Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens

Provider type affected
This MLN Matters® Article is for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for specimen collection services provided to Medicare beneficiaries.

What you need to know
CR11146 revises travel allowances payment amounts when billed on a per mileage basis using HCPCS code P9603 and when billed on a flat rate basis using HCPCS code P9604 for Calendar Year (CY) 2019. Make sure your billing staffs are aware of these changes.

Background
Medicare Part B allows payment for a specimen collection fee and travel allowance, when medically necessary, for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under Section 1833(h)(3) of the Act. Medicare bases the payment for these services on the clinical laboratory fee schedule.

The travel codes allow for payment either on a per mileage basis (P9603) or on a flat rate per trip basis (P9604). Medicare makes payment of the travel allowance only if a specimen collection fee is also payable. The travel allowance is intended to cover the estimated travel costs of collecting a specimen including the laboratory technician’s salary and travel expenses. MAC discretion allows the MAC to choose either a mileage basis or a flat rate, and how to set each type of allowance. Because of audit evidence that some laboratories abused the per mileage fee basis by claiming travel mileage in excess of the minimum distance necessary for a laboratory technician to travel for specimen collection, many MACs established local policy to pay based on a flat rate basis only.

Under either method, when one trip is made for multiple specimen collections (for example, at a nursing home),
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Beneficiary and Family Centered Care (BFCC) Quality Improvement Organizations (QIO) two-midnight short stay reviews demand and appeal process

The Centers for Medicare & Medicaid Services (CMS) contracts with QIOs to perform core functions that include case review and quality improvement. The case review functions of a QIO include review of health care services and items for which payment is made under Medicare Parts A, B, C, or D to determine whether services or items are reasonable, medically necessary, and allowable; meet professionally recognized standards of care; or in the case of inpatient care, could be provided more economically on an outpatient basis or in an inpatient facility of a different type.

Currently, the QIO is conducting reviews on the two-midnight rule for acute care inpatient hospitals, long term care hospitals, and inpatient psychiatric facilities impacted by the FY 2016 Outpatient Prospective Payment System Final Rule.

After the review, the QIO issues the provider a detailed results letter with claim-by-claim denial rationales. The letter that providers receive from the QIO is not an overpayment demand letter. The QIO sends a copy of the detailed results letter to First Coast Service Options (First Coast), who will perform a claim adjustment in the Fiscal Intermediary Shared System (FISS) and issue the overpayment demand letter.

Upon receiving the overpayment demand letter, providers may appeal the QIO medical necessity decision to First Coast.

Source: MM10600.

FEES from page 1

Medicare prorates the travel payment component based on the number of specimens collected on that trip for both Medicare and non-Medicare patients, either at the time the laboratory submits the claim or when the flat rate is set by the MAC.

Per Mile Travel Allowance (P9603), the per mile travel allowance is used in situations where the average trip to the patients' homes is longer than 20 miles round trip, and is prorated in situations where the technicians draw specimens from non-Medicare patients in the same trip.

The allowance per mile was computed using the Federal mileage rate of $0.58 per mile plus an additional $0.45 per mile to cover the technician's time and travel costs. (The Internal Revenue Service determines the standard mileage rate for businesses based on periodic studies of the fixed and variable costs of operating an automobile.) MACs have the option of establishing a higher per mile rate in excess of the minimum $1.03 per mile if local conditions warrant it. The minimum mileage rate will be reviewed and updated throughout the year, as well as in conjunction with the Clinical Laboratory Fee Schedule (CLFS), as needed. At no time will the laboratory be allowed to bill for more miles than are reasonable, or for miles that are not actually traveled by the laboratory technician.

Per Flat-Rate Trip Basis Travel Allowance (P9604), the per flat-rate trip basis travel allowance is $10.30.

Additional information


If you have questions, your MACs may have more information. Find their website at https://go.cms.gov/MAC-website-list.

