

BB REVIEW

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Healthcare News

November 2008

MEDICARE & MEDICAID

CMS Finalizes the Anti-Markup Rule in FY 2009 Physician Fee Schedule

On October 30, 2008, the Centers for Medicare and Medicaid Services ("CMS") posted the 2009 Physician Fee Schedule ("Final Rule"). Notably, the Fee Schedule finalizes CMS' proposed changes to the Anti-Markup Rule and Stark's incentive payment and shared savings programs.

In the proposed 2009 Physician Fee Schedule ("Proposed Rule"), CMS proposed to apply the Anti-Markup Rule to: (1) tests which are purchased from an outside supplier; or (2) tests which are performed by a physician who does not "share a practice" with the billing physician (73 FR 38502). Ultimately, CMS adopted an approach that incorporates aspects of both tests. CMS states that both parts of the test are measures of whether a performing/supervising physician "shares a practice" with the billing physician. CMS did not elect to change the definition of "net charge".

In the Final Rule, CMS has adopted a "flexible" standard utilizing a two-step process to determine if the Anti-Markup Rule applies. First, where the performing physician (that is, the physician who supervises the technical component ("TC") or performs the professional component ("PC") or both) performs substantially all (at least 75 percent) of his or her professional services for the billing physician or other supplier, none of the services furnished by the physician on behalf of the billing physician or other supplies will be subject to the Anti-Markup Rule. If the performing physician does not meet the "substantially all" services requirement, then the arrangement must be analyzed under the second-step, the site-of-service approach. Under the site-of-service approach, only TCs and PCs performed in the office of the billing physician or other supplier by an employee or independent contractor physician will avoid application of the Anti-Markup Rule.

The rule becomes effective January 1, 2009.

Practitioner Enrollment Requirements

In the Proposed Rule, CMS proposed to require that all physician and non-physician practitioner offices that furnish diagnostic testing services enroll in Medicare as independent diagnostic testing facilities ("IDTFs") and comply with the majority of Medicare's IDTF performance standards. With the enactment of Section 135 of the Medicare Improvement for Patients and Providers Act of 2008 ("MIPAA"), CMS has elected to defer the implementation of this proposal. Section 135 of MIPAA requires the Secretary of the Department of Health and Human Services to establish an accreditation process for non-hospital entities furnishing advanced diagnostic testing procedures which include MRI, CT, and other diagnostic procedures (but specifically excluding x-ray, ultrasound and fluoroscopy) by January 1, 2012.

Mobile Entity Billing Requirements

The Final Rule also includes a new requirement that any entity furnishing mobile diagnostic testing services to Medicare beneficiaries must independently enroll in Medicare as an IDTF and directly bill Medicare for the services it furnishes, regardless of the location where the services are performed. CMS clarified in the preamble discussion to the Final Rule that this new enrollment and billing requirement applies to any and all entities that furnish diagnostic testing services, including companies that are not currently enrolled and have instead been leasing equipment and technicians to physician offices and permitting the physician offices to bill for the technical component of the testing. This interpretation of the new rule may prohibit block leases of equipment with a technician to a physician practice.

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**Alabama Challenges CMS Mandate that
States Return Federal Share of Fraud
Recoveries**

The State of Alabama asked a federal district court on November 3, 2008, to reject a new policy requiring states to return the federal share of Medicaid money recovered from a legal action under a state's False Claims Act ("FCA") to the federal government. The complaint alleged that CMS exceeded its statutory authority and failed to engage in notice-and-comment rulemaking.

CMS sent a letter October 28, 2008, to state health officials explaining that the amounts recovered by a state through a state FCA action must be refunded at the federal Medical Assistance Percentage ("FMAP") rate. According to the letter, any state action taken as a result of harm to a state's Medicaid program must seek to recover damages sustained by the Medicaid program as a whole, including both federal and state shares.

