:9 11:22 13:22 help 8:17 9:11 Hi 7:16 HL7 5:16 hoping 8:19 Hospital 4:12 7:19 hot 6:14 Human 1:2 3:7</p> <hr/> <p style="text-align: center;">I</p> <hr/> <p>ICD 10:11 ICD-10 9:8,15 10:14 identified 6:14 identifier 11:8 identifying 12:21 illicit 1:6 3:19,24 5:21 13:2 immediately 5:4 implement 5:12 implementation 10:2 imply 8:12 important 4:14 10:13 include 6:18 8:17 included 8:22 9:6,10 11:2 inclusion 9:24 incomplete 4:17 increase 12:9,16 indicators 6:6 individuals 6:18 information 4:23 5:6,24 9:22 10:1 10:10 13:2 informing 12:14 initial 10:1 inpatient 4:13,18 instances 9:8 insufficient 12:13 insulin 8:15 intended 4:22 9:6 intent 9:13 intentional 8:13 interest 7:8 interested 10:15 interfaces 11:13 interpretation 8:23 interpreted 8:24 introduce 3:8 7:13 11:25</p>	<p>investigate 5:1 6:2 6:17,21 involved 4:1 involves 12:11 involving 3:18 it'd 4:24</p> <hr/> <p style="text-align: center;">J</p> <hr/> <p>Jared 1:12 3:10</p> <hr/> <p style="text-align: center;">K</p> <hr/> <p>K-o-g-o-w-s-k-i 12:7 keep 10:6 Klingshirn 1:18 know 3:21 9:3 Kogowski 2:5 12:1,2 12:3,7 13:12</p> <hr/> <p style="text-align: center;">L</p> <hr/> <p>laboratory 6:1 11:5 lag 13:8 lags 12:11 language 11:8,15 Lansing 1:7 3:1 late 11:22 latest 7:5 law 12:14,19 13:1,6 lethal 13:2 leveraging 5:14 limitations 4:15 limited 4:6 linking 11:13 list 9:15 10:11 little 8:3 9:20 11:10 local 4:25 5:8 6:15 logical 11:8 longer 11:12 look 4:6 Lyon-Callo 1:11 2:3 3:3,5,16 11:21 13:9</p> <hr/> <p style="text-align: center;">M</p> <hr/> <p>Ma'am 13:10 mail 7:3,3,4,5 manager 12:4 manually 6:11 March 1:8 3:2,4 7:1 7:2 Marcy 1:18 Mary 1:12 3:13 Matthew 1:11 3:8</p>	<p>MDHHS 3:12 5:6,13 5:19 6:2,4,11 MDHHS- 7:6 MDHS 5:22 6:6 mechanism 5:7 medical 4:9,24 8:1,1 11:13 13:6 medication 8:25 9:4 9:4 meeting 13:21 mentioned 10:25 messages 5:16 6:6 6:10 MHA 7:23 mic 11:24 Michigan 1:1,7 3:1 3:24 4:5,12 7:18 7:24,25 8:1,1 12:10,11,16 minimize 5:9 minimized 5:18 minimum 9:8 mining 6:6 missing 11:6 12:20 module 5:14 months 12:12 move 12:18 moving 10:18 