

**Effective and Confidential Communication of Prescription Information:
Accommodating the Blind and Visually-Impaired**

by John Little, JD, MSPH, CHE, CHC*

* John Little has served as General Counsel, Chief Compliance Officer and Chief Privacy Officer at two national healthcare companies, is Board Certified in Healthcare Management and Board Certified in Healthcare Compliance, and is currently engaged in the private practice of law exclusively for healthcare clients.

Executive Summary

Individuals with vision disabilities face unique difficulties in their attempt to utilize prescription information such as medication descriptions, dosage instructions, side-effect warnings and other information often considered to be detailed and complex, yet essential. Similarities in container shapes and sizes along with having multiple prescription medications compound these problems.

Legislation Regarding Labeling of Medications - Sighted pharmacy customers are obvious beneficiaries of state and federal requirements obligating pharmacies to provide detailed, written medication information to prescription containers. These requirements govern both the content of the information and the duty to physically affix or attach the content to prescription containers. The requirements serve to protect an important public health interest: to help ensure the safe and effective use of prescription drug products. Without special accommodation, blind and visually-impaired pharmacy customers are unable to take advantage of the protections afforded by these requirements.

The Americans with Disabilities Act (ADA) - The ADA addresses the obligation of pharmacies to provide their blind and visually-impaired customers with effective auxiliary communication aids. Based on current ADA legislation, regulation and enforcement guidance, pharmacies are required to furnish appropriate auxiliary aids and services where necessary to ensure effective communication with their blind and visually-impaired customers. In the past, pharmacies may have resisted providing auxiliary communication aids because they viewed the only such available aids as creating an undue burden on pharmacy operations; however, recent technological advances have facilitated the development of new auxiliary communication aids, specifically designed to benefit blind and visually-impaired pharmacy customers, which are economical, efficient and effective.

The Health Insurance Portability and Accountability Act (HIPAA) - Pharmacies are required to permit their customers, individually, to request that communications of the customer's protected health information be made by alternative means. The right of blind and visually-impaired pharmacy customers to request delivery of his or her health information by alternative means is significant because one of the primary methods pharmacies have utilized in the past to deliver prescription medication information to such customers is through the customers' family members. HIPAA regulations are designed to protect the right of an individual to keep his or her health-related information private and to prevent such information from being disclosed, even to family members if such a level of privacy is desired by the individual. While pharmacies may require that requests for alternative means communication be made in writing, reasonable requests must be accommodated.

What Auxiliary Communication Aids are Available? - Currently, the most commonly utilized auxiliary method of communicating prescription medication information to the blind and visually-impaired is face-to-face counseling. This method is also one of the most ineffective at communicating complex, detailed medication information to this population and can be considered one of the most burdensome methods that may be implemented by pharmacies. Other auxiliary communication methods have been attempted in order to alleviate some of the problems experienced by pharmacies and their blind and visually-impaired customers with face-

to-face counseling. Producing written prescription medication information in Braille is overly expensive for pharmacies, and such material can only be read by a small portion of the blind and visually-impaired population. Some pharmacies have attempted to utilize cassette and CD recordings, but these methods remain problematic, particularly with respect to blind and visually-impaired pharmacy customers taking multiple medications, due to the fact that the information contained on cassettes and CDs may not be securely affixed to the prescription containers to which the information relates, increasing the risk of coupling instructions with the wrong prescription medication. Recent technological advances, however, have led to the development of Audible Prescription Labeling Systems (APLS) specifically designed for blind and visually-impaired pharmacy customers, providing such customers, for the first time, a meaningful opportunity to enjoy the ability to keep their prescription medication information private. While each of the available APLS communication aids has a relatively insignificant impact on pharmacy expenses and operations, they do vary in communication effectiveness.

One of the four available APLS communication aids on the market overcomes issues related to communication effectiveness and pharmacy burden by utilizing text-to-speech technology and a Radio Frequency Identification (RFID) enabled label that securely affixes to any type of prescription medication container, including odd-shaped glass and plastic bottles, blister packs and boxes. Pharmacists or pharmacy technicians pass textual prescription medication information from their computer to a dedicated, small-footprint RFID label printer which encodes the prescription information in an electronic format on a microchip embedded in the label. In the home, the patient uses a hand-held reader, which decodes the label information using speech synthesis technology, to hear medication information such as patient name, drug name and dosage information, instructions for use, warnings and cautions, the prescription number and the name and phone number of the pharmacy and the prescribing doctor.

What are Pharmacies Required to do by law? - Pharmacies are required to communicate certain information to their customers concerning the medications they dispense. They are required to securely affix specific information to the containers holding these medications, decreasing the risk of medication errors such as the accidental consumption of the wrong medication. Pharmacies are prohibited from discriminating against their blind and visually-impaired customers with respect to the full and equal enjoyment of the goods, services, privileges and advantages available to sighted customers. They are required to furnish effective auxiliary communication aids for the benefit of blind and visually-impaired customers, and they are required to accommodate reasonable requests by such customers to receive their health information by alternative means in order to protect the privacy of such information.

Due to recent technological advances leading to the development of specially-designed audible prescription labeling systems, pharmacies now have the means and ability to provide effective auxiliary communication aids and services to their blind and visually-impaired customers with minimal burden on themselves and insignificant alteration of their current operations. In addition, thanks to these specially-designed systems, blind and visually-impaired pharmacy customers are now able to enjoy the same privacy rights enjoyed by sighted customers, rights which have historically been forfeited due to a lack of alternative means of receiving prescription medication communications.

