



SHOULD PHARMACIES AND PHARMACISTS PROVIDE LANGUAGE SERVICES FOR PEOPLE WITH LIMITED ENGLISH PROFICIENCY?¹

FEDERAL REQUIREMENTS

1. Is there a federal requirement that pharmacists and pharmacies offer interpreters to individuals who do not speak English well?

Yes. In 1964, Congress passed Title VI of the Civil Rights Act. This law prohibits discrimination. Its purpose is to ensure that federal money is not used to support health care providers – including pharmacies and pharmacists – who discriminate on the basis of race, color, or national origin.² 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.³

The federal Department of Health and Human Services (HHS) and the courts have applied this statute to protect national origin⁴ minorities who do not speak English well. Thus, recipients of federal funding must take reasonable steps to ensure that people with limited English proficiency (LEP) have meaningful access to their programs and services.

2. What if a pharmacist unintentionally discriminates against individuals?

HHS issued regulations to guide the implementation of Title VI that reiterate the statute and extend Title VI beyond the prohibition of intentional discrimination. They prohibit federal fund recipients from:

- using criteria or methods of administration that have the *effect* of discriminating because of race, color or national origin;
- restricting access to advantages or privileges enjoyed by others receiving services through the same program;
- providing services or benefits to an individual that are different, or provided in a different way, from those provided to others (a translated document should not be considered “different” since the content is the same as the English document although it is presented in a non-English language);
- treating an individual differently from others in determining admission, enrollment, eligibility, or other requirements to receive services.⁵

Through these regulations, the HHS Office for Civil Rights (OCR) can initiate investigations or respond to complaints of discrimination. While OCR must first work with an entity towards compliance, OCR has the authority to withhold federal funds for noncompliance.

3. Does Title VI cover pharmacies and pharmacists?

Yes. The obligations under Title VI and HHS' regulations 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.⁶ This includes payment for prescription drugs provided to Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) enrollees. It would apply to any pharmacy receiving payment through these programs and includes both independent and chain pharmacies. It also applies to pharmacies related to managed care plans such as Health Maintenance Organizations (HMOs) or Medicare Advantage plans that receive federal funds.

Further, the Title VI protections extend to all of the operations of the organization or individual, not just that part that received the federal funds.⁷ So if a pharmacy does not take federal funds but is located in a facility (such as a hospital or long term care facility) that does take federal funds the Title VI protections still apply. And once federal funds are accepted, language services must be provided to all pharmacy patients, not just those patients participating in federally funded programs.

4. Who is "limited English proficient?"

HHS defines "limited English proficient" or LEP as individuals who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English. This definition includes individuals with no English proficiency.

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 23 million individuals speak English less than "very well." In New York State, there are over 2.2 million LEP individuals, including over 305,000 in the Bronx, 492,000 in Brooklyn, almost 250,000 in Queens and almost 575,000 in Manhattan.⁸

5. How does a pharmacist know what to do to provide language services?

The Department of Justice, which coordinates the federal government's Title VI oversight, announced four factors for federal fund recipients to use to determine what steps they should take to assist LEP persons:⁹

- The number or proportion of LEP individuals served or encountered.¹⁰
- The frequency of contact with the program. If LEP individuals access the program on a daily 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. hospitals, schools) than in programs that are not as crucial (e.g. theaters, zoos).

- The resources available and cost considerations. If the number of LEP persons is limited, a small recipient with limited 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.¹¹

In balancing these factors, pharmacists should address the appropriate mix of written and oral language assistance, considering which documents must be translated, when oral interpretation is needed, and whether such services must be immediately available.¹²

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

Yes. On August 8, 2003, the HHS Office for Civil Rights (OCR) issued guidance for its recipients of federal funds, which includes pharmacists.¹³ This guidance does not impose any new requirements but merely brings together all of OCR's policies for overseeing Title VI since 1965.

ORAL LANGUAGE SERVICES

7. How should a pharmacy offer oral interpretation services?

The HHS Guidance describes various options available for oral language assistance, including the use of bilingual staff, staff interpreters, contracting for interpreters, using telephone interpreter lines,¹⁴ and using community volunteers. It stresses that interpreters need to be competent, though not necessarily formally certified. You may find that a combination of oral language assistance works best. You may have bilingual pharmacists who can provide services directly in some non-English languages. Other bilingual staff, including both 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. You must make sure that your interpreters – whether staff or contract – abide by the HIPAA privacy rules.¹⁵

The Guidance allows the use of client'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 the competence and appropriateness of ad hoc interpreters, considering not only the person's language and comprehension skills but also confidentiality and HIPAA issues (see Q.9 below).

The 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 the pharmacy encounter. Moreover, OCR says recipients should make the LEP person aware that he or she has the "option" of having the pharmacy provide an interpreter for him/her without charge.

Patient counseling is an area where the Guidance's emphasis on health and safety is highly relevant (also see New York's counseling requirement, discussed under Q.9). Another priority area, access to important benefits, is implicated if, for example, a pharmacist orally explains rejection codes to English-speaking patients when prescription transactions are rejected by the insurer but does not make the same information accessible to limited English speakers.

