



The Food and Drug Administration

LANGUAGE ACCESS PLAN

2024



FDA Language Access Plan Memo from the FDA Commissioner

July 29, 2024

The diversity of our nation is on full display with the fact that nearly 68 million Americans – about one in five – speak a language other than English at home. This is particularly important for the work that the U.S. Food and Drug Administration (FDA or Agency) does. This work entails a core responsibility to provide reliable and timely information to the public, which includes people with Limited English Proficiency (LEP) and people with disabilities, so that they can make well-informed decisions about their health. This responsibility is relevant to the Agency’s mission to protect public health and is critical for ensuring that FDA communicates health information and news in a manner that is equally accessible to the public.

FDA is pleased to release the 2024 Language Access Plan. This updated plan is consistent with the [U.S. Department of Health and Human Services’ 2023 Language Access Plan, Executive Order 13985 \(“Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”\)](#), sections 504 and 508 of the Rehabilitation Act of 1973, and the [HHS Equity Action Plan](#). FDA’s 2024 plan provides practical guidance and action steps for the Agency and its programs to ensure greater access to its information and services.

The Language Access Program, led by FDA’s Office of Minority Health and Health Equity, is part of the Agency’s ongoing efforts to make health information and materials accessible to LEP populations and people with disabilities.

FDA has been increasingly focused on advancing equity throughout its scientific work. This has included efforts not only to increase the enrollment of minorities, women, and elderly patients in clinical trials but also to bring the voice of under-represented populations to the world of drug and device development. Doing all that FDA can to ensure language access is a critical step toward achieving these goals.

I encourage you to review FDA’s plan and to be engaged in efforts to increase health equity in the important work the Agency does to protect and promote public health.

Sincerely,

A handwritten signature in blue ink, appearing to read "R. Califf".

Robert M. Califf, M.D.
Commissioner of Food and Drugs

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INTRODUCTION:

In November 2023, the U.S. Department of Health and Human Services (HHS) released their updated Language Access Plan, joining agencies across the federal government in prioritizing equitable communication of services available to the public. The HHS plan also requires the Food and Drug Administration (FDA) and other HHS agencies to develop an agency-specific language access plan that implements the 10 elements established in the HHS plan.

This FDA Language Access Plan supports the HHS plan and is an update to the FDA Language Access Plan released in 2013. Additionally, the plan has been updated to help ensure the agency provides meaningful access for individuals with limited English proficiency (LEP) to programs and activities administered and funded by HHS in accordance with Title VI and Section 1557, Executive Orders 13166, 13985, 13995, 14031, and 14091, and the HHS Equity Action Plan, which was [updated in 2023](#).

In addition, Section 504 of the Rehabilitation Act requires federal agencies to take appropriate steps to ensure that it provides individuals with a disability an equal opportunity to participate in, and have access to, program benefits and services. Provisions include effective communication formats that are accessible to individuals with communication disabilities, such as vision or hearing impairments.

The FDA Language Access Plan also supports the overall HHS goal of addressing barriers to equal opportunity that underserved communities may face and ensures access to timely, quality language assistance services (LAS) for persons with LEP.

When FDA announced the agency's first Language Access Plan in 2013, the number of people in the U.S. who spoke a language other than English at home was approximately 61.8 million. By 2019, according to the U.S. Census, that number had increased to 68.7 million people or about 1 in every 5 people living in the U.S.

In Section 1138, [*Ensuring Access to Adequate Information on Medical Products for All With a Special Focus on Underrepresented Subpopulations, Including Racial Subgroups*](#), of the Food and Drug Administration Safety and Innovation Act of 2012, FDA concluded that “first among the challenges in communicating with underrepresented subpopulations and racial subgroups are issues related to limited English proficiency, health literacy, and the need for targeted outreach to consumers, patients, and health care practitioners.”

FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. With this responsibility, the FDA has increased the amount of information the agency provides in multiple languages by delivering quality translations through written, electronic, and other communication channels to help ensure FDA information reaches targeted communities with LEP.

FDA LANGUAGE ACCESS PLAN SUMMARY:

In conjunction with the release of the FDA’s first Language Access Plan in 2013, the FDA established the FDA Language Access Steering Committee (LASC). The LASC, led by FDA’s Office of Minority Health and Health Equity (OMHHE), includes representatives from FDA centers and offices and has helped guide the agency’s language access efforts in communicating to various FDA audiences, including consumers, patients, health care professionals, veterinary professionals, industry, and others.

This plan charts the course for the FDA to continue to strengthen and expand upon its language access efforts to advance the FDA mission and the agency’s commitment to provide reasonable accommodations and meaningful access to individuals with disabilities and persons with LEP.

The FDA’s 2024 Language Access Plan will continue to leverage the LASC led by OMHHE to advance the 10 elements outlined by HHS in its 2023 Language Access Plan.

