LANGUAGE SCIENTIFIC®

CREATING VALUE THAT GOES BEYOND COMPLIANCE:

Best practices for meeting the Affordable Care Act's language access requirements

A LANGUAGE SCIENTIFIC WHITE PAPER

languagescientific.com

About Language Scientific

Founded and managed by translators with backgrounds in medicine, science, and engineering, Language Scientific is driven by a mission to set the standard of quality for scientific translation and localization. When you need precise global communication, you need Language Scientific's technical, regulatory, and language understanding. For more information, visit us at languagescientific.com.

Best practices for complying with Section 1557 of the Affordable Care Act–While creating value that goes beyond compliance

Section 1557 of the Affordable Care Act (ACA) — guaranteeing meaningful access for individuals with limited English proficiency (LEP) and clarifying what that entails — recently took effect. The U.S. Department of Health and Human Services' (HHS) final rule reaffirms longstanding language access requirements for federally funded entities while introducing important updates and clarifications.

For organizations covered under the ACA, compliance begins with understanding your audience. Evaluating your entity's language access needs and developing a thoughtful plan to meet them isn't just about checking a regulatory box — it's about building trust with the customers and patients who rely on you, whether they're in line at a pharmacy counter or calling in from an international clinical trial location. A strong language access plan helps ensure compliance with Section 1557 while improving your customers' experience, strengthening your reputation in the LEP community, and ultimately supporting your bottom line.

What does Section 1557 require?

Section 1557 doesn't outline specific expectations in all areas, but three things are clear. As stated in HHS's letter, "Language Access Provisions of the Final Rule Implementing Section 1557 of the Affordable Care Act," entities receiving federal funding must[1]:

1. Post a notice of availability for language assistance
2. Take reasonable steps to provide LEP individuals with qualified, on-demand interpreters
3. Provide accurate written translations of critical, or "vital" documents

[1] https://www.hhs.gov/sites/default/files/ocr-dcl-section-1557-language-access.pdf

Additionally, if your entity has more than 15 employees, you must designate a Section 1557 coordinator.

What are the potential consequences of non-compliance?

Section 1557 is enforced by the HHS Office of Civil Rights (OCR), and includes similar enforcement mechanisms to Title VI of the Civil Rights Act, prohibiting programs that receive federal funds from discriminating based on race, color, or national origin.

The key is that entities covered under Section 1557 of the ACA must take reasonable steps to ensure meaningful access for LEP individuals. For details, see HHS's online guidance, "Section 1557: Ensuring Meaningful Access for Individuals With Limited English Proficiency"[2]. If meaningful access isn't provided, HHS may:

- Take corrective action (intervene in the covered entity's policies or training; take on a monitoring role)
- Suspend or terminate federal financial assistance
- Refer the matter to the Department of Justice for litigation

It's also worth noting that, as stated in Item 6 of the HHS FAQ on section 1557[3], individuals can file lawsuits under section 1557.

A number of high-profile interventions demonstrate that HHS takes section 1557 seriously, and that entities hoping to "fly under the radar" risk being reported to HHS by advocacy groups, private individuals, and even their own employees. These cases also highlight the need to provide very specific assistance to LEP individuals, not just general access to language services, and are detailed on the civil rights enforcement section of HHS's website[4].

- Medco, one of the U.S.'s largest pharmacy benefit managers, was the subject of a complaint filed by the son of an LEP individual whose health plan contracts with Medco to provide prescription drug benefits. The complainant, on behalf of his mother, successfully argued that Medco failed to identify and track its customers' language preferences, left voicemail messages in English only, and sent written communication in English only, even when these messages and letters required a response or action on the part of the LEP individual. In multiple cases, the LEP individual's failure to respond resulted in the cancellation of a prescription for a chronic condition.

[2] https://www.hhs.gov/civil-rights/for-individuals/section-1557/fs-limited-english-proficiency/index.html
[3] https://www.hhs.gov/sites/default/files/section-1557-final-rule-faqs-7282017rev15.pdf
[4] For more examples of language access enforcement, see the "Effective Communication in Health Care" section of HHS's website https://www.hhs.gov/civil-rights/for-individuals/special-topics/hospitals-effective-communication/index.html

Following the OCR investigation, Medco was required to make a number of changes, including better identification and tracking of customers' language preferences, improvements to its telephone system to route LEP individuals' calls, and an overhaul of the methods for using bilingual staff, including assessments of the employees' language proficiency and ability to interpret accurately.

It's worth noting that these enforcement actions were taken *despite the fact* that Medco already contracted with a telephonic interpreting service for more than 150 languages; Medco's actions were deemed insufficiently proactive.

