

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

Prepared by: David Raistrick – En-Vision America, Inc.

Request for Comments

To assist in this effort, we are asking for public comment on the following issues:

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 (e.g., congenital defect versus disease-related versus injury); extent and type of impairment; association between visual impairment and age, hearing loss, comorbidities, health outcomes, socioeconomic status, health literacy, and adaptive learning capabilities)?

Please see Reference A: Testimony Before the Senate Special Committee on Aging Hearing on Technology and Prescription Drug Safety.

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

Please see Reference A: Testimony Before the Senate Special Committee on Aging Hearing on Technology and Prescription Drug Safety.

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?

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On an ongoing basis, people with sight impairment may use one of many “Memory Based Coping Strategies” to identify their prescriptions. Examples include: Using tactile identification markers (ie. rubber bands), Pneumonic memory aids (ie. writing a letter or number with a heavy black marker on top of medicine vial), and/or organizing medications inside a medicine cabinet or medication tray.

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 #AI) might be important to addressing this issue?

I. Safety - Lack of Communication: Oftentimes, communication breakdowns between the patient and primary care/pharmacy exist. Critical information that is not communicated related to the medication could lead to dire consequences.

Lack of Reinforcement - As with the sighted population, patients must receive ongoing education from physicians, pharmacists and the nursing staff about the brand and generic names of medications they are receiving, their indications, usual and actual doses, expected and possible adverse effects, drug or food interactions, and how to protect themselves from errors.

But, even with perfect communication, it would be expected that any memory based strategy would be prone to mistakes due to forgetfulness and organizational miscues of the patient.

Lack of Patient Involvement: Patients play a vital role in preventing medication errors. In fact, they are encouraged to ask questions and seek answers about their medications. Without full prescription information, the individual is severely limited in their ability to formulate cogent questions about their medications, instructions, dosage, side effects, efficacy, indications, or contraindications.

II. Privacy - Because visually impaired patients are unable to read their medication instructions, they will never have the ability to independently

manage their own medication regimen. They are therefore forced to give to give up their rights to privacy with regard to their medications and medical condition.

On April 14, 2003 the first-ever federal privacy standards to protect patients' medical records and other health information took effect. Developed by the Department of Health and Human Services (HHS), these new HIPPA standards provide patients with more control over how their personal health information is used and disclosed. In particular, with the new HIPPA privacy rule, patients can request that their doctors, pharmacies, health plans and other covered entities take reasonable steps to ensure that their communications with the patient are confidential. For example, a patient could ask a doctor to call his or her office rather than home, and the doctor's office should comply with that request if it can be reasonably accommodated. We believe this should include a patient's request of pharmacy to modify the mode the communication of their prescription information.

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

Voice is the best mode of communication to the patient. With this, it is also very important that the device have sufficient volume along with volume control. Another requirement would be for an earphone jack for privacy and use of augmented hearing devices.

Why not Braille? It is estimated that less than 10% of the visually impaired read Braille. In addition, it is very difficult for a pharmacist to verify Braille information.

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?

To our knowledge, there is a lack of reporting with regard to medication errors and their causes in the U.S. Also, very little is known about the poor therapeutic outcomes with regard to non-compliance.

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?

Please see Reference B for examples of ScripTalk product literature.

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

In the private sector, a very small proportion are currently taking advantage of these technologies primarily because lack of knowledge of such systems along with a lack of availability at local pharmacies.

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

One of the objectives of the VA Pilot Study of ScripTalk was to determine if the systems is easy and effective for the patient to use.

“The ScripTalk stands out when compared to competing devices in it overall adaptability to the needs of Blind Rehabilitation Center Clients, ease of use, and ease of pharmacy implementation.”
Hines VA Blind Rehabilitation Study; April 2001

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

Any of these solutions require a patient’s ability to self medicate. With a lack of data on medication errors being reported, we must rely on foresight and common sense with regard to how and why errors are made. Therefore, one can easily state that a patient with knowledge and information access will make far less errors than a patient without that information.