The elements, as listed in the HHS Language Access Plan are:

1. Assessment of Needs and Capacity
2. Interpretation Language Assistance Services
3. Written Translations
4. Policies, Procedures, and Practices
5. Notification of the Availability of Language Assistance at No Cost
6. Staff Training
7. Assessment & Accountability: Access, Quality, Resources, Reporting
8. Consultations with Health Care and Human Services Partners
9. Digital Information
10. Grant Assurance and Compliance by Recipients of HHS Funding

Element 1 – Assessment: Needs and Capacity

FDA will routinely take steps to assess the language assistance needs of the FDA’s current and potential patients and consumers (customers) to inform policy, processes, and budgeting necessary to increase awareness and implementation of language assistance services that increase access to FDA programs, activities, and services for LEP populations and people with disabilities.

This assessment can include 1.) identifying the non-English languages, including American Sign Language (ASL) or other sign languages, spoken by the population likely to be accessing or otherwise in need of and eligible for the agency’s services, and 2.) the barriers – including resource barriers – that hinder the agency from providing effective interpretation and written communication with individuals with LEP and people with disabilities.

Action Steps

1. The FDA OMHHE will regularly participate in at least one non-FDA listening session, hosted by a particular agency or HHS as a whole, and/or organize an FDA-specific listening session to learn about challenges and opportunities for improving the agency’s language access efforts, and consult subject matter experts to determine whether the agency’s current language access program is effective and complies with Section 1557, as well as this Language Access Plan. The agency will also consider other methods of gathering public input, including surveys or audits.
2. The FDA OMHHE will regularly participate in at least one inter- and/or intra-agency language access working group, such as the HHS Language Access Steering Committee, to identify methods for improving agency proficiency in providing language assistance services, such as hiring and equitably supporting qualified bilingual and multilingual staff, and staff proficient in ASL, to provide direct “in-language” communication and also ensuring the availability and effective use of contract interpretation and translation services.
3. On an ongoing basis, FDA OMHHE and the LASC will recommend new or amended policies or practices that ensure the agency’s language assistance services are adequate to meet customer needs and advise agency officials on updating the FDA Language Access Plan as needed.

Element 2 – Interpretation Language Assistance Services

Interpretation services are essential to ensure meaningful access and an equal opportunity to participate fully in the services, activities, programs, or other benefits administered or funded by FDA. Staff should ensure that all interpreters they use are qualified to provide the service and understand and apply interpreter ethics and client confidentiality needs. The FDA will take steps to identify interpretation language assistance services (e.g., face-to-face, virtual [videos/webinars], and/or telephone encounters) requested, that address the needs identified in Element 1. The definition of a qualified interpreter is in Appendix A.

Language assistance may be provided through a variety of means, including qualified bilingual and multilingual staff, and qualified interpreters providing in-person, telephonic, remote voice, video, or any other type of interpreting.

The FDA will respond in a timely and effective manner to persons with LEP and people with disabilities who contact the agency seeking assistance or information.

Action Steps:

1. FDA OEA has established the agency-wide procedures for providing interpreting services in a timely manner between persons with LEP and people with disabilities and FDA. Procedures must address the various methods for providing effective interpreter services, including remote voice and video.
2. FDA will identify agency points of contact (POCs) who are responsible for developing and administering a remote voice and video interpreting program that ensures individuals with LEP are aware that FDA will provide interpreter services at no cost and provide guidance on how to obtain the agency’s interpreter services, whenever available. Such programs should account for the fact that the rise in integrated voice prompt (IVP) systems has made it more difficult for individuals with LEP to get through various “phone trees” to get to an interpreter. Therefore, FDA should explore other options for customers to access language services more directly.
3. The FDA will take steps, with support from the LASC, to develop a strategy to assess availability of telephone services, remote voice and video interpreting program for public-facing offices and develop methods and mechanisms to help ensure persons with LEP are aware that FDA will provide interpreter services at no cost and provide guidance on how to obtain the agency’s interpreter services, whenever available.
4. FDA will develop methods for tracking and reporting the number of requests for interpretation services, the type of interpretation requested, the languages requested, and the response time in which interpretation was provided. FDA will also analyze request data compared to census data of the areas served.
5. Each fiscal year, FDA should submit a budget justification for outreach to raise awareness of available interpretation services.
6. FDA OMHHE, with support from the LASC, will maintain a list of qualified bilingual, multilingual, and sign language staff capable of providing competent interpretation services.
7. FDA will consider establishing a list of all contacts and other resources available to the agency offices and centers who are qualified in providing on-site interpreting (OSI), over-the-phone interpreting (OPI), and video remote interpreting (VRI) services to persons with LEP and people with disabilities who require sign language interpretation seeking information on or access to