- The University of New Mexico Hospital was the subject of several complaints for failure to provide professional interpreters, and encouraging or requiring the use of neighbors and family members, including minor children, as interpreters. The hospital was also cited for providing discharge information and prescriptions only in English, and failing to train its employees in proper language access procedures.

  As a result, the hospital took multiple corrective actions, including training staff on how to evaluate and document patients' preferred language, informing patients that it is their right to access free language services provided by professional interpreters, and requiring patients to specifically decline the offer of a professional interpreter before using a companion or family member as their interpreter.
- Marin (California) General Hospital was the subject of a complaint filed by a community advocate, asserting that the hospital's language access services and policies denied LEP individuals an equal opportunity to access the hospital's services. The hospital subsequently overhauled its procedures, identifying LEP individuals immediately upon intake, and prominently posting interpreter services notices.
- Numerous other entities have been the subject of OCR investigations for similar issues: failure to identify LEP individuals' language preferences; use of bilingual staff as interpreters without assessing their language skills and ability to interpret; allowing family members or companions to serve as interpreters without informing the LEP individual that professional interpreters are available at no cost; failure to maintain a roster of available interpreters or contract with a remote interpreting service.

Even when these types of enforcement actions do not result in monetary penalties or the withdrawal of funding, they are time-consuming and expensive to deal with, and they are also public, potentially resulting in harm to the covered entity's reputation. Rather than risking this type of situation, it's advisable to handle language access compliance proactively.

Sector-specific challenges

Compliance with Section 1557 isn't optional; it's a legal requirement, even if it involves a significant investment of time and money.

Federal law prohibits passing these costs on to patients, relying on untrained staff members to translate/interpret, or using poor-quality translation or interpreting services. Also prohibited are video or telephone interpreting with a poor connection, and automated translation that has not been reviewed by a qualified human translator.

While language access requirements also apply to entities like courts and schools, sectors covered by the ACA face specific challenges:

- Fast-paced environment: Healthcare settings often operate under intense time pressure. Fast access to interpreting services (rather than scheduling ahead of time) is critical.
- Complex, technical content: Medication administration instructions, drug interaction warnings, and similar information often involves complex medical jargon. This makes it risky to rely on staff with limited language skills.
- Space constraints: Printed information, particularly prescription labels, often has to comply with significant space restrictions.
- Emergencies and walk-ins: Healthcare entities often (and sometimes exclusively) serve unscheduled, drop-in customers. Interpreter capacity must be planned around this inability to plan.
- Cost and resource concerns: The cost of Section 1557 compliance may be a concern for smaller, independent entities. But federal law requires translation and interpreting services to be provided, and prohibits passing the cost on to the LEP individual.
- Coordinating with upstream providers: In settings like pharmacies and clinical trials, the LEP individual may already have received instructions from a prescriber or even an administrative employee. But this doesn't eliminate the requirement for interpreting or translation at the point of contact.
- Over-reliance on automated translation: The final rule emphasizes that if automated translation is used, its accuracy must be insured, and it must be reviewed by a qualified human. Automated translation cannot be used as a standalone solution.

What is a notice of availability?

Simply put, you must inform LEP individuals that language assistance is available at no cost. The easiest way to do this:

- Post, in a prominent location, a tagline such as “Language assistance available free of charge: just ask us!” or “We provide free language assistance. Please point to your language” in multiple languages.
- Depending on your location, you could consider posting your notice of availability in Spanish, Chinese (Traditional and Simplified), Vietnamese, Tagalog, Arabic, French, Korean, Russian, Haitian Creole, and Portuguese. Federal regulations generally recommend providing your notice of availability in the language of any group that makes up at least 5% of your local population.

This multilingual notice of availability ticks a few ACA compliance boxes, because it clearly states, in multiple languages, that:

- Language assistance is available at no cost,
- It’s offered to all patients or customers, and
- How to request it.

Interpreting: must be accurate, timely, and provided at no cost

Section 1557 requires that all covered entities must “offer a qualified interpreter when oral interpretation is a reasonable step to provide meaningful access.” In some healthcare environments (pre-scheduled appointments at a large medical center), meaningful access for LEP individuals is often provided by on-site interpreters.

The situation is trickier in a setting such as a pharmacy, operating largely without scheduled appointments and serving everyone who comes through the door, but still needing to provide a qualified interpreter in a timely manner.

