

4/12/13

State of Wisconsin Medical Examining Board

Dear Board Member:

Drug shortages have reached a national crisis and they are affecting the care of our patients. These shortages started around 2005, but were small and manageable at the time. Today, these shortages are affecting everyone, including emergency medical services (EMS) and the critical patients they serve. These shortages are not only affecting the nice-to-have medications such as pain medicine or anti-nausea medicine, but also life-saving medications such as epinephrine, benzodiazepines, and glucose.

EMS agencies have implemented several measures to address the shortages. This includes better inventory management and obtaining medications from other than their usual sources. Unfortunately, this has not been able to mitigate the problem completely and has led to other problems. Sometimes medications are arriving in different packaging and unfamiliar concentrations. While EMS providers are taught to check and double check the medication and the dose they are giving patients, when confronted with unfamiliar packaging and concentrations that may differ from package to package, the potential for a medication error is greatly increased.

Many services have also substituted medications that are not available with others. As EMS providers are typically accustomed to working with a small, consistent formulary, the substitution of medications and changes to protocols add to the complexity of pre-hospital care and also increase the risk for medication errors.

Another solution that I am a proponent of is utilization of medications beyond their listed expiration dates. Medications are required by the FDA to have an expiration date. Expiration dates are established by the manufacturer based on their internal testing. Understanding the process and purpose of expiration dates, the dates established by manufacturers are logically conservative. It is also logical that to assume that there is no difference in the efficacy of a medication the day before it expires as compared to the day after it expires.

Aside from logic, there is some scientific evidence that medications remain effective after their expiration dates. The military instituted a Shelf Life Extension Program (SLEP) in 1986 where national stockpile medications were put through testing to verify current efficacy which has led to the extension of shelf life for numerous medications for several years. It is important to understand that this program is for the military only, and the results of the testing were never meant to be released and made public. This program also applies to medications that are stored in a controlled environment and the extension only applies to those lots of medications that have been specifically tested. Nonetheless, it demonstrates that medications are capable of being effective after their expiration dates. <sup>1 2</sup>

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<sup>1</sup> <http://articles.mercola.com/sites/articles/archive/2000/04/02/drug-expiration-part-one.aspx>

<sup>2</sup> Lyon, RC. et al, Stability Profiles of Drug Products Extended beyond Labeled Expiration Dates. Journal of Pharmaceutical Sciences. Vol. 95, No. 7, July 2006.

The FDA is not in a position to grant extensions of expiration dates in the civilian environment. Manufacturers are the only ones that can establish expiration dates, and they have no motivation to change testing and extend any dates. Individual EMS services could send in medications for testing. This would not technically change the expiration date but would confirm the potency of a particular drug. This of course would only be applicable to that particular lot of medication. This type of testing is cost prohibitive, time consuming, and would ironically use up medication that is already in short supply which could be of benefit to a patient otherwise.

I argue that the use of a medication beyond its expiration date is a rational approach when shortages exist. Evidence suggests that medications remain safe. There is no evidence that they become dangerous. Probably the biggest concern is that medications may lose potency after some period of time. This may or may not be true for many of the medications used by EMS. Regardless, loss of potency is not a great risk to patients. Most medications are not delivered based on a known specific therapeutic dose. Rather they are titrated to effect. When a seizure patient is treated with midazolam, regardless of the starting dose, if the seizure continues, a repeat dose is given. If a diabetic with hypoglycemia is treated with an ampule of dextrose, regardless of whether they were given a non-expired package of 50gm or perhaps one that was 4 months past its expiration date, and for the sake of argument, was only at 50% potency, if they remain hypoglycemic, they will receive a repeat dose. Even for medications that have an “established” dose such as amiodarone, that established dose really is a scientific best guess and never proven to be the exact necessary dose.

Physician medical directors should be able to make a risk/benefit analysis and determine whether using a medication in an EMS system beyond its expiration date is of benefit to the patient. I would consider this akin to an off-label use and well within the purview of the ethical and appropriate practice of medicine.

Other states such as Nevada, Utah, and Oregon have authorized EMS to utilize expired medications.<sup>3 4</sup> The Wisconsin EMS Office does not feel they have the authority to do the same in Wisconsin. While the EMS Office defers to local physician medical directors as the ultimate decision makers regarding care provided to their patients, the Office has verbalized legal concerns regarding the use of expired medications. There have been concerns that the use violates FDA and DEA regulations and that physicians using expired medications may be subject to action against their medical licenses.

