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Language Access and CLAS Requirements for Determination of Need (DoN) Holders

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WHAT TO KNOW

Who Should Read This?

Determination of Need (DoN) Holders and Applicants

Why: DoN Regulation 105 CMR 100.310 requires Holders to submit a plan for approval by Department staff for the development and improvement of language access and assistive services for individuals with disabilities and patients who do not speak English, have Limited English Proficiency (LEP), or use American Sign Language (ASL). It is the position of the Office of Health Equity (OHE) that, to comply with this Condition, the Holder of a DoN must submit its Language Access and CLAS plan within one year of its Notice of DoN.

Purpose

This guidance will assist DoN Holders complete forms and related materials needed for the Language Access and CLAS Standards requirements for addressing Standard Conditions 14, 15, and 16.

What is the Overall Process to Ensure Compliance with Regulation*?

Prior to DoN Application

Prior to submitting a DoN application to the Department, applicants should notify OHE of their intent to file. OHE staff can offer technical assistance to all applicants. During the pre-application period, applicants can:

- Consult with OHE Health Care Interpreter Services staff to understand the process and deadlines, identify which form to organize, complete, and submit documents, and have questions answered.
- Use the forms to assess the Applicant's Interpreter Services Program.
- Begin to develop the Plan for Language Access and CLAS following the assessment findings.

After Notice of DoN

The Holder is required to:

- Submit a Language Access and CLAS plan to OHE within one year of receiving its Notice of Approval.
- Identify a contact for the submission of required documents. *If Holder constitutes a system with several licensed facilities, OHE will work with the Holder's designee to receive all required documents for all licensed facilities in one submission.*
- The plan will be complete once OHE has received all forms and related documents and has notified the Holder.
- OHE will provide its approval and listing with Corrective Actions as applicable, after review of all materials submission and review.

After OHE Notice of Approval

The Holder of a DoN shall comply with all "Standards and Other Conditions" as required by 105 CMR 100.310.

Background

DoN regulation 105 CMR 100.310 (sections 14 -16) requires that all Holders of a Notice of Determination of Need comply with three requirements which are overseen by the Office of Health Equity (OHE):

1. Provide a plan for approval by OHE for the development and improvement of language access and assistive services provided to the Holder's Patient Panel including individuals with disabilities and patients who do not speak English, or have Limited English Proficiency (LEP), or use American Sign Language (ASL);
2. Provide Interpreter Services to the Holder's Patient Panel and ensure that all individuals providing interpreter services to the Holder's Patient Panel maintain current multilingual proficiency and have sufficient relevant training; and
3. Provide ongoing education and training for administrative, clinical, and support staff in culturally and linguistically appropriate services (CLAS), including, but not limited to, patient cultural and health belief systems and effective utilization of available interpreter services.

This document provides guidance on documenting and reporting on each of these activities.

DoN regulation 105 CMR 100.310 also requires DoN Holders to report on these activities each year in a manner or form specified by the Determination of Need Program.

Holders must report on the progress of the projects and requirements, as well as corrective actions outlined by the Department in relation to the scope of the approved project.

DPH Expectations for Holders: Language Access Programs and CLAS

Department of Public Health (DPH) Priorities for Language Access Programs

Given the differing needs and resources of each facility and the various populations and communities they serve, flexibility is important in designing a program that provides meaningful access and efficient services to patients who do not speak English, have Limited English Proficiency (LEP), use American Sign Language, and individuals with disabilities. While each facility may offer a program tailored to its respective operational and population needs, certain core elements are instrumental to effectiveness and efficiency in service development, delivery, and evaluation.

These elements include the following:

- The program is defined, with comprehensive written policies and procedures¹;
- The program includes regular, systematic assessment of the language needs of its patient pool;
- The program uses a community needs assessment and an assessment of its own resources in determining what types of oral language assistance to include in its healthcare delivery system;
- The program establishes specific training and competency protocols for interpreters, providers, and staff; and,
- The program has a monitoring and evaluation system in place.

