

Frequently Asked Questions on Opioid Diversion

Responses provided by



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1. *Other than PDMPs, that would be prescription drug monitoring programs, what is being done in the US to monitor, minimize, and prevent prescription drug abuse?*

Dr. Coleman:

Well, it is a far-ranging question but one of the things that I think we can look at is the efforts being done by individuals who are prescribed these drugs. For example, I think it is important that people who are prescribed the drugs understand the potential for abuse, misuse and diversion of those drugs, and if you are uncertain or if a patient is uncertain about the type of drug that they have been prescribed, the easiest way for them is to look it up on the Internet, perhaps, using WebMD or one of the other reputable services that will give them a description of the medication and also indicate to them whether or not it is a controlled substance and whether or not they have to have some precautions with respect to how they store the drug and how they use the drug. Also, in terms of what else is being done by the state and local jurisdictions, we have a number of drug take-back programs because one of the things that we have identified in the last several years has been enormous volumes of unneeded drugs that remain in medicine cabinets, etc. It is

very typical that patients, particularly for an acute pain condition, have been prescribed a 30-day supply of drugs and yet the patient may only need those drugs for a limited period of time, less than 30 days. What happens with the remainder of the drugs is that they sit in a vial in a cabinet in some place for perhaps a year or two. In the meantime, they are vulnerable to being taken by either visitors to the home or members of the family who may abuse or misuse the drugs. So there are a number of things that can be done both on an individual scale as well as on a national scale. In terms of the federal authorities, they are looking very closely at the supply chain of pharmaceutical drugs, particularly controlled substances. They are looking at pharmacies, they are looking at hospitals, they are looking at major distributors of these products just to make sure that the control mechanisms that are in place are working and are doing the job to prevent these drugs from being diverted. But again, there are a lot of things that can be done both on a national scale, locally, and by individuals themselves.

2. *Would sending Class 2 orders electronically to pharmacies help reduce the abuse by eliminating the delivery of prescriptions by the patient? If so, why is it not considered?*

Dr. Coleman:

It has been considered. It is part of the electronic medical records provisions of the new laws that have been passed in the last 10 years or so with respect to electronic records. The DEA's provision has been put into an interim final rule, I believe it was about two years ago in 2010 when the DEA issued that. Now, the statute requires that a Class 2 prescription be signed by pen and ink. Of course, that statute was written in the 1969 and 1970 period, and they were not thinking about electronic transmissions very often; so, since that time, the DEA has issued authorization for Class 2 prescriptions to be done electronically. However, and this is very important, you have to use very specialized software that is encrypted to a certain level and that is certified by the government to be almost hack-proof so that people cannot hack into it and perhaps fabricate their own prescriptions. Now there are a number of vendors that are beginning to offer those programs. They have to be approved by the DEA for the type of security that is involved here, but ultimately we probably will see over the coming years a dramatic increase in the number of electronically transmitted Class 2 prescriptions when both pharmacies and the prescribers have the appropriate software. Now, in answer to the question, yes, of course, that will definitely not only reduce the incidence of forgery with respect to these prescriptions, it will construct a better record of the prescribing that can be then used by both the practitioners as well as the patient and the prescription drug monitoring programs that are in place, and it will also reduce the number of medical errors so that a drug like methadone is not interpreted as being methylphenidate, for example, as has happened in the past with tragic consequences. So we see a number of benefits in that, and again, I am happy to say that the initial rule was passed two years ago. It is going to take a little while for this to click in because of the necessity for the special software, but eventually that will happen.

3. *This question is from the state of Washington. How do they define a pain specialist? Do they have to hold a specific certification?*

Dr. Coleman:

For those of you who may not be familiar with Washington, the state of Washington legislature, a couple of years ago in 2010, passed a statute directing the medical boards and commissions there to adopt rules on the use of opioids in the management of chronic noncancer pain. In that legislation, the state requires that the medical boards for the five different medical professions actually establish criteria to identify who among those practitioners within that medical board may be considered a pain specialist. So, if you are practicing in Washington and you are interested in wanting to know what the criteria are for being considered a pain specialist in that state, you need to contact your particular board and ask for a list of those criteria, then you will be considered under the statute a pain specialist, and you will be of course responsible for a number of other provisions in the statute regarding your responsibilities as a pain specialist.