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Blind and visually-impaired pharmacy customers face unique difficulties in their attempt to utilize prescription information such as medication descriptions, dosage instructions, side-effect warnings and other information often considered to be detailed and complex, yet essential. These customers' difficulties are compounded dramatically by simple issues such as similarities in container shapes and sizes and having been prescribed more than one medication. While sighted pharmacy customers are obvious beneficiaries of state and federal requirements that detailed written information accompany prescription medications, the blind and visually-impaired require special accommodation in order to benefit from such information. Absent the provision of effective auxiliary communication aids, blind and visually-impaired pharmacy customers are incapable of taking advantage of the same goods, services and privileges available to sighted customers.

However, federal laws do exist which address the obligation of pharmacies to provide their blind and visually-impaired customers with effective auxiliary communication aids. Until recently, provision of the only such aids available has been viewed either as ineffective or as creating an undue burden on business operations. Fortunately, technological advances over the past few years, including Audible Prescription Labeling Systems (APLS) utilizing Radio Frequency Identification (RFID), now allow pharmacies to offer truly effective auxiliary communication aids to the blind and visually-impaired efficiently and economically, with only minor, insignificant alterations to their current operations.

I. Mandatory Prescription Medication Label Information

The nature and extent of medication information that pharmacies are required to provide their customers has been the subject of complex, overlapping and evolving state and federal regulation. The justification for this regulation is readily apparent upon review of recent reports estimating the number of deaths and other adverse health consequences related to medication errors in the United States each year.¹ The Food and Drug Administration's Center for Drug Evaluation and Research states that "medication errors cause at least one death every day and injure approximately 1.3 million people annually in the United States."² The problem is so significant that the American Pharmacists Association stresses that prescription medication users should "double check the label and the contents" prior to taking a medication.³ The association also warns prescription users to

¹ John P. Santell, et al., *Medication Error Trends for 1999-2003*, 149(4) Drug Topics HSE22 (February 21, 2005), Committee on Quality of Health Care in America, Institute of Medicine, *To Err is Human - Building a Safer Health System* (1999), available at <http://www.iom.edu/includes/DBFile.asp?id=4117>, and Susan Camp and Rodney Hicks, *Medication Errors in the Patient's Home*, 148(8) Drug Topics HSE14 (April 19, 2004).

² <http://www.fda.gov/cder/handbook/mederror.htm> (last visited August 29, 2005).

³ *Pharmacists offer tips to help patients avoid medication errors*, Patient Care Law Weekly, pg. 29, (August 21, 2005).

"read the label and follow the directions. Medications are powerful, that's why they work. But they can cause harm as well, particularly if they are not used correctly. Follow the directions on the label."⁴

Recognizing the importance of the availability of accurate and complete medication information, federal law establishes severe penalties related to the delivery of false, misleading or incomplete information attached to or included with prescription medications.

A. Content Requirements

The federal Food, Drug, and Cosmetic Act (FDCA) includes in the definition of "misbranding" any written, printed or graphic matter on or accompanying a drug which is false or misleading in any particular.⁵ Section 201(n) of the FDCA describes the concept of misleading and specifically provides that in determining whether the labeling of a drug is misleading,

"there shall be taken into account (among other things) not only representations made ... but also the extent to which the labeling or advertising fails to reveal facts material ... with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."⁶

Information accompanying prescription medications is specifically described as false or misleading if it omits the name and address of the dispenser, the serial number and date of the prescription, the name of the prescriber and patient, or any directions for use and cautionary statements.⁷ Other material facts related to prescription medications are described in regulations promulgated by the U.S. Food and Drug Administration, which add that any drug labeling that furnishes or purports to furnish information for use, or which prescribes, recommends or suggests a dosage for the use of the drug,⁸ must contain specific elements of information, unless clearly inapplicable, including:

- (a) a description of the drug, including (i) the proprietary name and the established name of the drug, if any, (ii) the type of dosage form and the route of administration, and (iii) qualitative and/or quantitative ingredient information;
- (b) a concise factual summary of the clinical pharmacology and actions of the drug in humans;
- (c) the drug's indications and usage;

⁴ *Pharmacists offer tips to help patients avoid medication errors*, Patient Care Law Weekly, pg. 29, (August 21, 2005) (emphasis added).

⁵ 21 U.S.C. 352(a).

⁶ 21 U.S.C. 321(n) (emphasis added).

⁷ 21 U.S.C. 353(b)(2).

⁸ 21 C.F.R 201.100(d).

(d) the drug's contraindications, including situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit;

(e) statements of (i) warning concerning serious adverse reactions and potential safety hazards, (ii) limitations in use imposed by them, and (iii) steps that should be taken if they occur;

(f) precautions to be taken including information regarding any special care to be exercised for safe and effective use of the drug, e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects;

(g) information concerning adverse reactions reasonably associated with the use of the drug;

(h) the types of abuse that can occur with the drug and the adverse reactions pertinent to them, including (i) identification of susceptible patient populations, (ii) a description of the characteristic effects resulting from both psychological and physical dependence that occur with the drug, and (iii) an identification of the quantity of the drug over a period of time that may lead to tolerance or dependence, or both;

(i) the signs, symptoms, and laboratory findings of acute overdosage and the general principles of treatment;

(j) information concerning dosage and administration, including (i) the recommended usual dose, (ii) the usual dosage range, (iii) if appropriate, an upper limit beyond which safety and effectiveness have not been established, (iv) the intervals recommended between doses, (v) the usual duration of treatment, and (vi) any modification of dosage needed in special patient populations; and