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New physician specialty code for undersea and hyperbaric medicine

Note: This article was revised on December 20, 2018, to reflect the revised CR10666 issued on December 19. The CR was revised to clarify certain MAC reporting requirements for the D2 specialty, the taxonomy requirements for the D4 specialty, and to reflect the D1 specialty code as a supplier specialty and not a physician specialty. In this article, only the CR release date, transmittal number, and the Web address of the CR are revised. All other information remains the same. This information was previously published in the July 2018 Medicare A Connection, page 3.

Provider type affected

This MLN Matters® article is intended for physicians, providers and suppliers billing Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

What you need to know

Change request (CR) 10666 informs you that the Centers for Medicare & Medicaid Services (CMS) has established a new physician specialty code for undersea and hyperbaric medicine. This new code is D4. Make sure your billing staffs are aware of these changes.

Background

Physicians self-designate their Medicare physician specialty on the Medicare enrollment application (CMS-855I or CMS-855O) or via the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) when they enroll in the Medicare program. Medicare physician specialty codes describe the specific/unique types of medicine that physicians (and certain other suppliers) practice. Specialty codes are used by CMS for programmatic and claims processing purposes.

The CMS-855I and CMS-855O paper applications will be updated to reflect the new physician specialty in the future. In the interim, providers shall select the 'Undefined physician type' option on the enrollment application and specify Undersea and Hyperbaric Medicine in the space provided.

Existing enrolled providers who want to update their specialty to reflect the new specialty must submit a change of information application to their Medicare administrative contractor (MAC). Providers may submit an enrollment application to initially enroll or update their specialty within 60 days of the implementation date of the new specialty.

MACs will recognize undersea and hyperbaric medicine (D4) as a valid specialty type for the following edits:

- Ordering/Referring
- Critical Access Hospital (CAH) Method II Attending and Rendering
- Attending, operating, or other physician or non-physician practitioner listed on a CAH claim

Additional information


If you have questions, your MACs may have more information. Find their website at https://go.cms.gov/MAC-website-list.

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Effective Date: January 1, 2019
Implementation Date: January 7, 2019

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How unsolicited/voluntary refunds are handled

Medicare contractors receive unsolicited/voluntary refunds (i.e., monies received not related to an open account receivable). Part A contractors generally receive unsolicited/voluntary refunds in the form of an adjustment bill, but may receive some unsolicited/voluntary refunds as checks. Part B contractors generally received checks. Substantial funds are returned to the trust funds each year through such unsolicited/voluntary refunds.

The Centers for Medicare & Medicaid Services reminds providers that:

The acceptance of a voluntary refund as repayment for the claims specified in no way affects or limits the rights of the federal government, or any of its agencies or agents, to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims.

Source: CMS Pub. 100-06, Chapter 5, Section 410.10

2019 Medicare Part B Participating Physician and Supplier Directory available after January 30

The Medicare Part B Participating Physician and Supplier Directory (MEDPARD) contains names, addresses, telephone numbers, and specialties of physicians and suppliers who have agreed to participate in accepting assignment on all Medicare Part B claims for covered items and services.

The MEDPARD listing will be available no later than January 30 on the First Coast Medicare provider website at https://medicare.fcso.com/MEDPARD/.

Source: Pub 100-04, Transmittal 4165, CR 10942

Provider enrollment

Medicare Enrollment Application Fee for CY 2019

On November 18th, CMS issued a notice: Provider Enrollment Application Fee Amount for Calendar Year 2019 [CMS–6079–N](https://go.usa.gov/xPhJk). Effective January 1, the CY 2019 application fee is $586 for institutional providers that are:

- Initially enrolling in the Medicare or Medicaid program
- Revalidating their Medicare, Medicaid, or CHIP enrollment
- Adding a new Medicare practice location

This fee is required with any enrollment application submitted from January 1 through December 31, 2019.

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SNF advance beneficiary notice of non-coverage

**Note:** This article was revised on January 11, 2019, to reflect the revised CR 10567 issued on January 11. The CR revisions had no impact on the content of the article. In the article, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same. This information was previously published in the April 2018 Medicare A Connection, pages 10-11.

