

LANGUAGE SERVICES IN PHARMACIES: WHAT IS REQUIRED?¹

A 10-month old girl was taken to a pediatrician's office by her parents, who spoke no English. The infant was diagnosed with iron-deficiency anemia and prescribed an iron supplement. The parents took the prescription to a local pharmacy that did not provide language services, and the prescription label on the bottle was provided in English. The pharmacist attempted to demonstrate the proper dosing and administration. The prescribed dose was 15 mg per 0.6 ml (1.2 ml) daily. Fifteen minutes after the parents administered the medication to the infant, she appeared ill and vomited twice. She was taken to the emergency room where it was discovered that the parents had administered 15 ml (a 12.5-fold overdose).²

As this example illustrates, it is critical that pharmacists and limited English proficient (LEP) patients be able to communicate effectively. As complicated as it may be for English-speakers to understand medication instructions, the difficulties are exacerbated for LEP individuals. In a recent study, over one-quarter of LEP patients who needed, but did not get, an interpreter reported that they did not understand their medication instructions, compared with only two percent of those who either needed and received an interpreter or did not need an interpreter.³

Given that more than 4 billion prescriptions are written yearly and that 8.7% of Americans are LEP,⁴ millions of prescriptions are likely for LEP patients. This issue brief provides an overview of existing federal laws addressing the provision of language services in the pharmacy setting.

FEDERAL REQUIREMENTS

1. Is there a federal requirement for communication assistance (also called language services) to individuals who do not speak English well?

Yes. In 1964, Congress passed Title VI of the Civil Rights Act. This law prohibits discrimination and ensures that federal money is not used to support health care providers – including pharmacies and pharmacists – who discriminate on the basis of national origin.⁵ Title VI says:

No person in the United States shall, on ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.⁶

The U.S. Department of Health and Human Services (HHS) and the courts have applied Title VI to protect national origin minorities who do not speak English well. Thus, recipients of federal

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financial assistance (hereafter “federal funding”) must take reasonable steps to ensure that LEP individuals have meaningful access to their programs and services.⁷

2. Does Title VI cover pharmacies and pharmacists?

Yes. The obligations under Title VI (and HHS’ regulations and guidance implementing Title VI, see Q. 4-5, and 12 below) apply broadly to any “program or activity” that receives federal funding, either directly or indirectly (through a contract or subcontract, for example), and without regard to the amount of funds received.⁸ For independent and chain pharmacies and pharmacists, federal funding includes federal payments for prescription drugs (including dispensing fees or any other related payments) provided to Medicare, Medicaid and State Children’s Health Insurance Program (SCHIP) enrollees. It also applies to pharmacies providing prescription drugs to enrollees of federally-funded managed care plans (such as Medicaid managed care and Medicare Advantage plans) or Medicare Part D prescription drug plans.

Further, the Title VI protections extend to all of the operations of the organization or individual, not just that part that receives the federal funds.⁹ So once federal funds are accepted, language services must be provided to all pharmacy patients, not just those patients participating in federally funded programs. And if a pharmacy does not take federal funds but is located in a facility that does (such as a hospital or long term care facility), Title VI still applies.

3. Who is “limited English proficient?”

HHS defines individuals as “limited English proficient” if they do not speak English as their primary language and have a limited or no ability to read, write, speak, or understand English.

In determining language ability, the Census Bureau asks how well a person speaks English – the options are “very well,” “well,” “not well” or “not at all.” Due to the complex nature of health care interactions, it is generally accepted that a person who speaks English less than “very well” is likely LEP and will need language services. Nationally, over 24 million individuals speak English less than “very well.”¹⁰

4. How does a pharmacist know how to provide language services?

The federal Departments of Justice and Health and Human Services (HHS) have adopted four factors for assessing how to assist LEP persons. These factors call upon the federally funded pharmacy to determine:¹¹

- The number or proportion of LEP individuals served or encountered.¹²
- The frequency of contact with the program. If LEP individuals access the pharmacy on a daily or weekly basis, a recipient has greater duties than if contact is infrequent.
- The nature and importance of the program to beneficiaries. More steps must be taken if a denial or delay of services may have critical implications for daily life (e.g. medication errors that can result from a misunderstanding of prescription drug instructions).

