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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration
[Docket No.2004N-0221]: Medicare Prescription Drug, Improvement, and Modernization Act of 2003; Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals; Establishment of Docket; Request for Comments AGENCY: Food and Drug Administration, HHS. ACTION: Notice; establishment of docket; request for comments. -----

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a docket to receive information and comments on certain issues related to the accessibility of pharmaceutical information to blind and visually-impaired individuals. This action is intended to ensure that there is a venue for information and comments to be communicated to the agency for consideration in a study on making prescription drug information accessible for blind and visually-impaired individuals, which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act). DATES: The agency encourages interested parties to submit information and comments by June 21, 2004. ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rmdd1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/stecomments>. FOR FURTHER INFORMATION CONTACT: Poppy Kendall, Office of Policy (HF- 11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, e-mail: poppy.kendall@fda.gov

Request for Comments SUBMITTED BY Barry Scheur, J.D., President and CEO, TALKING RX, INC., Newton, MA 02458.

The purpose of these comments is to provide information pursuant to the request of the Food and Drug Administration for comments regarding: A Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals.

PLEASE NOTE that Mr. Scheur is totally blind himself (from birth), and is a healthcare executive who has spent thirty years in consulting and working at senior corporate policy and operations levels within the pharmaceutical and insurance industries, as well as having served as a consultant to state governments and the predecessor of CMMS, the Health Care Financing Administration.

Talking RX, Inc. (formerly Millennium Compliance Corporation) has been providing accessible and inexpensive prescription devices for the past four years. Talking RX has patented, manufactures, and markets the Talking RX Prescription Accessory, which is a simple reusable digital recorder that attaches to the bottom of the most common sized prescription vials and allows for the recording of necessary medical and prescription information. Thousands of units have been distributed to the blind and visually impaired, the elderly, and those for whom written English comprehension is not their primary means of communication. The device meets FDA "light and tight" requirements and has been available through web-site and toll-free phone ordering for over four years. The device's inventor, John Dobbins, R.Ph, is a clinical pharmacist with some twenty years of practical experience in counseling visually challenged patients in both retail and hospital settings.

For the past ten years, recognizing that the obligations of pharmacists and pharmacies were not being met when it came to the needs of the visually impaired, Mr. Dobbins spent thousands of hours and hundreds of thousands of dollars evaluating, patenting, and then manufacturing the Talking RX device. In having the device used and evaluated over a four year period by healthcare agencies, pharmacists, physicians, and individuals that represent a cross section of blind and visually impaired, senior citizen, and non-English speaking users, the company has gained a great deal of knowledge about the market, the variety of needs that must be fulfilled, and the alternatives that should be considered in framing the study to evaluate the use and efficacy of Prescription Access Information materials and devices. The following sections address the questions raised in the Notice Seeking Comments on the proposed study.

A. Information about the Population of Interest:

1. What is known about the population of people who are blind and visually-impaired in the United States (e.g., information on age of onset; cause of impairment, congenital defect versus disease-related versus injury, extent and type of impairment; association between visual impairment and age, hearing loss, co morbidities, health outcomes, socio-economic status, health literacy, and adaptive learning capabilities)?

In our work with developing adaptive information technologies to meet the medication and prescription information needs of the blind and visually impaired, there are a number of issues about the definition, age of onset of blindness, and demographics of those with vision impairment that are relevant, and they are as follows :

(A) It has been estimated that there are approximately between 1.25 and 1.5 million people in the U.S. who are legally blind, in other words, with no better than 20 / 200 corrected vision in the better eye. For the purposes of those who have difficulty reading medication information or prescription bottle information, the estimate we use is that approximately between 3 and 4 percent of the population have vision loss sufficient to impede the performance of one or more of the activities of daily living. This would encompass caring for oneself as far as taking care of their medical needs is concerned, and this has been our experience in terms of those who purchase and use the Talking RX device.