**CMS Issues Changes for HOPDs and
ASCs**

CMS issued a [final rule](#) (CMS-1404-FC) on October 30, 2008, updating payment policies and rates for both hospital outpatient departments ("HOPDs") and ambulatory surgical centers ("ASCs") for calendar year ("CY") 2009.

The final rule seeks to promote higher quality, more efficient services by adopting improvements to the Hospital Outpatient Quality Data Reporting Program ("HOPD QDRP") and by finalizing new conditions for coverage for ASCs. Total payments under the Outpatient Prospective Payment System ("OPPS") will increase by \$1.6 billion to \$30.1 billion in CY 2009. It is projected that ASC payments will increase by \$0.4 billion to approximately \$3.9 billion.

Hospital Outpatient Departments

In addition to a 3.9 percent increase in payments to providers under PPS, CMS is attempting to strengthen ties between payment and quality of care. As a result, quality measures that must be reported will increase from seven to eleven in CY 2010. If a hospital fails to report quality measures, CMS will reduce its payments by two percent for most services. Additionally, CMS plans to implement a voluntary test validation program, involving fifty or fewer records, for eight hundred randomly selected hospitals, which will affect the CY 2011 payment update. In aligning payment incentives for high quality care, CMS intends to refuse payment for

medical care that harms patients or leads to preventable complications.

*Ambulatory Payment Classification ("APCs")
Changes*

In order to encourage imaging efficiencies under the OPSS, CMS is establishing a single APC payment when two or more imaging procedures using the same imaging modality are provided in a single session. They include:

- Ultrasound;
- Computed tomography ("CT") and computed tomographic angiography ("CTA"), with and without contrast; and
- MRI and MRA, with and without contrast.

Other Payment Provisions

Drugs and Pharmacy Overhead. CMS will pay for separately payable drugs and biologicals under the OPSS at the average sales price plus four percent. CMS will continue to transition to a claims-based payment rate for separately payable drugs and biologicals.

Changes Affecting Payment to ASCs

ASC Payment Rate Updates. The revised ASC payment rates were established to reflect the same relativity-of-resource use amount services as under the OPSS, taking into consideration the lower costs of the services in an ASC and maintaining budget neutrality. *Changes to the ASC List of Covered Surgical Procedures.* CMS adds twenty-seven additional surgical procedures and eight office-based procedures which Medicare will pay for when furnished in an ASC. CMS also updates the list of device-intensive procedures, and covered ancillary services and their rates.

FRAUD & ABUSE

**OIG Approves Sharing Performance-Based
Compensation**

On October 7, 2008, the OIG issued Advisory Opinion No. 08-16, which addresses a proposed arrangement under which a hospital would share with a physician-owned entity certain performance-based compensation available to the hospital under a quality and efficiency agreement with a private insurer ("Proposed Arrangement").

Pursuant to the Proposed Arrangement, in addition to the aggregate amount the private insurer pays the hospital for care of patients in a given year ("Base Compensation"), the insurer will pay the hospital an additional percentage of

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the Base Compensation ("Bonus Compensation") based on the extent to which the hospital meets certain standards of quality and efficiency. Under the Proposed Arrangement, the hospital would pay the physician-owned entity a portion of its Bonus Compensation as a result of the physicians' assistance in achieving certain quality targets.

While the OIG found the Proposed Arrangement could constitute an improper payment to induce reduction or limitation of services and could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of the federal healthcare program business were present, the OIG would not impose administrative sanctions or civil penalties.

To read more about the OIG 08-16, go to <http://www.balch.com/files/upload/AdvOpn08-16A.pdf>.

OIG OKs Gainsharing Arrangement between Cardiologist Groups and Hospital

On October 6, 2008, the OIG issued Advisory Opinion Number 08-15 concerning an existing arrangement in which a hospital shares a percentage of its cost savings with a group of cardiologists who implement cost reduction methods in certain procedures.