- The resources available and cost considerations. If the number of LEP persons is limited, a small recipient with few resources may not have to take the same steps as a larger recipient. Costs are a legitimate consideration in identifying the reasonableness of particular language assistance measures.¹³

In balancing these factors, pharmacies and pharmacists should consider the appropriate mix of written and oral language assistance, considering which documents must be translated, when oral interpretation is needed, and whether such services should be immediately available.¹⁴

The HHS Office for Civil Rights (OCR) will apply these factors when determining whether an entity is compliance with Title VI. OCR recognizes that one size does not fit all and will determine compliance on a case-by-case basis.

5. Are there specific guidelines that explain how to provide language services?

Yes. On August 8, 2003, HHS' OCR issued guidance for federal fund recipients, including pharmacies and pharmacists participating in HHS-funded programs.¹⁵ The guidance is available at <http://www.hhs.gov/ocr/lep/>. This guidance does not impose any new requirements but merely brings together all of OCR's policies for overseeing Title VI since 1965.

6. How should a pharmacy offer oral language services?

The HHS Guidance describes various options to provide oral language assistance, including the use of bilingual staff, staff interpreters, contracting for interpreters, using telephone interpreter lines,¹⁶ and using community volunteers. It stresses that interpreters need to be competent, though not necessarily formally certified. A combination of oral language assistance may work best. For example, bilingual pharmacists could provide services directly in some non-English languages while other bilingual staff (including pharmacy or non-pharmacy in-store staff) may be competent to interpret between pharmacists and patients. A telephone language line can offer coverage when existing staff are unavailable. In general, all interpreters – whether staff or contract – must abide by the HIPAA (Health Insurance Portability and Accountability Act) privacy rules (see Q. 7 below).¹⁷

The HHS Guidance allows the use of a person's family members and friends to interpret but clearly states that an LEP person may not be *required* to use a family member or friend and that "extra caution" should be taken if an LEP person chooses to use a minor to interpret. Similarly, an LEP person may not be required to use unrelated individuals, such as other customers, to interpret. These untrained interpreters are often called "ad hoc" interpreters. Pharmacists should verify and monitor their competence and appropriateness of ad hoc interpreters, including the person's language and comprehension skills and awareness of confidentiality and HIPAA issues.

The HHS Guidance notes that particular care must be paid in situations involving health, safety or access to important benefits, or when credibility and accuracy are important to protect the individual – all directly relevant to pharmacy interactions. Moreover, OCR says recipients should make the LEP person aware that he or she has the "option" of having the pharmacy provide an interpreter without charge.

Patient counseling, which may be required under state pharmacy laws, is an area where

the Guidance's emphasis on health and safety is highly relevant. Without being able to communicate with LEP patients, a pharmacist may be unable to provide information about correct dosing, drug interactions, and potential side effects. In addition to potential liability under state law, a pharmacy or pharmacist may be liable for malpractice or negligence if a patient suffers adverse harm because required information is not provided in a manner the patient understands.

The HHS Guidance's concern with access to important benefits is also implicated. For example, if a prescription coverage request is denied because the insurer refuses to cover it, the pharmacist should be able to explain the rejection codes or translate information provided about the denial. If the patient does not understand the basis for the denial, he may not understand his ability to appeal and thus is denied access to important benefits.

7. How does HIPAA impact pharmacies use of interpreters?

HIPAA protects individuals from the release of their private (or protected) health information. Generally, those working in a pharmacy setting may not disclose a patient's protected health information except in limited circumstances and to certain entities, as defined by law. If the pharmacy discloses the information to outside sources (for example, if it uses a language agency to provide interpreters), it should have a "business associate" agreement to ensure that the outside organization also protects the patient's health information.

The HIPAA privacy rule allows others to have access to a patient's health information *with the patient's consent*. To these persons approved by the patient, the pharmacy may disclose protected health information directly relevant to the patient's care or payment if the pharmacy:

- obtains the individual's agreement; *or*
- provides the individual with the opportunity to object to the disclosure and the individual does not express an objection; *or*
- reasonably infers from the circumstances, based on the exercise of professional judgment that the individual does not object to the disclosure. (For example, when a person comes to a pharmacy to pick up a prescription on behalf of an individual he identifies by name, a pharmacist, based on professional judgment and experience with common practice, the pharmacist may allow the person to do so.¹⁸)

Under any of these circumstances, if a patient consents, a family member or friend brought by the patient to the pharmacy would be allowed to interpret and have access to a patient's protected health information. This could also include, *but only if the patient consents*, an *ad hoc* interpreter such as another patient or pharmacy customer. Because in this situation the patient has consented *and* the interpreter is neither a member of the covered entity's workforce nor a business associate, the interpreter is not bound by the privacy rule.