- agency programs and activities.
8. FDA will develop criteria for assessing bilingual staff or sign language interpreting staff for their ability to provide interpretation services and ensure such employees are compensated appropriately if they are called to provide interpretation services. FDA will also consider developing criteria for giving points in hiring decisions for bi- and multi-lingual employment candidates. Extensive reliance on staff volunteers in lieu of utilizing professional interpreters is discouraged.
 9. FDA OEA, in collaboration with LASC, will develop a mechanism for monitoring and evaluating interpretation services.
 10. FDA will establish a point of contact for LEP individuals such as an official e-mail address, or phone number to access this service and ensure that this information is readily available to the public.
 11. FDA Office of Reasonable Accommodations will continue to advance efforts to ensure that interpretation services are accessible to people with disabilities, including those who are deaf or hard of hearing or who have other communication-related disabilities. This may include providing sign language interpreting, captioning, or additional accessible communication support. Some examples of common visual communication modes are found in the following source: [ADA Business Brief: Communicating with People Who Are Deaf or Hard of Hearing in Hospital Settings](#).
 12. ASL Interpretation services for people with disabilities can be requested through the FDA [Reasonable Accommodations Office](#).

Element 3 – Written Translations

FDA will work to identify, translate, and make accessible in various formats, including print, online, and electronic media, vital documents (see Appendix A) including important consumer/patient information, in an accessible format, in languages other than English in accordance with assessments of needs and capacity conducted under Element 1.

For purposes of this Language Access Plan, at a minimum, notice of rights to nondiscrimination and availability of free language and any appropriate auxiliary services will be provided in the top 15 languages spoken by persons with LEP.

FDA will prioritize translating vital documents or other critical public health information (especially during public health emergencies) based on assessments of need and capacity and develop translation strategies suitable to the medium for distribution. Translated documents should be easy to understand by intended audiences and provided in a timely manner, allotting time for interpretation. Matters of plain language, cultural communication, and health literacy should be considered for all documents, including when the document is originally composed in English.

To improve cultural communications and accuracy of translations, the FDA should use qualified translators and reviewers with the following credentials:

- A university-issued degree or certificate in translation in the language combination and direction required.
- Certification by a professional translation association or union, such as the American Translators Association (ATA) or other translation certification body in the language combination and direction required, when available. When certification is not available in a specific language combination and direction required (e.g., English to an Indigenous language), other minimum requirements can be used to assess qualification, including years of experience, references from individuals who are qualified to attest to the quality of their work, etc.
- At least 3 years of professional experience in a staff position or as a full-time freelancer dedicated to translation, completing work in the language combination and direction required.

In addition to this experience, the translator should have professional subject matter expertise in the topic(s) that will be translated by demonstrating relevant educational background or professional experience in those topics.

Machine translation, other artificial intelligence applications, or software designed to convert written text from one language to another should not be utilized without a qualified human translator reviewing the text before it reaches the intended audience.

Individuals with LEP and/or who have certain communication disabilities who want to access FDA services may not be literate in their country of origin's prevalent written language, or their languages might not have a written form such that translated material will not be an effective way of communicating with them. The FDA may want to consider sight translation, interpretation, or audio/video communication and should also ask the individuals about their preferred method to receive information that is typically available in written form.

Action Steps:

1. OEA has developed a program for offices and centers to ensure individuals participating or attempting to participate in programs and activities funded or administered by the FDA are provided written language assistance services in accordance with the agency's needs, capacity, assessment, and this plan.
2. FDA, through the LASC, will identify the most appropriate FDA materials for translation and identify the literacy skills of persons with LEP within certain communities, their preferred languages, and the frequency of their contact with the agency in accordance with the agency's needs, capacity, assessment, and this plan.
3. Each fiscal year, FDA OMHHE, with support from the LASC, will submit a budget justification for producing and distributing translated vital documents and other critical public health information.
4. The LASC should support OEA efforts in identifying and creating an index describing materials already available in non-English languages, including American Sign Language, and post the index to a website available to the public. The LASC will support OEA in revising the index as needed to ensure quality and plain language and update the index accordingly. When needed, FDA will use a qualified third party to review translations for accuracy, readability, usability, and cultural responsiveness.
5. OEA should identify agency staff who are responsible for managing the translation and interpretation contract(s) and share their contact information with managers and staff who communicate with the public.
6. FDA OMHHE and FDA OEA, with support from the LASC, will develop a strategy to offer translated written materials in other formats such as audio, video with subtitles, video with sign language, infographics, etc., for people with limited literacy or communication disabilities, and for those whose language does not have a written form.
7. All online translated content shall comply with Section 508 of the Rehabilitation Act and observe the requirements of the [21st Century Integrated Digital Experience Act](#).

Element 4 – Policies, Procedures, and Practices

The FDA LASC will annually review and, as necessary, update and recommend policies, procedures, and practices to ensure FDA staff are taking reasonable steps to ensure that individuals with LEP and people with disabilities have meaningful access to vital health information about FDA-regulated products.

The FDA will establish and maintain methods designed to implement and improve language assistance services within the agency. FDA should use the results of the assessment from Element 1 to develop policies, procedures, and practices that promote language access for individuals with LEP and people with disabilities.