4. *Is a release of information required from the patient for MDs to access PMP information? We are receiving complaints from patients alleging privacy violation when PMP was accessed.*

Dr. Coleman:

These are all state programs and as a result, the regulations have a tendency to change from one state's jurisdiction to another. Some of the older programs have built-in requirements that no longer exist in some of the newer programs and vice versa. In terms of the privacy issues, those are always one of the first issues that are addressed in the legislation. The privacy issue affects a third-party access. It does not affect the physician or the practitioner in those states where access is granted to practitioners. There are many, many states that the more recently adopted PDMPs or PMPs have that specific requirement in them allowing physicians and pharmacists for example to query the system for their own particular patients, only their own patients, and of course, the privacy concerns on that are addressed in the legislation. They also allow the patients to contact the system managers of the PDMPs to access their own records which they can then use to either correct, if they are incorrect, or for their own personal knowledge of the record. In terms of third-party access, the legislation authorizing the PMPs for each state is very difficult. The legislation is very, very strict in terms of restricting access. Most states require at least a court's subpoena, a court order or a warrant, and a search warrant issued by the competent court to access those records. There are a few states that only require official letterhead. For example, a law enforcement agency makes an official request for information from the PDMP, they may be able to get it provided the authorization and the legislation allows for the receipt of official letterhead correspondence from an authorized agency, for example a Medicaid agency or a Medicare provider, or perhaps a law enforcement authority that might make such a request. The information is very, very tightly guarded. There are strict penalties for

any leakage, so that if anybody lets any of that information out of the back door, they not only risk personal fines but in some cases they may risk actual imprisonment. So, the legislation definitely covers the issue of privacy. They are authorized under HIPAA. There are some people that might wonder whether or not HIPAA allows that. The HIPAA allows the prescription drug monitoring programs that are not in violation of that. Now, obviously some people feel that they might be adversely affected by the information in their PMP file and might make a claim it is an invasion of privacy to keep track of where they are obtaining drugs from and the different practitioners and so forth. That issue was of course dealt within the legislator phase of the laws that were passed to allow the prescription drug monitoring plans, and obviously the consideration of that information was secondary to the importance of having the program. So those complaints are not going to go very far either on a local or federal level.

5. *Can a pharmacist report MDs that are prescribing opioids in excess? If so, what agency would regulate that?*

Dr. Coleman:

Well the Department of Health in Florida basically would regulate that; also, the local sheriff's offices and the police department. The state of Florida has passed a very serious law in July of 2011, a very comprehensive law, it is over a hundred pages and it is extremely detailed. It essentially eliminates pill mills. Florida was of course the center in the United States for pill mills with over a thousand of these places that were basically just selling drugs out of the door. The doctors themselves were not just prescribing, they were dispensing. In Florida it was perfectly legal for doctors to dispense Class 2, 3, 4, 5 drugs. About 80% or 90% of all oxycodone that was actually dispensed by doctors in the United States have been dispensed from Florida pill mills. That new Florida law essentially closes down most of those pill mills because it basically prohibits doctors in Florida from being able to dispense Class 2s or Class 3s. They can still dispense Class 4s and Class 5s, but they cannot dispense Class 2s and Class 3s. That pretty much put the pill mill business out of business in Florida, at least a lot of them, and also the new law imposes a number of provisions that involve pharmacists. So the pharmacist now has more than just the general obligation to ensure the validity of the prescription that I explained earlier. A pharmacist in Florida now under the new law must report within 24 hours any prescription that is given to the pharmacist that appears to be fraudulent or otherwise invalid. So, it is no longer simply a pharmacist looking at a prescription and saying to a particular patient or person, 'I am sorry, I am not going to fill that, it does not have all the information on it,' or it just does not look right or anything like that and the person is saying, 'Oh! Thank you very much,' and grabbing the prescription and running out and trying to find another pharmacy. That no longer is going to happen. The pharmacist now has a legal obligation to report that incident immediately within 24 hours, at least to the sheriff. The pharmacist also is under obligation now in Florida to more or less take a greater interest in the validity of the prescription in a sense that they no longer can just simply say that receiving a large prescription is without question okay. Under the circumstances, it is not that they would not be able to fill it, but that probably under the new law would protect

