



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

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June 21, 2004

Docket No. 2004N-0221
Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: MMA Study on Making Prescription Pharmaceutical Information Accessible for
Blind and Visually-Impaired Individuals [Docket No. 2004N-0221]**

To whom it may concern:

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Then National Association of Chain Drug Stores (NACDS) appreciates this opportunity to submit comments on how to make prescription drug information, including drug labels and usage instructions, more accessible to blind and visually-impaired individuals. NACDS represents more than 200 chain pharmacy companies that operate nearly 32,000 community retail pharmacies in the United States. Our industry provides approximately 70 percent of all outpatient retail prescriptions.

NACDS members are committed to providing important prescription drug information to all patients, including those individuals who are blind or visually-impaired. Retail community pharmacies already provide many services that help such individuals better understand how to safely and effectively utilize their prescription drugs. Some of these services are listed below.

We preface our comments with what we currently know about the ability of these populations to obtain prescription medications. An informal survey of our members found that in most cases, blind or visually-impaired individuals are generally assisted by a caregiver when they obtain their prescription medications. Caregivers help instruct these individuals on how to take their medications, and supplement the information and counseling provided by the pharmacists regarding medications.

The vast majority of visually-impaired individuals served by chain pharmacies are elderly. Given that the elderly in general have compliance and adherence problems with their medications, a disability such as visual impairment can increase the difficulties in explaining medication regimens to these patients, and helping assure that they comply with their medications. Making products available in Braille to older Americans who may be blind or have severe visual impairments may not be very helpful because many of them probably did not have these visual impairment issues until later in life. For example, macular degeneration is a common problem among millions of Americans 65 or older.

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However, it may be difficult, if not impossible, to teach the elderly to read Braille at such late stage in life. Thus, innovative ways appear to be required to effectively communicate prescription information to elderly individuals who are blind or visually-impaired.

Services Provided by Retail Community Pharmacy to Assist the Blind and Visually-Impaired

Verbal-counseling: All retail community pharmacies provide detailed written prescription drug information to patients, as well as offer and provide face-to-face oral counseling. Direct interaction between patient and pharmacist is the most effective way to ensure that each individual, including the blind and visually-impaired, are aware of such details as dosage, whether or not a refill is required, and what potential adverse reactions are associated with each medication.

Some pharmacies provide kiosks to patients that serve as a resource for providing prescription information resources to all their patients. These kiosks might be adaptable to provide prescription information to blind or visually-impaired individuals. For example, pharmacies might be able to provide recordings of prescription information that can be listened to at the kiosk.

Magnifying Glasses in Aisles of Pharmacies: Some NACDS members make available magnifying glasses throughout their pharmacy aisles. This service can aid those visually-impaired individuals in reading the labels on over the counter drugs. Some elderly individuals could accidentally purchase the wrong medication leading to later complications, simply because they had trouble reading the label.

Assistance Filling Pill-Boxes: Another service that pharmacists provide is assisting blind or visually-impaired individuals coordinate their medications by using day by day pill-boxes, or even Braille pill-boxes that the individual could purchase. Some pharmacies may sell these special items or the individual could obtain them and bring them to their pharmacy for assistance.

Future Technology Available to Pharmacies

NACDS has identified various technologies that currently exist that could facilitate the manner in which blind or visually-impaired individuals receive their prescription drug information. Listed below are just a few of the technologies that are available:

- *Talking Rx:* This product attaches to the bottom of a standard prescription bottle and has an audio chip inside. By simply touching the only button (red) on the outside of the unit a patient can listen to the instructions for the particular medication such as; when to take it, how to take it, and possible side-effects. This product retails for around \$40. This could be expensive, though, for individuals that might need to take multiple medications. Attaching one of these devices to each medication container is important; however, to assure that an individual takes the correct medication in the correct way.

- *ScripTalk*: This product enables patients to use a small device no larger than a hand-held computer to read information embedded in a “smart label” on the prescription bottle. With the push of a button on the scanner that’s equipped with a speaker, label information is synthesized into audible language that provides patient name, dosage instructions, prescription date, number of refills remaining, drug interaction warnings, pharmacy phone number, etc. The cost of this technology might be high due to number of items required for its use. It is also not clear how pharmacies would incorporate these systems into their current workflow designs.
- *JAWS® for Windows*: This product works with a computer to provide access to software applications and the Internet. Using an internal software speech synthesizer and the computer’s sound card, information from the screen is read aloud, providing technology to access a wide variety of prescription information and education. JAWS also outputs to refreshable Braille displays. This technology could help patients access the information they need at home. However, it is limited to those individuals (or their caregivers) who are familiar with computers.

Recommendations

Based on discussions with our members, we would urge FDA to consider including the following recommendations in its report:

Create Braille-Based Written Information Leaflets: Retail community pharmacies do not create written prescription drug information on their own. They license the information from database companies such as First Databank and Medispan. While many blind individuals can read Braille, many elderly visually-impaired individuals cannot because their vision did not deteriorate until later in life. However, written prescription information provided in Braille-readable formats might help some blind individuals who can use these products effectively. The cost of developing this information, as well as the availability of systems and programs for distributing them, would have to be determined. Pharmacies can print traditional written information for almost all drugs, but it is not clear that the database companies produce, nor if the current pharmacy computer systems can provide Braille communications.

Create CDs of Prescription Information: It is possible that prescription information database companies can produce CD versions of their prescription information products that could be used by blind and visually-impaired individuals. These CDs could be used in computers, given that some blind and visually impaired individuals may have specially-designed computers.

Create a Telephone-Based Interactive Voice Prescription Information System: Many services now use voice response systems over the telephone (i.e. confirming airline reservations, ordering refill prescriptions). Prescription database companies could possibly create a 1-800 toll free voice-response system that would allow blind and visually impaired individuals to hear recordings of prescription information for the medications that they are taking.

Provide Grants to Prescription Database Companies to Develop New Information Products for these Populations: FDA could provide grants to public agencies and/or private sector organizations for blind and visually impaired individuals to help develop and test new products and services to provide prescription information to blind and visually impaired individuals.

Provide Payment to Pharmacies for “Special Packaging” for these Populations: MMA requires that Part D plans and Medicare Advantage plans provide medication therapy management programs to certain Medicare beneficiaries. Among the services provided under these programs is “special packaging” for pharmaceuticals that will enhance compliance with medications being taken. CMS should determine that blind and visually impaired individuals are eligible for this special packaging, and that pharmacist can then package their medications in these special containers. CMS should require Part D and MA-PD plan payment for these time and intensity involved in providing these services.

Conclusion

NACDS and its members companies are committed to providing quality health care to all patients, particularly those individuals with special needs such as the blind and visually-impaired. We feel that the services that our members already provide have proven beneficial to patients with special needs. Clearly, there are unique challenges to providing prescription information to this group, but the market appears to be responding with the development of new and innovative products. Pharmacies are eager to help provide these products, and want to be sure that the most cost-effective products are produced and used.

While written prescription information is currently provided as part of the array of professional services offered by pharmacies, other types of special written information or medication packaging for special populations may result in additional costs that should be borne by the third party payors or the individuals. Pharmacies are always willing to work with individuals and their caregivers to find the best way to enhance compliance with medication use.

Please contact us for any additional information you may need concerning this issue.

Sincerely,



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