multiple 13:5</p> <hr/> <p style="text-align: center;">N</p> <hr/> <p>naloxone 12:24 name 3:5 7:13,17,20 7:22 11:25 12:3,6 names 11:8 national 3:25 nationally 3:21 nature 11:4,10 near 12:19,22 necessary 10:1 need 10:17 12:16 needed 12:21 Network 1:19 new 4:1 non-controlled 8:14 nonfatal 4:2,10 5:17 12:17 nonspecific 4:17 note 10:4,13 Number 1:20 Nurse 7:24</p> <hr/> <p style="text-align: center;">O</p> <hr/>	<p>observation 11:8 officer 3:14 Oh 12:7 Okay 3:16 Opening 2:3 operational 10:3 opioid 3:22 8:17 9:5 12:4,9,15,17,18 12:22 opioids 8:8 13:2 opportunity 7:17 12:3 optimal 12:24 option 10:6 order 5:9 organizations 11:17 12:24 13:5 Osteopathic 7:25 outbreak 6:14,17 outbreaks 5:1 6:22 outpatient 4:13,18 outreach 6:16,18,19 overdoes 12:13 overdose 3:22 4:2 8:22,23 9:10 12:4 12:9,17,22,25 overdoses 4:3 6:7 12:11,15,18 overview 5:19</p> <hr/> <p style="text-align: center;">P</p> <hr/> <p>P-a-i-g-e 7:21 p.m 1:8 3:2,4 13:20 13:23 PAGE 2:2 Paige 2:4 7:15,16,17 7:21,21 PANEL 1:11 parameters 11:1 participate 6:9 particular 11:16 partner 6:16 passage 5:5 patient 5:24 Pending 13:16 permit 5:22 permits 6:1 person 11:21 pharmacy 9:5 plan 9:25 Planning 3:11 please 7:9,12,13,20 11:24 12:6</p>	<p>point 5:10 poisoning 4:5 5:23 6:15 8:19 poisonings 1:6 3:18 4:7,10,24 5:2,18 5:21 6:2,7 8:13 Policy 3:11 poly 9:5 Population 1:3 3:7 possible 8:22 11:2 postmarked 7:4 potential 6:14 practitioners 4:24 5:4 7:25 prepared 10:24 prescription 1:6 3:19 5:21 presentation 3:20 6:24 10:4 problematic 11:11 Proceedings 13:23 process 10:19 professional 5:20 professionals 9:15 10:21 project 12:4,8 proposed 7:12 11:23 provide 5:1 6:23 7:14 9:20,25 12:23 13:1 provided 12:20 13:21 provider 5:25 providers 6:5,7,9,17 6:19 8:12 9:2,19 10:7,9,12,17 11:17 provision 11:4 public 1:5 3:17 5:8 7:9 9:10 12:14,18 13:6,16,22 pulled 10:7,10 purchase 4:12 purpose 3:14 purposes 4:20</p> <hr/> <p style="text-align: center;">Q</p> <hr/> <p>quality 6:8 question 10:24 questions 6:25 7:2 quick 10:13 quickly 4:16</p>
---	---	--	--	---