Qualifications for Providing Medical Interpreters²

Consistent with the standards set out in DPH's hospital licensure regulation, 105 CMR 130, OHE expects that a medical interpreter shall be an individual who can demonstrate bilingual proficiency and have received training that includes the skills and ethics of interpreting, and knowledge in both languages regarding the specialized terms (e.g., medical terminology) and concepts relevant to clinical and non-clinical encounters.

¹ A description of core elements of the Policy and Procedures can be found in Appendix A, page 20.

² A Glossary for additional terms and definitions can be found on page 21.

CLAS

CLAS stands for “culturally and linguistically appropriate services.” It is a way to improve the quality of care provided to all individuals, which will help reduce health disparities and achieve health equity. CLAS means to provide health services that are respectful of and responsive to the health beliefs, practices, and needs of diverse patients. By tailoring services to an individual's culture and language preferences, health professionals can help bring positive health outcomes for diverse populations.

At DPH, the [CLAS standards](#) are used as a performance management / quality improvement (PMQI) framework for promoting health equity.

Each institution should be able to identify and describe key elements to formulate a robust Language Access and CLAS plan for OHE approval.

Required Forms and Documents

It is strongly recommended that Holder consults with OHE staff two months prior to submitting its plan for Language Access and CLAS to ensure timely submission of adequate information and forms. In order to minimize confusion regarding which forms to submit to OHE for approval, DoN Holders should review which section applies to their site:

Section 1 is for facilities whose language access program has been assessed by OHE through materials reviews and site visits within the last five years or who has submitted an annual survey³ to OHE on the provision of medical interpreter services for the most recent Federal Fiscal Year preceding the approval date of their DoN Approval. The Language Access and CLAS Plan begins on page 9.

Section 2 is for all other facilities. Requirements for a robust medical interpretation plan begin on page 12.

NOTE: If Holder is a system with many licensed facilities, each licensed facility is required to provide a plan to OHE. The Holder should submit all required materials in one emailed submission or a single thumb drive.

Holders are encouraged to contact OHE if further information is needed to identify which “Section” to complete for submission. OHE staff contact information is provided below.

Upon receipt of Notice of Determination of Need, the applicant is considered the Holder of a DoN. OHE requires the Holder of a DoN to submit a plan for Language Access and CLAS for each of its licensed facilities, within one year of receiving the Notice of Determination of Need.

Contact Information

Ph. 617-624-5905

Email: ohes@state.ma.us

With a subject line: Determination of Need Application

³ This annual survey is issued at the end of each Federal Fiscal Year by OHE to all Health Care Facilities that are part of its database. If the facility's Interpreter Services Program Coordinator or Director is unaware of the annual survey, has not submitted one, or has never heard of this survey, the holder can contact OHE or go to Section II.

Section 1

This section covers Holders of a DoN whose facilities provide every year a report to OHE through its online Database⁴ about its Interpreter Services Program. The Holder of a DoN may be one single facility or may comprised of several facilities.

This section pertains to Holder with a single or several facilities that have on-going and active interactions with OHE regarding their medical interpretation program. The Holder is eligible for Section 1 only if:

- The facility has submitted to OHE its Annual Medical Interpreter Services Survey⁵ for the most recent Federal Fiscal Year, preceding DPH approval notice for its most recent DoN application; or,
- The facility has received a site visit from OHE to assess its Interpreter Services Program.

If a facility did not:

- submit its Annual Medical Interpreter Survey for the FFY preceding the Department's notice of a DoN approval,
- receive a visit from OHE during the past five calendar years,
- submit any reports to OHE, including but not limited to, Organizational Chart, progress reports, IS policies and procedures, Annual Medical Interpreter Survey for **one Federal Fiscal Year⁶ during the last three years that preceded the Department's Notice of Determination of Need,**

Said facility can still be eligible for **Section 1** if the missing documents are submitted with the plan for Language Access and CLAS within one year after the Notice of Determination of Need.