The three-year gainsharing arrangement allows the hospital to pay the physicians for their part in reducing cardiac catheterization lab costs. The hospital agreed to pay the cardiologist group fifty percent of the yearly savings that resulted from the physicians implementing cost-saving recommendations, based on the historic practices of the cardiology groups in the hospital's catheterization lab. Payments for cost-saving efforts were based on procedures regardless of patients' insurance coverage and payments were subject to a cap for procedures paid for by federal health programs.

The OIG reiterated its long-standing concern about problems arising from gainsharing arrangements, but noted the importance of safeguards against fraud and abuse in the agreement that protected patients and federal health programs. Cost-saving actions were clearly identified in a transparent way, allowing for public scrutiny, and were vetted against credible medical evidence to ensure patient care was not adversely affected. The OIG noted that any risks against improper kickbacks to doctors were mitigated by safeguards that limited participation to cardiologists already on the hospital's medical staff.

To read more about the OIG 08-15, go to <http://www.balch.com/files/upload/AdvOpn08-15.pdf>.

OIG Approves Use of Motivational Incentives by Drug Treatment Centers

On September 24, 2008, the OIG issued Advisory Opinion Number 08-14, which addresses a substance abuse treatment center's ("Treatment Center") use of motivational incentives ("MI") to reward a patient's achievement of certain treatment-related goals. Under the MI program, motivational incentives include gift certificates redeemable at grocery stores, food outlets, and gas stations for approximately \$5 to \$10 value. MIs could also take the form of gift items and foods of modest value, but the total awarded to any individual patient did not exceed \$200 per month. MIs never took the form of cash.

The Treatment Center, a non-profit 501(c)(3) organization that provides outpatient treatment services for individuals with psychoactive substance abuse dependence, treats many patients who are federal healthcare program beneficiaries. As a result, federal healthcare programs cover a considerable amount of the treatment costs.

Prior to treatment, a prospective patient would be screened and his or her substance abuse problems assessed. In some cases, patients failed to make progress, or even deteriorated after starting treatment. In response, the Treatment Center clinicians could recommend the introduction of MIs into the patient's care in order to help a patient overcome difficulty with achieving abstinence or maintaining attendance and participation in his or her treatment plan activities. (MIs are only introduced for substance abuse patients after a clinician's determination that their use is necessary.)

The OIG found that such an MI program would not constitute grounds for civil monetary penalties and, while the MI program could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of federal healthcare program business were present, the OIG would not impose administrative sanctions in connection with the use of MI programs in substance abuse treatment centers.

To read more about the OIG 08-14, go to <http://www.balch.com/files/upload/AdvOpn08-14.pdf>.

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**OIG Approves Use of Preferred Hospital
Network as Part of Medigap**

On September 23, 2008, the OIG issued Advisory Opinion Number 08-13, addressing the use of a "preferred hospital" network as part of a Medicare Supplemental Health Insurance ("Medigap") policy.

Under the agreement in question, insurance subsidiaries that offer Medigap policies in almost every state, participate in an arrangement with a managed care organization ("MCO"), which has contracts with hospitals throughout the country, comprising the MCO's hospital network. Under the contracts, the Medigap policyholders receive discounts of up to 100 percent on Medicare inpatient deductibles incurred at network hospitals which would otherwise be covered by the Medigap plans. The discounts apply only to Part A inpatient hospital deductibles and not to any other co-insurance or cost-sharing amounts, and the hospitals provide no other benefit to the insurance subsidiaries or their policyholders.

The insurance subsidiaries pay the MCO a fee for administrative services each time one of its insureds receives the discount. If a policyholder is admitted to a non-network hospital, the insurance subsidiaries pay the full Part A hospital deductible, as provided under the Medigap policy. The arrangement does not affect the liability of any Medigap policyholder for payments for covered services, regardless of where provided, and the MCO hospital network is open to any accredited, Medicare-certified hospital that meets requirements of applicable state laws. The insurance subsidiaries return a portion of the resulting savings directly to any policyholder who has an inpatient stay at one of the network hospitals.