8. How does HIPAA impact pharmacies use of ad hoc interpreters?

The HIPAA privacy rule allows other individuals to have access to a patient's health information *with the patient's consent*. This includes a family member, other relative, friend, or any other person identified by the individual. To these "persons approved by the patient," the pharmacy may disclose protected health information directly relevant to the patient's care or payment related to the patient's health care if the covered entity: 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.

Thus a family member or friend brought by a patient to the pharmacy would be allowed to interpret and have access to a patient's protected health information even if not a member of a pharmacy's workforce or acting as a business associate. The "person approved by the patient" category 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. But if the patient is concerned about disclosing certain information to an ad hoc interpreter, the patient has the right not to consent. If the patient does not object, the covered entity may reasonably believe consent has been given and disclose the patient's information. But before a pharmacy relies on an ad hoc interpreter, the pharmacy should ensure that the patient is informed of the need to provide consent and that the pharmacy obtains informed consent; without informed consent, the pharmacy may be liable for a HIPAA violation.¹⁶ The patient may ask the covered entity to provide an interpreter who would be subject to the protections of the HIPAA privacy rule.

9. In addition to federal law, does New York State law require pharmacies to provide oral language services?

Yes. New York pharmacy regulations include a requirement for patient counseling. The law requires pharmacists to provide medication counseling when dispensing a prescription to a new pharmacy patient or when dispensing a new medication to a current patient.¹⁷ Although language services are not directly mentioned, the regulations do not include an exemption from the counseling requirement for LEP patients. Thus, a pharmacist will be unable to comply with the counseling requirement if language services are not provided. Thus, 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 which implies oral communication). Thus, to fulfill New York counseling requirements for LEP patients who come to the pharmacy and comply with Title VI language access requirements, the pharmacy should provide language services.

10. What about pharmacies located in hospitals?

In 2006, the New York State Department of Health issued new regulations regarding language access in hospitals, which also apply to co-located pharmacies. Hospitals must provide skilled interpreters and translations of all significant forms to ensure effective communication with all persons receiving treatment, regardless of language. Interpreters and translations shall be regularly available for non-English speaking groups comprising more than 1% of a hospital's service area. Interpreters must be available in inpatient and outpatient settings within 20 minutes and in emergency rooms within 10 minutes of a request by the patient, the patient's family or representative, or a health care provider. Hospitals must designate a Language Assistance Coordinator and develop a Language Assistance Program. For co-located pharmacies, pharmacists should obtain information about the hospital's policies and how to access interpreters and translated materials.¹⁸

WRITTEN TRANSLATED MATERIALS

11. When should a pharmacist translate written materials?

It depends on the relevant circumstances of each pharmacy based on the factors listed above (see Q.5). After the four factors have been applied, pharmacists can decide what reasonable steps they should take to ensure meaningful access. At a minimum, the pharmacist should work to translate dosage instructions and warning labels to ensure that a patient fully understands the instructions for usage. One research study found that for those who were prescribed medication and needed but did not get an interpreter, 27% did not understand the instructions for taking the medications, compared with 2% of those who either got an interpreter or did not need one.¹⁹ Many pharmacy software programs have translation capacity built in; you should check with your vendor about its availability.

Nothing in federal or state law prohibits the translation of prescription drug labels, instructions or inserts. While federal law requires certain information²⁰ to be on the label in English, 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 rights, such as the right to seek a written explanation or to appeal a denial in the Medicaid or Medicare Part D program are also items where the importance of translated materials should be considered.

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

12. Does New York state law require translations of prescription labels?

While there are no specific requirements in New York state law to translate the prescription labels, one may be inferred because the law states that a drug is misbranded if,

any word, statement, or other information required. . .to appear on the label or labeling is not. . .in such terms as to render it *likely to be read and understood by the ordinary individual* under customary conditions of purchase and use.²³

The question arises as to what an "ordinary individual" or "customary conditions of purchase and use" mean in a particular pharmacy practice. While there is no formal definition and the courts have not addressed this issue, in places such as New York City where 25% of the city's

population cannot speak or read English well and 46% of the population speaks a language other than English at home, it is reasonable that an “ordinary individual” could include an LEP customer and that “customary conditions of purchase and use” is likely to include dispensing and selling medications to LEP individuals who cannot understand instructions in English.²⁴ By failing to translate the directions for use on the prescription drug label into a language that is “likely to be read and understood” by an LEP individual, the pharmacist could be found to be dispensing a misbranded drug.

Additionally, a drug is misbranded, unless its label has adequate directions for use and adequate warnings against use by people with certain conditions or for children (that is, when the drug may be dangerous to a person’s health).²⁵

An English-only prescription drug label and English-only drug warnings dispensed to a LEP individual might violate the law because it would provide inadequate directions for use, would fail to allow the LEP individual to understand the warnings, and would not adequately protect users from misuse.