Before a pharmacy relies on an *ad hoc* interpreter, the pharmacy should ensure that the patient is informed of the need to provide consent; without informed consent, the pharmacy may be liable for a HIPAA violation.¹⁹ The patient may ask the covered entity to provide an interpreter who would be subject to the protections of the HIPAA privacy rule.

WRITTEN TRANSLATED MATERIALS

8. When should a pharmacist translate written materials?

It depends on the relevant circumstances of each pharmacy based on the four factors listed above (see Q. 4). After these have been assessed, pharmacies and pharmacists should decide what reasonable steps to take to ensure meaningful access. At a minimum, the pharmacist should translate dosage instructions and warning labels to ensure that a patient fully understands the instructions for usage. Many pharmacy software programs have translation capacity built in; pharmacies and pharmacists should check with their vendors about availability.

Nothing in federal or state law prohibits the translation of prescription drug labels, instructions or inserts. While federal law requires certain information to be on the label in English,²⁰ it takes a permissive approach and allows, but does not require, the inclusion of other languages on the prescription drug label.²¹ Posted information or handouts about patients' rights, such as the right to seek a written explanation or to appeal a denial in Medicaid or the Medicare Part D program, are also items where the importance of translated materials should be considered.

As noted, OCR will evaluate a provider's efforts on a case-by-case basis. For the translation of written materials, the HHS Guidance designates "safe harbors" that, if met, will provide strong evidence of compliance.²²

STATE REQUIREMENTS

9. In addition to federal law, do state laws require pharmacies to provide oral language services?

It depends on the state. All states have enacted laws that address the provision of language services in healthcare settings and some of these apply to pharmacies.²³ In the coming months, the National Health Law Program will be conducting a 50-state survey of pharmacy laws related to language access and will provide results when available. As one example, New York pharmacy regulations include a counseling requirement when pharmacists dispense prescriptions to new pharmacy patients or dispense new medications to current patients.²⁴ The regulations do not include an exemption for LEP patients. Thus, a pharmacist will be unable to comply with the counseling requirement if language services are not provided. The pharmacist should ensure that effective communication occurs, either by using an interpreter or translating drug information handouts (however, it is unlikely that providing translated documents alone would satisfy the counseling requirement because it implies oral communication).

10. What about pharmacies located in hospitals, nursing homes, or other health care settings?

For co-located pharmacies, Title VI may independently apply to both the pharmacy and host facility since both are likely recipients of federal funds. Even if the host facility does not receive federal funds, the pharmacy would still be subject to Title VI if it does. Further, additional state laws may require language access in the host facility.²⁵ For example, Massachusetts, Rhode Island and New York require hospitals to provide language services. A pharmacy located in a hospital would be subject to these laws.

The pharmacy should obtain information about the facility's policies and whether pharmacy staff can access the facility's interpreters and translated materials.²⁶

ADDITIONAL INFORMATION

11. Is a pharmacy liable if it does not provide language services to LEP patients?

Yes, it is potentially liable under both federal and state law. Under federal law, OCR investigates complaints against pharmacies and first has an obligation to seek compliance from those who fail to abide by Title VI. OCR is also available to provide ongoing technical assistance. If compliance is not obtained voluntarily, OCR may refer the issue to the Department of Justice for formal compliance proceedings that could result in suspension or termination of federal assistance.²⁷

If a patient suffers medical harm caused by the pharmacist, the patient could initiate a malpractice or negligence claim against the pharmacy or pharmacist. And if the HIPAA privacy rules are violated, a pharmacy may be liable for fines of \$100 per violation, up to \$25,000 per year.

Depending on state law, additional liability may apply. For example, under New York law, the failure to abide by the requirements for labeling and counseling could result in a pharmacist facing misdemeanor charges with fines and possible jail time for multiple violations.²⁸

12. What if a pharmacist unintentionally discriminates against individuals?

HHS' regulations prohibit federal fund recipients from:

- Using criteria or methods of administration that have the *effect* of discriminating against LEP patients;
- Restricting access to advantages or privileges for LEP patients that non-LEP patients receive from the same program;
- Providing services or benefits to LEP patients that are different, or provided in a different way, from those provided to non-LEP patients (NOTE: a translated document should not be considered "different" since the content is the same as the English document while being presented in a non-English language);
- Treating LEP patients differently from non-LEP patients in determining admission, enrollment, eligibility, or other requirements to receive services.²⁹