The OIG stated that while the arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of federal healthcare program business were present, the OIG chose not to impose administrative sanctions or civil monetary penalties. The OIG reasoned that the discounts offered on inpatient deductibles by network hospitals, in combination with Medigap, present a low risk of fraud or abuse because:

- The waivers would not increase or affect per service Medicare payments;
- The discounts should not increase utilization;
- The arrangement should not unfairly affect competition among hospitals; and

- The arrangement would be unlikely to affect professional medical judgment.

To read more about the OIG 08-13, go to <http://www.balch.com/files/upload/AdvOpn08-13.pdf>.

**Psychiatrist Did Not Report Payments from
Drugmakers**

"One of the nation's most influential psychiatrists earned more than \$2.8 million in consulting arrangements with drugmakers from 2000 to 2007, failed to report at least \$1.2 million of that income to his university, and violated federal research rules," according to a letter to Emory University from Sen. Charles Grassley (R-Iowa). *The New York Times* characterized Dr. Charles B. Nemeroff, of Emory University, as "the most prominent figure to date in a series of disclosures that is shaking the world of academic medicine and seems likely to force broad changes in the relationships between doctors and drugmakers."

As a result, Sen. Grassley "is promoting a bill called the Physician Payment Sunshine Act that would require pharmaceutical companies and medical device manufacturers to disclose all payments over \$500 that they make to physicians." Thus far, two companies, Eli Lilly & Co. and Merck & Co., said that they "will begin making such disclosures next year", regardless of whether the bill is enacted. The investigation is a product of concern over "the safety and efficacy of the stream of new drugs undergoing clinical trials." Research shows "that researchers who receive money from drug companies are more likely to report positive results from such trials." As a result, "universities and the National Institutes of Health, which funds many such trials and oversees others, have attempted to limit such subsidiary income or, at the least, make it known to the public."

Marietta Doctor Guilty in \$3M Fraud Scam

A Marietta chiropractor was found guilty of eighteen charges of healthcare fraud and five charges of money laundering in a \$3 million scam in which he fraudulently billed Blue Cross/Blue Shield of Georgia for two separate back-pain procedures. The procedure, known as Vertebral Axial Decompression ("VAX-D"), is a non-invasive back pain procedure that uses a mechanical table to stretch a patient's spine. Blue Cross considers VAX-D investigational and therefore not medically necessary. The chiropractor, along with two partners who both previously pleaded guilty, was convicted of lying to Blue Cross about what procedures they performed in order to receive payment for the

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non-covered procedures. He now faces a fine of up to \$5.75 million and up to 230 years in prison.

**Qui Tam Action Filed in Mississippi
Federal Court against McKesson Corp.**

The Department of Justice (“DOJ”) announced October 6, 2008, that the United States has intervened in a lawsuit alleging that McKesson Corp. and other companies submitted false claims to Medicare arising from illegal kickbacks and the establishment of sham durable medical equipment (“DME”) suppliers.

The False Claims Act *qui tam* action was filed by a private citizen in the U.S. District Court for the Northern District of Mississippi, the DOJ press release said. The lawsuit is under seal.

According to the DOJ’s press release, the government alleged in its complaint that McKesson Corp., through its subsidiary McKesson Medical-Surgical MediNet Inc. (“MediNet”), structured arrangements that ensured that McKesson supplies were used by Beverly Enterprises Inc.’s nursing facilities.

The lawsuit alleges that McKesson promised Beverly facilities (now known as Golden Horizons) it could gain significant profits by making it appear to Medicare that it was Beverly--not McKesson or MediNet--that was supplying the DME and supplies.

Further, the government alleged that MediNet’s management allowed CERES Strategies Medical Services Inc. (“CSMS”) to bill Medicare and retain millions of dollars in Medicare payments for services and supplies that actually were supplied by MediNet and not by CSMS, the release said. CSMS was thinly capitalized, had few employees, had almost no DME, and performed none of the DME patient services at the Beverly facilities.