**Provider type affected**

This MLN Matters® article is intended for skilled nursing facilities (SNFs) billing Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

**Provider action needed**

This article informs you about change request (CR) 10567, which advises you that the Centers for Medicare & Medicaid Services (CMS) has revised the skilled nursing facility notice of non-coverage (SNF ABN), Form CMS-10055. With this revision, CMS is discontinuing the five SNF denial letters (namely, the Intermediary Determination of Noncoverage, the UR Committee Determination of Admission, the UR Committee Determination on Continued Stay, the SNF Determination on Admission and the SNF Determination on Continued Stay), and the Notice of Exclusion from Medicare Benefits (NEMB-SNF), Form CMS-20014. Please ensure that your billing staffs are aware of these changes.

Please note that the Notice of Medicare Non-Coverage (NOMNC), Form CMS-10123 is not being discontinued with this revised SNF ABN. More information on the NOMNC is available at [https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-Expedited-Determination-Notices.html](https://www.cms.gov/Medicare/Medicare-General-Information/BNI/FFS-Expedited-Determination-Notices.html). You may download the revised Form CMS-10055 in the Downloads section of that web page.

SNFs will continue to use the advance beneficiary notice of non-coverage (ABN, Form CMS-R-131) for items or services that Medicare may be deny under Medicare Part B.

Please note that SNFs may start to implement this new notice any time up to the implementation date of CR 10567. Upon the CR 10567 implementation April 30, 2018, the use of the new notice is mandatory.

The revised notice incorporates suggestions for changes made by users of the ABN and by beneficiary advocates based on experience with the current form, refinements made to similar liability notices through consumer testing and other means, as well as related Medicare policy changes and clarifications.

**Additional information**


If you have any questions, your MACs may have more information. Find their website at [https://go.cms.gov/MAC-website-list](https://go.cms.gov/MAC-website-list).

**Document history**

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Ensuring Occurrence Code 22 is Billed Correctly on Skilled Nursing Facility Inpatient Claims

Provider type affected
This MLN Matters Article is intended for Skilled Nursing Facilities (SNFs) billing Medicare Administrative Contractors (MACs) for SNF inpatient services provided to Medicare beneficiaries.

Provider action needed
This article is based on Change Request (CR) 10922 which describes systems changes necessary to ensure SNFs bill Occurrence Code (OC) 22 correctly. Please make sure your billing staffs are aware of these changes.

Background
Medicare’s Common Working File (CWF) Maintainer recently discovered that an incoming inpatient claim was applied to the wrong benefit period when OC ‘22’ was submitted incorrectly on a SNF claim in history.

CR10922 will ensure OC ‘22’ is billed correctly so that the CWF can apply the appropriate benefit period.

Note that CR10922 contains no policy changes or new policies, and it improves the implementation of the existing policy in the Medicare Claims Processing Manual, Chapter 6 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf). As a result of CR10922, your MAC will Return to Provider (RTP) an inpatient SNF claim (Type of Bill (TOB) 21X or swing bed claim with TOB 18X) when all of the following are present on the claim:

- OC ‘22’ and
- OC ‘22’ date is equal to the through date of the claim and
- Patient discharge status code is other than ‘30’.

Additional information

If you have questions, your MACs may have more information. Find their website at https://go.cms.gov/MAC-website-list.

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Inpatient rehabilitation facility (IRF) medical review changes

**Note:** This article was revised on December 20, 2018, to remove the Admission order requirement from the portion of the article under “Required documentation elements for an IRF claim include, but are not limited to.” Please note that the regulation, CMS-1688-F, removed the admission order documentation requirement from the IRF payment regulation(s) in an effort to reduce duplicative documentation requirements. CMS will continue enforcement of the hospital conditions of participation. Also, a link to the CMS-1688-F is added in the Additional Information section. All other information remains the same. This information was previously published in the December 2017 Medicare A Connection, pages 35-36.

**Provider type affected**

This MLN Matters Article is intended for Inpatient Rehabilitation Facilities (IRFs), physicians, and other practitioners with patients in IRFs who are receiving Part A inpatient services.

