

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

August 31, 2010

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

***Re: Risk Evaluation and Mitigation Strategies; Notice of Public Meeting; Reopening of Comment Period [Docket Nos. FDA-2010-N-0284 and FDA-2009-D-0461]***

Dear Sir or Madam:

Thank you for the opportunity to submit our comments related to issues and challenges associated with the development and implementation of REMS. As the Food and Drug Administration (FDA) considers issues pertinent to REMS, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share the perspectives of independent community pharmacists. 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.

NCPA is pleased to have presented the views of independent community pharmacists at the FDA's 2-day public REMS meeting, held July 27-28, 2010. The comments below reflect our statements at that meeting and address specific questions and points of clarification posed by FDA staff during the panel discussions. We applaud the FDA for making the process that led to the July public meeting and reopening of the comment period a transparent one and appreciate yet another opportunity to officially comment on FDA's implementation of REMS and the impact on community pharmacists.

### **Community Pharmacists' Role in REMS and the Provision of Care Process**

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.

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 experiences with REMS continue to be challenging due to the lack of a common design or platform surrounding such programs. In fact, a fall 2004 survey of pharmacists found that, overall, 61% of pharmacists stated that risk-minimization programs had a negative impact on the practice of pharmacy because the plans were confusing and required more time, personnel, and cost to pharmacies.<sup>1</sup> In the same survey, 29% of pharmacists indicated they were not familiar with the term "Medication Guide".

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.

Pharmacists take seriously their role as the primary source of drug information for their patients and provide 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.<sup>2</sup> Ideally, that care, known as medication therapy management (MTM) is delivered by a pharmacist with whom a patient has an established relationship.

While other approaches to delivering these MTM 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.<sup>3</sup> MTM is defined as "a distinct service or group of services that optimize therapeutic outcomes for individual patients [that] are independent of, but can occur in conjunction with, the provision of a drug product." It remains the consensus of the pharmacy profession that in order to perform the most comprehensive assessment of the patient a face-to-face interaction is required as this type of encounter optimizes the pharmacist's ability to assess non-verbal cues as well as to enhance the pharmacist-patient relationship.<sup>4</sup>

---

<sup>1</sup> Journal of the American Pharmacists Association. "Drug-risk communication to pharmacists: Assessing the impact of risk-minimization strategies on the practice of pharmacy." Jul/Aug 2008, pgs 494-500

<sup>2</sup> Journal of the American Pharmacists Association. "Patients' needs and interest in a self-pay medication therapy management service." Jan/Feb 2010, pgs 72-77

<sup>3</sup> 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

<sup>4</sup> American Pharmacists Association and National Association of Chain Drug Stores Foundation. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0). J Am Pharm Assoc (2003) 2008; 48 (3): 341-53.

Clearly, these MTM services could be utilized to meet the goals of a REMS program and should be designed as part of the Elements to Assure Safe Use (ETASU). In addition, as MTM services are currently compensated in both public and private health care plans, they should also be duly compensated as part of REMS.

Pharmacists currently provide MTM services for a variety of patients and these services are primarily paid for by Medicare Part D plans, although there are multiple private payers and state Medicaid agencies that also cover MTM services. There are a multitude of ways to document MTM counseling services, including several commercially available products as well as specific documentation platforms, many of which interface with community pharmacy management systems. The majority of community pharmacists have access to at least 1 if not more of the commercially available solutions, and those who participate in specific MTM programs, such as a state Medicaid MTM program, would have access to that specific platform. As you can see, community pharmacists are already providing these vital counseling services and should be utilized for the value of care they can bring to the REMS process.

### **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 and independent pharmacists' 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.

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.

NCPA would like to make the FDA aware of a currently existing network of community-based specialty pharmacies that provide a distribution channel, which allows immediate availability of specialty medications. The Community Specialty Pharmacy Network (CSPN) is a company founded by a group of independent pharmacy owners who have specific expertise in the specialty pharmacy segment. These independent pharmacists deliver individualized medication therapy management and utilize web-based software to uniformly collect and report data. CSPN offers an alternative for managed care organizations and payers when looking for partners to distribute both the specialty pharmacy product and the necessary counseling.

The face-to-face interaction with patients to discuss their complicated therapy management in a location where they can also receive their other medication needs is vital to improving outcomes and closing gaps in care that are ultimately experienced when a patient is forced to receive certain products from their community pharmacy and others from a mail order specialty facility. CSPN is proof that models do exist whereby community pharmacists can be compensated for not just dispensing a product but also for the counseling services that go hand in hand with the provision of care process. This face-to-face care can and should be compensated at the same if not higher level at which specialty mail order facilities are currently being compensated to ship high-dollar, complex products to patients with little more than written and verbal counseling via phone available.

Therefore, NCPA respectfully requests that 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 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. NCPA recommends that for purposes of REMS the FDA track training and certification at the pharmacy level. This is similar to how the iPLEDGE program and the Combat Methamphetamine Epidemic Act of 2005 training and self-certification requirement to sell pseudoephedrine-containing products currently operate. 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, which 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 supports a collaborative REMS approach such as the REMS solution designed by three private healthcare service and technology companies (Surescripts, ScriptPro and Mirixa). Leveraging existing standardized technologies, this REMS solution provides an end-to-end, scalable, systems-based solution for REMS. This automated approach can improve patient safety while minimizing the burden on both physicians and pharmacists.

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

At the July 27-28 public REMS meeting, FDA inquired what efforts were currently underway by pharmacy organizations to develop best practices from currently available REMS. NCPA is pleased to participate in an upcoming gathering of stakeholders to discuss REMS, hosted by the American Pharmacists Association (APhA). The stakeholder meeting will be held October 6-7 and objectives include discussing and identifying guiding principles for REMS solutions moving forward and the opportunity after the meeting to co-sign a stand-alone principles consensus document. Ultimately, the principles and proceedings from the meeting would be published as a White Paper to serve as additional guidance. NCPA looks forward to this opportunity to engage with other REMS stakeholders in order to seek best practices.

### **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. Metrics for determining the effectiveness of REMS should be specified at the time REMS are approved. Efforts to evaluate the effectiveness and outcomes of a given REMS and its individual components are just as important as the process of creating REMS. The components of any REMS must be proven to be effective in mitigating the specific defined risks and most importantly be practical for all stakeholders. 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.

We would welcome the opportunity to discuss our comments regarding this important matter with you further. Thank you.

Sincerely,



Ronna B. Hauser, PharmD  
Vice President, Policy and Regulatory Affairs