(k) any special handling and storage conditions.⁹

Penalties for violating the federal misbranding prohibition range from 1 year imprisonment and a \$1,000 fine to 3 years imprisonment and a \$10,000 fine.¹⁰ At the same time, many states subject pharmacies and pharmacists to licensure discipline in cases where they are judged guilty of misbranding.¹¹

⁹ 21 C.F.R. 201.56 and 201.57. Many states also require specific content to be included on prescription medication labeling. For example, California prohibits pharmacies from dispensing prescription medication unless the medication is correctly labeled with all of the following elements of information: (i) manufacturer's trade name of the drug, generic name and the name of the manufacturer or principal active ingredients, (ii) directions for the use of the drug, (iii) name of the patient and prescriber, (iv) date of issue, (v) name and address of the pharmacy, (vi) prescription number or other means of identifying the prescription, (vii) strength and quantity of the drug, (viii) expiration date of the effectiveness of the drug, (ix) condition for which the drug was prescribed and (x) commencing January 1, 2006 with certain exceptions, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. Cal. Bus. & Prof. Code 4076(a).

¹⁰ 21 U.S.C. 333(a).

¹¹ See for example, Code D.C. Mun. Reg. 22-1909.5, Flo. Admin. Code 64B16-27.101, N.J. Admin. Code 13:39-7.18, and 22 Tex. Admin. Code 281.7(a)(29)(A).

B. The Obligation to Affix the Information to the Product

Another important requirement designed to protect the health and welfare of prescription medication consumers is the requirement that pharmacies securely affix certain basic information to the prescription medication containers they dispense to customers. At least 31 state legislatures and the District of Columbia have enacted such a requirement.¹² The obvious benefit of the requirement is to help prevent medication errors such as the accidental consumption of the wrong prescription medication.

The fact that certain basic information is required to be securely attached or affixed to prescription medications may be taken for granted by most pharmacy customers. And in the past, when no effective auxiliary communication of this information was either available or offered to the blind and visually-impaired, the requirement was largely irrelevant to this segment of the population. However, now that effective auxiliary communication aids for blind and visually-impaired medication users are available, which themselves can be securely affixed to prescription containers, the requirement to affix has new meaning, purpose and ability to benefit this particular segment of the population, whose desire to live an independent life and be able to care for themselves is the same as the rest of the population.

In summary, the regulatory requirements governing written information accompanying prescription medications, both in terms of the content required and the requirement to physically affix or attach such content to prescription containers, serve to protect an important public health interest: to help ensure the safe and effective use of prescription drug products. The inability of a significant segment of the population to read these written materials due to blindness and visual impairment,¹³ and the public health disadvantage at which this population segment is placed due to their disability, has led to the development of relatively inexpensive, effective, easy-to-use, assistive technologies designed to communicate essential written drug information to the blind and visually-impaired in a way in which they can understand. What remains, however, in order for the blind and visually-impaired to benefit from these assistive technologies, is for pharmacies to acknowledge their ability and obligation to implement them.

II. Americans with Disabilities Act (ADA)

According to Title III of the Americans with Disabilities Act, an individual may not be discriminated against, on the basis of disability, in the full and equal enjoyment of the goods,

¹² Ark. Code Ann. § 20-64-210; Cal. Bus. & Prof. Code § 4076; Colo. Rev. Stat. § 12-22-123; Conn. Gen. Stat. § 21a-256; Del. Code Ann. tit. 24, § 2536; D.C. Code Ann. § 48-903.08; Fla. Stat. Ann. §§ 465.186 and 893.04; Haw. Rev. Sta. §§ 329-38 and 39; Idaho Code §§ 37-2731 and 54-1732; Ill. Rev. Stat. ch. 225, para. 85/22 and ch. 720, para. 570/312; Ind. Code Ann. § 16-42-19-11; Ky. Rev. Stat. Ann. § 218A.180; La. Rev. Stat. Ann. § 37:1164; Mass. Gen. Laws Ann. ch. 94C, §§ 21 and 27; Minn. Stat. Ann. § 151.212; Mo. Rev. Stat. §§ 195.100 and 338.059; Neb. Rev. Stat. § 28-415; Nev. Rev. Stat. Ann. §§ 585.420 and 639.2801; N.H. Rev. Stat. Ann. § 318:47-a; N.J. Stat. Ann. §§ 24:21-17 and 45:14-15; N.M. Stat. Ann. § 30-31-18; N.Y. Educ. Law § 6810; N.C. Gen. Stat. § 106-134.1; N.D. Cent. Code, § 19-02.1-14.1; Ohio Rev. Code Ann. § 3719.08; Okl. Stat. Ann. tit. 59, § 355.1 and tit. 63, § 2-314; Or. Rev. Stat. § 689.505; Tex. Occ. Code § 567.001; Utah Code Ann. § 58-17b-602; Vt. Stat. Ann. tit. 18, § 4212; Wash. Rev. Code Ann. § 69.41.050; and Wis. Stat. Ann. § 450.11.

