

Q&A on Risk Evaluation and Mitigation Strategies (REMS)

October 18, 2010

This group of questions and answers is the first in a series you will receive, based on the REMS plenary session at the ASPMN 20th National Conference in Minneapolis, MN, September 25, 2010. The presenters, Michael Barnes, Esq.; Micke Brown, BSN, RN; Barbara St. Marie, ANP, GNP, RN-BC; and Marsha Stanton, PhD, RN, have provided answers to ASPMN member questions.

Q. Should there be a policy as part of REMS to require a covering provider to consult with the original prescriber?

A. In most of the discussions around REMS, NPs have not been considered, only physicians. Several of us are trying diligently and tirelessly to encourage the FDA and other stakeholders to include the NPs, CNS and DNP as well as certain PA and pharmacists in states where they have prescriptive authority. Wade Delk is your advocate in these discussions. Marsha Stanton, PhD, RN

A: The details of a policy like that would be tremendous. The cultures of practices across the country are very diverse and difficult to regulate across the country. However, continuing education and health care education can be augmented to enforce collegiality and collaboration among all providers, including prescribers. Barbara St. Marie, ANP, GNP, RN-BC

A. This is an excellent practice policy that could be adopted in every clinical setting. I would recommend that it is treated as a quality standard, not one that necessarily requires regulatory oversight. Legislation is not always the best solution, in fact can damage health care practice, as we are now seeing in some states. Micke Brown, BSN, RN

Q. Is there any plan to restrict APN prescribing compared to physicians?

A. I have read a number of constituency groups' proposals related to the Food and Drug Administration's call for a single REMS to cover all long-acting and extended-release opioids. I did not come across any legitimate proposal that recommended restricting APN prescribing as compared with physicians. Michael C. Barnes, Esq.

A: APNs are well positioned to have therapeutic relationships with their patients, taking time for education and monitor. Our educational preparation situates us for chronic disease management. This includes chronic/persistent pain issues and managing symptoms with an armamentarium of tools, including opioids. We have to keep the strengths of our practices front and center in these public forums. Barbara St. Marie, ANP, GNP, RN-BC

Q. I would support mandatory training for anyone who has a DEA number. What is the status of that?

A. Some responses to the Food and Drug Administration's call for a class-wide REMS to cover all long-acting and extended-release opioids have suggested that the right to prescribe this class of medications be tied to a practitioner's DEA registration. This approach would arguably require a Congressional amendment of the Controlled Substances Act. It is not likely that the FDA would incorporate such a requirement into a class-wide REMS.

Mandatory training of prescribers could be a component of REMS, although the FDA is permitted to require prescriber education only in cases when a medication would otherwise be too dangerous to remain on the market. In such a case, the FDA would be required by law to "minimize the burden on the health care delivery system." (See 21 USC 355-1(f)(1-2).)

An FDA advisory committee rejected the FDA staff's July 2010 proposal for implementing a class-wide REMS in part because it did not go far enough in requiring prescriber training or education. (*FDAnews Drug Daily Bulletin*, July 27, 2010.) Michael C. Barnes, Esq.

A. Most discussions with the FDA, stakeholders and other interested parties, including the Industry Working Group (IWG) agree that prescriber education is critical to the success of REMS. There is also significant interest in consumer education as an ongoing effort with opioid use. *[We should discuss this issue next month as separate issues, as there are many factors involved]*. Marsha Stanton, PhD, RN

A: I know from my discussions with other health care providers that no one likes the word "mandatory". But we have to think beyond what we want, and rather think what is best for our patients and our society as a whole. Barbara St. Marie, ANP, GNP, RN-BC

Q. Does the FDA have the power to change systems besides just adding requirements? For example, a national prescription database so a pharmacy could know the status of anyone picking up opioids could be helpful.

A. The Food and Drug Administration Amendments Act of 2007 sets forth specific steps the Food and Drug Administration may take to yield systemic changes when a medication would otherwise be too dangerous to remain on the market. (See 21 USC 355-1(f)(1).) It is possible that a pharmaceutical company could incorporate electronic prescription monitoring program (PMP) data checks as part of its product-specific REMS, but no company has done so. There has been little, if any, discussion regarding the use of PMPs as part of a class-wide REMS for opioids.

CLAAD has recommended that federal policymakers and pharmaceutical companies explore ways to utilize states' electronic prescription monitoring programs to achieve the same results a class-wide REMS for opioids is intended to yield. This approach received some attention during the September 2010 Congressional Prescription Drug Abuse Caucus forum on prescription monitoring programs. Michael C. Barnes, Esq.

