NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 03N-0017: Agency Information Collection Activities: Proposed Collection; Comment Request; Impact of Risk Management Programs on the Practice of Pharmacy

To whom it may concern:

The Food and Drug Administration (FDA) is asking to proceed with an information collection activity that would assess how risk management programs affect the practice of pharmacy drug safety. The National Association of Chain Drug Stores (NACDS) supports the FDA's initiative to improve safe medication use and assure that patients have access to valuable medication therapy, including those medications that have a higher risk of adverse effects.

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NACDS membership consists of more than 200 chain community pharmacy companies operating over 33,000 community pharmacies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice, with over 100,000 pharmacists. Chain operated community retail pharmacies fill over 70 percent of the 3 billion prescriptions dispensed annually in the United States.

Perspectives on Risk Management Programs: As a broad principle, NACDS supports the concept that, once a high risk drug is approved for marketing by the FDA, the drug should be available through any community pharmacy outlet that is willing and able to participate in the risk management program. This allows for appropriate use through educational programs, counseling, and other interventions available at community pharmacies. NACDS does not support the concept of risk management programs that involve distribution of medication through single or limited numbers of suppliers. It is important for the pharmacist that already has an established relationship with the patient, and who knows the patient's medical condition, to coordinate and integrate the "risk-managed" drug into the patient's existing prescription medication regimen. That is, if the patient is already taking multiple medications, it is important for the patient's regular pharmacy provider to help ensure that the new "risk managed" drug does not present any potential interaction problems for the patient. "Splitting" the patient's source of prescription medications in and of itself increases the risk of adverse drug reactions.

Chain community pharmacies are the primary and most frequent point of distribution for outpatient prescription drugs in the United States. In addition, community pharmacists provide an easily accessible point of contact for patients. Chain community pharmacies already have systems and procedures in place to assure the safe use of prescription drugs. As medication experts, community pharmacists also help ensure the safe and effective use of high-risk medications by patients. Integrating some of the systems and procedures used by community pharmacies into a risk management program is essential.

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It is also essential to ensure that risk management programs represent the collaborative efforts of the entire health-care team, including manufactures, physicians, pharmacists, the FDA and patients.

Comments on Survey Design: NACDS believes that information collected via Agency survey activity will be useful for the FDA regarding the impact of these programs on the practice of pharmacy. However, it is important that FDA recognize that it is often the chain pharmacy corporate headquarters that makes certain decisions regarding chain participation in these risk management programs, and how these programs will be implemented in the various pharmacies ir the chain.

Individual pharmacists that practice in chains can provide FDA with some insight into how these programs are implemented. However, the Agency would be missing a very important component of understanding the impact of risk management programs on pharmacy practice and operations if it did not survey a select number of pharmacy practice and operations executives of chain corpora headquarters.

The corporate level also makes determinations of how pharmacists in individual chains will be trained to participate in these programs, and how the programs can be integrated into the current workflow and patient care activities of the pharmacy. Many pharmacists that practice in chains may also first contact their chain management supervisor before completing any FDA survey on this topic. For these important reasons, the FDA should work with NACDS and chain pharmacy contacts to identify the best mechanism to assess the impact of these programs on the chain pharmacy environment. NACDS can assist FDA in contacting individual chain pharmacy companies for these consultations.

Comments on Survey Topics: NACDS previously submitted extensive comments to the FDA on issues relating to the implementation of risk management programs in pharmacy. We have appended a copy of those comments to this submission. We have highlighted several of these issues in this letter to reemphasize suggestions that any survey that is done assess the impact of th following aspects of risk management programs on the practice of pharmacy:

- **Registries and Patient Eligibility:** Professional or patient registries identify or provide important information about patients, physicians, or pharmacists involved with certain ris managed drugs. We understand the interest in using these registries, but there are operational concerns with using multiple registries. There is value to developing a centra registry or database that can be used by any manufacturer with a risk management progra that can identify those patients, physicians, and pharmacists who are eligible to participat in the program.

  This system would also indicate the quantity of medication that could be dispensed, whether or not refills are allowed, any monitoring or follow-up the pharmacy is required t do, as well as whether the patient has met all the qualifications and requirements for receiving the drug. Certain risk management programs require that patients have completed laboratory work, or met other clinical criteria before a drug could be dispensed This information could also be provided through a central database. We suggest that operational and practice issues relating to multiple registries, the importance of pharmacy access to patient-specific information, and similar issues be explored.

We are also concerned with the use of prescription "stickers" that indicate whether the patient has met the requirements of a risk management program. With electronic prescribing becoming a reality, paper-based sticker programs may quickly become outdated.

- **Restricted Pharmacy Access:** The survey should assess the impact on the practice of pharmacy if the distribution of the prescription is limited to certain pharmacies or just one pharmacy. That is because the patient's regular pharmacist or pharmacy may not be awar that the patient is taking a medication obtained through a restricted-distribution risk management program. This could present medication management problems for both the patient's traditional pharmacy and the other pharmacy providing the patient with the "risk managed" drug.

- **Patient Not Able to Present at Pharmacy:** It is common practice for persons other than the patient to bring in and pick up the prescription. It is not clear how the practice of pharmacy would be affected if the implementation of risk management program requires the patient to actually be present in the pharmacy to obtain the prescription.

- **Generic Versions:** NACDS is concerned about generic versions of brand name products that have risk management programs. That is, when a generic becomes available, does th generic have the same risk management program as the brand? We believe, that in order minimize confusion for the patient and the pharmacist, the program should be the same. I a survey, we would suggest that questions be asked about the impact on pharmacy of generic versions of drugs that have risk management programs.

  We also do not believe that risk management programs should be developed with the goa of potentially making it more difficult for generics to come to market, nor do we think tha FDA should approve generic versions with different risk management programs from the brand.

- **Assumption of Liability and Payment for Risk Management Services:** A fundamental question that must be answered as pharmacies consider participation in these programs is the nature of the risk and liability that pharmacies will be asked to assume, and how pharmacies will be compensated for taking on this additional liability. While pharmacies may be willing to participate in risk management programs, many are concerned about additional liability that they might incur by participating. In one scenario, the pharmacy may actually be asked to bear some of the additional liability that may result from providing a drug that has a higher than normal risk. In other cases, the manufacturer may assume the additional liability that is involved, shielding the pharmacy from any liability. These factors must be clearly articulated for pharmacies as they consider participation, an may affect participation. In a survey, questions should be asked regarding the type and level of risk that pharmacies and pharmacists might are willing to assume.

Payment to pharmacies must be commensurate with the liability that the pharmacy will be asked to assume. Regardless of the level of liability assumed, providing additional risk management services to patients results in additional costs to providers. FDA traditionally has not become involved in economic issues relating to the financing of prescription drugs. However, if the agency is going to require that health professionals perform certain additional activities relating to the management of a drug product, then it is logical to assume that pharmacists will be compensated for these services. The manufacturer should bear the financial burden of providing these services. We would ask that the agency explore some of these issues, since providing these services comes at a cost.

Please contact John Coster, Vice President, Policy and Programs at NACDS if we can provide additional information. Thank you.

Sincerely,

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