<p style="text-align: center;">R</p> <p>raise 9:2 rapid 4:21 12:14,18 realtime 12:19,22 reason 5:18 record 3:16 6:20 7:14 13:14,17,19 RECORDED 1:18 recorder 1:19 7:13 records 4:9 11:13 reducing 12:15 references 6:23 referrals 6:2,5,8,11 regarding 3:20 7:12 11:23 Registration 1:20 regular 6:9 regularly 6:8 Regulatory 3:14 relate 5:23 related 9:3 relatively 4:17 rely 13:5 remarks 8:2 replace 11:15 report 5:4 6:20 10:13,21,23 reported 9:4 reporter 7:20 11:25 12:6 13:14,18 reporting 1:6,19 3:18 5:9,14,15,22 5:25 8:13 10:6 11:5,16 12:11,17 reports 5:11,20 9:7 representatives 6:19 representing 7:23 7:24 request 5:19,22 6:4 8:8,16,21 9:24 10:1,11 11:1,3,14 requested 10:22,23 requestfully 9:9 require 5:3 9:14 required 10:20 12:15 requirements 8:10 requires 5:6 11:4,8 resources 12:21 respected 9:9 respectfully 8:8 9:24 11:1</p>	<p>response 4:21 12:19 responses 12:15 retain 9:16 retrospective 4:19 12:12 review 8:5,24 rich 4:18 room 7:10 routine 5:14 rule 6:1,3 7:12 11:11,23 rules 1:6 3:17,20 4:22,23 5:3,5,10 5:11,12,21 7:1 8:5 8:7,11,16,22,24 9:7,19 10:20 11:2 13:22</p> <hr/> <p style="text-align: center;">S</p> <p>Sarah 1:11 3:5 satisfaction 8:10 scenarios 10:25 section 8:11 sedation 9:5 see 10:23 send 7:5 services 1:2 3:7 13:7 set 4:12,19 6:4 share 3:10 sharing 5:8 9:21 sheet 7:10 shows 13:15 sic 9:9 side 8:25 9:4 10:4 sign 13:10 sign-in 7:10 similar 6:21 situations 9:21 slide 3:25 SnoMed 11:9,12,13 Society 8:1 somewhat 4:6 sources 4:15 South 1:7 spatially 13:1 speak 7:17 12:3 specific 10:14,25 13:2 specify 10:20 specifying 12:23 spell 7:13,20 11:25 12:6 spike 12:25</p>	<p>spot 6:14 stage 11:22 standard 12:10 standing 6:4 state 1:1 3:5,9 6:25 8:1 9:25 10:17 12:10,16 statement 2:3,4,5 11:6 strategies 13:4 submit 5:20 6:5,11 11:19 submitted 5:11 6:8 substances 8:8,14 8:14 supportive 9:17 sure 8:3 surveillance 4:5,11 4:19 5:13 12:5,18 12:20,23 13:7 syndromic 4:10,16 system 5:15 9:14 10:3 12:4</p> <hr/> <p style="text-align: center;">T</p> <p>TABLE 2:1 technical 11:3,10 term 8:17 11:7 testimony 13:21,21 thank 3:3 7:7,16 11:18,18,20,21 12:2 13:8,9,12,13 13:18 think 7:10 9:17 10:15 three 3:23 time 4:4 7:11 13:8 timeliness 12:9,17 timely 4:20,25 13:1 times 4:17 title 3:10 8:11,16 today 3:20 6:22 7:1 7:9,17,23 12:3 today's 7:3 toxicity 9:4 tracking 12:10 transfer 5:16 transmission 6:10 trends 3:25 Tuesday 1:8 3:2,4 two 10:25</p> <hr/> <p style="text-align: center;">U</p>	<p>unavailable 9:22 underlined 11:9 understand 10:8 understanding 4:9 9:13 Unfortunately 4:1 updated 8:16,20 urge 11:14 use 1:6 3:18,24 4:7 4:10,11 5:15 6:3 7:9 9:5,15,16 11:12 useful 12:12</p> <hr/> <p style="text-align: center;">V</p> <p>valuable 4:14</p> <hr/> <p style="text-align: center;">W</p> <p>waiting 13:15 want 5:3 13:14 wanted 5:10 6:23 9:3 10:13 waves 3:23 way 10:17 11:6 we're 4:8 5:14 9:16 11:22 13:15 we've 4:19 week 11:20 welcome 11:24 Welehodsky 1:12 3:10,11 work 3:11 workers 12:25 working 12:8 wouldn't 9:14 written 8:2 11:7,19 13:21</p> <hr/> <p style="text-align: center;">X</p> <hr/> <p style="text-align: center;">Y</p> <p>Yeah 13:12</p> <hr/> <p style="text-align: center;">Z</p> <hr/> <p style="text-align: center;">0</p> <p>0-0-0- 13:25</p> <hr/> <p style="text-align: center;">1</p> <p>1-800-632-2720 1:20 1:00 1:8 1:02 3:2,4</p>	<p>12 1:8 2:5 3:2 12th 3:4 7:1 15th 7:2 18 12:11 1999 3:22</p> <hr/> <p style="text-align: center;">2</p> <p>2017 3:22 2019 1:8 3:2,5 7:2</p> <hr/> <p style="text-align: center;">3</p> <p>3 2:3 3/15/19 7:4 3:30 13:20,23 333 1:7 3C 11:4</p> <hr/> <p style="text-align: center;">4</p> <p>400,000 3:22</p> <hr/> <p style="text-align: center;">5</p> <hr/> <p style="text-align: center;">6</p> <p>6924 1:18</p> <hr/> <p style="text-align: center;">7</p> <p>7 2:4</p> <hr/> <p style="text-align: center;">8</p> <p>8151 1:20</p>
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Brennan, Mary (DHHS)