(B) It has further been estimated that fifty percent of those with a visual impairment that results in difficulty with performing one or more activities of daily living is 65 years of age or older.

(C) It has been further estimated that one third of all individuals age 85 and over have a visual impairment.

(D) In considering this information with regard to the need for assistance with adaptive medication devices, the necessary conclusion is that any device must be simple to operate and maintain, given the predominance of the connection between visual impairment and the elderly population.

2. Is there an appropriate way to divide this population into subpopulations to better evaluate needs and beneficial technologies?

Several factors must be taken into account when evaluating how the visually impaired population should be viewed for assessing the utility of technology and other information

sources to aid in gaining access to medical and prescription information, and they are as follows :

(A) It is estimated that approximately ten percent of the legally blind population, or 500,000 individuals, have some level of facility with Braille. This is even a smaller percentage when those with any form of visual impairment are considered.

(B) Unlike the sighted population whose use of computers and the Internet has grown rapidly, it has been estimated that only about twenty percent of the legally blind population in the United States are able to utilize specially adapted software (screen readers or magnification devices) sufficient to access the Internet. This technology is both expensive and challenging to learn to use effectively. Screen readers or magnification software costs between \$500 and \$1,000 in addition to the price of the computer. For those individuals who prefer or by necessity, as in the case of deaf blind individuals, need to use Braille, Braille access displays cost between \$4,000 and \$10,000, depending upon the type of equipment.

(C) It is accepted that those who lose their sight later in life have a greater difficulty learning Braille. For seniors and those with other disabling conditions, in addition to visual impairment, gaining computer access skills with the adaptive technology available is even more difficult, and therefore, not a particularly acceptable solution when it comes to the necessity of having access to medical and prescription information that would permit an individual to continue to live independently.

(D) It should also be noted that dyslexia and other conditions that make reading and comprehending information more difficult account for a significant portion of the population far beyond the number of those individuals classified as either legally blind or having a condition that makes reading labels difficult. For illustrative purposes only, the largest provider of educational materials to the blind and visually impaired population, recording for the Blind and Dyslexia, estimates that less than twenty percent of their approximately 108,000 active users are legally blind, while the remaining eighty percent have conditions that still require the use of recorded information. Therefore, limiting the study as provided for in the Medicare Prescription Drug Improvement and Modernization Act to those who strictly fit the "blindness" definition may not be fulfilling the broader need for access to medical and prescription information.

B. Information about the Use of Prescription Medication Information by People Who Are Blind or Visually-Impaired:

1. How do people who are blind and visually-impaired currently get their prescription drug information?

In our five years of providing products that allow for accessing drug and prescription information, our experience has been as follows:

(A) For the most part, sighted assistance is required, either through information being read to a blind or visually impaired person by a sighted family member, caregiver, physician, or pharmacist. The devices that have been made available that facilitate gaining access to this information are not in wide circulation, primarily because they have not been covered under traditional health insurance or Medicare coverage.

(B) A variety of labeling devices exist to identify the contents of bottles or packages, but those devices generally do not permit duplicating the full range of information contained

on a prescription label, nor are any of the medication instructions or warnings accessible. For the most part, blind and visually impaired people are forced either to rely on sighted or caregiver assistance, or to label packages or bottles to identify the contents only.

(C) The low tech devices that are widely commercially available, such as pill organizers and timers, do not identify either what is in the container or a reminder about when to take it in any audible form. Pill organizers are sold with Braille labels, but this doesn't prevent the pills from spilling out and being randomly replaced, and all of the timers that are on the market only beep, but do not provide any verbal feedback to indicate the meaning of any beeps.