13. How can pharmacies document their language services?

Pharmacies and pharmacists can develop a written implementation plan as a means of documenting compliance with Title VI. The Office for Civil Rights suggests five elements when designing a plan:

- Identify LEP individuals who need language assistance, using for example, language identification cards or recording patient language needs in the pharmacy’s computer system.
- Describe language assistance measures, such as the types of language services available, how staff can obtain these services and respond to LEP persons, and how competency of language services can be ensured.
- Train staff, including pharmacists, pharmacy interns, and cashiers, to understand LEP policies and procedures and how to work effectively with LEP patients and interpreters (both in-person and telephonic).
- Provide notice of language services by, for example, posting signs in intake areas and other entry points, providing information in outreach brochures, working with community groups, using a telephone voice mail menu, providing notices in local non-English media sources, and making presentations in community settings.
- Monitor and update the LEP plan, considering changes in demographics, types of services, and other factors.³⁰

14. How can pharmacies pay for language services?

HHS’ Centers for Medicare & Medicaid Services (CMS) recognizes that federal Medicaid and SCHIP funds can be used for language activities and services.³¹ States can thus submit the costs of language services needed by Medicaid and SCHIP enrollees to the federal government for partial reimbursement.

Currently, twelve states plus the District of Columbia directly pay for language services in Medicaid and SCHIP. Some states have limited the reimbursement to “fee-for-service” providers so providers participating in managed care plans might not be eligible. Other states report that they currently set their reimbursement rates for all providers to include the costs of language services as part of the entity’s overhead or administrative costs.³²

15. Where can pharmacies and pharmacists get more information?

The federal government has launched a website called “Let Everyone Participate,” <http://www.lep.gov>. In addition to tracking federal activities, the website offers direct assistance to federal fund recipients and advocates. For example, fund recipients can download “I Speak” cards that allow LEP persons to identify their primary language. The presidential “Executive Order” (EO) entitled *Improving Access to Services for Persons with Limited English Proficiency*,³³ and OCR Guidance are also available on this website.

The “CLAS Standards” (Standards for Culturally and Linguistically Appropriate Services in health care) from the HHS Office of Minority Health, offer additional information and resources.³⁴

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² Agency for Healthcare Research and Quality, *Language Barrier: The Case*, Pediatrics (2006), at <http://www.webmm.ahrq.gov/>.

³ D. Andrulis, N. Goodman, C. Pryor, *What a difference an Interpreter Can Make* (April 2002), at <http://www.accessproject.org>.

⁴ LEP is defined as individuals who are unable to speak English “very well”. See U.S. Census Bureau, “*Language Spoken at Home*” (Table S1601), 2006 American Community Survey, at www.factfinder.census.gov.

⁵ 100 Cong. Rec. 1658 (1964). The United States Supreme Court has treated discrimination based on language as national origin discrimination. See *Lau v. Nichols*, 414 U.S. 563 (1974). “National origin” is not defined in federal law but generally refers to the country where one is born. The U.S. Supreme Court and federal agencies have determined that language can be a proxy for national origin.

⁶ 42 U.S.C. § 2000d. See also 45 C.F.R. § 80 app. A (listing examples of federal financial assistance, including Medicare, Medicaid, Maternal and Child Health grants).

⁷ While some states or localities have declared English as their official language, federal fund recipients must continue to follow federal laws regarding non-discrimination. See, e.g., 42 C.F.R. §§ 438.6(f), 438.100(d).

⁸ See 42 U.S.C. § 2000d-4a (defining “program or activity”).

⁹ *Id.*

¹⁰ 2006 American Community Survey, (Tables S1601, B16001), at <http://www.factfinder.census.gov>.

¹¹ See 65 Fed. Reg. 50123 (Aug. 16, 2000). In addition to Executive Order 13166, this Guidance is authorized by 28 C.F.R. § 42.404(a), directing agencies to “publish title VI guidelines for each type of program to which they extend financial assistance, where such guidelines would be appropriate to provide detailed information on the requirements of Title VI.” According to the Department of Justice, the Guidance does not create new obligations beyond those already mandated by law.

¹² See 67 Fed. Reg. 41459 (June 18, 2002). “But even recipients that serve LEP persons on an unpredictable or infrequent basis should use this balancing analysis to determine what to do if an LEP individual seeks services under the program in question.” *Id.* at 41460.

¹³ *Id.* at 50124-25. See also, e.g., 67 Fed. Reg. 41455, 41457 (June 18, 2002).