¹³ For purposes of this article, blind and visually-impaired refers to those with visual impairments severe enough that they are unable to read large print materials.

services, facilities, privileges, advantages, or accommodations of any place of public accommodation.¹⁴ Pharmacies are specifically listed in the ADA as public accommodations that must comply with this mandate.¹⁵

A. Auxiliary Communication Aids

Discrimination under the ADA includes a pharmacy's failure to take such steps as may be necessary to ensure that blind and visually-impaired individuals are not treated differently than sighted individuals because of the absence of auxiliary aids and services.¹⁶ Federal regulations implementing the ADA further explain that auxiliary aids and services must be furnished by pharmacies where necessary to ensure effective communication with disabled individuals, including the blind and visually-impaired.¹⁷ The term "auxiliary aids and services" is defined to specifically include qualified readers, taped texts, audio recordings, Brailled materials, large print materials, or other effective methods of making visually delivered materials available to individuals with visual impairments.¹⁸ The term also includes the acquisition or modification of equipment or devices and other similar services and actions.¹⁹

Under the ADA, the type of auxiliary aid or service necessary to ensure effective communication will vary in accordance with the length and complexity of the communication involved. The U.S. Department of Justice instructs pharmacies to consult with their blind and visually-impaired customers wherever possible to determine what type of auxiliary aid is needed to ensure effective communication.²⁰ Furthermore, the ADA's standard prohibiting discrimination in the full and equal enjoyment of pharmacy goods, services and advantages would indicate that if an effective, auxiliary communication aid is available that can be securely affixed to prescription containers, as described above, that communication aid is to be preferred over those potential aids that are not capable of being securely affixed to prescription containers.

B. Exceptions to Pharmacy ADA Compliance

Pharmacies are allowed to forgo provision of auxiliary aids and services to their blind and visually-impaired customers only if they are able to demonstrate that taking such steps would fundamentally alter the nature of the good, service, facility, privilege, advantage, or that the accommodation being offered or would result in an undue burden on the pharmacy.²¹ However, even if provision of a particular auxiliary aid or service by a pharmacy, brailled materials for example, were to result in a fundamental alteration or an undue burden, the pharmacy is still

¹⁴ 42 U.S.C. 12182(a).

¹⁵ 42 U.S.C. 12181(7)(F).

¹⁶ 42 U.S.C. 12182(b)(2)(A)(iii).

¹⁷ 28 C.F.R. 36.303(c).

¹⁸ 28 C.F.R. 36.303(b)(2).

¹⁹ 28 C.F.R. 36.303(b)(3) and (4).

²⁰ Department of Justice, ADA Title III Technical Assistance Manual, section III-4.3200. The Department of Justice provides the example of a theater providing a blind or visually-impaired individual with a tape-recorded version of its printed program as an effective communication of the contents of the program.

²¹ 42 U.S.C. 12182(b)(2)(A)(iii).

required to provide an alternative auxiliary aid or service, if one exists, that would not result in a fundamental alteration or undue burden.²²

According to the federal regulations implementing the ADA, the term fundamental alteration is defined as a modification so significant that it alters the essential nature of the goods, services, facilities, privileges, advantages, or accommodations offered.²³ An undue burden, on the other hand, is equivalent to the term "significant difficulty or expense."²⁴

1. The Undue Burden Standard

Among the factors to be considered in determining whether an action would result in an undue burden are the following:

- a) The nature and cost of the action;
- b) The overall financial resources of the site or sites involved; the number of persons employed at the site; the effect on expenses and resources; legitimate safety requirements necessary for safe operation, including crime prevention measures; or any other impact of the action on the operation of the site;
- c) The geographic separateness, and the administrative or fiscal relationship of the site or sites in question to any parent corporation or entity;
- d) If applicable, the overall financial resources of any parent corporation or entity; the overall size of the parent corporation or entity with respect to the number of its employees; the number, type, and location of its facilities; and
- e) If applicable, the type of operation or operations of any parent corporation or entity, including the composition, structure, and functions of the workforce of the parent corporation or entity.²⁵

2. Comparing the Undue Burden Standard for Provision of Auxiliary Communication Aids to the Readily Achievable Standard for Barrier Removal

According to the Department of Justice (DOJ), the undue burden standard requires a greater level of effort by a public accommodation in providing auxiliary aids and services than does the readily achievable standard found in Title III of the ADA for removing barriers in existing facilities. Although "readily achievable" is therefore a lesser standard, the factors to be considered in determining what is readily achievable are identical to those listed above for determining undue burden.²⁶ Regulations issued by the DOJ contain a list of 21 examples of

²² 28 C.F.R. 36.303(f) and Department of Justice, ADA Title III Technical Assistance Manual, section III-4.3600.

²³ Department of Justice, ADA Title III Technical Assistance Manual, section III-4.3600.

²⁴ 28 C.F.R. 36.303(a). The definition of undue burden is identical to the definition of undue hardship used in Title I of the ADA as the limitation on an employer's obligation to reasonably accommodate an applicant or employee.

²⁵ Department of Justice, ADA Title III Technical Assistance Manual, section III-4.3600.

²⁶ *Id.* Note that section III-4.4200 of the Technical Assistance Manual adds:

modifications that may be readily achievable.²⁷ Among the examples provided are modifications that may be considered more difficult and costly to achieve than a pharmacy's provision of effective, auxiliary aids for the benefit of their blind and visually-impaired customers:

- a) Installing wheelchair ramps;
- b) Making curb cuts in sidewalks and entrances;
- c) Installing flashing alarm lights;
- d) Widening doors;
- e) Removing high pile, low density carpeting; and
- f) Installing vehicle hand controls.

3. Availability of Tax Credit to Reduce ADA Compliance Burden

The already insignificant initial expense that may be incurred by pharmacies in implementing certain effective, auxiliary communication aids for the blind and visually-impaired is further diminished by a tax credit of up to \$5,000 available to assist businesses in the purchase of effective auxiliary communication equipment for the benefit of the blind and visually-impaired. The tax credit, established under § 44 of the Internal Revenue Code, was created specifically to help businesses cover ADA-related expenditures.²⁸ Among the examples of expenditures covered by the credit are expenditures made or incurred:

- a) for the purpose of removing communication barriers,
- b) to provide qualified readers, taped texts, and other effective methods of making visually delivered materials available to individuals with visual impairments,
- c) to acquire equipment or devices for individuals with disabilities, and
- d) to provide other similar services, modifications, materials, or equipment.