Once the applicant has obtained Notice of Determination of Need, the current Holder of the DoN has one year to submit a plan for Language Access and CLAS for each of its licensed facilities.

⁴ Facilities report annually to OHE about their Interpreter Services Program. The database facilitates analyses of many processes for certain domains based on 11 structural elements that comprise an efficient Interpreter Services Program.

⁵ If the facility's Interpreter Services Program Coordinator or Director is unaware of the annual survey, has not submitted one, or has never heard of this survey, the holder can contact OHE or go to Section II.

⁶ This exemption cannot exceed required documents that stem over 2 Federal Fiscal Years.

Two documents are required to be submitted for Holders of **Section 1**. They are:

- Each facility's FFY Annual Medical Interpreter Services Survey preceding the Department's notice of DoN's approval date with all required attachments.
- Each facility's Plan for Language Access and CLAS, as described below.

Plan Components for Language Access and CLAS

The plan must include a description of the Facility's Interpreter Services Program, including:

- Strength
- Quality improvement efforts with deliverables
- Activities and anticipated outcomes
- Current and future Culturally and Linguistically Appropriate Services (CLAS) initiatives
- Recently imposed corrective implementation measures, if any.

The plan is to be concise and written in a format that allows the reader to understand and assess its contents. The plan should identify each of the six questions it is addressing.

1. Provide the most recent information about your Interpreter Services Program's current milestones and future focus, addressing all bulleted points. Use descriptive and clear language and provide explanation where needed. Note a particular focus on patient panel and languages in the service area by addressing the following:
 - Type of facility
 - Identified Service Areas – including patient panel and languages
 - Specialty (if any)
 - Number of beds
 - Number of interpreter sessions so far
 - Interpreter Services Program (Department) Methodology: approaches used for language service provision
 - Any new affiliates, clinics, and/or satellite sites operating on its license
2. Provide an appraisal of the facility's current capacity and available resources to carry out language access services. Be sure to:

- Identify assets and values.
 - List and describe the effectiveness of the chosen interpreter services model used. Be sure to address components such as intensity, services, tracking, and responsiveness to demands.
 - List and describe available resources, including the use of and access to technology and provide a rationale for the use of a particular modality over another during a clinical interaction.
 - Describe the leadership support for Interpreter Services Program inclusion/authority in decision making and provision of needed resources.
3. Describe any made or planned changes in the Interpreter Services Program operations such as administration, staffing, hours of operations, service delivery modalities, including the use of technology.
- Explain how these changes have or will continue to impact and benefit the patient panel.
 - If changes occurred or planned for multiple sites, specify site for each corresponding change.
 - Highlight progress and list activities, anticipated date of completion, and deliverables, as applicable.
 - Describe the process to sustain practice over time.
4. Describe the facility's current and planned strategies for evaluating the Interpreter Services Program.
- Report on any changes made to your data collection mechanisms to improve monitoring, assessing, and capturing all activities, particularly collection on race, language, and ethnicity data.
 - Describe any quality improvement efforts initiated from your findings and analyses of the collected data.
 - Highlight progress and list activities, anticipated date of completion, and deliverables, as applicable.
 - Describe the process to sustain practice over time.
5. Clearly and succinctly summarize the facility's current and planned Culturally and Linguistically Appropriate Services with anticipated impact, identifying the benefits

to be incurred by the facility and sites on its license, as applicable. Describe how practices ensure that services delivered to the patient panel are/will be effective, equitable, responsive to the diverse cultural health beliefs and practices and health literacy. Be sure to include activities at sites on facility's license. Describe the process to sustain practice over time.

6. Provide an update on existing corrective implementation plans / benchmarks, highlighting progress made on action steps, listing the activities, deliverables, and anticipated date of completion, as applicable.

Section 2

This section covers all facilities that have never gone through an OHE language access review, had an OHE site visit, or submitted an Annual Medical Interpreter Services Survey for the Federal Fiscal Year preceding notice of approval from the Department⁷. This section includes but not limited to, services for a new location, new construction, new licensed facility, new satellites, and expansion of services in a new geographical area.