5. What is the cost of these technologies?

The current cost of the ScripTalk is approximately \$250 for the ScripTalk reader and about \$1.50 per label. The pharmacy printer costs about \$1,650 each.

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

Over the last three years, ScripTalk Talking Prescriptions have been effectively used by the U.S. Department of Veterans Affairs. Over 700 patients currently use the product in nearly 20 facilities across the U.S. The VA has also issued a Directive to provide “uniform criteria for the purchase of Audible Prescription Reading Devices and equipment by medical facilities”.

“It is VHA policy that audible prescription reading devices are furnished to eligible veterans by the facility Prosthetic and Sensory Aids Service.” **Department of Veterans Affairs - VHA DIRECTIVE 2004-006**

A small pharmacy chain in the Greater Omaha area (Kohll’s Pharmacy and Homecare) is providing ScripTalk labels to their customers. In addition, Kohll’s offers ScripTalk labels to customers on a mail-order basis. There is no extra charge for the special label.

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

Because of the relatively small size of this population, pharmacies are reluctant to gain further understanding as to the safety and privacy needs of these customers. The primary barrier for pharmacies’ is a failure to acknowledge a role in providing this private information in a usable alternate format.

8. What is the practicability of these assistive technologies?

The ScripTalk system has been in operation in many pharmacies for over three years. There have been no problems with regard to increasing labor or cost of delivery of prescriptions.

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

Most find out about these technologies by:

Primary Care: Doctors, Nurses, & Pharmacists;
Homecare Services: Nurses & Social Workers
Word-of-mouth: Friends & Family Members;
The Media: Radio, Television
Low Vision Trade Fairs

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

ScripTalk Readers should be prescribed by their Physician and issued as Durable Medical Equipment (DME). The minimal training necessary for the device can be accomplished through the registered DME retail outlet.

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

RFID continues to prove to be the most inexpensive and effective way to store prescription information onto medications. En-Vision America is continuing the development of ways to reduce the cost of the ScripTalk system components.



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David Raistrick
Vice President

**Testimony Before the Senate Special Committee on Aging
Hearing on Technology and Prescription Drug Safety
Peter A. Klein, R.Ph.**

May 3, 2001

Good afternoon. Mr. Chairman and Members of the Special Committee on Aging, thank you for the opportunity to speak with you this afternoon regarding technology and prescription drug safety. I am Peter A. Klein, a pharmacist and Vice President of Business Development for En-Vision America. En-Vision America is a privately held company that was founded in 1996 to develop and market technologies aimed at assisting the Visually Impaired to live a more independent lifestyle. Our most recent invention has been developed into a commercially available product known as the ScripTalk™ Talking Prescription Label System. The ScripTalk™ System is a cost effective method that promises to enhance the Safety of millions of Senior Citizens as well as a staggering number of Americans afflicted by other conditions or situations that prevent them from reading or understanding the directions that appear on their prescription labels.

Currently, there are over **120 million** Americans who have difficulty reading or understanding the instructions of their prescription medications. In many cases, even identifying the contents of the prescription package is impossible. The small print and look-alike packaging of medicine vials can lead to confusion, non-compliance, and ingestion errors. The repercussions of such adverse events are immense and increase healthcare costs through additional hospitalizations, doctor office visits and changes to or addition of drug therapies.

En-Vision America set out to develop a technology that would allow the visually impaired to safely manage their own medication regimen. The result is the ScripTalk™ Talking Prescription Label System, which combines radio frequency identification technology with advanced voice synthesizer capability to deliver a cost effective solution for those unable to read or understand their prescription instructions.

