



BEYOND HIPAA

NEW & CHANGING
LANGUAGE ACCESS
REGULATIONS

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AS AN ATTORNEY, SPEAKER, AND VENDOR RISK MANAGEMENT EXPERT, ELLEN IS INTERNATIONALLY RECOGNIZED IN the area of cybersecurity, privacy, data security, breach response, investigations, and information governance. She has years of legal and risk management experience in executing client enterprise-wide information governance, risk and compliance project engagements. Such engagements include risk assessment, data mapping and information classification, data minimization, records management, and leading compliance remediation project teams. Ellen is a Certified Information Privacy Professional (CIPP/US/C/G).

Ellen has deep experience in compliance with GLBA, HIPAA, state data breach and global data security laws, background checks and screening under the FCRA, identity theft and laws related to monitoring employees in the digital workplace. In addition, she possesses a background of board level advising on risk tolerance and extensive US, Canadian, EU data protection and compliance in the global transfer of data assets. As the founder and moderator of PrivacyHub, a LinkedIn Group established in 2008, Ellen has demonstrated her deep knowledge of regulatory forecasting, recognizing upstream risk and the effective use of social media to create a community of experts and academics available to collaborate on this dynamic and burgeoning discipline.

Ellen has advised multinational financial institutions, hospitals, healthcare providers, and large and medium-sized companies on risk management, data security and regulatory compliance of their new and existing products and services, including software, mobile applications, social media platforms, and cross border transactions.

Ellen represented a marketing firm which experienced a cyber-attack and exfiltration of over 100 million email accounts in 46 states and 33 countries around the globe. U.S. Government Privacy Officer noted breach handled by another attorney would have bankrupted company. Completed full remediation work-plan approved by Covered Entities including remediation of contracts.

Ellen has served as the Vice President, Senior Risk Manager and a Privacy Officer for a major global financial institution.

INTRODUCTION

The regulatory landscape continues to heat up for healthcare organizations providing interpretation and translation services – more commonly referred to as “Language Access.” Recipients of language access typically have a limited ability to read, speak, write or understand English and may be considered Limited English Proficient or “LEP.”¹

New actions from the Federal Trade Commission add to the existing standards derived from Title VI, Health Insurance Portability and Accountability Act (HIPAA), National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS standards), and more.

Public or private healthcare executives charged with managing language access vendors need to conduct a robust vendor risk assessment to ensure adequate vendor language capabilities and the vital safeguarding of personally identifiable information (PII) and protected health information (PHI).