PROVIDER REGULATION

**Alabama Business Services Agreement
Rejected, Court Rules Dental Practice
Management Illegal**

On October 24, 2008, a federal trial court said a business services agreement (“BSA”) between an orthodontist and Orthodontic Centers of America (“OCA”) is unenforceable because it violates Alabama laws governing dental practices and professional partnerships.

The BSA was invalid because Alabama law allows professional partnerships only between

“qualified persons” and OCA was not such a “person.” Although there was no express partnership created under the agreement, the BSA created a *de facto* partnership by sharing profits and giving OCA significant control over the orthodontist’s practice, the court said.

The arrangement also violated the Alabama Dental Practices Act by giving OCA authority that would allow it to influence or interfere with the orthodontist’s exercise of professional judgment because the BSA specifically controlled the dentist ability to hire other orthodontists and staff, establish hours of practice, and engage in advertising.

The litigation implicates OCA’s national business model under which the company would agree to handle office management, administration, and bookkeeping components of dental and orthodontic practices for a fee, allowing orthodontists to focus their energies and talents on the provision of care to their patients.

HIPAA

**E-Health Records Vulnerable Due to CMS’s
Ineffective Enforcement of Security Rule**

According to an OIG report released October 27, 2008, ineffective and incomplete enforcement of the federal healthcare security law has left “significant vulnerabilities” of electronic medical records undiscovered at hospitals across the nation. Because CMS relies on complaint-driven enforcement, the agency has not conducted any compliance reviews of covered entities, although it is authorized to do so.

As part of its audit of CMS, the OIG looked at one hospital’s implementation of the security rule and found significant vulnerabilities in the hospital’s systems intended to safeguard electronic protected health information. Despite criticism of CMS’s overall enforcement of the security rule, the OIG acknowledges the agency’s effective process of receiving, categorizing, tracking, and resolving complaints.

More information on the OIG report A-04-07-5064 is available at <http://oig.hhs.gov/oas/reports/region4/40705064.asp>.

RED FLAG RULES

FTC Delays Enforcement of ‘Red Flag’ Rules

The Federal Trade Commission (“FTC”) will suspend enforcement of the Red Flag Rules until

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May 1, 2009, to give creditors and the healthcare community additional time to adopt written programs to identify and respond to identity theft issues.

The Rules, developed pursuant to the Fair and Accurate Credit Transactions Act of 2003, require creditors with covered accounts to implement identity theft protection programs to identify, detect, and respond to patterns, practices, or specific activities that could be an indication of identity theft. Any person or entity that defers payment for goods or services, such as by billing in arrears for medical services and treatment, is considered a creditor. Because most healthcare providers bill patients after rendering services and in many cases accept payment over time, they fall within the Rule's broad definition of creditors. The FTC says its enforcement delay will enable entities sufficient time to establish and implement appropriate identity theft prevention programs in compliance with the Rules.

To learn more about the Red Flag Rules and the delay in enforcement, please visit <http://www.ftc.gov/opa/2008/10/redflags.shtm>.

CHARGING GUIDELINES

Justice Department Revises Charging Guidelines for Prosecuting Corporate Fraud

The DOJ has revised its Principles of Federal Prosecution of Business Organizations, which govern how all federal prosecutors investigate, charge, and prosecute corporate crimes and addresses issues such as cooperation credit. The revised guidelines state that credit for cooperation will not depend on the corporation's waiver of attorney-client privilege or work product, but on the disclosure of relevant facts.

Under the new guidelines, federal prosecutors are forbidden to request disclosure of non-factual attorney-client privileged communications and work product, with two exceptions (both are well established in existing law). Prosecutors are also instructed not to consider a corporation's advancement of attorneys' fees to employees when evaluating cooperativeness. The new guidance also makes clear that prosecutors may not consider whether a corporation has sanctioned or retained culpable employees in evaluating whether to assign cooperation credit.