(D) In summary, access to medical information and adaptive medical device technology has been severely neglected by the companies and organizations that are in the best position to facilitate providing such access. The President of Talking RX, Barry Scheur, J.D., is a blind healthcare executive who has spent thirty years in consulting and working at senior corporate policy and operations levels within the pharmaceutical and insurance industries, as well as having served as a consultant to state governments and the predecessor of CMMS, the Health Care Financing Administration. Neither health insurers, nor retail pharmacy chains, nor drug manufacturers have considered it a priority to facilitate the accessibility of medical or insurance information to this point. Pharmacy e-commerce and drug manufacturers' information websites are not required to meet standards of accessibility for adaptive computer software, so much of this information if available, must also be provided through the assistance of sighted individuals. Blind and visually impaired individuals are at a severe disadvantage when it comes to health and safety, not to mention the potential for life threatening mis-identification of drugs in the current environment.

2. What aspects of visual impairment are important to addressing the issue of access to prescription drug information? What other factors (see examples listed in Question A1) might be important to addressing this issue?

The most significant issues to address are as follows:

(A) Surveying a large enough representative sample of those classified as visually impaired within the broadest definition to ascertain the types of drug and medication information to which they want and need access, and the format in which it needs to be provided, e.g., Braille, large print, labeling type device; accessible web site, etc.;

(B) Surveying those same individuals as to how they currently receive, and to what extent they receive drug and medication information today, and identifying the best mechanisms for disseminating how such information and devices could best be made available to this population. Options would include the various consumer organizations of the blind (American Council of the Blind, National Federation of the Blind, Blinded Veterans' Administration), the specialty retail and catalog product companies that serve this population, state and governmental rehabilitation agencies that furnish training and assistance to this population, private agencies that do likewise, and various service and charitable organizations whose mission is geared to improve the quality of life for the blind and visually impaired, such as the Lions' Clubs;

(C) Surveying medical facilities and physicians that most frequently deal with visual impairment issues (ophthalmology and gerontology) to determine to what extent, if any,

they provide any special or unique services to facilitate the provision of medical or prescription information to visually impaired patients;

(D) Surveying insurance companies, HMO, PPOs, Medicare Plus Choice, Medicare Supplemental carriers, and Pharmacy Benefit Management companies on the ways, if any, that they have made their information accessible to those members with a visual impairment, particularly as it pertains to counseling as to the use of medications and the services they provide;

(E) Surveying the top twenty pharmacy retail chains as to their requirements, if any, for counseling and advising patients who are known to have or may have a visual impairment as to the best ways to use the drugs and medications that they proscribe, and the extent to which, if any, training programs for pharmacists or medical technicians in assisting visually impaired customers have been established.

3. How can essential drug information be effectively communicated to people who are blind or visually impaired?

Based on our company's experience in selling such adaptive products, and in the experience of the pharmacist and inventor of the Talking RX who has counseled visually impaired clients throughout his career in retail and hospital pharmacy, we believe the following options are viable and necessary:

(A) Encourage pharmacy retailers to establish training programs for their pharmacists and medical technicians to identify those visually impaired customers who might benefit from access to such alternative information and technologies, and alternatives that exist for identifying, labeling, or otherwise having access to such information;

(B) Encouraging and ultimately requiring drug manufacturers and PBM companies, as a condition of having their products and services provided and reimbursed under the Medicare program, to make available drug and medical information in a variety of formats and technologies sufficient to meet the needs of this population. Drug manufacturers spend hundreds of millions of dollars on promoting their products through mass media to consumers, and spend additional large sums on educating physicians and insurance companies about the benefits of their specific medications. We believe that the manufacturers and the PBM companies are in the best position, through their distribution channels, to educate and ultimately ensure that alternative technologies and information are put into the hands of those consumers whose very lives may depend on their ability to completely follow medication regimens.

4. Are there data associating medication errors with blindness? With visual impairment? What types of medication errors are most common among people who are blind or visually impaired?