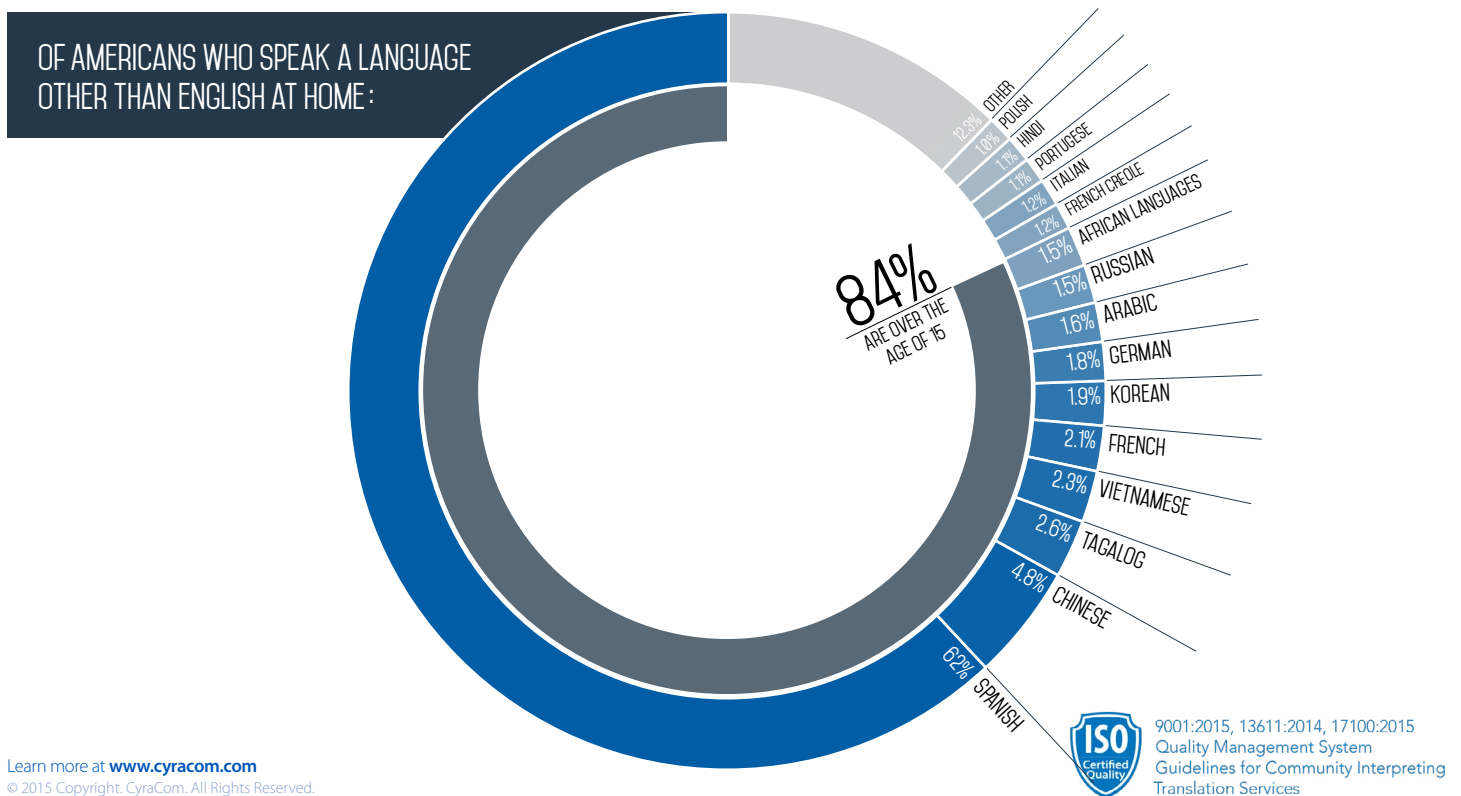
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BEYOND HIPAA: NEW AND CHANGING REGULATION

The U.S. Government’s recent focus on the protection of the LEP population has resulted in increased regulatory risk of fines, comment, and consent decrees to healthcare providers who do not maintain an effective and compliant language access program for their patient population.² Considering recent enforcement actions in the healthcare vendor risk management space by the Federal Trade Commission, this is an environment sensitized to regulatory requirements such as: having vendor risk management and assurance programs, and implementing privacy and data security safeguards. These requirements demand accuracy in selection, delivery, and oversight of services to the LEP consumer population.

Changes from the U.S. Department of Health and Human Services

The U.S. Department of Health and Human Services (HHS) defines health equity as the attainment of the highest level of health for all people.³ Health equity guides the HHS’s regulatory priorities for the healthcare providers that service the nearly 20% of Americans who speak a language other than English at home.



The HHS's Office of Minority Health has published the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Healthcare⁴ to advance health equity, improve quality, and help eliminate health disparities. The national standards advance these goals by establishing a blueprint for health and healthcare organizations to provide effective, equitable, understandable and respectful quality care and services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.

More recently, the Office for Civil Rights has stepped up enforcement with their Compliance Review Initiative: Advancing Effective Communication in Critical Access Hospitals.⁵

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and Human Services Office for Civil Rights began compliance reviews of critical access hospitals (CAHs) to confirm that they provide comprehensive language access services to LEP populations in rural and isolated areas. In 2012, the Office for Civil Rights piloted compliance reviews in ten states and conducted onsite visits. The compliance reviews consisted of evaluating language access services, their policies and procedures, and interviewing staff and stakeholders. In doing so, the Office for Civil Rights determined a voluntary resolution agreement was necessary to assist the healthcare organization with updating their language access policies and procedures and monitoring the effectiveness of their language access programs.⁸

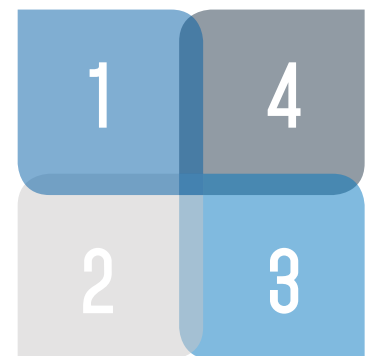
Vendor Risk Management - New U.S. Department of Justice Language Access Procurement Guidance

On May 6, 2014, the U.S. Department of Justice has issued guidance through the Federal Coordination and Compliance Section as part of their Translation and Interpretation Procurement Series (TIPS) for the Government Services Agency (GSA) outlining "Best Practices" named "TIPS on Hiring the Right Telephonic Interpretation Vendor", and "Before You Hire – Ask Yourself 'What Are My Project's Language Needs?'" While the guidance is drafted for the government sector, it is a private sector roadmap to hiring the right Telephonic Interpretation Vendor and is instructive for in-person interpretation as well.