**Provider action needed**

Special Edition article SE17036 reiterates policy related to claims submitted with regard to services provided to Medicare beneficiaries in an IRF. Please make sure your billing and coding staffs review these policies associated with the Medicare IRF benefit.

**Background**

The Medicare IRF benefit provides intensive rehabilitation therapy in a resource intensive inpatient hospital environment, including Inpatient Rehabilitation Hospitals and Inpatient Rehabilitation Units. The IRF benefit is for a beneficiary who, due to the complexity of their nursing, medical management, and rehabilitation needs, requires and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to rehabilitation care.

In order for IRF services to be covered under the Medicare IRF benefit, submitted documentation must sufficiently demonstrate that a beneficiary’s admission to an IRF was reasonable and necessary, according to Medicare guidelines. Key elements of IRF coverage criteria include a reasonable expectation that at the time of the beneficiary’s admission to the IRF the beneficiary:

- Requires the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics) one of which must be physical or occupational therapy
- Generally requires an intensive rehabilitation therapy program. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF

- Is sufficiently stable and can reasonably be expected to be able to actively participate in, and benefit significantly from, an intensive rehabilitation therapy program. The patient can only be expected to benefit significantly from the intensive rehabilitation therapy program if the patient’s condition and functional status are such that the patient can reasonably be expected to make measurable improvement (that will be of practical value to improve the patient’s functional capacity or adaptation to impairments) as a result of the rehabilitation treatment, and if such improvement can be expected to be made within a prescribed period of time

- Requires physician supervision by a rehabilitation physician, defined as a licensed physician with specialized training and experience in inpatient rehabilitation. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient’s stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient’s capacity to benefit from the rehabilitation process. (See 42 CFR 412.622, which is available at [https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec412-622.pdf](https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec412-622.pdf))

- Requires an intensive and coordinated interdisciplinary approach to providing rehabilitation

Required documentation elements for an IRF claim include, but are not limited to:

- A comprehensive preadmission screening that is:
  - Conducted by a licensed or certified clinician(s) designated by a rehabilitation physician
  - Completed within the 48 hours immediately preceding the IRF admission
  - Provides a detailed and comprehensive review of each patient’s condition and medical history

- A post-admission physician evaluation that:
  - Is conducted by a rehabilitation physician
  - Is completed within 24 hours of the patient’s admission to the IRF
  - Provides documentation of the patient’s status on admission to the IRF, including a comparison with the information noted in the preadmission screening documentation
  - Support the medical necessity of the IRF admission

- An individualized plan of care that:
  - Is developed by a rehabilitation physician with...
CHANGES
from page 8

- input from the interdisciplinary team
- Is based on the findings of the post-admission physician evaluation
- Is completed within the first 4 days of the IRF admission
- Supports the determination that the IRF admission is reasonable and necessary
- An inpatient rehabilitation facility patient assessment instrument (IRF-PAI)

Particular attention should be paid to documenting the patient’s need for intensive rehabilitation therapy services requiring care in an IRF. Documentation in the patient’s medical record must be accurate and avoid vague or subjective descriptions of the patient’s care needs that would not be sufficient to indicate the need for intensive rehabilitation services.

Recently, the Centers for Medicare & Medicaid Services (CMS) advised its medical review contractors that when the current industry standard of providing in general at least 3 hours of therapy (physical therapy, occupational therapy, speech-language patholgy, or prosthetics/orthotics) per day at least 5 days per week or at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period is not met, the claim should undergo further review. This further review will require the use of clinical review judgment to determine medical necessity of the intensive rehabilitation therapy program based on the individual facts and circumstances of the case, and not on the basis of any threshold of therapy time.

Also, CMS advised its medical review contractors that the standard of care for IRF patients is individualized (i.e., one-on-one) therapy. Group and concurrent therapy can be used on a limited basis within the current industry standard of generally 3 hours of therapy per day at least 5 days per week or at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period. In those instances in which group therapy better meets the patient’s needs on a limited basis, the situation/rationale that justifies group therapy should be specified in the patient’s medical record at the IRF.