themselves somewhat by at least calling back to the prescriber and saying, 'Do you really want to give this person 540 tablets of whatever?' and at least getting some sort of an acknowledgment from the prescriber that, 'Well you know, this person is suffering from this or that or whatever,' or 'The person picking it up is taking it to patient that has this or that.' There may be a legitimate reason for this and if there is, I think, the pharmacist is totally within his or her purview of responsibility to make a request directly to the prescribing authority to back that up and then make a note on the back of the prescription or the file somewhere that just basically says that 'I made this inquiry.' That way, if a subsequent investigation should happen, or something like that, the pharmacist is at least in the clear if he or she has made some effort to validate the prescription that they received, even though it may be for an unusually high amount of drugs, and particularly a drug that has a very, very large resale value on the street.

6. *What are some practical ways to prevent abuse in the home hospice setting where it is suspected that a caretaker or family member may be taking the medications prescribed for the patient?*

Dr. Coleman:

This obviously presents a very difficult scenario for a number of different reasons. My first inclination would be that you might want to obtain a relatively inexpensive lockbox, the type that they sell over places like Wal-Mart or wherever for about 10 dollars that you can use, a cashbox, or something people use for various small sales and things like that. It is obviously not going to be a major security, but it will allow you to at least put the medications in a safe place and prevent them from being tampered with. The other issue here that we run into with hospice settings, whether they are home hospice or at a hospice facility, is sometimes that the attendant, the person attending to the patient, will chart the drug but either not give it, partially give it, or substitute something that either looks like it or whatever so that the patient is actually deprived of the medication and the caregiver or the person who is supposedly taking care of the patient is actually stealing the drugs. This obviously is a serious crime and needs to be reported to the authorities, but in the practical setting of a home hospice situation, I would hope that the caregiver or family member would try to restrict access to the medications. And the other thing to do would be to monitor the patient's progress, monitor the patient's condition, and ask the attending physician at the hospice or hospice care person what are the obvious signs that the patient is in distress. Because if the medication is not given, obviously the result of that will be that the patient will go into some form of distress, and how are they to notice or recognize that when it happens because in a home hospice situation, quite often the patient is no longer competent to discuss these issues with the caregiver and may not even be conscious at the time this happens. But there may be other signs, physical signs that the caregivers can notice that would indicate that the patient is in distress, meaning perhaps that they have not received the proper medication, that certainly would be a warning signal to call the practitioner or person in charge of that case.

7. Does the DEA monitor physicians who write large amounts of opioid medications to patients?

Dr. Coleman:

No, that is a myth. That has been around for many, many years. The fact is that the DEA simply does not have the resources to be able to do that, and the other thing is that the prescription drug monitoring programs that we have that are up and running now in about 40 states, maybe more than 40, I think 48 states have authorized them but they are up and running in about 40 states. These prescription drugs monitoring programs are managed by the individual states, they are run by the states, and information is collected by the states, archived and compiled by the states, and so the DEA would have to have a complaint or a reason to begin an investigation. And during the course of investigation, the DEA might request assistance from the State Prescription Drug Monitoring Program on that particular practitioner to obtain the prescribing records of the practitioner that has been suspected of writing large amounts, which we have to assume were excessive amounts and improper amounts because just large amounts by themselves mean nothing, because in today's world, aggressive pain treatment can mean large amounts of pain drugs, particularly for patients that are being treated for chronic malignant pain. So the bottom line is, no the DEA does not monitor physicians, the 99% of the DEA's cases are complaint driven or the reports they get from outside sources, or state and local law enforcement regulatory officials that refer the cases to the DEA. The DEA does not do its own auditing of doctors.

8. Do you think that a lot of chronic pain patients are undertreated because the DEA rules are scaring most of primary care physicians from prescribe those medications? How could this problem be solved?