Copies of the TIPS best practices can be found at the end of this white paper.

The TIPS guide highlights the government's expectations for thoughtful and thorough due diligence when selecting healthcare Telephonic Interpretation vendors, including the following four requirements:

1. Identifying the LEP population language requirements, which should include more than just the commonly used foreign languages.
2. Including quality control plans, cost and availability schedules, staff training, regular vendor reporting, and detailed guidance on interpreter qualifications – all of which must be vetted whether performed onshore, outsourced, or via telecommuting.
3. Requiring written proposals that should disclose onshore versus offshore operations, vendor quality of operations, including the ratio of employees to contractors, inspections of physical and technical security, background check investigations, and business continuity and disaster recovery plans that will withstand and be active to support healthcare operations in storms, such as Hurricanes Sandy and Katrina. Language Access becomes a critical issue during these natural disaster events.
4. Conducting live testing – including business continuity exercises – of the telephonic interpretation vendor's operations and physical security. This testing must be done for both onshore and off-shore operations. If this cannot be done for offshore operations, consider whether this is a quality concern and perhaps a risk differentiator in choosing an onshore company. Recent guidance from the U.S. Department of Justice advises to, "Prioritize merit over price whenever possible." This is important guidance to help narrow the field of vendors when choosing a Telephonic Interpretation vendor. In fact, executives and risk managers should consider after the live testing, whether the risk of using contractors and offshore personnel is outside the organization's risk appetite.



The Federal Trade Commission and Healthcare Vendors

Another related area of increased enforcement is known in the privacy community as “Medical Unfair and Deceptive Acts and Practices.” These cases have been enforced heavily in the recent past by the Federal Trade Commission (FTC) under Section 5 of the FTC Act,⁹ seeking to protect vulnerable populations pursuing access to healthcare.

REGULATORY RISK

Healthcare providers without a compliant language access program in place are at risk for regulatory comment and compliance monitorships for interpretation and translation services that do not meet OCR and Centers for Medicare / Medicaid audits and compliance with the Health Insurance Portability Accountability Act (HIPAA) and its implementing regulations. In addition, privacy violations in each state for data breaches and for violations of data security regulations are on the rise and escalating quickly!

Not only is regulatory scrutiny increasing, but the cost of violations – like data breaches – is rising.

According to the May 2014, Cost of Data Breach Study¹⁰: conducted by the Ponemon Institute LLC, the cost of data breaches increased in 2014. Breaking a downward trend over the past two years, both the organizational cost of a data breach and the cost per lost or stolen record have increased. On average the cost of a data breach for an organization represented in the study increased from \$5.4 million to \$5.9 million. The cost per record increased from \$188 to \$201. “Record” is defined as information that identifies the natural person (individual) whose personal information has been compromised in a data breach.

PHI and Language Access Vendor – What is at Risk?

Under HIPAA, PHI is information that identifies an individual and relates to the following:

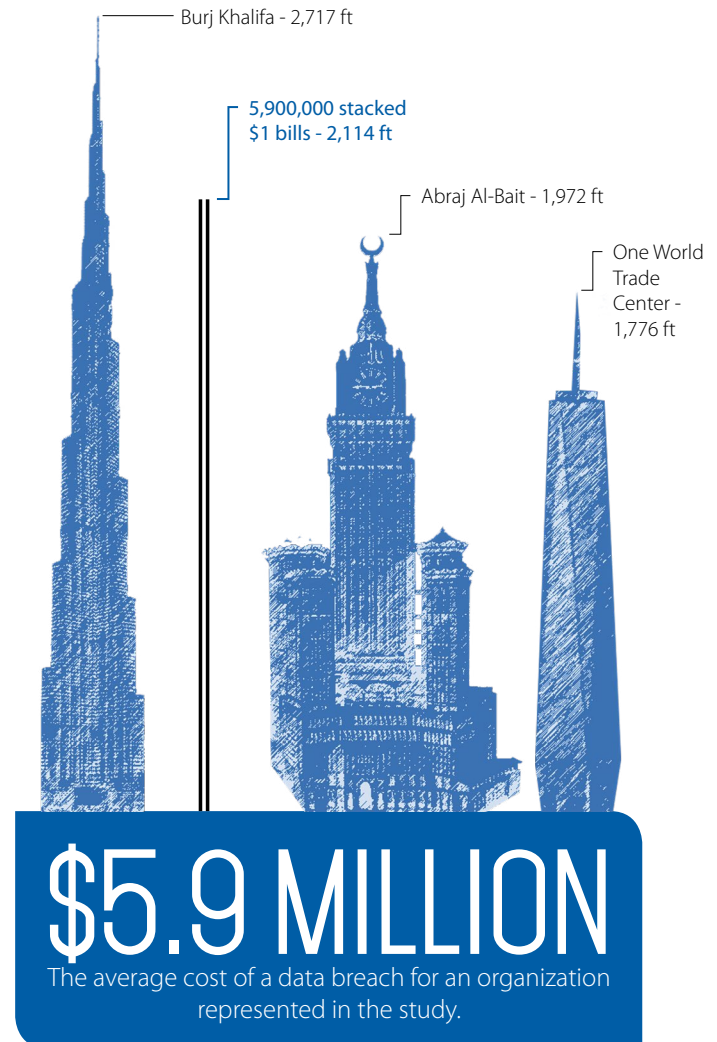
- The individual's past, present, or future physical or mental health
- The provision of healthcare to the individual
- The past, present, or future payment for healthcare

This patient information often shared during the delivery of interpretation services, and should be considered very high risk information for vendors to be managing for a covered healthcare entity.

Case Studies Highlighting Risk Types

HIPAA Enforcement Highlights Outsource Risk

A Connexions, Inc. call-center vendor employee was the cause of a patient data breach, lasting over a year long period, during 2011-2012. Patient data was stolen by the employee from a network server connecting three health insurance entities in Indiana and Ohio. HHS listed the breach as a “theft, unauthorized access and disclosure of patient data.” It is believed the Connexions employee shared patient information and Social Security Numbers with third parties. The health insurer notified 6,000 patients by mail, and provided identity protection services to patients whose information was abused. The Connexions employee was terminated after the incident.



VENDOR RISK MANAGEMENT COMPLIANCE

Vendor Risk Management (VRM) is a comprehensive plan for identifying and decreasing potential business and financial uncertainties and legal liabilities regarding the hiring of third party vendors of products and services.¹¹ When an enterprise outsources business processes to an external vendor, sensitive personal data may be transmitted, stored and processed on both company and vendor networks. Regulations such as the Sarbanes-Oxley Act, the Health Information and Portability and Accountability Act, and the Massachusetts Data Security Regulations¹² mandate that risk management policies extend to third-party vendors, outsourcers, contractors and consultants.¹³

A solid vendor privacy risk management strategy should include:

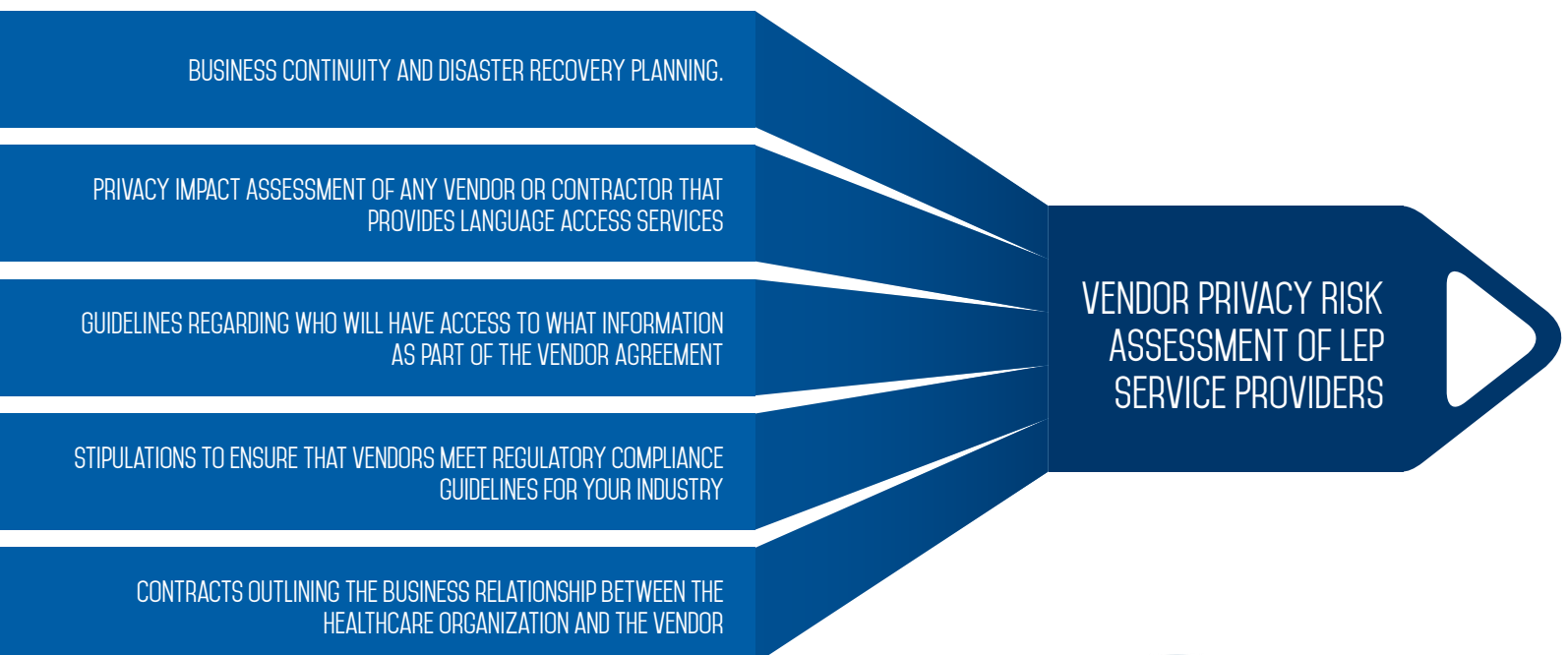
- Vendor Privacy Risk Assessment of LEP Service Providers
- Privacy Impact Assessment of any vendor or contractor that provides language access services
- Guidelines regarding who will have access to what information as part of the vendor agreement
- Contracts outlining the business relationship between the healthcare organization and the vendor
- Terms to ensure that vendors meet regulatory compliance guidelines for your industry
- Monitoring vendor compliance and performance to ensure contract stipulations are being met
- Business Continuity and Disaster Recovery Planning

Companies that conduct adequate vendor privacy risk assessments will soon learn about the strengths and weaknesses of their LEP vendor's company.



One common vendor privacy risk assessment task is to confirm the financial health of your service provider. If, the LEP service provider is compromised financially, decisions will be made to serve the bottom line, instead of the client and LEP consumer. This is an area of due diligence that must not be overlooked in the scoping of an LEP project. If you are serving a large LEP population and your Language Access Program goes down, you will be in the same situation as if there is a natural disaster or government emergency.

This is the main reason continuous monitoring of your vendors must take into consideration all risk factors including financial strength and a plan for business continuity and disaster recovery. See the Vendor Privacy Risk Assessment Strategy roadmap below and consider implementing in the vendor contracting process.



UNDERSTANDING AND MANAGING RISK WITH LANGUAGE ACCESS VENDORS

When healthcare providers fail to assess their Language Access vendors adequately, they run the risk of incurring the stigma of privacy violations, audits, fines, and regulatory comment, as well as FTC prosecution that may result in reputational damage and at times loss of accreditation. As noted above, healthcare providers required by Title VI of the Civil Rights Act of 1964 to provide language services to LEP consumers may fail to ensure that LEP individuals can effectively participate in, or benefit from, federally funded programs and this may violate the prohibition under Title VI against national origin discrimination.

Currently, one very prevalent privacy risk is the use of telecommuters and other “work from home” arrangements that may consist of offshore/onshore based LEP personnel. The privacy and security requirements required by regulation and FTC decree extend to interpreters that are based out of their homes, and companies are required to implement security programs that cover those remote interpreters and their access to PII and PHI. There are unique considerations for these types of interpreters including how a company can ensure that remote interpreters are properly using, processing, storing and destroying information. Some security policies can be enforced by defining user access, training employees on proper handling of PII and PHI, and monitoring to ensure compliance. However, there are some actions that can be enforced more easily by using onsite employees. For example, a supervisor may be able to observe a worker who takes a picture of a screen with customer information using their cell phone, while a home-based worker may not be observed so simply. It is critical to properly vet a service provider who uses home-based employees to ensure that they are aware of the risks posed by remote and telecommuting interpreters and that the service provider’s security program properly addresses those issues through training and enforces those requirements through continuous monitoring.