As far as we are aware, there is no clinical or empirical data available on the number and extent of medication errors caused by the inability to have access to medical information, to follow drug regimens, or to identify the contents, instructions, and warnings associated with different medications. Our company has currently launched several clinical trials in partnership with two hospitals to gather this information. Our anecdotal experience however, in serving thousands of blind customers, is that medication errors are of high

frequency when it comes to the visually impaired population. The most frequent errors seem to be mis-identification of a particular bottle and of forgetting the specific instructions on when and how to take medications. We are specifically aware of a number of instances where failure to take medications as needed has resulted in severe illness requiring additional hospitalization and treatment.

C. Information about Existing and Emerging Technologies (Including Internet-based Information Sources):

1. What assistive technologies are currently used by people who are blind or visually-impaired? In what setting?

Blind people typically either label their medications with Braille, or utilize one of several labeling type technologies to identify the contents and specific instructions connected with their medications. These technologies are neither widely available, nor are they covered by insurance or Medicare, nor have they been made available through traditional consumer retail outlets. Our own device, the Talking RX, is a simple digital recorder that securely attaches to the bottom of all prescription vials in common use, meets FDA "light and tight" requirements, and is re-recordable and re-usable for new prescriptions. The device has replaceable batteries, one set of which will last for approximately nine months with intended everyday use. The recorder has a built in, high quality, digital speech chip to permit sixty seconds of recorded information, which we have found sufficient to provide not only information about the contents of the bottle, but a detailed summary of instructions and warnings connected with the medication. The Talking RX requires no separate reader or connection to the retail pharmacy or mail order refill company's computer system. These devices retail at about \$9.95 and are available through the e-commerce sites of www.walgreens.com and www.cvs.com as well as through toll-free ordering and our web site, www.talkingrx.com. Discussions are ongoing with a large number of major insurance carriers, the Veterans' Administration, and private and public agencies that provide services to the blind and visually impaired. There are also a number of other such devices, some which require that consumers purchase separate "label reading" devices and others which attach to the computer system of the pharmacy to generate a recorded message.

2. What proportion of people who are blind and visually-impaired currently use these technologies? Are there specific characteristics (see examples listed in Question A1) of this "user" population that distinguishes them from blind and visually-impaired individuals who do not use these technologies?

We estimate that there are approximately 5,000 blind and visually impaired people utilizing our technology today. The greatest limitations that distinguish the use and availability for these technologies to be utilized, in our experience, consists of the following:

- (A) Knowledge by blind and visually impaired potential users that the device exists;
- (B) Coverage for the device by health insurance plans and Medicare;
- (C) Lack of availability of such devices through consumer retail outlets, and;
- (D) Lack of education among health care and medical professionals about the ways in

which blind and visually impaired patients can access prescription information. In discussing coverage for such devices with more than twenty major insurers, all of whom provide for coverage to Medicare patients, the prevailing response has been that in the absence of clinical data, there is no justification for making these devices available as a covered benefit or as part of a co-payment mechanism.

3. Is there data on the effectiveness of these technologies?

The data that we have on the effectiveness of this technology is through a significant number of testimonials from users on just how important the Talking RX has been to their ability to live independently and prevent harmful medication errors. We will be happy to provide such information to the FDA upon request.

4. Do these technologies contribute to an increase or decrease in medication errors reported amongst people who are blind or visually impaired?

We believe that those technologies result in a decrease of medication errors, and furthermore, in a significant savings derived from reduced hospitalization episodes and incidences of care. Testimonials from our users have indicated a belief that without the Talking RX, they would no longer be able to live independently and take care of their own medical needs. We further believe that blind and visually impaired consumers mirror the general population in mistakes made as a result of being unable to identify or follow through with a medication regimen. While a sighted person may hesitate in knowing the contents of a particular bottle due to night time or other conditions which make the visual identification of the bottle less certain, without any labeling at all, it is not difficult to surmise that faced with a similar situation, a blind or visually impaired patient will simply wait until sighted assistance is available, thereby not following the medication regimen. Common sense strongly suggests that medication errors would be much more prevalent among blind, visually impaired, the elderly, and those for who English is not their primary written means of communication than for sighted users that rely primarily on the use of written English instructions.

