

**Statement of
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**Food and Drug Administration
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Risk Evaluation and Mitigation Strategies;
Notice of Public Meeting; Reopening of Comment Period
July 27-28, 2010**

Good afternoon and thank you for allowing me this opportunity to share the community pharmacy perspective regarding issues and challenges associated with the development and implementation of REMS. I am Ronna Hauser, Vice President of Policy and Regulatory Affairs at the National Community Pharmacists Association (NCPA). NCPA represents America's community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises, and chains.

First, we would like to applaud the FDA for making the process that has led to this public meeting a transparent one and we appreciate yet another opportunity to publicly comment on FDA's implementation of REMS and the impact on community pharmacists.

Community Pharmacists' Role in REMS

NCPA appreciates the FDA's guidance documents related to REMS, as they provide the Agency's current thinking related to a topic that has a great impact on community pharmacy practice. State boards of pharmacy regulate the practice of pharmacy. However, REMS programs have the potential to interfere with that role if they are used too frequently.

Pharmacists take seriously their role as the primary source of drug information for their patients. Pharmacists provide both life-saving medications to their patients, as well as critical written and verbal drug information and counseling that allow medications to be used most appropriately and safely.

Recent studies have shown that patients recognize the value of, and are willing to receive pharmacist delivered care.¹ Ideally, that care is delivered by a pharmacist with whom a patient has an established relationship. While other approaches to delivering these services exist, studies have shown that community pharmacists providing face-to-face patient interactions may have a greater impact on patient behavior compared to other methods of service delivery.² Clearly, these services could be utilized to meet the goals of a REMS program, and should be duly compensated.

It is important to note that in the provision of care process, pharmacists have standard workflow procedures that ensure prescription medications are safely delivered to their patients. To date, community pharmacy's experience with REMS continue to be challenging due to the lack of a common design or platform surrounding such programs. Medication Guides have not provided the solution some had hoped. That is why NCPA is a strong advocate for the creation and use of a single, FDA approved plain language document to replace existing written information distributed by pharmacies. We greatly appreciate the Agency's movement in this direction, and additionally we support the Agency's seeking a way around imposing REMS when only a Medication Guide is required.

Restrictive REMS Systems and Adverse Affects on Patient Access

As previously mentioned, community pharmacies are highly regulated in each state by Boards of Pharmacy and the DEA. It is therefore NCPA's position that any state- and DEA- licensed pharmacy should be eligible to dispense specific REMS products. Not only do restricted distribution programs interfere with patient access to prescribed therapies, they may limit legitimate access to certain therapies and shift illegitimate use to other products.

¹ Journal of the American Pharmacists Association. "Patients' needs and interest in a self-pay medication therapy management service." Jan/Feb 2010, pgs 72-77.
² Journal of the American Pharmacists Association. "Impact of drug cost and use of Medicare Part D of medication therapy management services, delivered in 2007." Nov/Dec 2009, pgs 813-820

As an example, NCPA does not support REMS such as the FOCUS program approved for Onsolis. Based on studies and experience we know that direct face-to-face counseling is more effective than this program's method of shipment via courier service to the home and counseling provided by a call center phone bank. This omits the necessary pharmacist-patient contact, which can lead to greater risk in patient safety.

NCPA contends that many independent pharmacists can meet stringent REMS requirements such as being "on call" 24 hours a day, as this is the level of service many of our members offer patients on a daily basis, regardless of REMS. The independent community pharmacists who choose to participate in a given REMS program and can meet all of the requirements should be allowed to do so and not be restricted by a special arrangement between the manufacturer and a specialty pharmacy provider.

Therefore, NCPA respectfully requests that FDA verify that REMS elements will not impede patient access to life-saving medications by placing products in a restricted distribution program. In instances where products have been placed in such a program, NCPA requests that FDA study the prescribing patterns for these products, where oftentimes prescription volume significantly decreases, thereby reducing patient benefits. It also limits the ability of the pharmacist to manage the patient's entire drug therapy.