Dr. Coleman:

Well, for years and years and years we have heard of this so-called chilling effect that the regulations have, not just DEA regulations, all the regulations, state/federal regulations, have on scaring doctors from prescribing these medications, and there has been sort of anecdotal accounts of this from various pain docs and people in the industry. However, when we look at the actual facts and when we look at the data, they do not support that hypothesis. For example, if you go to the DEA website, DEAdiversion.usdoj.gov, you can access in that website, I believe, under the legal information area, you can access a history of distributions of controlled substances in the United States going back about 10 years, and this would be for Class 2 drugs and Class 3 narcotic drugs. Now, if you look at those numbers over a spread of 10 years or so, you will see that they are increasing year after year after year by sizable percentages. We are not talking about 1% or 2%, we are talking maybe 7%, 8%, 10% a year. It is astronomical the volume of medical use of opioids that we have seen in the last 10 years. Now, there are a number of studies from the CDC and elsewhere that show that as a volume

of medically used drugs goes up, the diversion of those drugs increases as well and so does their abuse, which is a very logical and self-evident type of a situation. However, if you look at the number of estimated pain patients, the number does not increase each year as quickly or as fast or as high as the volume of opioids increase on that system that the DEA keeps very close track of. So, bottom line is that if there is a chilling effect, it is a very mild one. It will only affect certain practitioners, and who knows, maybe they have reason to be afraid, but the bottom line is that it is not widespread. And again, the data do not suggest that it has a much of an effect on the overall treatment of pain patients because the volume of medically used opioids continues to increase almost dramatically each year far and excessive of any number additional patients that we might expect and anticipate to have. Commander Burke, do you have anything to add?

Commander Burke:

I think like you said at the end, most of it is anecdotal kind of information, and the data as you have pointed out does not support that. That certainly has been a cry that I think we have heard over the past few years. I think one thing that you need to understand is the law enforcement, and I think we have done a better job that this is the fact that we recognize, and Dr. Coleman certainly does. We recognize the legitimate patients, in fact the vast majority of people that take these medications are legitimate patients, and we recognize that the last thing that we want to do is negatively impact those people. The people that are negatively impacting them as people are the criminals, the people that are diverting drugs, or the people that are the pill mills. They are the ones that unfortunately create the ultimate problem and then ultimately, legitimate pain patients can suffer. So I think you hit it on the head and I do not think there is much more to be said. This is something though that I think you and I both have heard for probably many years.

I am a strong promoter of let's educate legitimate patients about the drugs that they are prescribed as far as how the potential is for diversion from them. They sometimes, as you know, become unwitting enablers of these drugs, whether it is at home, you mentioned about locking the medications, they need to know the pill is worth a certain amount of money on the street and that there are people that are very much interested in the medication and they need to safeguard it. It is not proper to give it to another person. All those things, I just think more patient information could be done. I know we have been a little concerned about that if we tell them and they know, somehow we think legitimate patients may become diverters themselves. I just do not think that is the issue. They need to know what the safeguards are that they need to take to safeguard their medication.

9. *How can family, friends, or the public in general make a difference in the fight against prescription drug diversion?*

Commander Burke:

I think to answer it in probably one term that I can think of is *awareness*. I think that there has been an increasing awareness over the past few years, a lot of education and a lot of stuff in the media in regards to prescription drug abuse, but I think that maybe sometimes the individuals that we are missing are maybe the legitimate patients, patients that have these drugs legitimately, to make sure they safeguard them, make sure that they do not have drugs in the home that are kept there unnecessarily and that they are properly disposed off. I think it comes down to awareness because I think with that, again the vast majority of people that get these drugs are responsible folks, they do not want their drugs diverted out of the household. And we look at the 12- to 17-year-old population, prescription drugs are there, probably they are #1 substance of abuse now and one of the main ways they get them is through family and friends and people's medicine cabinets. So, I just think an overall awareness, make yourself aware of the problem and make yourself aware of how you cannot be unintentional leveler.