Thus, pharmacies are required by law to furnish appropriate auxiliary aids and services where necessary to ensure effective communication with their blind and visually-impaired customers.

If the public accommodation is a facility that is owned or operated by a parent entity that conducts operations at many different sites, the public accommodation must consider the resources of both the local facility and the parent entity to determine if removal of a particular barrier is "readily achievable." The administrative and fiscal relationship between the local facility and the parent entity must also be considered in evaluating what resources are available for any particular act of barrier removal.

²⁷ 28 C.F.R. 36.304 and Department of Justice, ADA Title III Technical Assistance Manual, section III-4.4200.

²⁸ 26 U.S.C. § 44. A business that for the previous tax year had either revenues of \$1,000,000 or less or 30 or fewer full-time workers is able to take advantage of this credit. For 2004, the appropriate form to use in claiming the credit was 2004 IRS Form 8826, available at <http://www.irs.gov/pub/irs-pdf/f8826.pdf>

While this requirement is to be balanced against any "undue burden" or "fundamental alteration" experienced by pharmacies, it is apparent that certain effective auxiliary communication aids available on the market today are less expensive and have less impact on pharmacy operations than the established practice of removing certain physical barriers for the benefit of customers who live with other types of disabilities. Furthermore, many pharmacies are entitled to take advantage of a significant tax credit specifically designed to encourage the implementation of effective auxiliary communication aids for the benefit of blind and visually-impaired customers. In any event, the Americans with Disabilities Act is not the only federal law addressing the obligation of pharmacies to provide their blind and visually-impaired customers with communications concerning prescription medication information by other means.

III. Health Insurance Portability and Accountability Act (HIPAA)

Health care providers considered to be "covered entities" according to privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act (HIPAA) are required to permit individuals to request that communications of "protected health information" (PHI) from the health care provider be made by alternative means or at alternative locations. While health care providers may require that such requests be made in writing, reasonable requests must be accommodated.²⁹

A. Pharmacies are "covered entities" obligated to comply with HIPAA.

The term covered entity under HIPAA includes health care providers who transmit any health information in electronic form in connection with a transaction covered by the Health Insurance Portability and Accountability Act. The term healthcare provider includes entities that furnish, bill for or are paid for health care in the normal course of business, and the term health care includes the sale or dispensing of a drug, device, equipment or other item in accordance with a prescription.³⁰ Thus, pharmacies are covered entities obligated to comply with HIPAA privacy regulations.

B. Prescription information is "protected health information" under HIPAA.

Protected health information, the use and disclosure of which is regulated by HIPAA privacy regulations, means individually identifiable health information that is transmitted by or maintained in electronic or other forms of media.³¹ Individually identifiable health information is health information created or received by a health care provider, including demographic information collected from an individual, which

- a) identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and

²⁹ 45 C.F.R. 164.522(b). The two conditions a pharmacist may place on the provision of an alternative means accommodation are (i) information concerning how payment for pharmaceuticals will be handled; and, if applicable, (ii) specification of an alternative address or method of contacting the individual. *Id.*

³⁰ 45 C.F.R. 160.103.

³¹ *Id.*

b) relates to

- (i) the past, present, or future physical or mental health or condition of the individual,
- (ii) the provision of health care to the individual, or
- (iii) the past, present, or future payment for the provision of health care to an individual.³²

C. A blind or visually-impaired customer's request to receive communication of prescription label information via an auxiliary communication aid, as opposed to utilizing a family member as a reader, is reasonable.

There are many valid reasons an individual may request PHI communications to be made by alternative means, including for example, the desire to prevent family members from learning about a particular treatment and the fear that all or part of the protected health information could subject the individual to abuse.³³ In its commentary concerning the HIPAA privacy rules, the U.S. Department of Health and Human Services (DHHS) has stated that a covered health care provider is not permitted to refuse to accommodate such a request based on its perception of the merits of the individual's reason for making the request. In fact, DHHS stated that a covered health care provider is not permitted to require the individual to provide a reason for the request as a condition of accommodating the request.³⁴

D. Communicating prescription label information via a privacy enabled auxiliary communication aid ensures that blind and visually-impaired individuals are able to exercise confidentiality rights they otherwise would may not be able to exercise.

As stated by Rebecca Criswell of the Iowa Department for the Blind, "Currently, the only viable alternative is for the [blind or visually-impaired] individual to relinquish control over his or her medication to someone else such as another family member, a friend, or a paid in-home health provider. Obviously, this creates a dependency on others for care that is critical to one's good health and well-being, and individuals who were accustomed to being self-sufficient are given another reason to feel both diminished and vulnerable." However, the HIPAA privacy rules are designed to protect the right of an individual to not have his or her private health-related information disclosed to others, even family members if such a level of privacy is desired by the individual.

According to the rules, where a customer presents himself at a pharmacy and has the capacity to make health care decisions on his own behalf, the pharmacy is allowed to disclose the customer's PHI to the family members or close personal friends of the customer only if one of three conditions have been satisfied:

- (i) the pharmacy obtains the customer's agreement;

³² 45 C.F.R. 160.103.

³³ 65 F.R. 82462, 82553 (Dec. 28, 2000).

³⁴ *Id.*

(ii) the pharmacy provides the customer with the opportunity to object to the disclosure, and the customer does not express an objection; or

(iii) the pharmacy reasonably infers from the circumstances, based on the exercise of professional judgment, that the customer does not object to the disclosure.