I have queried both the FDA and the local DEA regarding this issue. Please find attached the email correspondence from each. In summary, the FDA’s regulations as it relates to expired medications applies to manufacturers and distributors. They state that they do not apply to physician use of a medication and they defer to state rule and regulation to address that. In searching the State’s rules and regulations, the only thing I can find relates to expired medications is within the scope of the Pharmacy Board and only applies to distribution and dispensing. It does not apply to physicians. I have asked the EMS Office to have their legal

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<sup>3</sup> <http://www.katu.com/living/health/Oregon-paramedics-turn-to-expired-drugs-due-to-shortages-162325276.html>

<sup>4</sup> [http://health.utah.gov/ems/rulereg/medication\\_shortage\\_policy.pdf](http://health.utah.gov/ems/rulereg/medication_shortage_policy.pdf)

counsel search for any statute or rule that would apply to a physician's use of an expired medication and was told verbally that none could be found.

The DEA simply states that their regulations do not address expiration dates and again they defer to the State for further regulation if it exists.

What is left then is possible action against a physician's medical license for using an expired medication as a possible unprofessional activity or otherwise negligent practice. I would argue that if an appropriate risk/benefit analysis is made, like with any therapy for any disease process, use of an expired medication is within the realm of appropriate medical care. As you are aware, malpractice requires duty, breach of standard of care, harm, and a causality link between the breach and harm. I think the potential for harm in using an expired medicine is quite low to non-existent. I also think there is enough support in the medical community to demonstrate that this use is not a breach of standard of care, but would like some affirmation of that. However, I do think that forgoing medication treatment of a patient in a life-threatening situation simply because a non-expired medication is not available will undoubtedly lead to harm and I personally would find that omission unethical.

In summary, I suggest that the use of expired medications by EMS providers when an appropriate risk/benefit analysis by the physician medical director has been completed and shows favor towards benefit to such treatment should be deemed appropriate, if not encouraged.

I would be happy to discuss this in further detail as needed.

Sincerely,



Charles E. Cady, MD, FAAEM  
Associate Professor of Emergency Medicine  
Section of Emergency Medical Services and Disaster Medicine

Medical Director  
Kenosha Fire Department

Medical Director  
State of Wisconsin Emergency Medical Services

Medical College of Wisconsin  
9200 West Wisconsin Avenue 1-P  
Milwaukee, Wisconsin 53226

Tel: 414-805-9923  
Fax: 414-805-6464  
email: cecady@mcw.edu <<mailto:cecady@mcw.edu>>

**From:** CDER DRUG INFO <DRUGINFO@fda.hhs.gov>  
**Subject:** RE: expired drugs  
**Date:** March 30, 2012 2:25:35 PM CDT  
**To:** "Cady, Charles" <CECady@mcw.edu>

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Dear Charles,

Thank you for contacting the Division of Drug Information, in the FDA's Center for Drug Evaluation and Research. We apologize for the delay in responding to your inquiry.

Expired drug products are considered to be adulterated within the meaning of Section 501(a)(2)(B) of the Food, Drug and Cosmetic Act, which states that drugs must be manufactured, processed, packed, and held in conformance with current good manufacturing practice. The holding of drug products past their expiration dates supports the 501(a)(2)(B) charge. Please note that it would not be appropriate to cite a retailer for deviations from the current Good Manufacturing Practice (CGMP) regulations in 21 CFR Parts 210 and 211, because the CGMP regulations apply to drug product manufacturers. Additionally, openly disclosing that the drugs are expired is not any basis for an exemption from the Act. From a public health standpoint, there is no assurance that drug products held past their expiration dates are safe and effective, even if they are OTC drugs.

You may view the Federal Food, Drug and Cosmetic Act at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm>.

Regarding health care professionals, state regulations most likely prohibit the use of expired drug products. Each state has drug regulations and the health care professionals are regulated by the state that licenses the individual. We recommend that you check with the appropriate licensing board and the board of pharmacy in your state regarding the use of expired drug products.

In addition, we appreciate your comments regarding drug shortages. The FDA has an established Drug Shortages Program to respond to drug shortages that have a significant impact on public health. You may learn more about how the FDA handles the drug shortages on the FDA website at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm>.