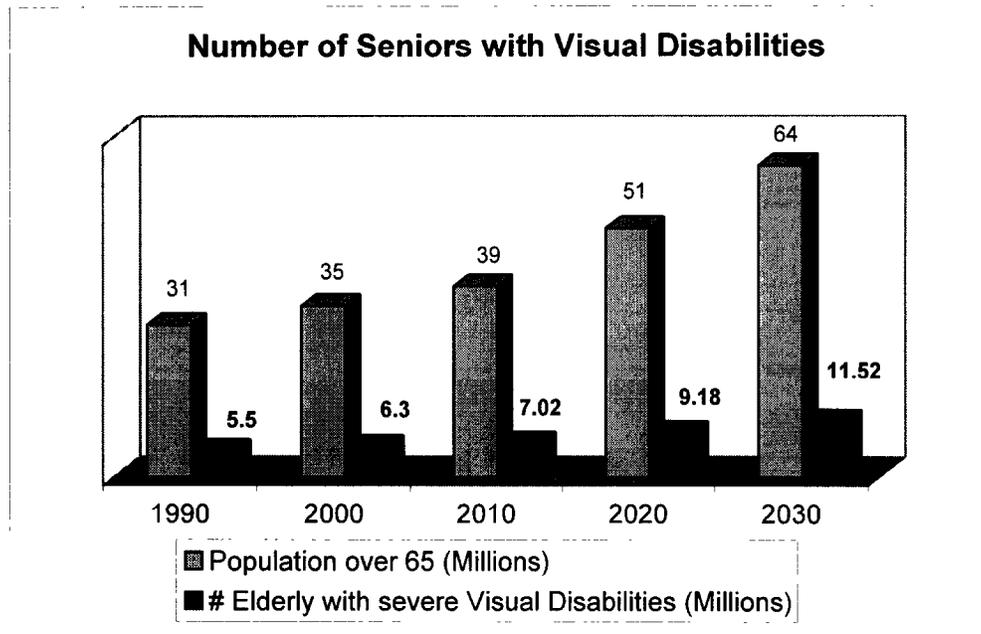
Medication errors have been in the forefront of the news lately. The seriousness of this issue has been articulated by Institute of Medicine (IOM) reports that state up to 2 million people are hospitalized from side effects or reactions to prescription drugs. The IOM survey, however, does not consider statistics related to poor therapeutic outcomes as a result of **non-compliance**. A non-compliant patient does not achieve the expected benefit of their drug therapies, and their conditions may not improve or even worsen because they did not take enough medication or they did not take it at the proper interval, or worse yet, they overmedicated themselves.

Compliance cannot occur for up to 42% of United States Citizens due to their inability to read, translate, or comprehend the instructions and warnings that appear on their prescription containers. The ScripTalk™ Talking Prescription Label System eliminates this barrier to compliance by actually reading the text of a prescription label aloud to the user.

Seniors with Severe Visual Impairment

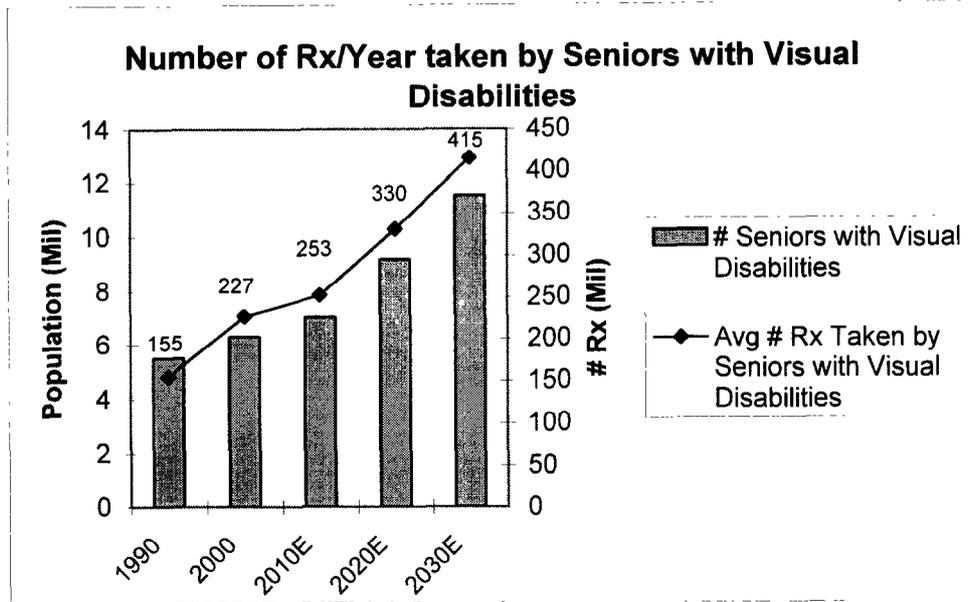
The United States Census Bureau reports that at least 18% of Americans over the age of 65 have a functional limitation seeing words and letters or are unable to see words or letters. There are currently more than 35 million Americans over the age of 65, and approximately 6.3 million may not be able to safely read the directions that appear on their prescription labels.