10. *What type of tactics are you aware of throughout the country, but also particularly in Ohio area, being used to get rid of non-legitimate prescription writing or the doctor pill mills? We know that Florida has had a significant amount of legislation and impact, but what about other parts of the country?*

Commander Burke:

Well, it is interesting you said that because Ohio had what turned out to be sort of a powerful legislation that was passed probably 1½ to 2 years ago and it actually made a huge dent. And again what we talked about here are non-legitimate pain management sessions. Hopefully, the efforts are to get rid of the non-legitimate. I think that Ohio's laws, there are several things, one of the things is if more than a 51% of your patients are pain patients, you have to register as a pain clinic. The pain clinics now, you cannot have anybody working for you that is a felon, they passed these laws and really they have been effective. I mean if you have to have these laws you have to have law enforcement involved certainly to be able to enforce these, and the laws and the regulations that I saw that were passed in the state of Ohio, I never heard any of our many legitimate pain clinics complain about it. The only people that I remember complaining about it are the people that are involved in an illegal activity. We had a pretty good concentration in southeastern Ohio and I believe virtually all of those are gone because of this legislation. So, legislation can help, but I also say through this standpoint that we have to also be careful about some of these kinds of legislations because sometimes we, I am talking about government and legislators, have a knee-jerk reaction and we still have to ultimately keep the legitimate patient in mind. Yes, we need to certainly shut down those that are illegitimate, but I believe we need to make sure we safeguard the others.

11. How many states have prescription monitoring programs that will allow you to access basically all of the prescriptions and all of the scheduled drugs that the patient is taking?

Dr. Coleman:

I believe there are about 48 states that have actually authorized it by legislation, probably around 40, maybe 42 now are up and running, actually have live systems to do this. Those states all individually, depending upon the legislation that used to act these programs, will obtain the legislation, specific safeguards to protect the privacy and confidentiality of the information. And in some cases, for example, in order to obtain information from the system, you have to have a court order; and in some case you have to have a court subpoena; in some cases you can use administrative subpoena from the district attorney or the federal prosecutor; in some cases just a letterhead from an official government agency, state or federal, that has a need to know, such as investigators of Medicare and Medicaid programs, etc. So each state is different. The states do require some process, the law enforcement officer cannot simply access the computer and go right to the PMP, that is not allowed in any state.

Dr. Webster:

John, I think Utah allows that.

Dr. Coleman:

Utah is one of the first interactive systems that allowed the practitioners and pharmacists to obtain information from the PMP system. Now, many of these programs do allow practitioners to query the system for their own patients and also allow pharmacists to query the system for their patients as well. You cannot ask about other patients, but you can ask about your own patients, and all your information requests are tabulated and captured by the system, so you cannot walk around that, but the bottom line is that law enforcement officers, including the federal agents, have to have some form of official reason to request access to these systems.

12. A patient may have leftover opioids because of adapt or improvement in their condition. What should the physician or the pharmacist be telling their patients about disposal of unused Class 2 drugs?

Commander Burke:

This is a very, very important question and hopefully we have got some answers. Obviously, this can happen in a hospice situation, certainly a lot of different situations, and we ask people to routinely check their medicine cabinet; see what you have in there. Typically, we have things in there that are outdated we do not need, and all those drugs left there become as a target for those folks that are drug seekers. And so there is a lot of different ways to dispose of Class 2 drugs and there is some controversy here I have to tell you. FDA will tell you Class 2 drugs you can flush down the toilet. There are others that are concerned about that. Other proposals are that you

grind them up and put them into things that are undesired, baby's diapers, coffee grounds, whatever. And the third option that has come up are drug drop boxes, and I bring this up because we have NADDI who are providing this along with several other people. If you go to NADDI.org and click on the drug drop box, and put in your zip code, it will show you where the closest box is. These boxes are at law enforcement agencies because essentially law enforcement is really the only one right now that can take these substances back. And now we see cocaine, we see all kinds of things, and when these drugs are deposited in these boxes you can do it anonymously, some places 24/7. Then we destroy them just like we do any other drugs that we get court orders to destroy. So, I think the point of the matter is to get rid of them, but get rid of them responsibly.

