

New Federal Nondiscrimination Regulation Imposes Requirements on Pharmacies

On May 18, HHS and its Office of Civil Rights released the Nondiscrimination in Health Programs and Activities [Final Rule](#). According to HHS, under the Rule, individuals are protected from discrimination in health coverage and care on the basis of race, color, national origin, age, disability and sex, including discrimination based on pregnancy, gender identity and sex stereotyping. In addition to implementing Section 1557 of the Affordable Care Act's prohibition on sex discrimination, the Final Rule also enhances language assistance for people with limited English proficiency and helps to ensure effective communication for individuals with disabilities. This regulation is applicable health care entities and providers receiving federal funds from HHS, such as health insurers, hospitals, physicians and pharmacies. Most of the provisions relevant to pharmacies take effect on [July 18, 2016](#).

Compliance and Notice Requirements. The Final Rule requires entities to file an assurance of compliance (form [HHS-690](#)) as a condition of any application for Federal financial assistance¹ and to take continuous steps to notify the public regarding the following: (1) the entity does not discriminate; (2) the entity can provide free services and materials for those with limited English proficiency or a disability; (3) how to obtain aids and services; (4) contact method for the employee responsible for compliance; (5) the availability of a grievance procedure; and (6) OCR's contact information for discrimination complaints. Posting of such information must be in conspicuous physical locations, on entities' websites and in significant public communications. Translated resources made available by HHS for the purpose of satisfying notice requirements are available [here](#).

Individuals with Limited English Proficiency (LEP). Covered entities must take reasonable steps to provide meaningful access for each LEP individual eligible to be served or likely encountered. The Proposed Rule listed relevant factors to consider when determining whether language obligations have been satisfied. The Final Rule only specifies one relevant factor - whether or not the entity had an effective and appropriate written language access plan. Although such a plan is not explicitly required by the Final Rule, APhA strongly encourages pharmacies to develop such plans to establish a framework to provide health care and services

¹ Nondiscrimination in Health Programs and Activities; Final Rule, 42 C.F.R. 92, §92.4 (2016) stating. "Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of: (i) Funds; (ii) Services of Federal personnel; or (iii) Real and personal property or any interest in or use of such property, including: (A) Transfers or leases of such property for less than fair market value or for reduced consideration; and (B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government. (2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage."

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non-discriminatorily and the reasonable steps that will be taken to provide access to persons with LEP. HHS notes that substantial weight will be given to the nature and importance of the program or activity and the particular communication in relation to whether language obligations have been satisfied.

The Final Rule reiterates that covered entities may not rely on family members, friends, and minor children to provide interpretation services. In addition, the Final Rule describes the skills needed for on-site staff able to provide interpretive services (i.e. qualified bilingual/multilingual staff standard). The Final Rule provides exceptions to these prohibitions, clarifies that the individual with LEP is not required to accept language assistance services² and encourages staff to record when language assistance services were offered and denied.

The Final Rule does not set thresholds for the number of languages assistance services that must be provided but does set a threshold for taglines — short statements written in non-English languages that indicate the availability of language assistance services free of charge. Covered entities must supply taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

Individuals with disabilities. Covered entities must provide effective communications with individuals with disabilities and must adhere to federal law and standards of Title II of the Americans with Disabilities Act (ADA), which are more stringent standard. Under the Final Rule, covered entities must provide auxiliary aids and services to individuals with impaired sensory, manual or speaking skills, and certain facilities will need to conform for ADA 2010 accessible design standards. The rule does not adopt specific technology standards but does require covered entities to ensure that programs and activities provided in electronic or information technology are accessible to individuals with disabilities unless doing so would pose undue financial/administrative burden and would result in a fundamental alteration in the nature of the program or activity. If such conditions occur, the entity must provide information in another format that strives to ensure that individuals with disabilities have access to the services or benefits.

Sexual Orientation. The proposed rule does not resolve whether there is a prohibition of discrimination based on sexual orientation, but OCR will evaluate sexual orientation discrimination complaints to determine whether they involve discriminatory stereotyping of sexual attraction or behavior.