Exhibit 1 demonstrates the current population, along with well-known projections that depict "The Graying of America".



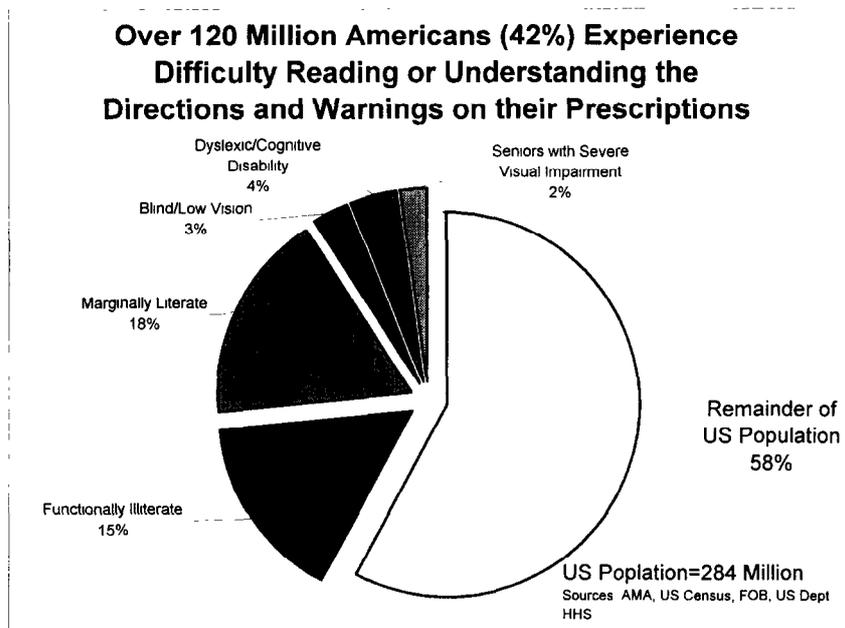
According to several Prescription utilization reporting agencies, Seniors over the age of 65 consume, on the average, 36 filled prescriptions annually. Therefore, in the year 2000, Seniors experiencing a visual impairment consumed over 227 million prescriptions. (See *Exhibit 2*) This means that 7% of the prescriptions dispensed in the US were for only 2% of the population, who may not have been able to read the instructions or warnings on the label. This alarming statistic illustrates the need for technology that enables this population to self-medicate.

Exhibit 2 examines the total number of Prescriptions taken by this Visually Disabled Senior population, based on recently reported statistics.



Others who would benefit from ScripTalk™

Seniors with visual impairment are not the only group who could benefit from the use of the ScripTalk™ System. **Exhibit 3** illustrates other Segments of the population who would also benefit from ScripTalk™.



Health Illiteracy in the U.S.