Action Steps

1. FDA OMHHE will participate in at least one inter- and/or intra-agency working group that is focused, at least in part, on identifying and implementing effective practices for improving language access for persons with LEP.
2. FDA OMHHE, in coordination with LASC, will develop, review and, as necessary, make recommendations to update policies, procedures and practices for implementation to ensure the agency is taking reasonable steps to provide persons with LEP and customers with disabilities who require auxiliary aids or services for effective communication of programs and activities that are funded or administered by FDA to have meaningful access to vital health information on FDA-regulated products.
3. The LASC will support the review of documents to ensure they align with the [National Standards for Culturally and Linguistically Appropriate Services \(CLAS\) in Health and Health Care](#).
4. OMHHE, with support from the LASC, will recommend to the HHS Language Access Steering Committee policies and procedures, highlighting those that might be more effective or efficient if adopted on a Department- or government-wide basis. The Language Access Steering Committee will include this information in the annual progress report.
5. OMHHE and the LASC will routinely collect and share metrics to monitor implementation and efficacy of the FDA Language Access Plan. This may include but is not limited to: identifying the languages most frequently encountered by staff at FDA who work with the public, identifying the way people with LEP prefer to communicate with FDA (whether telephonic, in person, correspondence, web-based, etc.), reviewing offices' activities related to language access, and maintaining an inventory of staff who attended language access training.

Element 5 – Notification of the Availability of Language Assistance Services at No Cost

The FDA will take reasonable steps to ensure meaningful access to their programs and activities, including proactively informing individuals with LEP and people with disabilities, who are current or potential customers (patients and consumers) that language assistance is available at no cost. At minimum, FDA must provide information about rights to nondiscrimination and the availability of language assistance and auxiliary aids in the 15 most commonly spoken languages in the state according to the most recent relevant data from the U.S. Census Bureau.

Action Steps

1. FDA OMHHE, with support from the LASC, will develop a strategy for notifying individuals with LEP and people with disabilities who contact the agency or are being contacted by the agency that language assistance is available to them at no cost. This includes, but is not limited to, providing information about the availability of language services as part of the initial recorded options on FDA’s telephone line (1-888-463-6332).
2. FDA OMHHE, with support from the LASC, will develop a strategy for distributing and making available resources, such as the Department’s *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (HHS LEP Guidance) and Federal Plain Language Guidelines, directly and over the internet to all current recipients, providers, contractors, and vendors.
3. FDA will develop and prominently display language notifying intended audiences that language assistance is available at no cost and how it can be obtained on: vital documents, web pages currently available in English only or only in a limited number of non-English languages, technical assistance and outreach materials, as well as other documents.
4. FDA OMHHE, with support from the LASC, will develop an ongoing strategy for providing information and technical assistance to entities funded by FDA to make them aware that language assistance services must be provided at no cost to those in need of such services, in compliance with Title VI and Section 1557.
5. FDA OMHHE, with support from the LASC, will submit a budget justification for outreach to raise awareness of available language assistance services.
6. FDA will highlight the availability of consumer-oriented materials in plain language and languages other than English on Department websites and ensure such materials inform individuals with LEP about available language assistance services.

Element 6 – Staff Training

The FDA will offer employee training as necessary to increase awareness of FDA’s efforts to support language access. The offered training will support the capacity and capability of FDA employees to effectively communicate with individuals with LEP and people with disabilities and raise awareness of the importance of effectively communicating with such individuals in FDA programs and outreach activities.

The staff training can include the following components:

- a. The Department’s and agency’s legal obligations to provide language assistance services.
- b. The Department’s and agency’s language access resources and designated points of contact.
- c. Identifying the language needs of individuals with LEP and people with disabilities.
- d. Working with an interpreter in-person or on the telephone.
- e. Requesting documents for translation.
- f. Accessing and providing language assistance services through multilingual employees, in-house interpreters and translators, or contracted personnel.
- g. Duties of professional responsibility with respect to LEP individuals.
- h. Interpreter ethics.
- i. Tracking the use of language assistance services.
- j. Tips on providing meaningful language assistance services to LEP individuals.
- k. How to request translation and interpretation services.
- l. How the public can request language assistance services or file a complaint.

Online training will be available to all employees on a regular basis.

Action Steps

1. FDA OMHHE, with support from the LASC, will work with the agency’s management and communications offices to notify employees that FDA provides language assistance services and to explain how the employees can provide such assistance, including how to contact the office or official responsible for ensuring the availability of language assistance services. FDA OMHHE will also make employees aware of the FDA Language Access Plan.
2. FDA OMHHE, with support from the LASC, will develop a strategy to disseminate training materials, whether newly developed or pre-existing, that assist management and staff in procuring and providing meaningful communication for individuals with LEP.
3. FDA OMHHE, with support from the LASC, will develop a dedicated internal webpage that will serve as a repository of resources, training opportunities related to language assistance services.
4. FDA OMHHE, with support from the LASC, will regularly monitor the effectiveness of the language assistance trainings and will consult with subject matter experts to make recommendations for which FDA trainings should be made available to staff.