² Language assistance services may include, but are not limited to:

- (1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;
- (2) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English; and
- (3) Taglines.

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Exceptions to the discrimination rule. The proposed rule does not answer whether an exception exists for discrimination rooted in religious beliefs.

Enforcement. OCR will enforce section 1557 using the procedures detailed in Title VI of the Civil Rights Act. However, the procedures of the Age Act will be used in issues regarding age discrimination. Covered entities must provide OCR with requested information in a timely manner or be at risk of being found in noncompliance. In such circumstances, OCR can apply enforcement tools, including suspension or termination of funding. Although OCR has discretion when evaluating efforts entities have taken to maintain and achieve compliance, good faith attempts are not a defense.

In addition to OCR's authority, individuals may sue directly under section 1557 in federal court, and compensatory damages are available in such actions.

Discrimination by insurers and in employee health benefit programs. The proposed rule also addresses discrimination by insurers and employee health benefit programs.

More information regarding the Final Rule is available [here](#).

Summary of Key Requirements Affecting Pharmacies:

The compliance date of the below requirements is July 18, 2016 unless otherwise noted.

1. Designation of responsible employee (only if the covered entity has 15 or more employees)
 - Must designate at least one employee to coordinate its efforts to comply with and carry out Section 1557 and this regulation's requirements, including investigation of any grievance or allegation that action would be prohibited by Section 1557 or this regulation)
 - **Tip:** Pharmacies that have a designated employee to satisfy standards under Section 504 or Title IX may use that individual to comply with Section 1557

2. Adoption of grievance procedures (only if the covered entity has 15 or more employees)
 - Must adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this regulation)
 - **Tip:** Pharmacies that have a grievance procedure to satisfy standards under Section 504 may use that procedure to address disability claims under Section 1557 and all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin sex, and age discrimination

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- **Resource:** Example of a Section 504 grievance procedure that incorporates due process standards (<http://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/section-504-grievance-procedure/index.html>)
3. File assurance of compliance form when applying for federal funding
- Will be revised to include all civil rights law which covered entities must comply
 - **Resource:** Assurance of compliance form (HHS 690 Form):
<http://www.hhs.gov/sites/default/files/hhs-690.pdf>
4. Training (encouraged, not required)
- Covered entities are encouraged, but not required, to train employees periodically on compliance with Section 1557. In the assumptions of the proposed rule, used to determine cost, it assumes that employers are most likely to train employees who interact with the public which is estimated to be 50% of employees. Pharmacists are included in the pool of staff anticipated to need training.
 - **Useful resource:** To facilitate training that covered entities choose to provide, OCR will make available a training curriculum, and will engage in outreach and technical assistance to promote understanding of and compliance with the final rule (as of 5/25 this resource has not been made available)
5. Notices of nondiscrimination (a), taglines (b), and significant publications and communications (c & d) [*Pharmacies must comply within 90 days of the rule's July 18 effective date*]:
- a. *Notice of nondiscrimination:* Must be placed in conspicuous physical locations where the entity interacts with the public (i.e. in store) and in a conspicuous location on the covered entity's website accessible from the home page of the covered entity's website – the notice posting must adhere to the following:
 - (1) the covered entity does not discriminate on the basis of race, color, national origin, sex, age or disability in its health programs and activities;
 - (2) the covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;
 - (3) the covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;
 - (4) how to obtain aforementioned aids and services;

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- (5) an identification of, and contact information for, the responsible employee (required if there are 15 or more employees);
- (6) the availability of a grievance procedure and how to file a grievance; and
- (7) how to file a discrimination complaint with OCR.
- b.** *Taglines*³: Must be in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States
 - Tagline example:** ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).
- c.** *Significant publications and significant communications* targeted to beneficiaries, enrollees, applicants, and members of the public (except those that are small-sized) posting must include:
 - Content: same as that of notices in physical locations/ website
 - Taglines: same as that of physical locations
- d.** *Significant publications and significant communications that are small-sized* (e.g., postcards and tri-fold brochures) posting must include in a conspicuously visible font-size:
 - (1) Non-discrimination statement (the covered entity does not discriminate on the basis of race, color, national origin, sex, age or disability in its health programs and activities)
 - (2) Taglines: In at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

Tip: A covered entity may combine the notice’s content with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this regulation.