13. *There are a lot of prescription monitoring programs in the country now, and some of the data that I see is that there is still a low utilization. In some places, 20% is common in some of the states. Do you think that the prescription monitoring programs are having any impact on diversion? If so, tell us how or if not, tell us why not?*

Commander Burke:

What a great question and you are a 100% right. The utilization level I found frankly kind of alarming and this may need some time, although I know that Ohio started out and it was somewhere around 18% to 20%, I think that rate in Ohio has gone up now to about 30% to 35%. Of course, I think there is probably a certain number of those DEA registrants that may or may not be prescribing controlled substances, but nonetheless, it is still a low level in my opinion, and sometimes I wonder why because I know when the medical boards and pharmacy boards put out a lot of literature, a lot of information on it is free. In Ohio, it is very, very easy. They are now making it so even your employee can actually run the PMP. And to answer your question about how effective they are, they are extraordinarily effective as far as from a law enforcement perspective, even though we do not appear to be using them as much as health professionals do.

Dr. Webster:

So if it is going to be used, let's say a pharmacist accesses it, what would be on the report that would be alarming? I mean give me an example of maybe what a pharmacist should do if they find x, y, and z on the report. What could be on the report that should lead them to take some action?

Commander Burke:

What would be on the report that obviously would be a red flag would be to see that they are going to multiple prescribers, multiple pharmacies, essentially for the same drug, essentially in the same time. Usually, what you will see on these is not a one-time thing. This is only a tool and you have to look deeper into it.

14. Florida has implemented their prescription monitoring program. They had some struggles in bringing it up to a usable state. Now that it is there, can you, Dr. Coleman, tell us what is going on in Florida? I mean we have heard so many things about the pill mills down there. Can you clarify the laws down there about prescribing Class 2s and Class 3s and then even about the pharmacists, their responsibility, or the legal issues about filling a script?

Dr. Coleman:

In July of 2011, actually July 1, 2011, the new law went into effect. So it has been in effect now for almost a year and a half, and basically it requires practitioners prescribing any controlled substances for the treatment of chronic nonmalignant pain to register with the Department of Health as a controlled substance prescribing practitioner. Each practitioner in the state of Florida has a profile on record with the Department of Health as to what their field of practice is, and so they have to amend that if they prescribe controlled substances for the treatment of chronic nonmalignant pain. Now, the new law also ended dispensing of Class 2 and Class 3 drugs by physicians, so that is banned and that was one of the biggest problems in Florida, especially with the pill mills because the doctors were not only prescribing but actually dispensing on the premises of the pill mills the same drugs, and so the dispensing of Class 2 and Class 3 drugs in Florida now is totally banned. They can still of course prescribe the drugs, but then the person has to take the prescription to a regular pharmacy and get their drugs in conventional means. Now, the standard of care for chronic nonmalignant pain is now designated by regulation. It requires, for example, in the state of Florida, that pain practitioners have to execute a signed agreement with their patients and they must refer those patients to a pain specialist if there are any abuse signs apparent in the patient. It requires a pharmacist to report within 24 hours any attempt to obtain controlled substance through fraud, they have to report that to the local sheriff, and the clinics have to report the number of new and repeat patients that they treat for chronic nonmalignant pain, the number that they discharge for drug abuse and diversion, as well as the number of who is not in Florida. So they will try to go after those out of state folks that come in to buy the drugs in the pill mills, and there is also a very important provision in the Florida statute that requires wholesale drug distributors to file monthly sales reports with the Department of Health and assess their orders whenever they receive an order from a customer, say a pharmacy or a hospital, for more than 5,000 doses of any one particular controlled substance within a month. That also requires counterproof prescription pads that are obtained from state-approved vendors, and those vendors will notify the state when they provide those pads to the practitioners. That requires the dispensers of controlled substances in the state, the pharmacists, to report to the prescription drug monitoring plan or program within seven days of dispensing the drugs. So, there are quite a few new regulations in Florida, and a lot of other states are looking at the Florida model because the results so far are quite dramatic in Florida in terms of the reduction of controlled substances being diverted and the number of pill mills that have been put out of business, and so I would not be surprised to see some of the

regulations that I just described that are now in force in Florida, being picked up by other states as we move along on this.

15. Assume that you have done all of your due diligence to make sure in good faith that the script is legit, but you later find that it is fraudulent. Are there legal ramifications for the pharmacist?