Risks and Considerations for Language Access Vendors

A primarily offshore, work-at-home company using 1099 contract where calls are recorded.

- Do the interpreters understand how the data security safeguards must be implemented in their own home?
- Are they willing to implement the data security safeguards in their own home as well as with all other occupants?
- Will they agree to be monitored in and around their remote work stations?
- How will they securely collect, protect, share PII and PHI and then destroy it at home?
- Will their contractors and household members execute confidentiality agreements to protect PII and PHI they may see or hear?
- Will they have a dedicated space with privacy screens for their work stations?
- Will they be able to secure any mobile devices?

A primarily onshore, contact center company using W-2 employee where interpreters take notes on calls.

- Do the interpreters have onsite training to understand how the data security safeguards must be implemented at the contact center?
- Are the interpreters willing to cooperate and report any non-implementation of data security safeguards?
- Will they agree to be monitored in and around their onsite work stations?
- Will they securely collect, protect, share PII and PHI and then destroy any paper and electronic records made at the contact center?
- Will they be restricted from making any records containing PII and/or PHI?
- Will the interpreters execute confidentiality agreements to protect PII and PHI they may see or hear?
- Will they have a dedicated space with privacy screens for their work stations?
- Will they be able to secure any mobile devices from theft?

Final Special Considerations for Medicare and Medicaid Compliance

Offshore Subcontract Attestations must be submitted for those entities contracted to receive, process, transfer, handle, store, or access Medicare beneficiary Protected Health Information (PHI) or Personally Identifiable Information (PII) in any form (oral, written, electronic, etc.). PHI and PII can include, but is not limited to: Medicare beneficiary name, date of birth, and health insurance claim number. Basically, this is information in any field or documentation that could identify the beneficiary by their personal information and may contain their personally identifying health information. The Centers for Medicare and Medicaid Services first announced the Offshore Subcontracting Attestation guidance in the *Calendar Year 2008 Call Letter* (issued 4/19/2007) and clarified the guidance in three separate memos: *HPMS Memo 7/23/2007*, *HPMS Memo 9/20/2007* and *HPMS Memo 8/26/2008*. The CMS implementation date for submission of Offshore Subcontractor Attestations was 9/30/2007. The Offshore Subcontractor Attestation is an attestation that must be completed by any business unit, vendor, service provider or First Tier, Downstream or Related Entity (FDR) that intends to contract with an offshore subcontractor who has access to PHI or PII about a Medicare beneficiary or fulfills their contract through offshore employees. If an offshore subcontractor has access to any Medicare beneficiary PHI or PII through any means, they are subject to completing the Offshore Subcontracting Attestation.

With respect to the Centers for Medicare and Medicaid Services, "Offshore" is considered any country that is not one of the fifty states of the United States or one of the United States Territories such as: American Samoa and Puerto Rico. Countries such as Mexico, India and the Philippines are considered "Offshore."

Regardless of whether the subcontractor is American or foreign-owned, if the services are performed by employees located in Offshore countries, they are subject to complete an Offshore Subcontractor Attestation.

U. S. GOVERNMENT, INTERAGENCY WORKING GROUP, AND THE U. S. DEPARTMENT OF JUSTICE LEP GUIDANCE

On August 11, 2000, President William Clinton signed Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency". The Executive Order requires Federal agencies to examine the services they provide, identify any need for services to those with limited English proficiency (LEP), and develop and implement a system to provide those services so LEP persons can have meaningful access to them. It is expected that agency plans will provide for such meaningful access consistent with, and without unduly burdening, the fundamental mission of the agency. The Executive Order also requires that Federal agencies work to ensure that recipients of Federal financial assistance provide meaningful access to their LEP applicants and beneficiaries.¹⁴

To assist Federal agencies in carrying out these responsibilities, the U.S. Department of Justice has issued a Policy Guidance Document, "Enforcement of Title VI of the Civil Rights Act of 1964 - National Origin Discrimination against Persons with Limited English Proficiency" (LEP Guidance). This LEP Guidance sets forth the compliance standards that recipients of Federal financial assistance must follow to ensure that their programs and activities normally provided in English are accessible to LEP persons and thus do not discriminate on the basis of national origin in violation of Title VI's prohibition against national origin discrimination.¹⁵

In addition, the U.S. Department of Justice produced two information graphics to assist those in the government with choosing the most optimal Language Access Provider and with scoping an LEP project.