Required Documents

Within one year of receiving a Notice of Determination of Need, OHE requires the Holder to complete and submit, for each of its licensed facilities, a completed DoN Language Access and CLAS Application Form⁸, with the following 5 attachments:

1. The facility's Interpreter Services Program Policy and Procedures (See Appendix A);
2. The facility's translation guidance;
3. A completed job description of the Coordinator or Manager of Interpreter Services on the facility's letterhead;
4. The facility's Organizational Chart; and,
5. The Plan for Language Access and CLAS as described in the following pages.

⁷ If unfamiliar with the annual survey, it is likely that Section 2 applies to the Holder's facilities. Holder can also consult OHE to be sure.

⁸ The Language Access and Application Form, download at <https://www.mass.gov/how-to/apply-for-a-determination-of-need>

The Plan for Language Access and CLAS

It is recommended that Health Care Facilities complete the DoN Language Access and CLAS Application Form first and use its contents to inform the components of the plan. This form is intended to provide a current profile on the state of the facility's Interpreter Services Program. The CLAS Application Form's structure and elemental components frame the foundation of an efficient Interpreter Services Program. Through this process, Interpreter Services Programs will be able to identify areas of engagement and support needs in their operations and services.

By reviewing the CLAS Application Form, the facility can begin to design a path and detail the activities relevant to the development, growth, and efficiency for operations and services for IS. OHE expects facilities⁹ that are required to conduct an annual language needs assessment to incorporate its findings in the review and plan. This review process may also underscore current and emerging needs and the various components of the Interpreter Services Program that require immediate attention as facilities formulate the language access implementation component of the plan.

To further assist in the development of the Language Access and Assistive Service Plan, the Culturally and Linguistically Appropriate Services Guidance (<http://www.mass.gov/eohhs/docs/dph/health-equity/chapter-6-ensure-language-access.pdf>). This guide provides fundamental information on developing a tailored plan for facilities, based on their patient panels, and available resources.

The plan describes the facility, its operations, services, patient panels, and the different components that form its Interpreter Services Program. The plan is to be concise and written in a format that allows the reader to understand and assess its contents. The plan must fully and accurately answer each of the 7 questions and identify them accordingly. This plan covers the following the questions:

1. Provide a clear and brief description of the Interpreter Services Program operations such as administration, staffing, hours of operations, service delivery modalities, including the use of technology, oversight, and support system to all sites on its license. Be sure to highlight sufficiency in facility's structure, resources, and demonstrated management's support and accountability.

⁹ DPH Regulation CRM 105 130.1103 requires acute care hospitals to conduct an annual language needs assessment of the emergency department. Information and Resources on the annual language needs assessment can be found in the Resource Section at the end of this guide and download at: <https://www.mass.gov/service-details/interpreter-services-information-for-healthcare-facilities>.

- Describe the facility's experience in providing interpreter services.
 - Describe the facility's standards for determining medical interpreter's competency.
 - Explain how current model of operation benefits the patient panel, with a particular focus on the primary means for service provision.
 - Describe the facility's algorithm for selecting a particular modality to provide interpreter services.
 - If provision of services is contracted with outside vendors and/or interpreters, describe how it will function, structures for operations and accountability to meet IS standards like training and competency.
 - List the training staff, volunteers, and outside vendors and/or interpreters have received regarding compliance to IS Policy and Procedures.
 - Describe current process to mitigate or resolve cross-cultural issues with the provision of language services.
 - Describe the facility's process for language access throughout the continuum of care for a patient.
 - Describe how internal collaboration have and will benefit the facility's patient panel and promote efficiency in services.
 - Describe all quality measures instituted when using technology for service provision, especially with Video Remote Interpretation. Be sure to explain the effectiveness of the facility's system, provider, and patient comfort with using the system, and its assessment thereof.
 - Identify existing or future acquisition of resources and equipment for the delivery of services.
 - Identity any new initiatives to be undertaken.
 - Describe the process to sustain practice over time.
2. Describe the patient panel and languages in the service area by addressing the following:
- Type of facility
 - Identified Service Areas – including patient panel and languages
 - Specialty (if any)
 - Number of beds (if any)