ADDITIONAL INFORMATION

13. 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, the Office for Civil Rights investigates complaints against pharmacies and first has an obligation to seek compliance from those who fail to abide by Title VI. It also provides technical assistance. But if compliance is not obtained voluntarily, OCR must secure compliance through the termination of federal assistance although it has not yet had to resort to this.

Under New York law, the failure to abide by the requirements for labeling and counseling could result in a pharmacist facing state liability. It is a misdemeanor to put an “untrue label” on a prescription medication with fines and possible jail time for multiple violations.²⁶ But this provision also indicates that pharmacists must ensure that label translations are accurate so that they do not put an “untrue label” on the dispensed prescription medication.

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.

14. How can pharmacies document their language services?

Pharmacists can develop a written implementation plan as a means of documenting compliance with Title VI. The following five elements are suggested when designing such 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 know about LEP policies and procedures and how to work effectively with in-person and telephone interpreters.
- Provide notice to LEP persons 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.
- Monitoring and updating the LEP plan, considering changes in demographics, types of services, and other factors.²⁷

15. How can pharmacies pay for language services?

On August 31, 2000, the Health Care Financing Administration (now Centers for Medicare & Medicaid Services (CMS)) stated that federal Medicaid and SCHIP funds can be used for language activities and services.²⁸ States can thus submit the costs incurred by themselves or health care providers serving Medicaid and SCHIP enrollees to the federal government for partial reimbursement.

States could also use the Medicaid/SCHIP funds to pay for language services in pharmacies for Medicaid and SCHIP enrollees although no state has yet done this. Some states have limited the reimbursement to “fee-for-service” providers and thus providers participating in managed care plans might not be eligible. Many states 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.²⁹

16. Does New York provide language services through Medicaid/SCHIP?

Not yet, but efforts are underway to enact legislation to assist hospitals in paying for language services (S.3686, Sen. Sabini).

17. Where can I 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*,³⁰ and OCR Guidance are available on this website. In addition, the “CLAS Standards” (Standards for Culturally and Linguistically Appropriate Services in health care) from the Office of Minority Health, offer additional information and resources.³¹

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² 100 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).

³ 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).

⁴ “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.

⁵ 45 C.F.R. § 80.3(b).

⁶ *See* 42 U.S.C. § 2000d-4a (defining “program or activity”).

⁷ *Id.*.

⁸ 2005 American Community Survey data, Table B16001, “*Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over*,” available at <http://www.factfinder.census.gov>. Note: Data for Staten Island is not available because the number of sample cases is too small.

⁹ *See* 65 Fed. Reg. 50123 (Aug. 16, 2000). In addition to EO 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 DOJ, the Guidance does not create new obligations beyond those already mandated by law. *Id.* at 50121-22.

¹⁰ *See* 67 Fed. Reg. 41459. “But even recipients that serve LEP person 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.”

¹¹ *Id.* at 50124-25. *See also, e.g.*, 67 Fed. Reg. 41455, 41457 (June 18, 2002).

¹² *See* 67 Fed. Reg. 41460 (June 18, 2002).

¹³ 68 Fed. Reg. 47311 (August 8, 2003). To review previous versions of this guidance, *see* 65 Fed. Reg. 52762 (Aug. 30, 2000).

¹⁴ 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.

¹⁵ For more information on the use of interpreters and HIPAA, *see* *HIPAA and Language Services in Health Care*, National Health Law Program, <http://www.healthlaw.org>.

¹⁶ *Id.*

¹⁷ 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 on premise delivery to the patient, dispensing to a person authorized to act on behalf of a patient, and mail delivery of prescription drugs.

¹⁸ N.Y. Comp. Codes R. & Regs. tit. 10, § 405.7(a)(7).

¹⁹ D. Andrulis, N. Goodman, C. Pryor, *What a difference an Interpreter Can Make* (April 2002), available at <http://www.accessproject.org>.

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 NY CLS Educ. § 6815(2)(c) (2007) (emphasis added). It is a misdemeanor for “any person to adulterate or misbrand any drug. NY CLS Educ § 6811).

²⁴ See Mike Mitka, For Non-English Speakers, Drug Label Instructions Can Be Lost in Translation, 297 JAMA 2575, 2576 (2007).

²⁵ NY CLS Educ § 6815(2)(f).

²⁶ 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.

²⁷ 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.

²⁸ See CMS, *Dear State Medicaid Director* (Aug. 31, 2000), available at <http://www.cms.hhs.gov/states/letters/smd83100.asp>.

²⁹ 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 *Medicaid and SCHIP Reimbursement Models for Language Services, 2007 Update*, available at <http://www.healthlaw.org>.

³⁰ See 65 Fed. Reg. 50121 (Aug. 16, 2000), see also 67 Fed. Reg. 41455 (June 18, 2002).

³¹ See 65 Fed. Reg. 80865 (Dec. 22, 2000), available at <http://www.omhrc.gov/clas>.