For more information on billing and payment criteria related to IRFs, please refer to the following documentation:

- Chapter 3, Section 140.1.1 of the Medicare Claims Processing Manual (Pub. 100-04), titled, Criteria That Must Be Met By Inpatient Rehabilitation Facilities, which can be downloaded at https://www.cms.gov/Regulations-and-Guidance/Guidance/manuals/Downloads/clm104c03.pdf

Additional information
If you have questions, your MACs may have more information. Find their website at https://go.cms.gov/MAC-website-list.


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This section of Medicare A Connection features summaries of new and revised local coverage determinations (LCDs) developed as a result of either local medical review or comprehensive data analysis initiatives. These initiatives are designed to ensure the appropriateness of medical care and to make sure that the Medicare administrative contractor (MAC) jurisdiction N (JN) Part A LCDs and review guidelines are consistent with accepted standards of medical practice.

Refer to our LCDs/Medical Coverage web page at https://medicare.fcso.com/Landing/139800.asp for full-text LCDs, including final LCDs, draft LCDs available for comment, LCD statuses, and LCD comment/response summaries.

**Effective and notice dates**

Effective dates are provided in each LCD, and are based on the date services are furnished unless otherwise noted in the LCD. Medicare contractors are required to offer a 45-day notice period for LCDs; the date the LCD is posted to the website is considered the notice date.

**Electronic notification**

To receive quick, automatic notification when new and revised LCDs are posted to the website, subscribe to the First Coast eNews mailing list. Simply go to https://medicare.fcso.com/Header/137525.asp, enter your email address and select the subscription option that best meets your needs.

**More information**

For more information, or, if you do not have internet access, to obtain a hardcopy of a specific LCD, contact Medical Policy at:

Medical Policy and Procedures
PO Box 2078
Jacksonville, FL 32231-0048

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**Looking for LCDs?**

Would you like to find local coverage determinations (LCD) in 10 seconds or less? First Coast's LCD lookup, available at https://medicare.fcso.com/coverage_find_lcds_and_ncds/lcd_search.asp, helps you find the coverage information you need quickly and easily. Just enter a procedure code, keyword, or the LCD's “L number,” click the corresponding button, and the application will automatically display links to any LCDs applicable to the parameters you specified. Best of all, depending upon the speed of your internet connection, the LCD search process can be completed in less than 10 seconds.

**Advance beneficiary notice**

Modifier GZ must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny an item or service as not reasonable and necessary and they have not had an advance beneficiary notification (ABN) signed by the beneficiary.

**Note:** Line items submitted with the modifier GZ will be automatically denied and will not be subject to complex medical review.

Modifier GA must be used when physicians, practitioners, or suppliers want to indicate that they expect that Medicare will deny a service as not reasonable and necessary and they do have on file an ABN signed by the beneficiary.

All claims not meeting medical necessity of a local coverage determination must append the billed service with modifier GA or GZ.
**New LCD**

**Frequency of hemodialysis – new Part A and Part B LCD**

**LCD ID number: L37564 (Florida/Puerto Rico/U.S. Virgin Islands)**

The local coverage determination (LCD) for frequency of hemodialysis was developed to continue to provide coverage for additional dialysis treatments beyond the standard thrice weekly payment as it is outlined on the Medicare Benefit. The list of diagnosis codes supporting additional treatments has been expanded. Also, additional clarifying language related to documentation requirements to support the additional services and the use of Modifiers and clear limitations have been established. Furthermore, in creating this new LCD, the current LCD for frequency of hemodialysis services (L33970) and the companion “Coding Guidelines” will be retired when this new LCD and coding & billing article becomes effective.

**Effective date**

This new LCD is effective for services rendered on or after February 25, 2019. LCDs are available through the CMS Medicare coverage database at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

A coding article for an LCD (when present) may be found by selecting “Related Local Coverage Documents” in the “Section Navigation” drop-down menu at the top of the LCD page.