Element 7 – Assessment & Accountability: Access, Quality, Resources, Reporting

FDA OMHHE, with support from the LASC, will regularly monitor and annually assess the language assistance services available to individuals with LEP and people with disabilities, maintain an accurate record of language assistance services provided by the agency, document financial and staff resources dedicated to providing language assistance, and annually report progress made to fully implement the 2023 HHS Language Access Plan.

The assessment can include efficacy, quality, and availability of FDA’s language access services, including customer waiting time; quality of written translations and interpretation utilization of appropriate communication channels; barriers to providing services; and overall customer satisfaction.

Action Steps:

1. FDA OMHHE and FDA OEA, in coordination with the LASC, will regularly monitor and annually assess relevant practices and procedures, focusing on progress made by FDA to improve and ensure the quality and accuracy of language assistance services provided to individuals with LEP and people with disabilities, while also addressing challenges.
2. FDA OMHHE, in coordination with the LASC, will work to implement methods for measuring improvements in language access in individual programs and activities and take steps to ensure that such information is collected in a manner that increases comparability, accuracy, consistency across programs and activities and takes into consideration guidance provided by the HHS Language Access Steering Committee.
3. FDA OMHHE, in coordination with the LASC, will annually report to the HHS Language Access Steering Committee on agency progress implementing each element of this plan, effective practices, and barriers to improving language access services, in accordance with the HHS Language Access Steering Committee reporting timelines.
4. FDA OMHHE, with support from the LASC, will address complaints received regarding language assistance services, in a timely manner and retain a record of the resolution of such complaints.

Element 8 – Consultations with Health Care and Human Services Partners

The FDA OEA Stakeholder/Patient Engagement Staff, supported by OMHHE, will engage in robust dialogue with health care and human services partners, consumers, and patients in accordance with this and other federal policies, to identify language access needs of individuals with LEP and people with disabilities, implement appropriate language access strategies to ensure individuals with LEP and people with disabilities have meaningful access in accordance with assessments of customer need and agency capacity, and evaluate progress on an ongoing basis. The information obtained from health care and human services partners, including consumers and patients, may be critical for FDA to adequately assess the needs, capacity, and accessibility under Elements 1 and 7 of this plan. Health care and human services partners, consumers, and patients can provide the FDA with qualitative and first-hand data on the need for language access services.

Action Steps

1. The FDA Office of External Affairs, supported by OMHHE, will be responsible for identifying and developing opportunities to include health care and human services partners (as well as consumers and patients) in the development of policies and practices that enhance access to agency programs and activities for persons with LEP and people with disabilities.
2. FDA OMHHE will plan and coordinate conversations with health care and human services partners (including consumers and patients) to assess the adequacy, accessibility, accuracy, cultural appropriateness, and overall quality of the FDA’s language access services.
3. FDA OMHHE will share the HHS and FDA Language Access Plans and resources with health care and human services partners, consumers, and patients, in an accessible manner and solicit their feedback. Incorporate health care stakeholder input in the FDA Language Access Plan, as appropriate and consistent with this plan.
4. FDA OMHHE will annually participate in at least one listening session, whether hosted by a particular agency or HHS as a whole, to learn about ways to improve the agency’s language access program. These listening sessions may result in concrete action steps to be taken by the FDA.
5. FDA OMHHE will post the FDA Language Access Plan and resources on the FDA website in accessible formats, and in multiple languages, as well as contact information to receive questions and comments. Where feasible, FDA should share relevant data and information pertaining to language access with health care and human services partners.

Element 9 – Digital Information

The OEA Web Council, with the support of the FDA LASC, will develop and implement specific written policies and strategic procedures to ensure that, in accordance with assessments of LEP population needs, the needs of people with disabilities, and agency capacity, digital information is appropriate, available, and easily accessible to people with LEP in need of language assistance services in languages other than English.

Description:

To help ensure individuals with LEP have digital/online access to in-language program information and services and to help ensure they are aware of and can obtain language assistance needed to access important program information and services, FDA OEA, with support of the FDA Web Council and the LASC, will be responsible for establishing and maintaining an infrastructure that aligns with the 21st Century Integrated Digital Experience Act (IDEA) to effectively distribute in-language information online in a manner that promotes meaningful access for individuals with LEP. In addition, FDA OEA, with the support of LASC, will regularly monitor the efficacy, quality, readability, and accessibility of translated materials on FDA’s website.

FDA center web managers are encouraged to work with their internal web content staff and LASC representatives to periodically assess and monitor translated digital content to improve meaningful access for persons with LEP. FDA will maintain an updated inventory of translated web pages, PDFs, and multimedia assets (graphics, videos, images, etc.).

FDA will continue to comply with Section 508 of the Rehabilitation Act of 1973 (Section 508), which requires federal agencies to ensure that their information and communication technology, including websites, electronic documents, and software applications, are accessible to individuals with disabilities. Components shall work with Section 508 program managers and/or the FDA web team/managers to ensure that translated digital content meets Section 508 requirements.