From: Joyce deJong <Joyce.deJong@med.wmich.edu>
Sent: Tuesday, March 12, 2019 9:56 AM
To: MDHHS-AdminRules
Cc: LyonCallo, Sarah (DHHS)
Subject: REPORTING OF POISONINGS DUE TO THE USE OF PRESCRIPTION OR ILLICIT DRUGS
Rule Set 2018-071 HS

Greetings –

As the Medical Examiner for 12 Michigan Counties (Allegan, Barry, Berrien, Calhoun, Grand Traverse, Kalamazoo, Leelanau, Mason, Muskegon, Osceola, St. Joseph, and Van Buren Counties), our office directly feels the impact of the increase in deaths caused by prescription and illicit drugs. The increased mortality rate has caused a significant increased stress on our county funded resources. The rules proposed by the Bureau of Epidemiology and Population Health, "Rules for Reporting of Poisonings Due to the Use of Prescription or Illicit Drugs - Rule Set 2018-071 HS" place an additional unfunded burden on Medical Examiners. Nearly everything that is requested by these rules is already provided on death certificates. The death certificate includes the: last and first name and middle initial, sex, race, birth date, residential address, and the date of diagnosis (death). As our office follow the standards established by the National Association of Medical Examiners*, all of the responsible substances by generic name are listed on the death certificate. Granted, the death certificate does not include the phone number of the deceased individual (which would be of limited value) or a clinical history with vital signs, but the very nature of our work means there are no vital signs. The State Registrar, within DHHS, already has access to all of the requested information.

We have ZERO capacity to meet the requests for this information through a duplicate reporting system. All of the work performed by Medical Examiners is 100% funded by counties. There is no funding from the state to assist with the additional burden. I recognize the importance of being able to track this information at the state level, however, **I respectfully request that Medical Examiners be exempted from these rules. If Medical Examiners are included, the change should only be that all county medical examiners must list the substances responsible for the death on the death certificate.**

Respectfully submitted,

Joyce deJong, D.O.

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March 15, 2019

Michigan Department of Health and Human Services
Bureau of Epidemiology and Population Health
Rules for Reporting of Poisonings Due to the Use of Prescription or Illicit Drugs
Rule Set 2018-071 HS

Attention: Policy Analyst
333 South Grand Avenue, 3rd Floor
Lansing, MI 48909

Dear Policy Analyst:

On behalf of five health care organizations, we respectfully submit the following comments based on the proposed draft rules for Reporting of Poisonings Due to the Use of Prescription or Illicit Drugs. In addition, we respectfully request clarification on a number of provisions within these rules to better facilitate the satisfaction of the final rule requirements.

Definitions

1. If the intent of the rules is to focus on opioids, as was suggested in the original "Finding of Emergency," we respectfully request the title of the rules themselves be renamed, "Reporting of Poisoning Due to the Use of **Opioid** Prescription or Illicit Drugs." Should this change be considered, we respectfully recommend that a formal definition of opioid be added to the rule set. Additionally, references to "reports of prescription or illicit poisonings" throughout the document should also be updated to read "reports of **opioid** prescription or illicit drug poisonings."

✓ If the intent of the rules is to focus on controlled substances, we respectfully request changes consistent with those noted above – "Reporting of Poisoning Due to the Use of Controlled Substance Prescriptions or Illicit Drugs" and "reports of controlled substance prescriptions or illicit drug poisonings."

