

**VIA Electronic Submission to <http://www.regulations.gov>**

December 30, 2009

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

*Re: Food and Drug Administration [Docket No. FDA-2009-D-0461] Draft Guidance for Industry on Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications*

Dear Sir or Madam:

Thank you for the opportunity to submit our comments regarding the draft guidance for industry on the format and content of proposed Risk Evaluation and Mitigation Strategies (REMS), assessments and proposed modifications. As the Food and Drug Administration (FDA) considers issues pertinent to REMS, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives on the draft guidance.

NCPA represents America's community pharmacists, including the owners of more than 22,700 independent community pharmacies, pharmacy franchises, and chains. Together they represent an \$88 billion health-care marketplace, employ over 65,000 pharmacists, and dispense over 40% of all retail prescriptions.

**Overview**

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. Traditionally, the state boards of pharmacy have regulated the practice of pharmacy. However, REMS programs have the potential to interfere with that traditional role of state boards if they are used too frequently and interfere with pharmacy practice.

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.

NCPA urges the FDA use REMS sparingly, and only in cases where it is essential to prevent a rare or dangerous side effect of a medication. REMS should not become a standard of practice, as continuity of patient care may be severely compromised. REMS should always be a last resort and used rarely as there are enormous ramifications to patient access when prescription medications are placed into a REMS program.

### **Content of a REMS**

Section 505-1(e) of the Federal Food, Drug and Cosmetic Act (FDCA) lists “Additional Potential Elements” of a REMS that may include Medication Guides, a patient package insert and/or a communication plan to health care providers. NCPA asserts that Medication Guides as currently implemented by FDA have not provided the solution some had hoped. For this reason, 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. NCPA has joined our pharmacy and patient care partners on a citizen’s petition urging the FDA to issue guidance permitting pharmacies to distribute such documents and was pleased to have participated in and provided comments to the docket regarding the FDA workshop “*Providing Effective Information to Consumers about Prescription Drug Risks and Benefits*,” held on September 24-25, 2009. NCPA commends the Agency for holding this workshop and for the Agency’s recognition of a one-document solution, long advocated by NCPA, as the most logical proposal to address the multitude of written information currently disseminated with prescription drugs.

### **Posting of REMS documents on FDA Web sites**

NCPA appreciates the FDA posting approval letters and appended documents related to the final REMS on various web sites. In our view, the most useful web site currently containing important REMS information for pharmacists is the list of approved REMS found at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>. From a practical standpoint, NCPA would appreciate a single location to visit for up-to-date information regarding the multitude of REMS currently in existence, which will most likely grow in the future.

As the majority of REMS currently listed on the site contain a Medication Guide as their only component, pharmacists would benefit greatly from being able to access the most recent version of the Medication Guide with one click. In addition, pharmacists would appreciate a link to documents prepared by the sponsor that describe in a step-by-step fashion their responsibilities regarding a given REMS. Since the FDA has access to copies of all relevant materials that are appended to the final REMS, such as enrollment forms, provider attestations, and training materials, it makes sense to have them available in one location. This greatly assists the health care providers who are responsible for provision of REMS elements. This would also benefit patients who could access documents they are responsible for reading and understanding as well.

### **Elements to Assure Safe Use**

Section 505-1(f)(3)(B) generally pertains to how the drug is dispensed. Elements under this category might require certification of training or attestation of specific experience or knowledge

before the product can be dispensed. 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 special 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 home study 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.

Regarding section 505-1(f)(3)(D), evidence or other documentation of safe use conditions that must be met by patients before drug exposure, NCPA asserts that patient education should occur first and foremost at the physician level, as this is the optimal time to educate a patient as to why a specific medication has been prescribed, expected risks and benefits, and the overall goals of therapy. The provision of a single, FDA-approved plain language document referenced previously, and that NCPA has been a strong advocate for, could also be presented to the patient at point of prescribing. When the patient then visits their community pharmacy, the pharmacist provides valuable education through appropriate counseling on effective and safe use of the medication. Technology currently exists that allows for patient education in the pharmacy through a nationwide, systemized, platform, which can be used to deliver targeted patient education that may be required in REMS.

### **Patient Access**

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


Section 505-1(f)(2) requires the FDA to consider how to ensure access and minimize the burden of a REMS that includes ETASUs. 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 a specialty pharmacy distribution scheme, the prescribing for these products is significantly curtailed, thereby reducing patient benefits. It also limits the ability of the pharmacist to manage the patient's entire drug therapy.

## **In conclusion**

Community pharmacists are an integral part of the healthcare delivery team. We serve our patients each and every day and help them to take their medication correctly to avoid costly mistakes down the road. With the FDA looking to manufacturers to implement REMS for certain products, it is vital that community pharmacy have an active role in the design and creation of these programs. When utilized, REMS must align the interests of all parties—manufacturer, supplier, physician, pharmacist, and most importantly the patient/caregiver.

NCPA appreciates the opportunity to comment on Docket No. FDA-2009-D-0461: Draft Guidance for Industry on Format and Content of Proposed REMS. If you have any questions, please contact me at (703) 683-8200 or [john.coster@ncpanet.org](mailto:john.coster@ncpanet.org).

Sincerely,

A handwritten signature in cursive script that reads "John M. Coster".

John M. Coster, Ph.D., R.Ph.  
Senior Vice President, Government Affairs  
National Community Pharmacists Association