

**RULES FOR REPORTING OF POISONINGS
DUE TO THE USE OF PRESCRIPTION OR
ILLCIT 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.

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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

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.

1 AMANDA KOGOWSKI

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

6 REPORTER: Can you spell your last name, please?

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

8 So this is a CDC funded project working to
9 increase the timeliness of opioid overdose data across the
10 state of Michigan. So the current standard for tracking
11 overdoses in Michigan involves reporting that lags up to 18
12 months. And while such data can be useful for retrospective
13 analysis of changes in overdoses, they are fully insufficient
14 for informing rapid public health and law enforcement
15 responses that are required for reducing opioid overdoses.
16 Thus, the state of Michigan has great need to increase the
17 timeliness of fatal and nonfatal opioid overdose reporting
18 to move to rapid surveillance of opioid overdoses for public
19 health and law enforcement response. Near realtime
20 surveillance have provided currently missing basis for
21 identifying when and where resources are currently needed.
22 An example of this is near realtime opioid overdose
23 surveillance will provide an empirical basis for specifying
24 optimal naloxone distribution to community organizations and
25 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.)

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