Unfortunately, even though pharmacy customers have the right to have their personal health information protected from disclosure to family and friends, according to comments received by the Food and Drug Administration during its Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals, mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,³⁵ blind and visually-impaired pharmaceutical users do not believe they are able to object to such a disclosure because they have no meaningful alternative to relying on their family members or friends to read the prescription label and insert describing the medication, usage and side effects on their behalf. However, certain auxiliary communication aids now on the market which are specifically designed for blind and visually-impaired pharmacy customers are providing such customers, for the first time, a meaningful opportunity to enjoy the ability to keep their prescription medication information private.

IV. The Effectiveness of Currently Available Auxiliary Communication Aids and their Impact on the Pharmacies that Provide Them

Any available auxiliary communication aide should be judged from at least two perspectives: the effectiveness of the aide to the prescription medication user and the impact of providing the aide on pharmacy operations. With respect to the effectiveness of the aide to the prescription medication user, consideration should be given to:

- (i) the ability of the aide to communicate information completely,
- (ii) the integrity of the information being communicated,
- (iii) the ease of use, or user-friendliness, of the aide,
- (iv) the ability of the user to access the information repeatedly,
- (v) the ability of the aid to be securely affixed to prescription containers, and
- (vi) the ability of the aide or service to preserve the customer's privacy.

With respect to the impact of providing the aide on pharmacy operations, consideration should be given to:

- (a) the nature of the pharmacy action,
- (b) the initial cost of implementing the auxiliary aid or service,

³⁵ <http://www.fda.gov/ohrms/dockets/dockets/04n0221/04N0221.htm>

(c) the portability of the information from the pharmacy or pharmacist to the customer or the auxiliary aide,

(d) the ongoing effect of providing the auxiliary aid or service on the pharmacy's expenses and resources, and

(e) any other impact on the pharmacy.

The chart attached as Appendix A provides a summary of both traditional and recently developed methods of attempting to communicate prescription medication information to the blind and visually-impaired. These methods are judged against the specific elements of communication effectiveness and pharmacy impact issues described above.

A. Face to Face Counseling

Face-to-face counseling is currently the most commonly used form of auxiliary communication or service. However, it is also one of the most ineffective.

Commentary received by the U.S. Department of Health and Human Services during its "Study on How to Make Prescription Pharmaceutical Information, Including Drug Labels and Usage Instructions, Accessible for Blind and Visually-impaired Individuals" (hereinafter referred to as the "DHHS Accessibility Study") indicates that the most common alternative method of communicating written prescription medication information to the blind and visually-impaired is in the form of a verbal explanation from a pharmacist to the customer or to a friend or family member of the customer.³⁶ While some form of face-to-face, verbal counseling is provided in nearly all pharmacies today and the impact of such communications on pharmacies' initial and ongoing operations can be insignificant if the communications are brief, the effectiveness of relying on face-to-face, verbal communications as an effective auxiliary communication aide to the blind and visually-impaired is questionable.

A brief verbal counseling session would not typically provide the customer with complete medication information, as described above and mandated by some states and the FDA. And while a complete communication of the written information is possible, the impact to pharmacies on expenses and resources rises in relation to the amount of time spent in face-to-face counseling sessions. In fact, comments received over the course of the DHHS Accessibility Study reported that those providing drug information are often too busy to provide sufficient verbal counseling or information.³⁷ Thus, there is predictably a wide degree of vulnerability in the completeness of the information communicated by pharmacies in verbal counseling sessions. One of the primary reasons for legal mandates governing the content of prescription labeling again becomes apparent. An incomplete communication is not an effective communication.

³⁶ Report to Congress, The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 107(f): A Study on How to Make Prescription Pharmaceutical Information, Including Drug Labels and Usage Instructions, Accessible for Blind and Visually-impaired Individuals, Department of Health and Human Services, May, 2005, page 24-25 (hereafter referred to as "Report to Congress").

³⁷ Id.

During face-to-face counseling, customer privacy concerns may be addressed by pharmacies by implementing safeguards such as speaking to the customer in an area separate from other waiting customers or asking the other waiting customers to keep an appropriate distance from counters used for patient counseling. However, while customers are able to enjoy their privacy rights in face-to-face verbal counseling sessions, problems remain with respect to issues such as user-friendliness and information integrity, repeatability and portability.

Whether the verbal communication is brief or extensive, the integrity of the communication is as variable as the reading and speaking skills of the thousands of pharmacists and pharmacy technicians delivering the communication. Such a wide variety in reading and speaking skills increases the potential for miscommunication, including mispronunciations, omissions and erroneous statements. Such faulty communications are not effective.

With respect to user-friendliness, blind and visually-impaired pharmacy customers are forced to rely on their memory of the verbal communication. Such a reliance on the customer's ability to later recall complex information received from a verbal explanation is predictably problematic, especially considering that the customer may be taking numerous prescription medications simultaneously. The risk of memory failure leading to adverse health consequences rises in relation to the amount of time having transpired since the verbal explanation and in relation to the number of prescription medications being utilized by the blind or visually-impaired customer. For the customer to be forced to return to the pharmacy for numerous repeat face-to-face verbal communications only further increases the burden of this method of auxiliary communication on both the customer and the pharmacy.