2. "Drug" is defined in the rules, but it is not exclusive to controlled substances or opioids. Currently, the rules read that providers and health facilities would be reporting on all accidental or intentional poisonings using both controlled substances and noncontrolled substance medications (i.e., Coumadin, insulin, etc.).
3. We also request the inclusion of a formal definition of "drug overdose." Without a formal definition, the interpretation of drug overdose could include a continuum of side effects of overmedication. For example, in certain patients with undiagnosed liver or kidney dysfunction, an "overdose" could occur if the patient takes a medically standard dose of medication, i.e., a dosage typically prescribed for patients with normal kidney/liver function. Without a clear definition, providers and facilities have no way of knowing if "medication toxicity," "medication side effects," "polypharmacy," or "sedation due to opioid use" should be included in the reports. There is not currently a code in ICD-10 for these instances.

At minimum, we respectfully request using the drug overdose definition found in MCL 333.7404 (6)(a) of the Public Health Code, if the reporting includes controlled

substances, to provide healthcare professionals and health facilities with clearer guidance.

4. The definition of "poisoning" is vague. Poisoning uses the term "morbid condition" without giving the definition of morbid in the rules.

Automated System Reports

It is our understanding that the intent of the department is to have an automated system that does not require healthcare professionals to enter data, use a list of ICD-10 codes, or retain files for future use. While we are extremely supportive of this approach to lessen the administrative burden on facilities and providers, the rules should provide more specificity to address situations in which automated data sharing is unable to be collected from existing information feeds.

Therefore, we respectfully request the inclusion of both a state plan to provide a form that will ensure the capture of all necessary information in the initial request from the department and a delay in implementation until the automated data collection system is operational. We appreciate the current flexibility in the reporting format and would like to keep that option available as well since some providers and facilities will have the capability of using their electronic medical records system to pull a report for the department.

We also request a list of ICD diagnoses that facilities and providers are expected to report on. However, it is important to note that there is not an ICD-10 specific code for Fentanyl.

Reporting: Lack of Criteria for Requesting Report

Currently, rule 7 specifies actions required of health professionals and health facilities when a report is requested by the department or local health department. The rule does not, however, indicate criteria that precipitate a request for a report. In a Frequently Asked Questions document prepared by MDHHS, two specific scenarios are mentioned as follows:

- 1) Routine Surveillance Data Request: MDHHS is developing a system to collect information on medicinal and illicit drug poisoning events using existing information feeds. This system will utilize admission/discharge/transfer (ADT) messages from health facilities to identify events with an ICD-10 code related to poisonings and overdoses. This system will be automated, and, as far as we understand at this time, healthcare professionals and health facilities will not have to enter data, use a list of ICD-10 codes to select cases, or retain data files for future use.
- 2) Specific Event Investigation Request: In the case of a suspected outbreak of overdoses or poisoning events, this rule would be used by MDHHS or local public health departments to obtain information on the circumstances surrounding those specific cases. This information would be used to aid in immediate public health response. MDHHS or local public health departments would contact the healthcare provider caring for those overdose cases, as is done currently for communicable disease investigation.

We respectfully request the inclusion of the parameters for requesting a report.

Reporting: Under Rule 3. (1)

Under provision (3)(c), which requires the reporting entity be a clinical laboratory, the following information shall be provided in addition to information specified in subrule (3)(a) of this rule. The concern lies in the fact that this statement is missing "if applicable."

Looking at (c)(iii), the language is currently requiring both LOINC *and* SnoMed. This rule is problematic as some health systems no longer use SnoMed codes and do not have an interface linking the electronic medical records with the laboratory vendor (i.e., EPIC or Sunquest), making them only use LOINC. Therefore, our organizations respectfully urge the department to replace the current language in the proposed rule with the following language:

(c) If the reporting entity is a clinical laboratory, the following information shall be provided *if applicable* in addition to information specified in subrule (3)(a) of this rule:

Thank you for your consideration of our comments.

Respectfully submitted,

Health Care Association of Michigan
Michigan Council of Nurse Practitioners
Michigan Health & Hospital Association
Michigan Osteopathic Association
Michigan State Medical Society