Studies sponsored by the AMA have concluded that 90 million people in the U.S. have difficulty comprehending medical information, which limits their ability to care for their own medical problems. Of this group, 21% (40 million to 44 million people) are functionally illiterate (reading at or below a fifth grade level), while an additional 27% of adults (50 million people) are only marginally literate (having difficulty with reading comprehension and/or computational skills). These Americans are unable to read and/or understand prescription medication labels and auxiliary warning labels. Low health literacy skills cost the US health care system approximately \$73 billion annually in unnecessary doctor visits, hospitalizations, and longer hospital stays. Low health literacy is particularly common among the older population and low-income people. Some studies indicate that 66% of US adults age 60 and over have either inadequate or marginal literacy skills; about 45% of all functionally illiterate adults live in poverty.

The Blind

There are roughly 8.8 million people in the U.S. and 80+ Million people worldwide that have visual disabilities and are categorized as "legally blind". Only a small percentage (less than 1%) of this population can actually read Braille, which renders Braille prescription labeling useless for the majority of the population.

Reading and Comprehension Difficulties

It is estimated that approximately 11 million people (4% of the US population) are severely affected by dyslexia (10% of the population "show some sign" of dyslexia).

How ScripTalk Works

When a patient using a ScripTalk™ reader submits a prescription, the pharmacy software prints and programs a Talking Label using a dedicated, small-footprint Talking Label printer. The Talking Label stores textual prescription information in an electronic format onto a microchip embedded in the label. The pharmacist or technician then places the Talking Label on the prescription container. In the home, the patient uses a hand-held ScripTalk™ Reader that decodes the label information using speech synthesis technology. The patient then *hears* all of the information that is printed on the label.

By simply moving the prescription within an inch of the ScripTalk™ reader, pertinent information such as, the name of the patient; the name of the drug; the dosage; general instructions; warnings; prescription (Rx) Number; along with the doctor's name and phone number are converted into speech.

A clinical trial of the ScripTalk™ system was conducted at the Veterans Administration Hospital in Hines, IL. The study began in September 2000 and concluded March 15, 2001.

Based on information provided to En-Vision America during a meeting in early April, we anticipate that a favorable report outlining the benefits of ScripTalk™ will be presented to the appropriate Veterans Administration officials. It is our understanding that the VA will then determine how the product may be made available to visually impaired Veterans. The Hines VA Pharmacy Chief who was involved in the initial Study has indicated his

interest in planning another Study to determine the usefulness of the product for marginally literate Veterans.

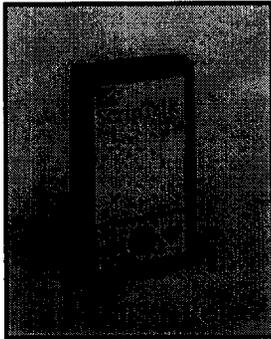
We at En-Vision America are confident that this technology will be of great benefit to the Elderly, visually impaired and functionally illiterate users. We are working diligently to create opportunities to make this technology available to as many Americans as possible. We appreciate the support of the Veterans Administration who recognized the need for such a technology within that Health System. Their support has been vital in helping us develop and refine the ScripTalk™ functionality.

Thank you so much for providing the opportunity to present information on our technology to the Special Committee.

Reference B

What is ScripTalk™?

ScripTalk™ allows individuals that have difficulty reading or understanding their prescription labels a better way to manage their own medication regimen.



How it works...

A Talking Label™ is printed and programmed in the pharmacy

The pharmacy dispenses Rx in standard vials or pre-packaging

A Talking Label™ is placed on the prescription container

At home, when the patient moves the prescription within an inch of the ScripTalk™ reader, the reader recites label information such as:

- Patient Name
- Drug Name and Dosage
- Instructions for Use
- Warnings & Cautions
- Pharmacy Name & Phone
- Doctor Name & Phone
- Pharmacy Rx#

Who benefits from Scriptalk™?