Training and Certification of Pharmacists

Regarding certification of pharmacists or pharmacies to dispense certain drugs with REMS, and education of pharmacists to ensure understanding of these products, NCPA asserts that self attestation of completion of education should serve as confirmation of receipt of training. If additional education is required, any provider of continuing pharmacy education (CPE) must be accredited by the Accreditation Council for Pharmacy Education (ACPE).

In addition, education should be allowed to be provided by entities such as national, state, or local pharmacy associations or schools of pharmacy, who are experts in developing pharmacy specific training and certification programs. For pharmacists to receive a certificate of completion awarding CPE credits for a home study program, they must review the content of the activity and successfully complete the post-test before their statement of credit is issued. They also must complete an evaluation of the activity.

Any REMS-related CPE programs offered by an ACPE accredited provider would be required to follow this process. In addition, the provider could track which pharmacists had completed a given program if it's necessary to specifically track completion of training. After education is verified through either self-attestation or a special tracking system, there should be no further requirements to re-certify annually.

Drug Distribution Models under REMS

NCPA cannot stress enough that any REMS system be created using a standard platform. As stated before, workflow standardization is an important component of safely filling prescriptions. A standardized REMS process that can be integrated within existing pharmacy workflow is critical to the successful execution of the program. If the need for verification of certain elements to assure safe use does exist, we urge FDA and manufacturers to utilize existing nationwide technologies that provide automation, scale, and efficiency in the transmission of electronic or hand-written prescriptions. Electronic prescribing, any registry, the pharmacy management system, and technology used to document patient understanding at the point of dispensing should all be interoperable.

NCPA is aware of multiple technologies currently on the market that can offer assistance in complying with certain REMS elements to assure safe use, as we know both the FDA and manufacturers are also aware via their process to propose a class wide REMS for opioid analgesics. We encourage the

FDA request stakeholder feedback regarding different approaches to create a standardized REMS process, and hope this can be part of future public meetings and opportunities to formally comment to the Agency.

Evaluating the Effectiveness of REMS

REMS should be monitored and assessed frequently enough to evaluate effectiveness as well as to evaluate overall burden on the health care system. For example, the number of minutes a healthcare provider dedicates to each component of a given REMS should be captured and evaluated. In certain instances this information may be collected by online methods, especially related to provider training or enrolling of patients in a specific REMS program. In other instances, methods should be developed or expanded that will allow for capture of time spent by the provider with their patient discussing elements associated with REMS.

Metrics for determining the effectiveness of REMS should be specified at the time REMS are approved. NCPA recommends that efforts to create REMS are equally matched by efforts to evaluate the effectiveness and outcomes of a given REMS and its individual components. FDA must ensure that the components of any REMS are proven to be effective in mitigating the specific defined risks and are workable for patients, prescribers, pharmacists, manufacturers, wholesalers, and system vendors. In addition, FDA should make outcomes information available to required participants of any given REMS program, as this applies transparency to the process so that participants are aware of their contributions to achieving agreed upon goals.

In order to measure the effect of REMS on health outcomes, we recommend that data be classified into general categories. Depending on the specific product, these categories could be further defined as patient/prescriber/pharmacist knowledge, behaviors such as inappropriate prescribing and nonmedical use and abuse, and outcomes such as serious adverse effects and patient access to care.

Though we all admit the challenges of trying to measure these outcomes, NCPA believes that through a concerted effort to define a set of metrics, REMS will meet the goals of reducing serious adverse outcomes while maintaining access to medications.

Lastly, surveys can provide an initial view of patient and healthcare provider understanding of the risks and safe use of a drug. Optimally, data drawn from systems such as electronic health records could serve as validation of the surveys. As the industry moves toward a fully electronic, interoperable healthcare system, this will become a more robust option for measuring the effectiveness of REMS.

Conclusion

In conclusion, we urge you to leverage the value that community pharmacists offer related to the proper use of medications and avoidance of costly mistakes down the road. NCPA appreciates the opportunity to provide comments on this issue and appreciates the FDA for recognizing the importance of the role and involvement of independent community pharmacists in the creation of REMS programs. Thank you for your time.