A. Currently there are PMPs or PDMPs in most states (the number fluctuates often); however, they are not being utilized for a variety of reasons. Funding, lack of interest, concern over privacy issues, time constraints, etc. have created a sense of insecurity for many prescribers. Pharmacies have the capacity to utilize these systems, so if used properly this could provide an additional layer of protection for prescribers and patients, should the systems be utilized to their maximum potential. Although there has been some discussion, as Mr. Barnes states, there has been no statement as to the final verdict on the use of these systems. There has also been discussion around the use of "switch technology" which is a mechanism by which a prescription is entered into a system by a pharmacist or technician – the prescriber, patient and prescription are verified within seconds and the prescription is either filled or declined in a much more expedient fashion. If REMS is implemented in the way it is envisioned, this could also validate educational requirements of prescribers for a pre-designated opioid training. Marsha Stanton, PhD, RN

A. As a prescriber in the State of Minnesota, I use the PMP daily in my clinical practice. I consider it a good patient education tool. However, it does have its limitations. These limitations are:

1. When patients take a prescription from one state to get it filled in another state the current tracking in the original state is inadequate.
2. When patients receive methadone from a methadone clinic, it is not recorded on the state PMP.
3. When patients receive their prescription and medication from the VA systems, it is not recorded on the state PMP.
4. When patients receive their medication while in a nursing facility, it is not recorded on the state PMP.
5. When patients receive their take home medication from an inpatient hospital pharmacy, it is not recorded on the state PMP.

The PMPs need to address these issues before they can offer a totally reliable service to our patients and our practices. Barbara St. Marie, ANP, GNP, RN-BC

Q. Is there any way to control meds when they are changed or discontinued? For example, if the physician changes from MSContin to methadone, there should be a standard practice for getting the old drug back.

A. Health care providers are not authorized to accept patients' unused medications. As a best practice, it would be possible for a prescriber to ask patients to dispose properly of their unused medications and even watch them do so before prescribing a new medication. Michael C. Barnes, Esq.

A. You may be aware that there has been a recent push for the elimination of unused medications from the home. September 25th, the day of this plenary session, the DEA sponsored a very successful national drug take back. You will undoubtedly see more of these in the future. Prescribers and other healthcare providers are not authorized agents to accept unused medications, as Mr. Barnes suggests. Only law enforcement professionals/officers are able to accept medications in certain situations. Marsha Stanton, PhD, RN

A. Right now there are no regulations requiring unused medications to be taken back. And the patient bought and owns the prescriptions, it is therefore their possession. There are a voluntary "take back" programs (<http://www.takebacknetwork.com/>) that can be helpful to get rid of excess medications and properly dispose of these in "earth friendly" ways. Barbara St. Marie, ANP, GNP, RN-BC

Q. My question is more rhetorical: Why is there no responsibility on the patient? Manufacturers, prescribers, pharmacies, etc., must take responsibility, but the responsibility does not exist with patients.

A. Patients and the public must take responsibility for preventing the diversion, misuse, and abuse of medications. The national Lock Your Meds™ campaign (www.lockyourmeds.org) is one of many grassroots and multimedia efforts to educate the public to secure their medications and never to share or sell them. Most proposals for REMS do include substantial patient education provisions. Michael C. Barnes, Esq.

A. Patient education is and has been one of the many debated issues throughout the REMS process. There is no doubt that education for all constituents is needed, however, it is the transfer of education to knowledge that will begin to change the culture. There are varying schools of thought regarding this issue, but the fact remains that all who are involved in the opioid experience must be responsible for their portion of this significant area of concern. That said, we cannot hold everyone responsible for the irresponsibility of a few. Marsha Stanton, PhD, RN

A. It is our responsibility to educate our patients. In our educational teachings, we must consider language/culture variations. Topics of education include side effects, proper storage, lock your meds campaigns, dangers of sharing medications, danger of mixing with alcohol and other CNS suppressing medications/drugs, etc. But, as with all medications, if the patient does not comprehend or indicate understanding of safety parameters, then a trusted individual is brought in to help support safe patient care. That trusted individual is then educated in the same manner. Emphasize that lack of understanding of safety standards does not mean "no prescribing", it means the social support needs to be evaluated and when necessary, adjusted. A social worker should be involved so community services are made available to help keep our patients safe. Barbara St. Marie, ANP, GNP, RN-BC

A. HCP have the responsibility to teach risk and benefit as part of the informed consent process. Safe use should be emphasized by the prescriber and reinforced by the dispenser. There are quick tips that are covered by the Six Opioid Safety (SOS) steps. These can be found on APF's PainSAFE website (www.painsafe.org). They SOS steps are:

1. Never take a prescription pain medication unless it is prescribed for you.
2. Do not take pain medicine with alcohol.
3. Do not take more doses than prescribed.
4. Use with other sedative or anti-anxiety medications can be dangerous.
5. Avoid using prescription pain medication to help you fall asleep.
6. Lock up prescription pain medicines.