The ACA prohibits some solutions that might spring to mind. Covered entities may not:

- Require LEP individuals to provide their own interpreter
- Rely on a child or untrained family member as an interpreter, other than in an emergency
- Use bilingual staff members as interpreters, unless they are formally qualified as an interpreter

The HHS rule’s text and guidance specify that, in order to be “qualified,” an interpreter must:

- Have demonstrated proficiency in both languages and be able to interpret in both directions; from English into the non-English language, and the other way around,
- Be able to interpret domain-specific and medical terminology, and
- Follow interpreter ethical standards such as confidentiality, impartiality, and accuracy.

It's also important for interpreting services to be provided in a timely manner. "Undue delay," such as requiring an LEP individual to wait for an unreasonable amount of time for an interpreter, or asking the individual to come back at another time, can be construed as a violation of Section 1557.

How to provide ACA-compliant interpreting services

For most covered entities that don't have the demand or the resources to employ on-site interpreters, complying with language access requirements generally involves partnering with a qualified language services company (LSC). Remote interpreting is generally provided over the phone, or via a video interpreting system. Choosing an LSC with a track record of successfully providing on-demand, remote interpreting sets covered entities up for success. For details, see the "Requirements and Use of a Qualified Interpreter" section of HHS's letter on the Final Rule[5].

- **Qualified interpreters**. Most critically, an LSC with experience providing remote interpreting for ACA-covered entities has a full slate of qualified professional interpreters. This allows covered entities to meet federal language access requirements, even if they need interpreter assistance on an irregular basis. Qualified interpreters are the key to avoiding violations for using unqualified staff, family members, or ad hoc interpreters, and an experienced LSC provides qualified interpreters on a contract basis.
- **Easy access**. Qualified LSCs should offer 24/7 on-demand interpreting via phone or video; this may be as simple as dialing a toll-free number, saving staff from scrambling to find a bilingual employee or having to use a complex and potentially unreliable technology platform to secure an interpreter.
- **Centralized coordination**. One LSC should cover all of a covered entity's language needs; staff should be able to contact a central "hotline" to request an interpreter in any language.
- **Documentation and billing**. A qualified LSC should be able to provide call logs that can help document ACA compliance. For example, call logs can show wait times and call drop rates, both of which are key to proving a "reasonable effort" to provide timely and reliable service. Some LSCs can provide coded billing statements so that language costs are allocated to the correct internal budget center; these can also help document

[5] https://www.hhs.gov/sites/default/files/ocr-dcl-section-1557-language-access.pdf

which departments use the most interpreting services, and which languages are the most requested.

Translating vital documents

Section 1557 also requires the translation of "vital documents" into a language that the patient can understand. The HHS definition of "vital documents" is broad, and is generally understood as any written materials that are essential to an individual's participation in, or understanding of, a health program or service. In addition to a notice of availability, a typical pharmacy would be required to translate materials such as:

- Prescription drug labels and auxiliary warning stickers (e.g., "Take with food," "Do not drive while taking this medication")
- Medication guides, package inserts, or patient education leaflets
- Instructions for use for medical devices or self-injectables

Some LSCs provide both interpreting (spoken) and translation (written) services that can help covered entities comply with both aspects of the ACA.

Benefits beyond compliance

For many ACA-covered entities, compliance with federal language access requirements is an initial motivator; but providing meaningful access to LEP individuals has additional benefits for entities and their patients and customers.

- **Improved patient safety and health outcomes**. LEP patients who understand their care plan are more likely to follow through with medication adherence and follow-up care. High-quality interpreting and translation services can help reduce medication errors and treatment noncompliance.
- **Greater patient satisfaction and trust**. When patients see language access as the standard of care, they feel respected and valued. This can foster loyalty and word-of-mouth recommendations, especially within multilingual communities.
- **Operational efficiency**. Handing interpreting and translation over to a qualified LSC reduces the burden on bilingual staff who are pulled away from other duties. Qualified, on-demand interpreting services mean shorter encounters, less confusion, and fewer requests for clarification. Having a consistent protocol for serving LEP individuals makes it easier to train staff and use standardized workflows.
- **Alignment with mission and values.** Providing meaningful access to LEP individuals isn't just the law; it aligns with the healthcare sector's broader commitment to health equity, inclusion, and service to the community.

Meaningful language access may start out as a checkbox, but it's also a tangible way to improve patient safety, employee satisfaction, and customer loyalty.