- Number of interpreter sessions, so far
 - Any affiliates, clinics, or sites on facility's license
3. Describe on-going training activities undertaken for administrative, clinical, and support staff in Culturally and Linguistically Appropriate Services (CLAS).
 - Describe how practices ensure that services delivered to the patient panel are/will be effective, equitable, responsive to the diverse cultural health beliefs and practices and health literacy.
 - Explain benefits of the activities to be undertaken.
 - Provide clear description of anticipated measurable outcomes, date of completion, and deliverables as applicable.
 - Describe the process to sustain practice over time.
 4. Describe the facility's strategies for evaluating the Interpreter Services Program, including but not limited to, quality of services, feedback from providers and patients, interpreters' competence, and use of modalities.
 - Describe the facility's data collection mechanism that monitors, assesses, and captures all activities, including collection on race, language, and ethnicity data.
 - Describe any quality improvement efforts initiated from the findings and analyses of the collected data that address gaps in areas listed above.
 - Highlight progress, list activities, anticipated date of completion, and deliverables, as applicable.
 - Describe the process to sustain practice over time.
 5. Describe how race, language, and ethnicity data are being used and will be used to improve patient care and achieve health equity.¹⁰
 - Describe collaboration with internal and external programs or organizations to address disparities issues.
 6. List and describe the facility's internal and external outreach activities to ensure that its patient panel has information about the facility and the availability of interpreter services.

¹⁰ Health Equity is the ongoing process for ensuring that everyone has the opportunity to attain and maintain their full health potential.

- Describe how efforts will benefit the patient panel.
 - Be sure to demonstrate the facility's active engagement with and promotion of services to the patient panel.
7. Provide a timeline that covers the facility's current IS initiatives and/or quality improvement efforts, specifies target dates for implementation, anticipated outcomes, and assigned responsible staff.

The Approval Process

OHE will consider a plan for Language Access and CLAS¹¹ complete once all appropriate documents have been submitted within the appropriate allotted time. Upon receipt of all documents, OHE will notify the Holder's designee and proceed with the review. OHE will contact each licensed facility to request additional documentation, clarify confusing elements, and/or schedule an assessment visitation.

After review of all materials, conversations, and site visits, OHE will issue its findings upon receipt of a completed application, to the Holder of the DoN, each respective facility, the Determination of Need program, and Office of the Commissioner.

The Holder must submit acknowledgment of receipt to OHE, signed by the Holder's Chief Executive Officer and/or board chair. It is the responsibility of the Holder to ensure implementation of the agreed upon corrective action measures, if any, for each of its facilities and sites on its license.

Upon OHE's approval of the Language Access and CLAS plan and in addition to the required DoN annual reporting required pursuant to 105 CMR 100.310(17), the Holder must submit to OHE:

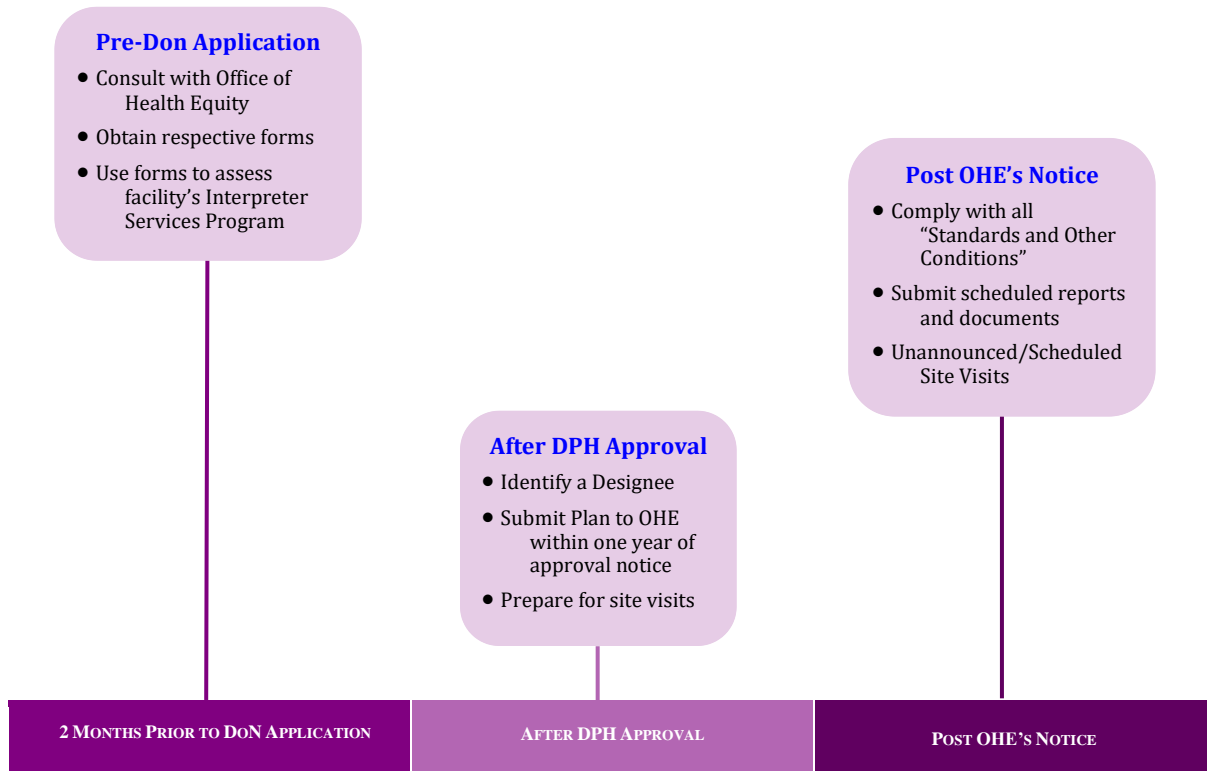
- A completed Annual Medical Interpretation Survey¹² with all required attachments within 45 days at the end of each Federal Fiscal Year; and,
- Notification of substantial changes in its Interpreter Services Program as it occurs.

The Office of Health Equity will conduct unannounced site visits at all facilities and sites on its license.

¹¹ 105 CMR 100.310 (14)

¹² OHE will issue the Annual Medical Interpreter Survey to the Facility's designee at the end of each Federal Fiscal Year with instructions.

Précis



Frequently Asked Questions

Question:

- What if a facility obtained approval for its Language Access and CLAS plan within the last three years, does the facility still need to go through the same process with OHE while it is implementing the corrective action measures for its last DoN?

Answer:

- **Yes.** The Holder has now become a new applicant and should contact OHE to determine process for plan submission.

Question:

- Is the Annual Medical Interpretation Survey submitted to OHE the same as the required DoN annual report?

Answer:

- **No.** These are two different reports that cover different areas and questions. The Holder is required to submit both to the identified respective portal, which will be highlighted during the application review.

Question:

- What is the difference between Annual Medical Interpretation Survey and the required DoN annual report?

Answer:

- The DoN annual report generally addresses a facility's progress corrective action measures after a review. It is focused on contents.
- The Annual Medical Interpretation Survey is one of OHE's processes to review and assess language services at a facility. This survey covers 12 areas of an efficient medical interpretation program. Summarily, it helps determine the degree to which a facility measures demands, services, and accomplishments as it identifies areas of engagement and support needs in operations and services.