- ❖ Visually Impaired (Blind/Low Vision)
- ❖ Elderly with Cognitive Difficulties
- ❖ Reading Difficulties: Dyslexic/Illiterate

ScripTalk™ also alleviates fears of part-time caregivers concerned with their patients' ability to self-medicate in their absence.

- ✓ Reduces medication error
- ✓ Increases compliance
- ✓ Makes re-ordering easier

About Talking Labels™...

Inexpensive

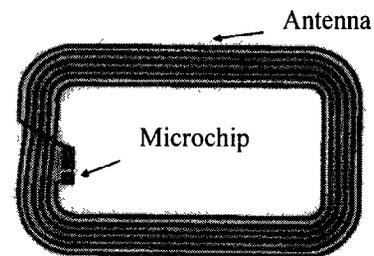
Serve as the primary label or can be placed under your standard pharmacy label

Non-Volatile Memory – Prescription information cannot be erased

Data retention > 10 years

Information can be read over and over

Label Operating Temperature Range: -40° F to +185° F



About ScripTalk™

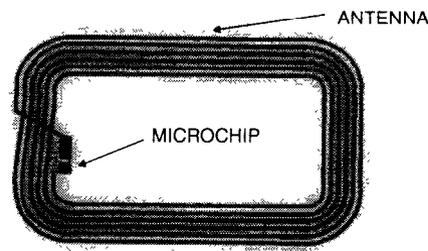
When a pharmacist fills a prescription, an "all-too-familiar" label is printed and affixed to the pill bottle or medicine container. But, an obvious problem arises for the millions of patients that have difficulty reading these extremely important labels. Currently, those with sight impairments, dyslexia or reading difficulties must rely on the assistance of others to determine the contents and instructions on their medications.

ScripTalk allows those who cannot read their prescription label, a better way to manage their own medication. The product uses smart-label and speech synthesis technologies to verbalize the users' prescription information.



About Talking Labels™

Talking labels work by connecting a tiny microchip to a small, paper-thin antenna. When a Talking Label is within range, the ScripTalk reader sends a signal that energizes the Talking Label which, in turn, sends the stored information back to the reader. The Talking Label can be read as many times as necessary. Since it is inexpensive, when you're done with the prescription, throw it away.



ScripTalk, Talking Label, and i.d. mate are all trademarks of En-Vision America, Inc. Patents Pending.

Where Can I Get ScripTalk Talking Labels™?

Talking Labels are available at any pharmacy that retails the device. When you request a Talking Label, the pharmacy prints and programs the special label and places it on your prescription along with the standard prescription label. From that point forward, you will have all the information needed for safety and independence.



Since 1995, En-Vision America has been dedicated to providing medical and non-medical related solutions for visually impaired individuals. The company's other products include its well known "i.d. mate", a talking bar code identification system.

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Can We Talk? You Bet We Can!



It's Easy to Use!

Move the prescription within an inch of the ScripTalk reader and you will hear all the label information spoken to you.

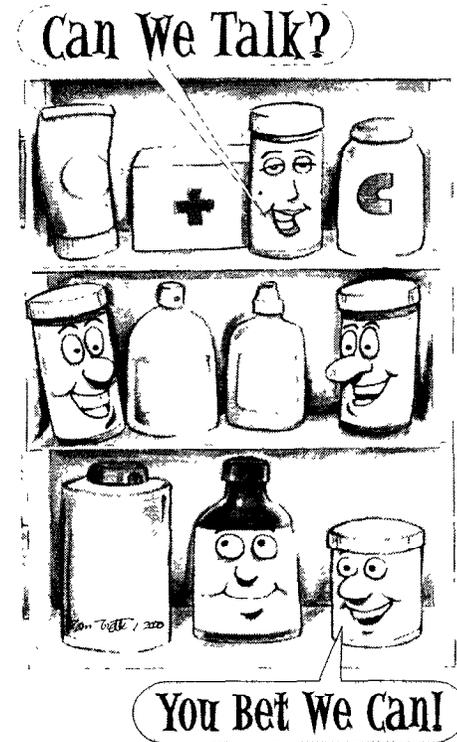
Information such as:

- Patient Name
- Drug Name
- Dosage
- Instructions
- Warnings
- Prescription (Rx) Number
- Along with the pharmacy name and phone number are converted into speech.