To read more about this, please go to <http://www.usdoj.gov/opa/pr/2008/August/08-odag-757.html>.

CERTIFICATE OF NEED

Georgia Court of Appeals Clarifies CON Standards

On October 8, 2008, the Georgia Court of Appeals issued an opinion denying a certificate of need ("CON") for a proposed orthopedic surgery center. In 2005, Hughston Surgical Institute, LLC ("HSI") filed an application to obtain a CON concerning a proposed ambulatory surgery center specializing in orthopedics to be located in Columbus, Georgia. In its application, HSI admitted that no barrier to quality care existed in the Columbus area, but it asserted that the project would remedy an atypical barrier to orthopedic ambulatory surgery services based on quality through enhancements and improvements achieved through direct research conducted by HSI staff members.

At the administrative level, the Department determined the application should not be granted; however, the Superior Court of Muscogee County (where HSI is located) reversed the Department's administrative decision and granted the CON.

On appeal, the Georgia Court of Appeals held that the Superior Court erred when it substituted its judgment for that of the Department on the question of whether HSI's CON application should be approved. In its opinion, the Court of Appeals stated that, in order to qualify under an exception, an applicant must show that a service is not available in the area, that a particular group of patients needs the service, and that the proposed project would reach that population.

Justice Blackburn, Presiding Judge, Georgia Court of Appeals, concurred specially in the October final opinion, and noted he could not agree with all that is included in the majority opinion. Specifically, Justice Blackburn stated: "Our founding fathers never intended that the government limit new businesses to those it felt were economically necessary. It is clear that the purported justification for such control, reduction of the cost of medicine, has not been accomplished by this socialist approach."

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COMMENTARY

Healthcare Providers Should be Aware of their Obligations to Ensure Effective Communication for Hearing Impaired Patients and Patients with Limited English Proficiency

Hearing Impaired Patients

Under the Americans with Disabilities Act (“ADA”), places of public accommodation, such as hospitals and physician’s offices, are prohibited from discriminating against individuals with disabilities by denying them the “full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations” offered by the place of public accommodation. The ADA goes on to define “discrimination” to include a failure to furnish appropriate auxiliary aids and services, including those that are necessary to ensure effective communication with individuals with hearing impairments. What constitutes “effective communication” depends, of course, on the circumstances, but generally includes qualified interpreters, notetakers, computer-aided transcription services, written materials, telephone handset amplifiers, assistive listening devices, telephones compatible with hearing aids, closed-captioning decoders, open and closed captioning, telecommunications devices for deaf persons (“TDDs”), and videotext displays. However, this list is not exclusive and healthcare providers should not labor under the false assumption that they will be in compliance with the ADA so long as they have picked one of the above listed auxiliary aids or services.

Determining which auxiliary aid or service to use depends on the information that is being communicated. Generally speaking, the more complex the issue, the more likely a sign language interpreter must be used. The Department of Justice has taken the position that, “[i]t is not difficult to imagine a wide range of communications involving areas such as health, legal matters, and finances that would be sufficiently lengthy or complex to require an interpreter for effective communication.”

In addition to focusing on the type of information to be communicated, a healthcare provider should also focus on whether an interpreter is necessary to provide a hearing impaired patient with an opportunity to benefit from the healthcare provider’s services equal to that of patients who are not hearing impaired. Thus, for example, using notes to communicate with a patient to discuss his or her medication may be effective communication, but if doctors verbally communicate with non-hearing impaired patients about the various side effects,

as well as the dosage amount, then this may constitute an ADA violation.

A healthcare provider is not required to provide an auxiliary aid or service if doing so would impose an “undue burden” (defined as entailing significant difficulty or expense) or would constitute a fundamental alteration to the program or service. Nevertheless, even if one auxiliary aid or service is deemed too expensive or constitutes a fundamental alteration to the program or service of the public accommodation, a healthcare provider remains obligated to provide another alternative auxiliary aid or service that would ensure, to the maximum extent possible, access to the place of public accommodation.