B. Braille Embossers/Printers

Braille printers, also called embossers, have mixed communication effectiveness and a mixed impact on pharmacies. The printers have the capability of printing complete medication information, and the difference to a pharmacist or pharmacy technician of sending information to an ordinary printer versus sending information to a braille printer is insignificant. Those pharmacy customers who are able to read braille are able to read the printouts repeatedly and are able to keep the printouts private in the same manner that sighted pharmacy customers are able to keep ordinary written medication information private. However, there are several significant problems associated with the utilization of braille as an auxiliary communication aid.

One of the biggest problems with braille as an auxiliary communication aid is that only a small percentage of the blind and visually-impaired population (approximately 10%) are able to read it, primarily those who became blind in early life. The vast majority of older blind and visually-impaired individuals do not know braille.³⁸ In addition, very few pharmacists would be able to read the braille printout in order to confirm the accuracy of the medication information produced.³⁹ Another significant problem with utilizing braille printers as an auxiliary communication aid is their impact to pharmacies in terms of cost. According to the American Foundation for the Blind, "the price of a braille printer is directly related to the volume of braille

³⁸ Report to Congress, page 27.

³⁹ *Id.*

production required—between \$1,800 and \$5,000 for smaller volume production and between \$10,000 and \$80,000 for larger volume production."⁴⁰ Finally, braille printouts containing even basic information are known to be particularly bulky or large, and pharmacies would find it difficult if not impossible to securely affix more than a few words of brailled prescription medication information on a small prescription container.

C. Cassette, Human Voice Recording

Speaking medication information into a cassette recorder is similar to face-to-face counseling in many respects. The nature of the pharmacy action, the ongoing effect of the action on the pharmacy's expenses and resources, and issues involving information portability, integrity and completeness are virtually identical. To illustrate, there is little difference between a pharmacy or pharmacy technician reading medication information into a recorder versus reading the information directly to the pharmacy customer. Brief verbal communications are typically provided already at most pharmacies across the United States. However, dictating comprehensive medication can result in undesired, lengthy interruptions of pharmacy operations. Therefore, information communicated via cassette recordings may tend to be incomplete, the extent of the incompleteness being related to the pharmacist's or pharmacy technician's perceived need to attend to other pharmacy matters. The integrity of the information communicated is also questionable due to pharmacists' and pharmacy technicians' variable reading and speaking skills, leading to an increased potential for miscommunication, including mispronunciations, omissions and erroneous statements.

Unlike face-to-face counseling, however, pharmacies do incur a small initial cost to implement cassette recording as an auxiliary communication aid. The initial cost of a cassette recording device is between \$15 to \$550, depending on the type of device and manufacturer. Handheld microcassette recorders are priced from \$15⁴¹ to \$300⁴², while microcassette transcribers are priced from \$200⁴³ to \$550⁴⁴. Microcassettes with a recording time of 60 minutes cost approximately \$1 to \$1.50 each.

Cassette recordings containing complete medication information offer blind and visually-impaired pharmacy customers the option to receive the communication repeatedly and privately. However, because the cassette recording is likely to contain only basic medication information, the customer would need to either return to the pharmacy for more complete information or possibly sacrifice desired privacy by relying on friends, family members or others to read the information.

In addition, the benefits gained by requiring that medication information be physically and securely affixed or attached to prescription containers is lost with the cassette recording method, which inherently requires the ability to place the cassette into a cassette player. Blind and

⁴⁰ <http://www.afb.org/Section.asp?SectionID=4&TopicID=31&DocumentID=1282> (last viewed on August 30, 2005).

⁴¹ COBY CX R122 Microcassette Dictaphone.

⁴² Dictaphone Voice Processor Microcassette Dictation Recorder.

⁴³ Sony M2000 Microcassette Transcriber.

⁴⁴ Voice Solutions DA-116 Universal Deluxe Digital Transcriber Dictaphone.

visually-impaired pharmacy customers taking multiple prescription medications risk mismatching a particular cassette recording with the drug it relates to.

D. Text-to-Audio Software and CD Writer Combination

Another potential auxiliary communication aid pharmacies may implement is a combination of text-to-audio software and a compact disc (CD) writer. This method of communication offers information completeness, integrity, portability, repeatability and privacy. However, the initial and ongoing cost and impact of this solution on any given pharmacy depends largely on information technology support available to the pharmacy or the level of information technology skills possessed by existing pharmacy staff. At the same time, the CD recording method of communication suffers the same flaw as cassette recordings in terms of the inability of both methods to ensure that important medication information be physically and securely affixed to the prescription containers they contain information about.

Text-to-audio programs range in price from \$25⁴⁵ to \$70⁴⁶, and compact disc writers range from \$20⁴⁷ to \$685.⁴⁸ After properly installing the hardware and software on an existing computer, medication information data residing on the computer is converted by the text-to-audio software to an audio format such as MP3. The MP3 audio file is then written onto a compact disc which is given to the blind or visually-impaired customer, who is then able to listen to the medication information on any compact disc player supporting the MP3 format.

Technical difficulties encountered with do-it-yourself software and hardware installation and operation, however, may have a negative impact on pharmacies. For example, cursory reviews of compact disc writer support websites reveal problems such as (i) errors occurring resulting in termination of the installation process, (ii) drive letters not recognized, (iii) the CD writer not recognizing the media inserted into the drive, (iv) the burn process apparently completing coupled with no data being written to the disc, and (v) numerous other technical error messages. As an alternative to self help trouble shooting, pharmacies may conclude that third-party technical support availability is required. Thus, the costs associated with such third-party technical support may result in a negative impact to ongoing expenses and resources as a result of implementing the text-to-audio and CD writer combination as an auxiliary communication aid solution.