Appendix A: Interpreter Services Program Policy and Procedures

This document not only explains the overall process by which services are conducted but also establishes the facilities' priorities and culture, describes current model of operations, helps staff understand their roles and responsibilities, and provides specific steps in service provision, relating to different situations. Common components include:

- Legal Implications
- Program Justification
- Definition of Terminology
- Description of Current Model of Operations
- Steps to Identify, Engage, and Assess Language Needs for the patient panel
- Procedures to Access Services
- Availability and provision of medical interpretation services, 24/7 or during hours of operations, and at no charge to the patient panel
- Use of only trained medical personnel for all medical interpretation, unless otherwise allowed under law
- Prohibition of minors as interpreters
- Determent of the use of family members and friends as interpreters
- Training for all staff, medical providers, new hires, and volunteers
- Consistency of practice across all departments and site on its license
- Job protection measures for medically trained employees who provide medical interpretation
- Assurance of posting of signage at all points of contact and public points of entry informing patients of the availability of interpreter services at no charge
- Grievances procedures with internal and external contact information, and language that ensures continued quality in health services upon the filing of a grievance
- Procedures for identifying and assessing the language needs of its patient panel
- Continuing education for medical interpreters
- Addendum that defines specific procedures on the appropriate use of modalities for different medical situations

Glossary

Affiliate:

- Any relationship between two organizations that reflects, directly or indirectly, a partial or complete controlling interest or partial or complete common control.

Applicant:

- The Provider Organization that files the Application for Determination of Need with the Department for, or on behalf of, the Entity seeking a Notice of Determination of Need for a Proposed Project pursuant to 105 CMR 100.00. In instances where there is no Provider Organization, Applicant shall mean the Entity which files the Application for Determination of Need with the Department for itself or, on behalf of, an Affiliate seeking a Notice of Determination of Need for a Proposed Project pursuant to 105 CMR 100.00.

Bilingual Healthcare Providers:

- Individuals who speak one or more languages other than English, usually employed as regular, part-time, or full-time, and whose primary job involves the provision of medical/clinical services.

Completed Interpretation Session (Encounter):

- A billable visit or meeting where patient(s) and healthcare provider(s) communicate health information in 2 different languages with the assistance of a trained medical interpreter.

Contracted Interpreter:

- An individual or outside interpreter service agency/vendor whose duty, defined in a contract with the hired organization, is to provide medical interpretation.

Employee Bank:

- A list of bilingual employees whose primary jobs are not medical/clinical interpretation but may be called upon to interpret.

Holder:

- The Provider Organization which has been issued a Notice of Determination of Need by the Department pursuant to 105 CMR 100.000. In instances where there is no Provider Organization, Holder shall mean the Entity which has been issued a Notice of Determination of Need by the Department pursuant to 105 CMR 100.00.

Hours:

- The total number of hours worked for the year.

Interpretation:

- The act of receiving a message in one language and relaying the exact message in another language through spoken or sign language exchange.

LEP (Limited English Proficiency):

- Individuals who do not speak English or speak English less than very well.

Encounter:

- A visit or meeting involving healthcare providers and patients.

On-Call:

- Medical interpreters scheduled on an as needed basis to provide medical interpretation solely for unanticipated or emergent needs.

Per Diem:

- Medical interpreters hired to provide medical interpretation when needed but generally do not receive benefits.

Staff Interpreter/Employee:

- Individuals hired as full-time or part-time regular employees, whose primary duty is to provide medical interpretation for healthcare providers and patients during clinical encounters.

Standardization:

- Provide consistency, uniformity, sameness across different entities while removing irregularities and variation.

Resources

- CLAS Self-Assessment Form, download at:
<http://www.mass.gov/eohhs/docs/dph/health-equity/clas-self-assessment-fy15.pdf>
- DPH Interpreter Services Posters, download at:
<http://www.mass.gov/eohhs/gov/departments/dph/programs/admin/health-equity/interpreter-services.html>
- Language Needs Assessment Guidance, download at:
<http://www.mass.gov/eohhs/gov/departments/dph/programs/admin/health-equity/interpreter-services.html#guide>
- Making CLAS Happen: Six Areas for Action, download at:
<https://www.mass.gov/lists/making-clas-happen-six-areas-for-action>