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

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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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Lansing, Michigan

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PAIGE FULTS

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

REPORTER: Can you spell your name, please?

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

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

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

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

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

that has happened. So without 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 had to do with medication toxicity, medication side effects, poly pharmacy, or sedation due to opioid use. Was that something that was intended to be included in these rules and reports or not? There also currently is not an ICD-10 code for those instances and at a minimum, we requestfully respected (sic) -- would ask that the drug overdose definition would be included in the public health code because that would help clear up some of the confusion that has been created.

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

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

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

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

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

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

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

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

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

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 overdoes, 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

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

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

MS. LYON-CALLO: Thank you.

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

MS. AMANDA KOGOWSKI: Yeah. Thank you.

MS. BRENNAN: Thank you.

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

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

REPORTER: Thank you.

(Off the record)

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

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

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