¹⁴ See 67 Fed. Reg. 41460 (June 18, 2002).

¹⁵ 68 Fed. Reg. 47311 (Aug. 8, 2003). For previous versions of this guidance, see 65 Fed. Reg. 52762 (Aug. 30, 2000).

¹⁶ Previous guidance cautioned the fund recipient that telephone interpreter lines should not be the sole language assistance option, unless other options were unavailable. See 67 Fed. Reg. at 4975.

¹⁷ For more information on the use of interpreters and HIPAA, see *HIPAA and Language Services in Health Care*, National Health Law Program, at <http://www.healthlaw.org>.

¹⁸ HIPAA Frequently Asked Questions, Notice and Other Individual Rights, *Does the HIPAA Privacy Rule permit a doctor to discuss a patient’s health status, treatment, or payment arrangements with the patient’s family and friends?* at <http://www.hhs.gov/hipaafaq/notice/488.html>.

¹⁹ See footnote 17.

²⁰ This information includes the date of filling; pharmacy name and address; serial number of the prescription; name of the patient; name of the prescribing practitioner; and directions for use and cautionary statements, if any contained in such prescription or required by law. 21 C.F.R. § 1306.14(a) and § 1306.24.

²¹ 21 C.F.R. § 201.15.

²² The safe harbors designate that the recipient provides written translations of “vital” documents (e.g. intake forms with the potential for important consequences, consent and complaint forms, eligibility and service notices) for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally. Or, if there are fewer than 50 persons in a language group that reaches the five percent trigger, above, the recipient provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of vital written materials, free of cost. 68 Fed. Reg. at 47319.

²³ See J. Perkins and M. Youdelman, “Summary of State Law Requirements Addressing Language Needs in Health Care,” National Health Law Program (March 2007), at http://www.healthlaw.org/library/item.174993-Summary_of_State_Law_Requirements_Addressing_Language_Needs_in_Health_Care.

²⁴ N.Y. Comp. Codes R. & Regs tit. 8, § 63.6(b)(8). Counseling can include, but is not limited to: (1) the name and description of the medication and known indications; (2) dosage form, dosage, route of administration and duration

of drug therapy; (3) special directions and precautions for preparation, administration and use by the patient; (4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur; (5) techniques for self-monitoring drug therapy; (6) proper storage; (7) prescription refill information; and (8) action to be taken in the event of a missed dose.

Counseling requirements are also required, but adapted to the specific situations of in-pharmacy delivery to the patient, dispensing to a person authorized to act on behalf of a patient, and mail delivery of prescription drugs.

²⁵ For more information on state laws related to language access and health care, see J. Perkins and M. Youdelman, “Summary of State Law Requirements Addressing Language Needs in Health Care,” National Health Law Program (March 2007), at http://www.healthlaw.org/library/item.174993-Summary_of_State_Law_Requirements_Addresssing_Language_Needs_in_Health_Care.

²⁶ N.Y. Comp. Codes R. & Regs. tit. 10, § 405.7(a)(7).

²⁷ 45 C.F.R. § 80.8.

²⁸ NY CLS Educ § 6816 (1)(a). A second conviction for violation of § 6816 (“untrue labels” violation) can result in the pharmacist being fined a maximum of \$1,000 fine and/or a maximum of one year in prison. A third conviction can result in the above fines and/or jail time in addition to the individual pharmacist’s license revocation.

²⁹ 45 C.F.R. § 80.3(b).

³⁰ 68 Fed. Reg. at 47319-21. Previous guidance called on recipients to develop and implement a language assistance program that addressed: (1) assessment of language needs; (2) development of a comprehensive policy on language access; (3) training of staff; and (4) vigilant monitoring. See 67 Fed. Reg. at 4971.

³¹ See CMS, *Dear State Medicaid Director* (Aug. 31, 2000), available at <http://www.cms.hhs.gov/states/letters/smd83100.asp>.

³² Of the 13 states currently using Medicaid/SCHIP funds to pay for language services, none are doing so in the pharmacy setting. However, there is no prohibition on this. For more information on this issue, see M. Youdelman, *Medicaid and SCHIP Reimbursement Models for Language Services, 2007 Update*, at <http://www.healthlaw.org>.

³³ See 65 Fed. Reg. 50121 (Aug. 16, 2000); see also 67 Fed. Reg. 41455 (June 18, 2002).

³⁴ See 65 Fed. Reg. 80865 (Dec. 22, 2000), at <http://www.omhrc.gov/clas>.