**Note:** To review active, future and retired LCDs, please click here.

**Revisions to LCDs**

**Syphilis test – revision to the Part A and Part B LCD**

**LCD ID number: L33754 (Florida/Puerto Rico/U.S. Virgin Islands)**

Based on review of the local coverage determination (LCD) for syphilis test, typographical errors were corrected. In addition, the “Sources of Information and Basis for Decision” section of the LCD was revised to remove outdated sources.

**Effective date**

The LCD revision related to the typographical errors is effective for claims processed on or after January 15, 2019.

The LCD revision related to the sources of information is effective for services rendered on or after January 15, 2019. LCDs are available through the CMS Medicare coverage database at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

A coding article for an LCD (when present) may be found by selecting “Related Local Coverage Documents” in the “Section Navigation” drop-down menu at the top of the LCD page.

**Note:** To review active, future and retired LCDs, please click here.

**Vertebroplasty, vertebral augmentation; percutaneous – revision to the Part A and Part B LCD**

**LCD ID number: L34976 (Florida/Puerto Rico/U.S. Virgin Islands)**

Based on review of the local coverage determination (LCD) for vertebroplasty, vertebral augmentation; percutaneous, language was removed in the “Limitations of Coverage” section of the LCD.

In addition, based on change request (CR) 10901, the “Documentation Requirements” section of the LCD was revised to update the section number for Pub. 100-08, Chapter 13 from 13.5.1 to 13.5.4.

**Effective date**

The LCD revision related to the “Limitations of Coverage” section of the LCD is effective for claims processed on or after January 22, 2019.

The LCD revision related to CR 10901 is effective for claims processed on or after January 8, 2019, for services rendered on or after September 26, 2018. LCDs are available through the CMS Medicare coverage database at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.

A coding article for an LCD (when present) may be found by selecting “Related Local Coverage Documents” in the “Section Navigation” drop-down menu at the top of the LCD page.

**Note:** To review active, future and retired LCDs, please click here.
New local coverage determinations process

Note: This article was revised on January 11, 2019, to reflect the revised CR 10901 issued on January 11. In the article, we added language to show that MACs have the discretion to host multi-jurisdictional CACs. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same. All other information remains the same. This information was previously published in the October 2018 Medicare A Connection, pages 1, 9-11.

Provider type affected

This MLN Matters® article is intended for physicians, providers, and suppliers billing Medicare administrative contractors (MACs) for services provided to Medicare beneficiaries.

Provider action needed

Change request (CR) 10901 notifies MACs that, in accordance with Section 4009 of H.R. 34-21st Century Cures Act (Public Law No: 114-255), the Centers for Medicare & Medicaid Services (CMS) is updating the Medicare Program Integrity Manual with detailed changes to the local coverage determination (LCD) process. You should ensure that your staffs are aware of these changes.

Background

Through feedback received in the proposed Calendar Year (CY) 2018 Physician Fee Schedule (PFS) Rule (82 FR 33950), and through meetings and correspondence; stakeholders, including providers and healthcare associations, have provided CMS with valuable insight regarding modernization of the LCD process. Most stakeholders acknowledged that the local coverage process is an important means to provide decisions related to the items and services that benefit Medicare’s beneficiaries and to ensure beneficiary access to life saving and medically necessary products and procedures. However, there is concern about the lack of local coverage process transparency, including notifying stakeholders of proposed revisions to, and drafting of, new LCDs. Additional stakeholder concerns include: ineffective MAC processes for soliciting from, and providing to, stakeholders feedback on information provided during open public meetings, a lack of non-physician representation on Contractor Advisory Committees (CACs), and concerns that CAC meetings are not open to the public.

In CR10901, the revisions to the Medicare Program Integrity Manual, Chapter 13, CMS is revising instructions to MACs, reflecting policy process changes in response to the new statutory (21st century Cures Act) requirements and to the stakeholder comments. These changes will help to increase transparency, clarity, consistency, reduce provider burden and enhance public relations while retaining the ability to be responsive to local clinical and coverage policy concerns.