FDA's actions for a drug shortage depends on the specific drug product and the impact on public health. As a policy matter, the FDA will help prevent or alleviate shortages primarily of medically necessary drug products, since these can have significant public health consequences. However, the actions taken to achieve this will be determined case-by-case depending on the circumstances surrounding the shortage. You may find more information and the Drug Shortage Manual of Policies and Procedures (MaPP) at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

We hope this information is helpful.

Best regards,

Division of Drug Information LC  
Center for Drug Evaluation and Research  
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter at [http://twitter.com/FDA\\_Drug\\_Info](http://twitter.com/FDA_Drug_Info)

This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

From: Cady, Charles [mailto:CECady@mcw.edu]  
Sent: Wednesday, March 28, 2012 12:22 AM  
To: CDER DRUG INFO  
Cc: Cady, Charles  
Subject: expired drugs

Given the current situation of drug shortages, some providers are considering the use of certain expired medications.

I fully understand the purpose of expiration dates and understand that expiration dates are set by manufacturers based on their testing.

I also understand that in general the FDA recommends that medications not be used beyond their expiration dates.

However, are there any rules or regulations that specifically prohibit the use of a medication beyond its expiration date? If so, can you direct me to the regulation.

If a physician made an informed decision weighing risks against benefit and chose to use an expired medication, are there any sanctions that could/would be brought against the physician?

I am not looking for you (the FDA) to say use beyond exp is OK, safe, or appropriate. I am simply looking for any regulation or rule that explicitly prohibits it.

Thank you for your prompt attention to this question.

Sincerely,

Charles E. Cady, MD, FAAEM  
Associate Professor of Emergency Medicine

Medical Director  
Kenosha Fire Department

Medical Director  
State of Wisconsin Emergency Medical Services

Medical College of Wisconsin  
9200 West Wisconsin Avenue 1-P  
Milwaukee, Wisconsin 53226

Tel: 414-805-9923

Fax:414-805-6464

email: [cecady@mcw.edu](mailto:cecady@mcw.edu)<<mailto:cecady@mcw.edu>><<mailto:cecady@mcw.edu>>

**From:** "Federico, Kathy L." <Kathy.L.Federico@usdoj.gov>  
**Subject:** RE: controlled substance question  
**Date:** March 25, 2013 9:45:22 AM CDT  
**To:** "Cady, Charles" <CECady@mcw.edu>

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Charles,

There is no regulation in Title 21 relating to the use of expired meds. My guess if there is one it would be something that FDA or the State Medical Board would deal with. Sorry !

-----Original Message-----

From: Cady, Charles [mailto:CECady@mcw.edu]  
Sent: Sunday, March 24, 2013 9:03 PM  
To: Federico, Kathy L.  
Cc: Cady, Charles  
Subject: Re: controlled substance question

Dear Kathy,

Can you direct me to the resources or right person that can answer my questions below?

Thank you,

Chuck

On Mar 5, 2013, at 9:44 PM, Charles Cady wrote:

Dear Kathy,

As I am sure you are aware, there is a nationwide shortage of many medications used by EMS, including some controlled substances.

Some states have "authorized" the use of a medication beyond the manufacturers expiration date. I think most physicians believe this is safe and appropriate for patients with little to no risk in using an expired medication.

However, this practice is not without some that disagree with it.

Some believe that the DEA forbids the use of an expired medication and that physicians risk having their registrations pulled and subject to fine and criminal conviction if they administer an expired controlled substance to a patient.

I cannot find anything in the DEA regulations/law that address this.

Can you tell me if the DEA has a prohibition against using a controlled substance beyond its expiration date? I am not asking for an opinion on whether it is safe or if it is authorized/allowed. I want to know if there is anything in DEA rules/law/regulations that would prohibit it and subject a physician to any action from the DEA.

Thank you for your assistance.

Chuck

Charles E. Cady, MD, FAAEM  
Associate Professor of Emergency Medicine Section of Emergency Medical Services and  
Disaster Medicine

Medical Director  
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Medical College of Wisconsin  
9200 West Wisconsin Avenue 1-P  
Milwaukee, Wisconsin 53226

Tel: 414-805-9923

Fax:414-805-6464

email: [cecady@mcw.edu](mailto:cecady@mcw.edu)<<mailto:cecady@mcw.edu>><<mailto:cecady@mcw.edu>>