5. What is the cost of these technologies?

Technology that provides labeling assistance for medication bottles costs between \$10 and \$300. We believe that, given the number of medications that are routinely prescribed for seniors that it is essential for any device to be cost effective to be re-usable and inexpensive.

6. Who are the primary purchasers of these technologies? Is use of these technologies currently subsidized by any government or private program?

From our experience with thousands of these devices being purchased, we believe that approximately fifty percent of them are purchased either for re-sale by vendors that specialize in providing merchandise to the blind or visually impaired or by agencies that provide services to the visually impaired. The remaining fifty percent are either

purchased directly by blind or visually impaired individuals or by members of their families for their use. None of our purchases have been subsidized by governmental or private agencies, although we expect that within the next several months, several insurance plans will begin to provide coverage of the Talking RX as a benefit under their health insurance plans.

7. What are barriers to use of these assistive technologies?

The barriers, in order of being ranked from most to least significant, in our experience are as follows:

- (A) Awareness within the potential marketplace - there is no single frequently consulted source for information on availability of devices such as these;
- (B) Unfamiliarity of medical personnel with the widespread need for and use of such devices;
- (C) Lack of availability of these devices through major retail pharmacy outlets;
- (D) Cost of such devices;
- (E) Failure of insurance plans and Medicare to provide coverage for such devices.

8. What is the practicality of these assistive technologies?

We believe, based on five years of feedback from customers, that a simple, affordable, and easily replaceable device represents the most practical solutions to the issue of availability and accessibility of prescription information and reduction of compliance errors arising from the failure to have such a technology readily available. Given the propensity of seniors making up the vast majority of the population that will benefit from these devices, any such device needs to be:

- (A) Usable independently;
- (B) Inexpensive, so that multiple units can be used where the patient takes multiple prescriptions;
- (C) Re-usable, and contain replaceable batteries;
- (D) Easily recordable by the patient's pharmacist, physician, or care giver;
- (E) Accommodate language differences, and;
- (F) Conform to multiple vial sizes and those most frequently utilized in mail order programs.

9. How do people who are blind or visually-impaired learn of these technologies?

Blind and visually impaired consumers most frequently learn of these devices through the following mechanisms:

- (A) Consumer organizations to which they belong;
- (B) Rehabilitation professionals providing education or training to assist such individuals;
- (C) Private and government agencies providing a wide array of services to the blind;
- (D) Publications directed to the blind population;
- (E) Charitable organizations making those devices available to clients to whom they provide services, such as the Lions' Clubs;

- (F) Merchandise catalogs directed at blind or visually impaired consumers;
- (G) Word of mouth by other users.
- (H) In summary, at present, traditional advertising and retail channels have not been available for these devices, and they will not be given their proportion of the limited market, until the price of the device is sufficiently inexpensive to make it viable for the retailer to gamble on carrying the product or it is covered as a benefit by health insurers, Medicare, or Medicaid.

9. What is the most effective resources for conveying information about these assistive technologies to blind and visually impaired individuals?

The most effective mechanisms seem to be word of mouth from satisfied users, blindness related specialty publications, agencies providing services to the blind and visually impaired, and catalogs of specialty merchandise directly to the blind and visually impaired.

10. Are there emerging technologies that show promise? If so, what is the anticipated cost and timeline for market entry?

The principal barrier to the use of such technologies is the willingness of retail pharmacy chains to make them available and to provide the information necessary to make their use simple. Retail pharmacy companies do not want to engage in extra expense, computer modifications, or additional training to make such technologies readily available. At some point in the future, an automated recording and delivery system may well be an effective way for conveying such prescription information, but for the next three to five years, we believe that an inexpensive and simple digital recording bottle attachment that meets FDA requirements is the preferred delivery mechanism for such information.

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