EXECUTIVE ORDER 13166

"Improving Access to
Services for Persons
with Limited English
Proficiency"

1 U.S. Department of Health and Human Service, Office for Civil Rights (2014). Retrieved from Compliance Review Initiative: Advancing Effective Communication in Critical Access Hospitals <http://www.hhs.gov/ocr/210>

3 U.S. Department of Health and Human Services, Office of Minority Health (2014). Retrieved from <http://www.ThinkCulturalHealth.hhs.gov>

4 See the website of the Office of Minority Health at: <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15>

5 See the Office for Civil Rights website for a copy of the Compliance Review Initiative at: http://www.hhs.gov/ocr/civilrights/activities/agreements/compliancereview_initiative.pdf

6 See 42 U.S.C. § 2000d, et seq. The HHS Title VI implementing regulation is set forth at 45 C.F.R. Part 80.

7 See the Compliance Review Initiative at: http://www.hhs.gov/ocr/civilrights/activities/agreements/compliancereview_initiative.pdf

8 See the U.S. Dep't of Health & Human Services, Office for Civil Rights v. Shenandoah Memorial Hosp., Case No.12-134888 (voluntary resolution agreement) (Aug. 28, 2012), available at http://www.hhs.gov/ocr/civilrights/activities/agreements/shenandoah_vra.pdf

9 Provider of Medical Transcription Services Settles FTC Charges that it failed to Adequately Protect Consumers' Personal Information.

10 2014 Cost of Data Breach Study : United States, Benchmark research sponsored by IBM and independently conducted by Ponemon Institute LLC (May 2014).

11 Definition of Vendor Risk Management. Retrieved from SearchCIO: Definition Vendor Risk Management <http://searchciotechtarget.com/definition/Vendor-Risk-Management>.

12 Massachusetts Regulations, 201 CMR 17.00

13 ID

14 Executive Order 13166 can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2000-08-16/pdf/00-20938.pdf>

15 The LEP Guidance can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2002-06-18/pdf/02-15207.pdf>



TIPS ON HIRING THE RIGHT TELEPHONIC INTERPRETATION VENDOR



STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
IDENTIFY YOUR LANGUAGE REQUIREMENTS Consider your language needs; project interpreter usage in minutes; develop a list of likely encountered target languages. Using this information, bargain for the level of services that best match agency need.	ISSUE A REQUEST FOR QUOTATION (RFQ) REFLECTING LANGUAGE AND AGENCY-SPECIFIC NEEDS Solicit bids for services from state, local, or regional vendors. For federal agencies, see the GSA's Language Services Schedule (Schedule 738 II). Require quality control plans, cost and availability schedules, staff training, regular vendor reporting, and detailed guidance on interpreter qualifications.	REQUIRE WRITTEN PROPOSALS AND EVALUATE THEM PRIOR TO LIVE TESTING Assessing vendor quality is an essential component to hiring the right vendor. Requiring written proposals allow agencies to focus in on quality concerns prior to live testing, and to narrow the field when written proposals fail to meet agency requirements.	CONDUCT A LIVE TEST TO EVALUATE HOW POTENTIAL VENDORS PERFORM DURING AGENCY-SPECIFIC HYPOTHETICAL EXERCISES Live testing is essential to assessing vendor quality. Live testing demonstrates the quality, logistics, and suitability of vendors. Involve known language professionals in the live testing process, and craft effective agency-specific hypothetical scenarios to test vendors.	SELECT A VENDOR BASED ON BOTH THE WRITTEN PROPOSAL AND HOW THE VENDOR PERFORMED DURING THE LIVE TEST Consider written proposals, live testing, and prior agency experience with vendors in making a selection. Narrow the field by comparing live testing results. Prioritize merit over price whenever possible.

COMMON ERRORS IN TELEPHONIC INTERPRETATION

BEWARE

WHAT TO LOOK OUT FOR DURING LIVE TESTING:

- Inaccurate or inconsistent systems to accurately identify the language spoken by the LEP individual
- Unreasonably long wait times
- Unavailable languages (don't only test for Spanish)
- Interpretation errors and inaccuracies
- Failure to convey the substance and tone of the entire conversation in English or the non-English language
- Use of old, outdated, or archaic terminology
- Lack of skill in the target language
- Inappropriate conversations with LEP individuals or intervening in the conversation