**En-Vision
AMERICA™**

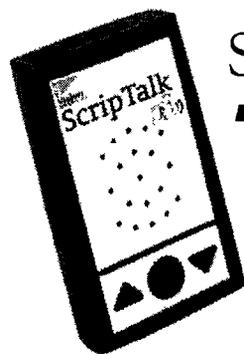
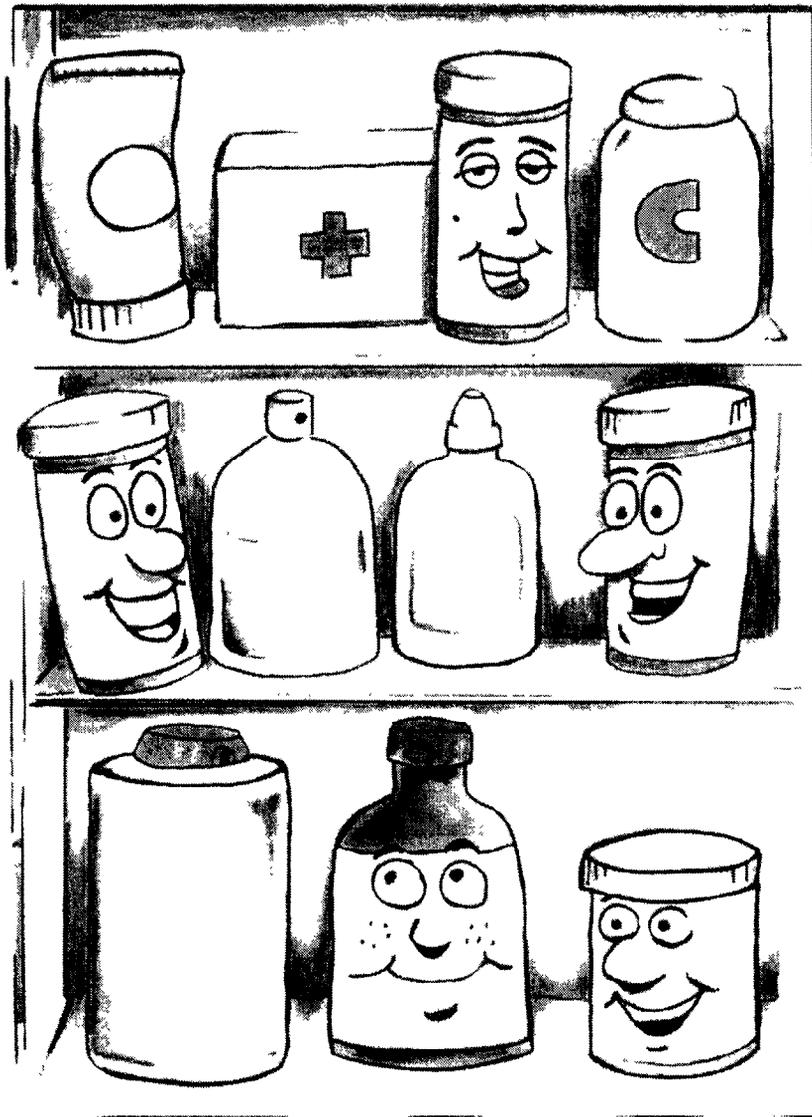
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Normal, Illinois 61761

TALKING PRESCRIPTIONS



ScripTalk™


Can We Talk?



ScripTalk® **Talking Prescription Reader**

If you are a veteran or you know one that has difficulty reading and understanding prescription labels, ask a VA Pharmacist about ScripTalk® today!

