

NORTHEASTERN ASSOCIATION OF THE BLIND AT ALBANY
NABA ~ *providing vision for a brighter future since 1908!*

June 4, 2004

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

To whom it May Concern:

This is to provide input in response to the Request for Comments published in the Federal Register dated May 20, 2004 (Docket number 2004N-0221). On behalf of the Northeastern Association of the Blind at Albany, Inc. (NABA), the New York State Rehabilitation Association (NYSRA), and the consumers we serve, I am happy to provide some background and focused comments regarding accessibility to prescription pharmaceutical information by people who are blind or visually impaired.

I am the Executive Director of the Northeastern Association of the Blind at Albany, Inc., (NABA) located in Albany, New York. NABA is a not-for-profit organization providing services, support, employment and training to people who are legally blind throughout New York's greater Capital Region. Prior to this position, I was Assistant Commissioner for the New York State Medicaid program with particular focus on long-term care services for seniors throughout New York State. Additionally, I am a member of the Board of Directors for the New York State Rehabilitation Association, an organization representing providers of services to people with varying disabilities including people who are blind. I also am co-chair of the Vision Services Division representing all agencies serving people who are blind in New York State. As such, I hope to provide a more comprehensive perspective to the needs of people who are blind; especially seniors who are experiencing vision loss and legal blindness.

Clarifying Blindness:

Blindness is caused by a variety of factors affecting people of all ages. Some of the major causes of blindness include age-related macular degeneration (ARMD), glaucoma, diabetic retinopathy, cataracts, retinitis pigmentosa, and other causes. While blindness is a serious and significant disability, it is important to know that only about 10 percent of people who are blind throughout the United States have no sight. Approximately ninety percent of people experiencing legal

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blindness have some remaining useful vision. Legal blindness occurs when people have a reduced field of vision of 20 degrees or less or when they have vision of 20/200 after best correction. Of the population that is legally blind served by our agency (NABA), between 65 and 70 percent are over the age of 65. This is not unique to NABA but is a fair representation of the statewide and potentially nationwide population of people who are legally blind. ***Hence, legal blindness is a much broader problem affecting seniors than most people would think.***

Impact on Activities of Daily Living:

Vision loss has a direct impact on the ability of people to perform Activities of Daily Living (ADLs) as well as Instrumental Activities of Daily Living (IADLs). As people lose their ability to manage IADL and ADL functions, there is an increasing likelihood they will require more costly interventions and services. The list includes hospitalizations resulting from falls or other incidents in their home, community-based long-term care services to assist with the IADL and ADL activities, increased risks of isolation and depression, and increased misadministration or non-compliance with medication regimens.

Our experience demonstrates that vision impairment results in a loss of feelings of independence and confidence. Our professional staff spends a considerable amount of time working with people experiencing vision loss and blindness to help them cope with the loss of their vision. In addition to the emotional supports offered, professional staff from blindness agencies throughout New York State and the country provide hands-on training, tools and techniques to help people enjoy as much independence as possible despite their vision loss. The ADL and IADL training provided captures a full range of activities that people who are sighted generally take for granted including mobility training, maintaining a household, maintaining health and personal care, safe travel, and communication with various media. ***This training also includes helping people better manage their medications and related items.***

Blindness agencies throughout the country offer training that provides people who are legally blind with the techniques and devices to improve their management of prescription drugs.

Prescription Drug Utilization:

Seniors take, on average, 7 or more prescription drugs daily. When that volume is combined with vision loss or legal blindness, problems can occur. If we assume that only 10 percent of hospitalizations of seniors are the result of medication errors (either misadministration or failure to follow drug regimens due to inability to discern the drugs), there is an estimate of over 80,000 inappropriate hospitalizations in New York State alone. At approximately \$16,000 per hospitalization, preventable hospitalizations in NYS only, from medication misadministration, could total over \$1.2 billion. The error rate for seniors who are visually impaired (estimates indicate that there are as many as 26% of seniors experiencing vision loss) could be significantly higher.

The FDA's interest in making prescription pharmaceutical information more accessible for people who are blind and visually impaired is to be commended. However, understand that people who are blind are just like people who are sighted in many ways. Some people who are blind are extremely sophisticated at using technology and other assistive devices, while others have never used a computer or any other form of technology. There are people who are blind who do not read Braille and while others read using large print. There are people who are blind who cannot read or speak foreign languages. ***Therefore, success in producing accessible prescription pharmaceutical information must take many forms.***

How Information is Accessed:

People who are blind access their pharmaceutical information in much the same way sighted people do- from their doctor, from their pharmacist, from research. The only difference is printed material must be available in whatever format is best for the individual who is blind or visually impaired. This means providing the written material in large print format, audible, Braille or even other formats. People who are losing their sight late in life (e.g., seniors) from Age Related Macular Degeneration have additional challenges. Being used to sight but not yet fully accepting their new limitations they are struggling with loss of vision. This group of the population needs reminders, verbal cues, and organizational techniques or tools to assist in their management of medications.

Consideration for the multitude of options available for this population is truly necessary. Blindness agencies throughout the country can and do provide the tools and techniques necessary to help people experiencing blindness and vision loss better understand the information about their pharmaceuticals. These people learn to better manage their medications. Pharmacies, medical professionals and others should utilize these valuable services from blindness agencies so that their patients and customers have improved health outcomes.

Other Public Policy Implications:

The implications for Medicaid and Medicare are significant in the long-term care realm. Interventions are necessary and appropriate to ensure people stay as independent as possible as long as possible.

Interventions and Approaches:

There are many different potential means to provide life-enhancing pharmaceutical information to people who are blind. Some are basic such as large print or Braille. However, some people require other means to get their information for example, the use of talking devices that explain what prescription drug the person is taking. Or perhaps it may be decidedly low tech including

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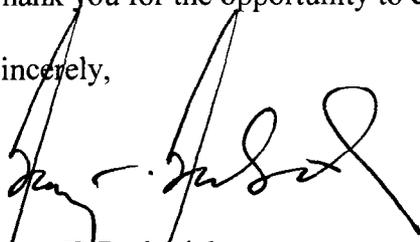
simple pill organizers. ***However, like people who have sight, people who are blind are not functioning all the same. Different approaches to getting information are necessary.***

Affordability of the various approaches also has to be a real consideration. While a complex computerized bar code scan-based system might provide tremendous information distribution capabilities for consumers as well as pharmacies and regulators, it most likely will be far too costly and cumbersome to address the basic issue. ***That basic issue is: what can be done to ensure people who are blind get the information that is necessary to safely and intelligently manage and adhere to their pharmaceutical regimens? Simple approaches should not be overlooked- especially if they can help achieve significant cost-efficiencies and cost savings to taxpayers and others.***

Blindness agencies have for over 50 years provided simple yet effective interventions, tools, and techniques to help people who are blind manage their lives with their vision loss. The approaches used shall be very effective in ensuring people who are blind receive important information about the pharmaceutical drugs they are taking and manage the administration of those drugs.

Thank you for the opportunity to comment on this important area.

Sincerely,

A handwritten signature in black ink, appearing to read "Barry T. Berberich". The signature is fluid and cursive, with a large loop at the end.

Barry T. Berberich
Executive Director

Northeastern Association of the Blind at Albany, Inc.
Member, Board of Directors, New York State Rehabilitation Association