Patients with Limited English Proficiency

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person shall “on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance.” Section 602 authorizes and directs federal agencies that are empowered to extend federal financial assistance to any program or activity “to effectuate the provisions of [section 601] . . . by issuing rules, regulations, or orders of general applicability.”

Regulations issued by the Department of Health and Human Services (“HHS”) prohibit recipients of federal funds (such as healthcare providers) from discriminating based on race, color, or national origin. Specifically, the regulations make it a violation of Title VI if a health care provider fails to provide assistance to patients who have limited English proficiency (“LEP”).

HHS has published guidance to assist healthcare providers in complying with Title VI as it applies to LEP individuals. Under the Guidance, healthcare providers must provide meaningful access to patients who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English. The Guidance contains a four-factor test in order to make an individualized assessment as to whether a healthcare provider must take *reasonable steps* to ensure meaningful access to their programs and activities by LEP persons. They are:

1. The number or proportion of LEP persons eligible to be served or likely to be encountered by the healthcare provider;
2. The frequency with which LEP individuals come in contact with the program;

3. The nature and importance of the program, activity, or service provided by the program to people's lives; and
4. The resources available to the grantee/recipient and costs.

It is important to remember that a healthcare provider should document its application of the four-factor test and apply the four factors to the various kinds of contacts it has with the public to assess language needs and decide what reasonable steps, if any, it should take to ensure meaningful access for LEP individuals. Finally, when interpretation is needed and is reasonable, it should be provided in a timely manner. To be meaningfully effective, language assistance should be timely.

Based on the four-factor analysis, a healthcare provider should then develop an implementation plan. The following four steps are typical of an effective implementation plan:

1. Identifying LEP individuals who need language assistance
2. Language assistance measures
3. Training staff
4. Providing notice to LEP persons

The most problematic aspect of any implementation plan is implementing appropriate language assistance measures. Healthcare providers have two primary ways in which to provide language assistance: oral communication (interpretation) and written communication (translation). Each presents its own unique challenges.

Interpretation is the act of listening to something in one language (source language) and orally translating it into another language (target language). If interpretation is needed and is reasonable, recipients should consider some or all of the following options for providing competent interpreters in a *timely* manner:

- Hiring bilingual staff
- Hiring staff interpreters
- Contracting for interpreters
- Using telephone interpreter lines
- Using community volunteers

While there is no single definition for what constitutes a “timely” interpretation, a useful guide for healthcare providers is to keep in mind that any interpretation should be provided in such a way that it ensures the effective delivery of the service or benefit sought by the LEP patient. On the other hand, where access to a service or benefit would not be effectively

precluded by a reasonable delay, then language assistance can likely be delayed for a reasonable period.

Translation is the replacement of a written text from the source language into an equivalent written text in the target language. Healthcare providers should assess whether specific documents or portions of documents are “vital” to the program, information, encounter, or service involved and the consequences to the LEP person if the information in question is not provided accurately or in a timely manner. What constitutes a vital document will typically vary with the circumstances; they typically include for the healthcare provider: intake forms, consent forms, complaint forms, plan of care documents, and HIPAA privacy documents.

The next question, of course, is into what languages should the documents be translated? In answering this question, a distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered languages. To translate all written materials into the hundreds of languages spoken in a large metropolitan area like Atlanta, Houston, or New York would be unrealistic, if not impossible. Furthermore, such an undertaking would incur substantial costs and require substantial resources.

The Guidance recognizes this reality and contain a “safe harbor.” Consequently, a healthcare provider will be considered in compliance with its obligations under Title VI as to LEP individuals if: the recipient provides written translations of vital documents for each eligible LEP language group that constitutes the lower of 1,000 individuals or five percent, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally. In addition, if there are fewer than 50 persons in a language group that reaches the five percent then the healthcare provider will be considered in compliance with its Title VI requirements.

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