Micke Brown, BSN, RN

Q. In our practice, we use quite a few medications “off-label” for treatment of pain. Sometimes they work; sometimes they don't. We always let patients know this up front and are careful to review possible side effects and adverse reactions with patients. How will REMS impact this practice? Specifically, what ramifications are there if we continue to prescribe “off-label”?

A. Risk evaluation and mitigation strategies have already limited off-label prescribing. For example, the REMS for Onsolis™ (fentanyl buccal soluble film) requires that prescribers agree in writing not to prescribe the product for off-label purposes. (Prescriber Enrollment Form, The FOCUS™ Program for Onsolis™.) Michael C. Barnes, Esq.

A. There has always and will always be off label prescribing. I doubt that REMS will change this too much. Prescribers will always do what they feel is best within the scope of their medical knowledge and practice. The FDA and each company create a product label that has the best language and information possible for a given product. If a prescriber chooses to utilize that product in a way not authorized by the product insert or product information sheet (PI), the responsibility for the outcome resides with that prescriber. The FDA and REMS will not likely control these uses, other than those specific cases such as stated by Mr. Barnes. Marsha Stanton, PhD, RN

A. Limitations on off-label use create barriers to pain management practice. For example, treating pain in the pediatric populations involves many analgesics used as off-label. Another example, adjuvant analgesic medications such as anti-convulsants, tri-cyclic antidepressants, topical analgesic agents, all are off-label for most pain problems. You are correct; “off label” use is common in pain management and helps us serve our patients with medications that work on different pain pathway sites in the peripheral and central nervous system. Barbara St. Marie, ANP, GNP, RN-BC

Q. What is the responsibility of a covering provider when writing an opioid script for a chronic pain patient in the absence of the original prescriber? For example, what if a patient needs a refill on Oxycontin 80 mg TID, the original prescribing physician is not present, and the nurse practitioner needs to cover the script? Is it necessary to do a full assessment, including urine screen?

A. There has been no discussion of this exact point. There would need to be the same level of evaluation and assessment normally provided to ensure adequate safety and compliance. Marsha Stanton, PhD, RN

A. As you know, some providers will not cover for each other with opioid medications, even if they are in the same practice. Some will not out of fear and some because the patients are under treatment agreements and prescribers make sure their patients have enough opioid before leaving town. Within any practice, patients with treatment agreements should be educated on the process for prescription coverage when the primary provider is out of town. As well, the covering prescribers should know up front what the expectations are when the main prescriber is out of town. This sounds like, in the above scenario the MD was not available, and the NP was approached about a refill and may have felt more information was needed, such as:

1. What the patient is being treated for?
2. When were the last refill and how many pills were given to the patient?
3. Assuming the patient ran out early, has the patient been re-evaluated for cause of pain, running out early, etc?

A prescriber cannot assume this scenario implies opioid misuse or abuse or diversion.

In sum, what would I do? I would have the patient come in to see me the day of the request (I know, we all have busy schedules, but this should be taken as seriously as anything else), check the prescription monitoring program or the pharmacy the patient gets refills from and find out as much as you can from these resources. When the patient arrives to your clinic, obtain a full history, perform a focused exam, document the differential diagnoses, then use your best judgment to direct your plan, and document your rationale thoroughly. If you do supply opioid consider a small volume but keep same dose (verified by the medical records). Barbara St. Marie, ANP, GNP, RN-BC

Q. With REMS, will *any* opioid prescription require a full assessment?

A. There will likely be varying levels of REMS complexity. Those medications with the highest risk factors will have the most stringent risk management programs. The FDA has not determined the magnitude of this as yet. Currently, the only medications under consideration are the long acting and sustained release opioids, however, there is significant interest in expanding the class wide REMS to include the short acting opioids as well. Marsha Stanton, PhD, RN

A. This is already a clinical practice recommendation that is best articulated in the Federation of State Medical Boards Model Policy and supported by ASPMN, APS, AAPM, AAPMgt. See: http://www.fsmb.org/pdf/2004_grpol_controlled_substances.pdf. Also refer to the ***APS/AAPM Clinical Guidelines for Chronic Opioid Therapy in Patients with Noncancer Pain*** at: <http://www.jpain.org/article/PIIS1526590008008316/fulltext>. Micke Brown, BSN, RN

A. As Advance Practice Nurses, we are trained that the type of evaluation is dependent on the chief complaint. Before a treatment is decided, the assessment occurs first. Listening to what the patient is saying to you and further asking them questions (including pain assessment questions and questions from screening tools for risk factors), is paramount. Then after examining the patient and determining if any further tests are need, you can establish your diagnosis/assessment. Lastly, treatment is determined. All the above is documented including the plan for follow up evaluation and patient teaching, including teaching of medication safety. Examples of patient education of medication safety are found on the following websites:

<http://www.nfp.org>.

<http://www.PainSAFE.org>.

<http://www.opioids911.org>.

Barbara St. Marie, ANP, GNP, RN-BC