Where to start? A language access plan

No matter the size of a covered entity's LEP patient or customer base, a language access plan is a great starting point for ACA compliance, and the business benefits that go along with it. For detailed guidance, see the Centers for Medicare and Medicaid Services' Guide to Developing a Language Access Plan[6]. Here are five questions that can help craft a simple and effective strategy:

1. **Who are you serving, and how?**

Using internal surveys, local census data, or data on your current patient and customer base, determine the languages that your clients speak, and how often language services may be needed. Then, look at what language services you're currently providing: if you're currently providing interpreting or translation services, how are you doing this, and are you in compliance with Section 1557? For example, if you are using bilingual staff and automated translations, you are at risk of noncompliance penalties.

2. **What language services do you need to provide, and what is the best way to do this?**

Do you need to provide oral interpretation? If so, would in-person, over-the-phone, or video remote interpreting work best? Begin to identify potential Language Services Companies with experience providing what you need: qualified, on-demand interpreting services. Do the same for written translation: identify what vital documents need to be translated in order to comply with Section 1557 and meet the needs of your patient/customer base.

3. **How will staff be trained?**

Staff need to be well-informed about language access requirements and policies, how to use language services, and how to inform LEP individuals about availability. Standardizing these procedures saves time, avoids frustration, and avoids repeat requests for clarification from staff, patients, and customers.

4. **What notices and outreach do you need to display or publish?**

Create notices, such as taglines, that inform the public about the ready availability of free language services. Make sure that vital documents such as prescription labels and patient instructions are available in multiple languages.

5. **Once your plan is implemented, how effective is it?**

Consider using internal surveys of employees and patients/customers to measure the qualitative success of your plan, and partner with your LSP on data trends such as average wait times and

[6] https://www.cms.gov/about-cms/agency-information/omh/downloads/language-access-plan.pdf

dropped calls to interpreter lines. Consider a yearly update so that your plan responds to the changing needs of your community.

Getting it right

Language access isn't just the law; it makes good business sense and leads to better outcomes for LEP individuals. HHS's own guidance letter states that, "Approximately 68 million people in the United States speak a language other than English at home, and of those, 8.2 percent speak English less than very well…Numerous studies also show that patients' inability to communicate with their providers is a barrier to quality care, resulting in worse health outcomes. Thus, the provision of language access services is not only a legal obligation but necessary for patient care[7]."

A key step in getting it right: test your language access procedures from end to end, envisioning someone who speaks little to no English trying to navigate them. Sometimes, there are alarming inadequacies, even if your entity complies with the letter of the law. A recent report, Justice Disrupted: Improving Language Access at the Massachusetts Trial Courts[8], gives examples from the criminal justice system, which has similar language access requirements to the healthcare system. Despite a clear recognition of LEP individuals' right to interpretation and translation services, observers noted that only 17% of the time did court clerks announce the availability of these services in a language other than English. Fully 62% of LEP individuals surveyed for the report said that their cases had been postponed due to the lack of an interpreter, 36% had experienced a legal proceeding that went forward despite the lack of an interpreter, and "almost half (45%) of the survey respondents noted that the interpreter never showed up." These statistics are shocking on their own, but here's where the system really breaks down: "The Office of Language Access does have a complaint form on its website for LEP and D/HH (deaf/hard of hearing) court users to report issues…However, the form is not easily found on OLA's website and, glaringly, is available only in English."

Similar issues exist in every sector covered by the Affordable Care Act. Paying attention to every step of the language access process, having a solid language access plan, prominently posting a notice of availability in multiple languages, and ensuring that LEP individuals are immediately identified and provided with high-quality interpreting and translation services can ensure that you are on the right side of the law, while creating long-term relationships of trust with your customers and patients.

[7] https://www.hhs.gov/sites/default/files/ocr-dcl-section-1557-language-access.pdf
[8] https://massappleseed.org/wp-content/uploads/2025/10/Justice-Disrupted.pdf

HOW LANGUAGE SCIENTIFIC CAN HELP

Language Scientific offers comprehensive solutions to address the language translation challenges posed by IVDR and recent tariff realities. With expertise in medical and technical translations, the company ensures that all documentation meets the stringent requirements of IVDR.

Key services include:

Multilingual Translation

Accurate translations of labeling, IFUs, and other mandatory documents into all required EU languages.

Phone Interpreting

Real-time support for healthcare, legal, and business industries to facilitate communication and compliance.

Regulatory Expertise

Guidance on navigating IVDR requirements and tariff implications to streamline compliance efforts.

By enlisting Language Scientific as your translation services provider for IVDR compliance, stakeholders can proactively address the challenges of IVDR and tariffs, ensuring patient safety, regulatory compliance, and market success.

Contact Language Scientific to learn more.

Language Scientific Inc.
100 Crescent Drive
Needham, MA 02494 / USA
+1 (617) 621-0940
info@languagescientific.com