E. Audible Prescription Labeling Systems

Fortunately, technological advances in recent years have enabled the development of new types of auxiliary communication aids which overcome many of the limitations inherent in traditional types of aids. Audible Prescription Labeling Systems (APLS) are relatively new developments designed specifically to address prescription medication information concerns involving blind and visually-impaired pharmacy customers. Four APLS technologies have been marketed in the

⁴⁵ Alive Text to Speech v5.2.1.0 by Alive Media.

⁴⁶ Text-to-Audio v7.0 by Premier Assistive.

⁴⁷ Norcent RW-532 CD-RW IDE drive.

⁴⁸ Plextor PlexWriter Premium CD-RW IDE drive.

U.S. since 2000,⁴⁹ one of which combines radio frequency identification (RFID) technology with text-to-speech capabilities to create the most effective auxiliary communication aid available on the market today. While each of the APLS communication aids have a relatively insignificant impact on pharmacy expenses and operations, they do vary in communication effectiveness.

Three of the four available APLS aids rely on human voice recordings⁵⁰ which, as described above in relation to face-to-face counseling and cassette recordings, pose problems with respect to information completeness, integrity and portability due to pharmacists' and pharmacy technicians' time restraints and variable reading and communication skills. These three also are further limited to prescription medications packaged in standard-sized prescription vials (i.e., pill bottles) and are not functional for use with other commonly used prescription medication packaging such as odd-shaped glass and plastic bottles (for example, dropper bottles and oval-shaped cough medicine bottles), blister packs and boxes.

One of the four available APLS communication aids on the market overcomes issues related to information integrity and portability by utilizing text-to-speech technology.⁵¹ This aid also utilizes an RFID enabled label that securely affixes to any type of prescription medication container, including odd-shaped glass and plastic bottles, blister packs and boxes. Pharmacists or pharmacy technicians pass textual prescription medication information from their computer to a dedicated, small-footprint RFID label printer which encodes the prescription information in an electronic format on a microchip embedded in the label. In the home, the patient uses a hand-held reader, which decodes the label information using speech synthesis technology, to hear medication information such as patient name, drug name and dosage information, instructions for use, warnings and cautions, the prescription number and the name and phone number of the pharmacy and the prescribing doctor.

Unlike face-to-face counseling, the utilization of text-to-speech APLS aids takes a minimal amount of pharmacy time, and the integrity of the communication is ensured because the variable communication skills of pharmacists and technicians are not being relied upon. Furthermore, the information is easily repeatable, so there is no excessive need for the blind or visually-impaired customer to rely upon their memory. In addition, unlike braille embossed medication information sheets, text-to-speech APLS communications are able to be understood by the vast majority of blind and visually-impaired pharmacy customers, and unlike cassette and CD recordings, RFID labels used by text-to-speech APLS systems are able to be securely affixed to, and do not need to be removed from, prescription medication containers.

V. Conclusion

While several methods of communicating prescription medication information to the blind and visually-impaired exist, the development of text-to-speech APLS systems utilizing RFID labels has now made it possible for pharmacies to effectively communicate such information to the

⁴⁹ Report to Congress, , page 25. The four products identified are (i) En-Vision America's ScripTalk, (ii) MedivoxRx Technologies, Inc.'s Rex Disposable Talking Bottle, (iii) TalkingRx, Inc.'s Talking Rx and (iv) ASKO Corporation's Aloud Audio Labeling System.

⁵⁰ The products made by MedivoxRx, TalkingRx and ASKO rely on human voice recording.

⁵¹ En-Vision America's ScripTalk.

blind and visually-impaired with minimal difficulty and expense and with insignificant alteration of the essential nature of pharmacy operations. In addition, thanks to these specially-designed systems, blind and visually-impaired pharmacy customers are now able to enjoy the same privacy rights enjoyed by sighted customers, rights which have historically been forfeited due to a lack of alternative means of receiving prescription medication communications. At the same time, pharmacies can be confident that their provision of text-to-speech APLS systems utilizing RFID labels is the most appropriate and cost-effective solution to compliance with numerous state and federal laws governing prescription medication information content, placement, privacy and non-discrimination in communications.

Appendix A - Available Auxiliary Communication Aids - Communication Effectiveness and Pharmacy Impact Issues

		Face-to-Face Counseling	Braille Printer	Cassette Recordings	Text-to-Audio Software and CD Writer	Voice Recorded APLS Systems	Text-to-Speech APLS with RFID Labels
Communication Effectiveness Issues	Information Completeness	variable based on pharmacy's available time	yes	variable based on pharmacy's available time	yes	basic information	basic information
	Information Integrity	variable based on counselor	consistent, but ability of pharmacy to verify problematic	variable based on reader	consistent and verifiable	variable based on reader	consistent and verifiable
	User Friendliness	customer must rely on memory	usable by only 10% of the affected population	increasing difficulty with multiple medications	increasing difficulty with multiple medications	good	good
	Repeat Communications	problematic	yes	yes	yes	yes	yes
	Ability to Affix	no	no	no	no	No, limited to common sized pill bottles	yes
	Privacy Protection	only on-site at pharmacy	yes	yes	yes	yes	yes
Pharmacy Impact Issues	Nature of Pharmacy Action	some level of counseling typically provided already	easy to send information to printer	equivalent to face-to-face counseling	moderate software difficulties	equivalent to face-to-face counseling	easy to send information to RFID label printer
	Initial Cost of Pharmacy Action	none	expensive	low	low	low	moderate
	Information Portability	problematic	good	problematic	moderate software difficulty	problematic	good
	Ongoing Effect on Expenses and Resources	insignificant if communications are brief	insignificant	insignificant if communications are brief	insignificant	moderate	insignificant