The 2016 21st Century Cures Act included changes to the LCD process, adding language to 1862(l)(5)(D) of the Social Security Act (the Act) to describe the LCD process. Section 1862(l)(5)(D), of the Act requires each MAC that develops an LCD to make available on their Internet website on the Medicare website, at least 45 days before the effective date of such determination, the following information:

- Such determination in its entirety
- Where and when the proposed determination was first made public
- Hyperlinks to the proposed determination and a response to comments submitted to the MAC with respect to such proposed determination
- A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence
- An explanation of the rationale that supports such determination

CMS revamped the format of the manual so that it could be used as a roadmap to understand the steps of the local coverage process, which enable stakeholders to effectively engage in the process. This transparency also carries through to the reconsideration process, which is a process by which stakeholders can request a MAC take a second look at an existing decision using evidence that has developed since its first review.

The manual also sets forth consistent requirements for communication to providers and other stakeholders to occur at predictable milestones so anyone with an interest in the local policy can stay informed as the policy moves through the process.

NEW LCD process

The key parts of the new LCD process are summarized as follows:

1. The New LCD Process may begin with informal meetings in which interested parties within the MAC’s jurisdiction can discuss potential LCD requests. These educational meetings, which are not required, can be held either in person, using web-based technologies, or via teleconference, which allow discussions before requestors submit a formal request.

2. New LCD requests

The New LCD Request Process is a mechanism through which interested parties within a MAC’s jurisdiction can request a new LCD. In this process, MACs will consider all new LCD requests from:

- Beneficiaries residing or receiving care in the MAC’s jurisdiction
- Health care professionals doing business in the MAC’s jurisdiction
- Any interested party doing business in the MAC’s jurisdiction

MACs will consider a New LCD Request to be a complete, formal request if the following requirements are met. The request:

- Is in writing and is sent to the MAC via e-mail,
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- Clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service applies.
- Identifies the language that the requestor wants in an LCD.
- Includes a justification supported by peer-reviewed evidence (full copies of published evidence must be included or the request is not valid).
- Addresses relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service.
- Fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

Within 60 calendar days of the day they receive the request; MACs will review the materials and determine whether the request is complete or incomplete. If the request is complete, the MAC will follow the New LCD Process, as described in the revised manual. If, however, the process is incomplete, they will respond, in writing, to the requestor explaining why the request was incomplete.

3. Clinical Guidelines, Consensus Documents and Consultation

During an LCD’s development, MACs should (when applicable and available) supplement their research with clinical guidelines, consensus documents, or consultation by experts (recognized authorities in the field), medical associations or other health care professionals for an advisory opinion. They will summarize the opinions they receive as a result of this consultation with healthcare professional expert(s), professional societies, and others prior to the drafting of a proposed or final LCD, and include this information in the proposed or final LCD. Note that acceptance by individual health care providers, or even a limited group of health care providers, does not indicate general acceptance of the item or service by the medical community.

4. Publication of the Proposed LCD

The public announcement of a MAC’s proposed determination begins with the date the proposed LCD is published on the Medicare coverage database (MCD) at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Once the proposed LCD is published, MACs will provide a minimum of 45 calendar days for public comment, and will contact the CMS if they determine an extension to the comment period is needed.

These processes shall be used for all LCDs except in the following situations:

- Revised LCD being issued for compelling reasons.
- Revised LCD that makes a non-substantive correction - For example, typographical or grammatical errors that do not substantially change the LCD.
- Revised LCD that makes a non-discretionary coverage update - Contractors shall update LCDs to reflect changes in NCDs or when a conflict with national policy occurs, coverage provisions in interpretive manuals, and payment systems.
- Revise LCD to effectuate an administrative law judge’s decision to nullify an existing LCD due to an LCD challenge.

5. Contractor advisory committee (CAC)

The CAC is to be composed of healthcare professionals, beneficiary representatives, and representatives of medical organizations; and is used to supplement the MAC’s internal expertise, and to ensure an unbiased and contemporary consideration of “state of the art” technology and science. Additionally, all CAC meetings will be open to the public to attend and observe.