In addition to the requirements of Section 508, Section 504 requires that HHS/FDA take steps to ensure effective communication with people with disabilities, including individuals with LEP, providing appropriate auxiliary aids, applying plain language principles, and offering services such as sign language interpreters. For example, at virtual meetings, FDA may be required to provide a sign language interpreter or live captioning and the virtual meeting platform should be able to accommodate a screen for a sign language interpreter that can be seen by the person with the hearing impairment. FDA staff are also encouraged to provide timely information, such as deadlines or significant policy shifts, through videos in sign language or captioning.

Action Steps:

1. The FDA Web Council is responsible for and capable of establishing and maintaining an infrastructure that aligns with the 21st Century Integrated Digital Experience Act (IDEA) to effectively distributes in-language information online in a manner that promotes meaningful access for individuals with LEP, and regularly monitor efficacy, quality, readability, and accessibility of translated materials.

2. The FDA website should prominently display links and/or symbols at the top-right corner of the agency's English language website indicating available languages in that the particular page or document is also available in languages other than English, including ASL.
3. FDA website should prominently display links on the agency's English language homepage that effectively steers visitors to telephonic interpreter services in the visitor's language.
4. FDA should notify visitors with LEP to FDA webpages that language assistance is available at no cost in alignment with the action steps outlined in Element 5, including multilingual technical support and alternatives for individuals who cannot navigate digital spaces.
5. FDA OEA and other designated officials should serve on at least one inter- and/or intra-agency working group that focuses in part on making government websites more accessible to persons with LEP in multiple languages and people with disabilities through various multimedia formats.
6. FDA should use and promote the resources on www.lep.gov by providing links to the LEP.gov website on agency and program webpages.
7. FDA OEA, in collaboration with the FDA Web Council, should develop procedures for creating, posting, and updating multilingual web content, digital materials, and social media posts that are accessible to all audiences.
8. FDA should leverage social media, email dissemination, and/or text message services to increase awareness and utilization of agency programs, activities, language assistance services, and products available in non-English languages by individuals with LEP and people with disabilities.
9. FDA should leverage HHS digital policies and U.S. Web Design Standards for guidance on multilingual display guidance and options:
<https://designsystem.digital.gov/components/language-selector/>.
10. FDA should conduct a usability test with visitors with LEP every two (2) years to collect data (including intersectional and disaggregated demographic data), identify features, and components that might need to be addressed to improve access and navigation of webpages, products, or services online. Manage visitors' expectations by also considering URL best practices and general site functionality. If displaying or showcasing forms, consider what the experience is for the user clicking on call-to-action buttons and their journey across the digital ecosystem. Ensure that multiple last names, short names, and/or diacritics are acceptable by the fields created. The FDA Web Council and FDA OEA will regularly monitor the efficacy, quality, readability, and accessibility of translated materials provided online to promote ease of use and access. Regularly consider and evaluate advancements in technology such as artificial intelligence, including machine learning, to expedite translation while committing qualified human translators and editors review.
11. FDA, with the assistance of the FDA Web Council, should take steps to develop benchmark efforts and regularly evaluate through data (including intersectional and disaggregated data), analytics, user feedback, and customer feedback mechanisms such as customer satisfaction surveys (in-language) to assess the usefulness of information to determine and address gaps and focus resources on critical online information and services.
12. FDA should work to develop and maintain a list of in-language content provided on the agency's webpages or separate websites.
13. For virtual meetings, FDA should take steps to ensure that the platform being used provides for closed captioning and that the captioning function is enabled by the host. As a best practice, FDA should consider using real time translation services such as Communication Access Realtime Translation (CART) to ensure better accuracy of the closed captioning.

14. For virtual meetings, FDA should take steps to ensure participants are able to highlight another participant's screen and keep focus on that screen so that sign language users can focus on a sign language interpreter, even if the interpreter is not speaking.
15. As a best practice for virtual meetings, FDA should provide attendees the option to request auxiliary aids and services or reasonable modifications in the meeting invitation so that people with disabilities may participate. In practice, this will generally amount to requests for closed captioning and/or ASL interpreters. The invitation may require that any requests for auxiliary aids and services or reasonable modifications be made by a certain date prior to the meeting to allow the meeting organizer sufficient time to accommodate the request.

Element 10 – Grant Assurance and Compliance by Recipients of HHS Funding

Recipients of federal funds must comply with federal civil rights laws and all regulations related to language access services, especially Title VI and Section 1557. FDA’s Office of Acquisitions and Grants Services (OAGS) and the LASC will work together to ensure that compliance language is included in grant announcements and that current and potential recipients of agency funds are aware of their legal obligations.