Dr. Coleman:

This is basically under the federal rules. There is sort of a good faith exception that if the prescription looks really good and it has all the proper information and it seems like a valid prescription and the pharmacist fills it, only to find out maybe later that the prescription or pad was stolen and those were fraudulent prescriptions, the pharmacist is basically indemnified here. However, they have to be careful because if the prescription turns out to have a clearly fraudulent appearance, and we had a number of wonderful examples in the organization that John runs and that where people have misspelled the name of the drug and other things, if there is clear indications that this is not a real prescription and it is filled, then the pharmacist could have a problem.

16. Is there a regulation that requires wholesalers to cap the quantity of controlled substances that a pharmacy can order, and if so, can these limits be shared with the pharmacy? This is causing interruption in the continuum of care for many of my patients in the pain management pharmacy where I practice. What do you suggest be done to prove that the dispensing of the substances are only for legitimate prescription for patients with chronic pain in an effort to have my caps raised?

Dr. Coleman:

This is a very interesting question because it crosses a number of different areas. First of all, there is no regulation under federal law that I am aware of and I am not aware of any state law that would cap the actual quantity of controlled substances that a pharmacy can order. Now, there are may be caps on the amount of drugs that can be delivered based on the overall requirements in the federal statute that registrant distributors are required to have systems to identify what is considered as suspicious order, and the law is very clear in defining exactly what a suspicious order is. It is an order, for example, of unusual size or one that deviates substantially from a normal pattern or an order of unusual frequency. So the wholesalers should have records of the customer's orders for a given period of time, and if an order comes in that has an unusual size to it or it is deviating substantially from the normal pattern for that particular customer, that wholesaler is required to conduct an inquiry of some sort before filling it, and it may be inappropriate to fill it, in which case the wholesaler is prohibited from filling that order if it is truly suspicious. We have seen in the past few years a numbers of wholesalers that have been actually fined and had their registration suspended for filling suspicious orders. The customer might look at

that as having a cap on it, but it is not really what it is. It is basically the overall regulation that requires due diligence on the part of the wholesaler before filling the orders.

Now there is a new law in the state of Florida that went into effect in July of last year which requires that distributors sending 5,000 doses of a controlled substance to a single customer within a 30-day period must notify the Department of Health of that and also conduct due diligence to make sure that order is appropriate. But that is the only state right now that I am aware of that has that 5,000 dose unit requirement, again it is not a cap on the quantity. The customer is still able to order whatever quantity they need or require, but there is a requirement on the distributor to conduct the due diligence before filling that order.

Commander Burke, what do you suggest a pharmacist do if they receive a fraudulent prescription, and the questioner here is sort of suggesting potential responses. One would be return it to the patient, the second would be immediately call a police, and the third would be put some markings or something on the prescription. I do not know what the purpose of that would be, but Commander Burke what are your suggestions here?

Commander Burke:

Well, it's a good question because I know the pharmacists struggle with this. Certainly, we would like them to not return it to the patient because now you have evidence. Obviously, it is fraudulent prescription, whether it has been altered or it is fraudulent in its whole, it is evidence. Now, I know it is easy for me to say that you should not return it to the patient because I know sometimes those folks get pretty irate and you could be concerned for your own safety, so I don't want that to happen. I obviously don't want you to be in a position where you are uncomfortable because you are not returning the prescription to the patient or that you feel like you are in some kind of physical danger. If that is the case, return it. What we would like to do at the very least if somehow you feel you have to is to make a photocopy of it if you can walk away from the counter and do that, but the first thing would be that you not return it, that you tell the patient I need to check on this, I need to call the doctor, or whatever and see what their reaction is. Many times, as you know, they also then just leave the pharmacy. Do we want you to call police? Yes, this is a crime. It is crime in progress, but a lot of different pharmacies we have developed situations where they are able to maybe make something of it, they would give it to the people in front or tell somebody to call the police and bring him into the building. Sometimes it is not possible, I understand that, but obviously, we want you to call the police because this is a crime, and if they have left the building, obviously we would like for you to get some kind of description if somebody is able to see what they leave in. And obviously again, I cannot stress enough that we do not want you to put yourself in physical danger in any case at all. It is not worth that, and I am certainly not suggesting that. So in a perfect world, I would like for you not to return it to the patient and call the police, but I realize that does not always work that way, but regardless, once the situation is over, if you have not called the police, please do call them.