Resource: Translated materials for covered entities (<http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html>): includes a sample notice of nondiscrimination, statement of nondiscrimination and taglines, all translated into various languages and developed for compliance with the regulation.

- 6.** Take reasonable steps to provide meaningful access, free of charge and in a timely manner, for individuals with limited English proficiency to each individual with limited English proficiency eligible to be served or likely encountered in its health programs and activities
 - Must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency

³ Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

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- Specific requirements for interpreter and translation services (required if it is a reasonable step)
 - o Offer a qualified interpreter⁴ to an individual with limited English proficiency
 - o Use a qualified translator⁵ when translating written content in paper or electronic form
- Restrictions: Covered entity cannot:
 - o Require a LEP individual to provide his/her own interpreter
 - o Rely on an adult accompanying an individual with LEP to interpret or facilitate communication, exceptions are:
 - i. Emergency involving imminent threat to safety of welfare of an individual or the public and no qualified interpreter is immediately available
 - ii. Specific request from the LEP individual to have the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances
 - iii. Rely on staff other than qualified bilingual/multilingual staff to communicate directly with LEP individuals
 - o Additional requirements are listed for video remote interpreting services
- Language Access Plan: not required, but **APhA strongly encourages** covered entities to develop a language access plan to establish a framework to deliver health care and services non-discriminatorily and outline the reasonable steps that will be taken to provide access to persons with LEP

Tip: Although individuals with LEP are not required to accept language assistance services, covered entities should document when such services are offered and the patients refuses them

Resource: HHS Language Access Plan (2013)

<http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf> (referenced in the Final Rule)

⁴ Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

- (1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;
- (2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and
- (3) is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

⁵ Qualified translator means a translator who:

- (1) Adheres to generally accepted translator ethics principles, including client confidentiality;
- (2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and
- (3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

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7. Take reasonable steps to provide meaningful access, free of charge and in a timely manner to provide effective communication for individuals with disability
 - A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities

8. Must make accessible electronic and information technology programs or activities to individuals with disabilities unless there is undue financial and administrative burdens or a fundamental alteration in the nature of the health program or activity
 - Expectation to adapt: When undue financial and administrative burdens or a fundamental alteration exist, the covered entity must provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

9. Requirement to make reasonable modifications to policies, practices or procedures
 - A covered entity shall make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term “reasonable modifications” shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

10. Covered entities that were required to adhere to the 2010 ADA Standards for Accessible Design prior to July 18, 2016 must comply with those standards for new construction or alteration prior to July 18, 2016
 - *If construction or alteration commenced on or after July 18, 2016:* Must comply with 2010 ADA Standards for Accessible Design.
 - *If a facility was not covered by the 2010 ADA Standards prior to July 18, 2016:* Must now comply with the 2010 Standards if the construction was commenced after December 18, 2017 (18 months after the effective date of the Final Rule).
 - *If a facility was constructed or altered in conformance with the 1991 Standards or the 2010 Standards:* Will be deemed to comply with the requirements of this section and other relevant sections noted in the Final Rule
 - *If a facility was constructed or altered in accordance with the Uniform Federal Accessibility Standards (UFAS):* Will be deemed compliance with this section only if construction or alteration was commenced before July 18, 2016 and the facility or part of the facility was not covered by standards under the ADA

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- *Note:* According to the Final Rule “As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.”

11. Evaluation of compliance – the Director shall consider:

- Nature and importance of the health program or activity and the particular communication at issue, to LEP individual
- Other relevant factors, including whether a covered entity has developed and implemented an effective written language access plan, the is appropriate to its particular circumstances, to be prepared to meet the obligation of this section

Tip: A language access plan is not required, but APhA strongly encourages covered entities to develop a language access plan to establish a framework to provide health care and services non-discriminatorily and the reasonable steps that will be taken to provide access to persons with LEP

Resource: HHS Language Access Plan (2013)

<http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf> (referenced in the Final Rule)

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