Action Steps:

1. FDA will designate an office or official responsible for working with the Assistant Secretary for Financial Resources (ASFR) or the relevant HHS budget office to 1.) develop a mechanism for funding language assistance services provided by recipients of agency funds; and 2.) establish a reasonable schedule for providing such funding depending on the recipient’s size, service population, and capacity for covering costs for language assistance services through non-federally funded resources.
2. OAGS, with support from OMHHE, will develop a strategy to raise the awareness of FDA-funded entities about the requirements of Title VI and Section 1557.
3. OAGS, with support from OMHHE, will develop a strategy raise the awareness of agency staff who communicate with FDA-funded entities about the requirements of Title VI and Section 1557. OAGS will also offer training resources to agency staff to promote awareness of the FDA LEP Guidance.
4. OAGS, with support from OMHHE, will develop a strategy to provide and promote links to resources and technical assistance documents on the grant-making agency’s program website(s).

APPENDIX A: Definitions

Note: Any related definitions that may be issued under Section 1557 will complement or supersede the broad working definitions set forth below.

Document Terminology	Terminology Defined
Applicant	Any person who inquires about or submits an application for public assistance benefits under any program or service.
Auxiliary Aids and Services	Tools or assistance provided to communicate with people who have communication disabilities.
Beneficiary	Anyone who has applied for and is receiving Medicare, Medicaid, or other health benefit.
Bilingual/Multilingual Staff	A staff member who has advanced proficiency (e.g., proficiency at or above the Federal Interagency Language Roundtable (https://www.govtilr.org) level 3 in listening, reading, and speaking or above the American Council on the Teaching of Foreign Languages “Superior” level in listening, reading, and speaking)) in English and at least one other language and has knowledge of and experience with specialized terminology necessary for meaningful communication. A staff member who only has a rudimentary familiarity with a language other than English shall not be considered Bilingual/Multilingual Staff. Bilingual/Multilingual Staff should not interpret or translate unless they have separately met the requirements of being a qualified interpreter or translator. Bilingual/Multilingual Staff will be given clear roles and expectations regarding whether they are performing their job duties in-language or serving as qualified interpreters or translators. A distinction should be made between Bilingual/Multilingual Staff who provide services directly in a non-English language (e.g., call center staff) and those who interpret, as the assessment and skills required for each differ.
Certificate	An academic recognition demonstrating the successful completion of a program of study, usually based on amount of instructional time and a minimum grade.
Certification	Institutional recognition demonstrating successful passing of an examination that tests knowledge, skills, and abilities related to an occupation.
Contractor	Any entity that performs work or provides services on behalf of an agency or division under a contractual agreement with reimbursement
Customer	Individuals, businesses, and organizations that interact with an HHS agency or program. The term customer is inclusive of beneficiaries and health care and human services partners.
Digital Information	Information, as defined in OMB Circular A-130, which the government produces and provides digitally to help individuals access HHS conducted programs and activities for which they are individually eligible to participate. OMB Circular A-130 defines digital information as any communication or representation of knowledge such as facts, data, or opinions in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.
Direct “in-language” communication	Monolingual communication in a language other than English between a multilingual staff and a person with LEP (e.g., Korean to Korean).
Disaggregated Data	Data that separates out subgroups to provide the most descriptive and detailed information possible; for example, rather than using data about “Asian languages” or “Native American languages,” disaggregated data would indicate which specific languages are spoken by an individual or at the community level. Disaggregated data may also include information about varied dialects, as well as more specific national origin information.

Document Terminology	Terminology Defined
Effective Communication	For communication disabilities, it refers to aids and services to ensure that communication with people with disabilities, such as people who are deaf or hard of hearing, is as effective as communication as for people without disabilities. Auxiliary aids and services will be provided when needed to achieve effective communication.
Health Care and Human Services Partner	Beneficiaries, including recipients of federal financial assistance, contractors, vendors, advocacy groups, religious institutions, non-governmental organizations, hospital administrators, health insurers, translators, interpreters, community health clinics, and representatives from a broad cross-section of the language access community, individuals with disabilities, etc.
Interpretation	The act of listening, understanding, analyzing, and processing a spoken communication in one language (source language) and then faithfully orally rendering it into another spoken language (target language) while retaining the same meaning. For individuals with certain disabilities that affect communication, this can include understanding, analyzing, and processing a spoken or signed communication in the source language and faithfully conveying that information into a spoken or signed target language while retaining the same meaning.
Intersectional Data	Data that combines or otherwise includes information about more than one demographic or other characteristic; for example, intersectional data would include data regarding national origin and LEP status, and/or data regarding Native American women (thus analyzing data about the intersection of race and gender). It may also include data about literacy rates, poverty rates, familial status, or other characteristics relevant to social determinants of health.
Language Access	The ability of individuals with LEP to communicate with HHS employees and contractors, and meaningfully learn about, apply for, or participate in HHS programs, activities, and services.
Language Assistance Services	All oral, written, and signed language services needed to assist individuals with LEP and people with disabilities to communicate effectively with HHS staff and contractors and gain meaningful access and an equal opportunity to participate in the services, activities, programs, or other benefits administered by HHS.
Limited English Proficiency (LEP)	An individual who does not speak English as his or her preferred language and who has a limited ability to read, write, speak, or understand English in a manner that permits him or her to communicate effectively with HHS and have meaningful access to and participate in the services, activities, programs, or other benefits administered by HHS. Individuals with LEP may be competent in English for certain types of communication (e.g., speaking or understanding), but have limited proficiency in English in other areas (e.g., reading or writing). LEP designations are also context-specific; an individual may possess sufficient English language skills to function in one setting (e.g., conversing in English with coworkers), but these skills may be insufficient in other settings (e.g., addressing court proceedings). An individual who is deaf or hard of hearing may also have limited proficiency in spoken or written English.
Machine Translation	Automated translation that is text-based and provides instant translations between various languages, sometimes with an option for audio input or output.
Meaningful Access	Language assistance that results in accurate, timely, and effective communication at no cost to the individual with LEP needing assistance. Meaningful access denotes access that is not significantly restricted, delayed, or inferior as compared to programs or activities provided to English-proficient individuals.
Participant	Any person who has applied for and is receiving public assistance benefits or services under any HHS program or service.