Hopefully your cameras are on and maybe we will have a picture of the person, but remember they are committing a crime when they do this.

17. What is your standard of care in your practice when you encounter a new patient presenting a prescription for a controlled substance that you are not sure about? There is nothing about the prescription itself that you are particularly questioning. You just have a gut feeling about the issue and you are unable to verify the prescription at the time, what do you do?

Dr. Hahn:

Calling the doctor and verifying the prescription always if we are not sure of what is going on, looking at the PDMP. So, I will say the majority of the time now because we have got this great PMP, the first thing that I do is walk over, run the person, and I would say 99% of the time the person is showing up on our PDMP and giving me a history of where this person has been. I was looking at one yesterday that told me all of the doctors the person had been going to for the last year, all the pharmacies, and when we get a story, we talk to the patient and you have get to know the patient. If they are brand new to you, you are like, 'Okay, so what is your history, what are you here for?' We always ask for ID, and a lot of times, the PDMP is the thing that makes me feel more comfortable. I can see, okay they have been going to this pain specialist and then they stopped and then they started going to this one, and this one was prescribing this. And it fills in a history that I have never been able to know before, and it gives me a sense of either comfort at being able to take care of this person, or more questions and concerns.

18. Can Class 2s be written for a 90-day supply on one single prescription?

Dr. Coleman:

Well, technically under federal rules, yes, because there are no quantitative requirements under federal rules for a prescription for controlled substance. Now there is an exception. If you are writing sequentially fillable prescriptions for Class 2 drugs, that rule allows the practitioner to write a 90-day supply of drugs on three separate prescriptions, each one authorizing a 30-day amount of drug to be dispensed; however, the practitioner must write on two of those prescriptions a 'do not fill before' date in the text of the prescription. These are instructions to the pharmacist who is not authorized to fill that prescription until the date that is indicated on two of those prescriptions. So, theoretically, a practitioner could write a single prescription for a 90-day supply of Class 2 drugs or do the sequentially fillable procedure. Now the reason for the second procedure is of course because most states, particularly states that have prescription drug monitoring programs, limit the amount of Class 2 drugs that can be prescribed; in fact, they limit the amount of controlled substances that can be prescribed to a 30-day supply. That is the route the information can be uploaded from the pharmacy into the computer that the state uses for its monitoring program. **That is not a federal program and so the federal rule is still in place; however, for any practitioner out there who is interested in**

knowing whether or not this can be done in his or her state, you really need to check with the Board of Pharmacy in your state. The chances are very high that you are going to have a restriction placed on the quantity that you can prescribe.

19. Can a provider write Suboxone for an individual with a heroine addiction without being in a rehabilitation facility?

Dr. Webster:

I assume the question means a methadone maintenance treatment center and the answer is yes, that is the purpose of Suboxone. The purpose of Suboxone was to allow primary care and physicians that are not a part of a methadone maintenance treatment center to treat opioid addicts, not just prescription opioid addicts but even heroine addicts in their offices without having to go to a substance abuse treatment center.

Dr. Coleman:

Yes, the Drug Addiction and Treatment Act of 2000, which is called DATA 2000, approved that physicians in a private practice could treat up to 30 patients at a time using Suboxone, prescribing it as a Class 3 drug, so it is sort of an outpatient treatment for opiate addiction. And that later on was increased to 100 patients, and now private practitioners can treat up to a 100 patients. However, before they are authorized to do that the practitioners have to take a CME course, I believe it is online, but they have to take this CME training and send that certificate to Department of Health and Human Services, I believe it is the substance abuse treatment center abuse and authorization, after that CME course. And then with that authorization, the practitioner gets a special number from the DEA which is appended to the existing controlled substances registration number and that authorizes the practitioner to prescribe Suboxone for outpatient opioid addiction treatment, and the pharmacist of course then will see if that number is on there and authorized to dispense the drug for that purpose.