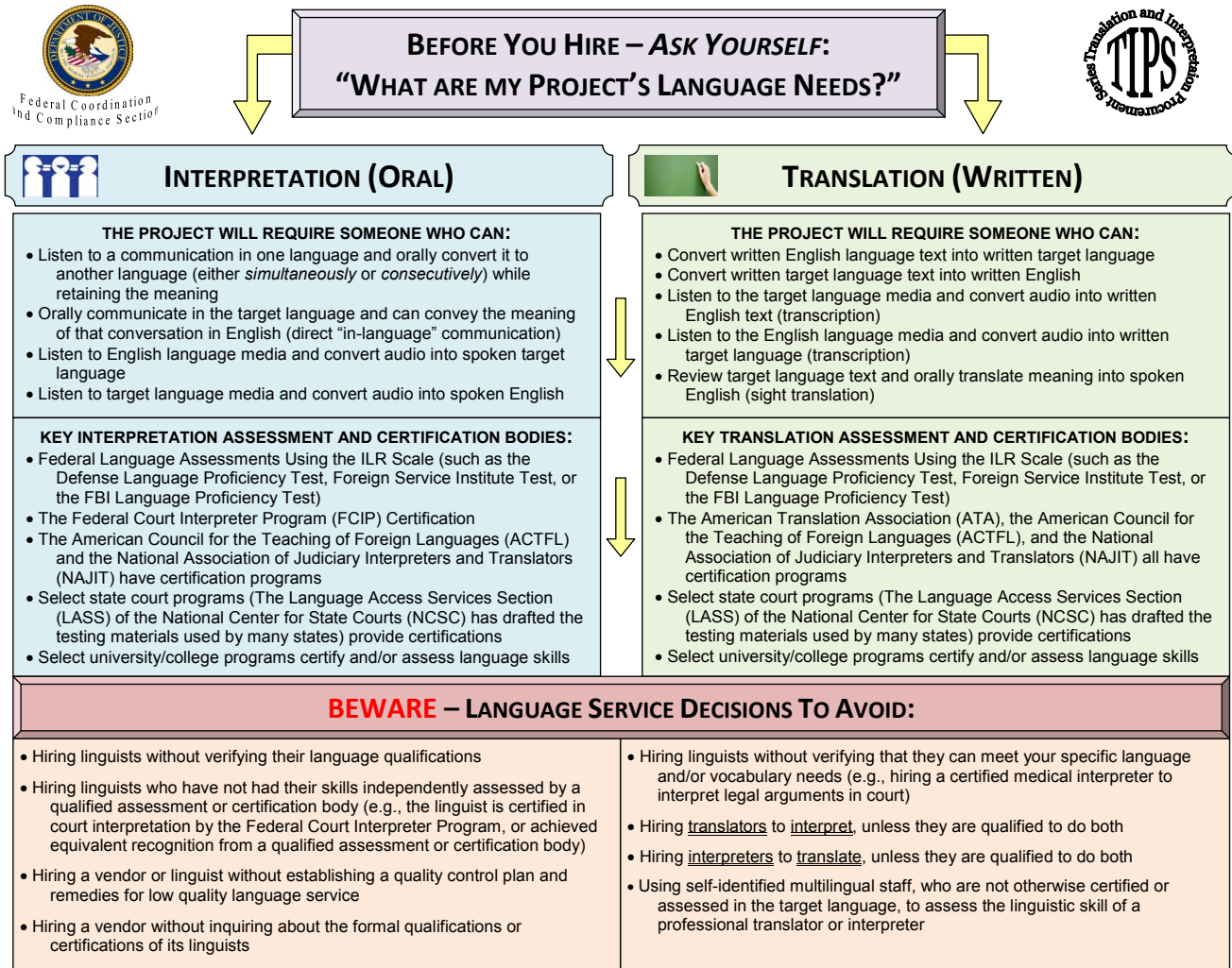
VENDOR SEARCH REMINDERS

ENSURING VENDOR CAPABILITIES

- Require vendors to discuss how they identify languages
- Require vendors to commit to specific connection times and on-demand services, if necessary
- Require vendors to explain their system for quality control and/or quality assurance
- Require specific interpreter qualifications (e.g., certification, formal assessment, experience)
- Require vendors to provide clear training materials for agency staff and periodic reports on usage, by language and by office
- Require vendors to submit past performance reviews from other local, state, or federal agencies
- Require intermittent testing throughout the contract period

For additional copies or technical assistance in language access matters, contact the Federal Coordination and Compliance Section at LEP@usdoj.gov

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