Document Terminology	Terminology Defined
Plain Language	Plain language as defined in the Plain Writing Act of 2010 is writing that is “clear, concise and well organized.”
Preferred/Primary Language	The language that LEP individuals identify as the preferred language that they use to communicate effectively. The language that LEP individuals identify as the preferred language that they use to communicate effectively.
Qualified Interpreter or Translator	A bilingual/multilingual person who has the appropriate training and experience or demonstrated ability to fully understand, analyze, and process and then faithfully render a spoken, written, or signed message in one language into a second language and who abides by a code of professional practice and ethics. In the context of disabilities, a qualified interpreter is one who is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary. A child shall not be considered a qualified translator or interpreter, nor shall a family member or employee who does not meet the minimum qualifications specified above.
Sight Translation	The oral or signed rendering of written text into spoken or signed language by an interpreter without change in meaning based on a visual review of the original text or document.
Sign Languages	Languages that people who are deaf or hard of hearing use in which hand movements, gestures, and facial expressions convey grammatical structure and meaning. There is no universal sign language. Different sign languages are used in different countries or regions. For example, British Sign Language (BSL) is a different language from American Sign Language (ASL), and Americans who know ASL may not understand BSL.
Sub-recipient	An entity that, on behalf of and in the same manner as a recipient of federal financial assistance, provides services to and has contact with applicants to and participants in a program administered by a recipient of federal financial assistance, but does not include an individual applicant or participant who is a beneficiary of the program.
Tagline	Brief message that may be included in or attached to a document. Taglines in languages other than English are used on documents (including websites) written in English that describe how individuals with LEP can obtain translation of the document or an interpreter to read or explain the document. Section 1557 and Title VI will prescribe the languages that will be included in such tagline notices but covered entities may also add more languages.
Translation	The process of converting written text from a source language into an equivalent written text in a target language as fully and accurately as possible while maintaining the style, tone, and intent of the text, while considering differences of culture and dialect.
Vital Document	Paper or electronic written material that contains information that is critical for accessing a component’s programs or activities or is required by law. Vital documents include, but are not limited to: critical records and notices as part of emergency preparedness and risk communications; online and paper applications; consent forms; complaint forms; letters or notices pertaining to eligibility for benefits; letters or notices pertaining to the reduction, denial, or termination of services or benefits that require a response from an individual with LEP; written tests that evaluate competency for a particular license, job, or skill for which knowing English is not required; documents that will be provided by law; and notices regarding the availability of language assistance services for individuals with LEP at no cost to them.

APPENDIX B: Language Access Related Resources

- **American Translators Association:** <https://www.atanet.org/>
- **Certification Commission for Healthcare Interpreters:** <https://cchicertification.org/>
- **Department of State Office of Language Services:** <https://www.state.gov/frequently-asked-questions-office-of-language-services/>
- **Federal Interagency Working Group on Limited English Proficiency (LEP):** www.lep.gov
- **Federal Plain Language Guidelines:** <https://www.plainlanguage.gov/guidelines/>
- **FDA Language Access:** <https://www.fda.gov/consumers/minority-health-and-health-equity/language-access>
- **Health Literacy Online: A Guide to Writing and Designing Easy-to-Use Health Web Sites:** https://health.gov/healthliteracyonline/2010/Web_Guide_Health_Lit_Online.pdf
- **HHS Limited English Proficiency (LEP):** <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html>
- **Interagency Language Roundtable:** www.govtilr.org/
- **International Organization for Standardization:** Translation, interpreting and related technology (ISO/TC 37/SC 5) <https://www.iso.org/committee/654486.html>
- **National Action Plan to Improve Health Literacy:** <https://health.gov/our-work/national-health-initiatives/health-literacy/national-action-plan-improve-health-literacy>
- **National Board of Certification for Medical Interpreters:** <https://www.certifiedmedicalinterpreters.org/>
- **National Council on Interpreting in Health Care:** <https://ncihc.memberclicks.net/>
- **Office for Civil Rights:** Language Access Resources: www.hhs.gov/lep
- **Office of Minority Health:** National CLAS Standards <https://thinkculturalhealth.hhs.gov/clas>