March 10, 2004

AUDIBLE PRESCRIPTION READING DEVICES

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides uniform criteria for the purchase of audible prescription reading devices and equipment by medical facilities.

2. BACKGROUND

a. The identified need for independent safe management of prescriptive medication by individuals who comprehend better by hearing than by seeing is a long-standing issue. It is known that the ability to understand and manage personal prescriptive medication is a key factor in helping individuals maintain an independent life style.

b. The audible prescription reading device enhances the medication safety of patients who have difficulty reading or understanding the instructions and warnings that appear on their medication bottle labels. When prescriptions are not taken as prescribed, serious and sometimes life threatening consequences can follow.

3. POLICY: It is VHA policy that audible prescription reading devices are furnished to eligible veterans by the facility Prosthetic and Sensory Aids Service.

4. ACTION

a. Process

(1) When a veteran who can benefit from the issuance of an audible prescription reading device is identified by the veteran's primary health care team, the team will initiate the assessment, evaluation, review, and training in the use of the device by the Nurse Educator, or designee.

(2) When the veteran has successfully completed the workup, the case manager notifies Pharmacy Service that the veteran can be enrolled in the audible prescription reading device program.

(3) When Pharmacy Service has verified the patient information and concurs with the enrollment, a consult is generated by the appropriate health care practitioner and sent to the facility Prosthetic and Sensory Aids Service requesting the audible prescription reading device.

b. Responsibilities

(1) **Primary Care Team.** The veteran's primary care team is responsible for the coordination of service delivery through the Nurse Educator and health care providers to ensure the following issues are addressed and documented in the patient's record:

THIS VHA DIRECTIVE EXPIRES MARCH 31, 2009

VHA DIRECTIVE 2004-006
March 10, 2004

- (a) Confirmation that the veteran has an identified need for the device.
- (b) Implementation of standardized evaluation procedures that include:
 - 1. A review of the veteran's current knowledge of the veteran's medication.
 - 2. Education on drug interactions.
 - 3. The ability to operate the audible prescription reading device independently.
 - 4. A review of the clinical record and the training of the veteran to determine potential for independent self-medication.
 - 5. A VA contact and phone number to consult in case of malfunction of the audible prescription reading device.
 - 6. A VA contact for questions about medication.
- (c) The veteran's ability to operate and maintain the device independently is verified by the team.
- (d) The veteran's cognitive and physical ability to independently self-medicate is verified by the team, prior to issuance of the medication.
- (e) All pertinent information is recorded in the Computerized Patient Record System (CPRS).

(2) **Blind Rehabilitation Service.** The Visual Impairment Services Team (VIST) Coordinator is responsible for:

- (a) Identifying visually impaired individuals who may be appropriate candidates for training with the device.
 - (b) Acting as a resource to the Nurse Educator on aspects dealing with visual loss.
- (3) **Pharmacy Service.** The Chief, Pharmacy Service, is responsible for:
- (a) The purchase of appropriate printer, software, ribbons, and labels.
 - (b) Instructing Pharmacists to test each automated message that is generated to make sure that what is printed is accurate and matches what is spoken by the reader.
 - (c) Recording patient information, transactions, and expenditures into the Veterans Health Information Systems and Technology Architecture (VistA) Pharmacy Software Package.

(4) **Prosthetics Service.** The Chief, Prosthetic and Sensory Aids Service, is responsible for the:

- (a) Purchase of hand-held electronic reading device.
- (b) Recording all transactions and expenditures in the Prosthetics Software Package.

6. FOLLOW-UP RESPONSIBILITY: Chief Consultant, Prosthetic and Sensory Aids Service Strategic Healthcare Group (113), is responsible for the contents of this Directive. Questions may be addressed to 202-273-8515.

7. RESCISSIONS: None. This VHA Directive expires March 31, 2009.

S/ Louise Van Diepen for
Robert H. Roswell, M.D.
Under Secretary for Health

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