MACs will establish one CAC per state or have the option of establishing one CAC per jurisdiction or multi-jurisdictional CAC with representation from each state. If a MAC chooses to have one CAC per jurisdiction or multi-jurisdictional CAC, the MAC must endeavor to ensure that each state has a full committee and the opportunity to discuss the quality of the evidence used to make a determination.

The CAC’s purpose is to provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and promote communications between the MACs and the healthcare community. The CAC is advisory in nature, with the final decision on all issues resting with MACs.

6. Open Meeting

After the proposed LCD is made public, MACs will hold open meetings to discuss the review of the evidence and the rationale for the proposed LCD(s) with stakeholders in their jurisdiction. Interested parties (generally those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, caregivers, etc.) can make presentations of information related to the proposed LCDs. Members of the CAC may also attend these open meetings. MACs must notify the public about the dates and location for the open meeting. MACs have the option of setting up email listservs to announce this information or may use other education methods to adequately inform the public. The listserv or other method should clearly identify the location, dates and telephone/video/on-line conference information for the open meeting to ensure that this information is clearly distinguished from the information for the CAC meetings.

7. Publication of the Final Determination

After the close of the comment period and the required meetings and consultation, the final LCD and the response to comment (RTC) article will be published on the MCD.

8. Response to Public Comments

MACs will respond to all comments received during the comment period of the proposed LCD by using the RTC article associated with the LCD. The RTC Article is published on the start date of the notice period. The RTC Article will remain publicly available indefinitely on the
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MCD or the MCD Archive.

9. Notice period
The date the final LCD is published on the MCD, marks the beginning of the required notice period of at least 45 calendar days before the LCD can take effect. If the notice period is not extended by the MAC, the effective date of the LCD is the 46th calendar day after the notice period began.

Full details of this new process are contained in the updated manual which is an attachment to CR 10901.

LCD reconsideration process
The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC’s jurisdiction can request a revision to an LCD. The LCD reconsideration process differs from an initial request for an LCD in that it is available only for final effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative. This process is summarized as follows:

1. MACs shall consider all LCD reconsideration requests from:
   - Beneficiaries residing or receiving care in a contractor’s jurisdiction
   - Providers doing business in a contractor’s jurisdiction
   - Any interested party doing business in a contractor’s jurisdiction

2. MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall not be accepted for other documents including:
   - National coverage determinations (NCDs);
   - Coverage provisions in interpretive manuals;
   - Proposed LCDs;
   - Template LCDs, unless or until they are adopted and in effect by the contractor;
   - Retired LCDs;
   - Individual claim determinations
   - Bulletins, articles, training materials; and
   - Any instance in which no LCD exists, i.e., requests for development of an LCD.

3. Process Requirements - The requestor shall submit a valid LCD reconsideration request to the appropriate MAC, following instructions on the MAC’s Web site. Within 60 calendar days of the day the request is received, the MAC shall determine whether the request is valid or invalid. If the request is invalid, the MAC will respond, in writing, to the requestor explaining why the request was invalid. If the request is valid, the MAC will open the LCD and follow the LCD process as outlined in the above for new LCDs or include the LCD on the MAC’s waiting list. The MAC shall respond, in writing, to the requestor notifying the requestor of the acceptance, and if applicable, wait-

Other important changes
Other key changes to the manual include the following:

- MACs shall finalize or retire all proposed LCDs within one calendar year of publication date on the MCD.
- Upon further notice from CMS, it will no longer be appropriate to routinely include Current Procedure Terminology (CPT®) codes or International Classification of Diseases-Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. All codes will be removed from LCDs and placed in billing & coding articles that are linked to the LCD.

Additional information

If you have questions, your MACs may have more information. Find their website at https://go.cms.gov/MAC-website-list.

As part of the CMS commitment to continuous improvement, CMS invites interested stakeholders to submit feedback on their experience with the revised LCD process. CMS will collect feedback via submissions to LCDmanual@cms.hhs.gov and consider additional revisions based on stakeholder feedback.

Document history

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 11, 2019</td>
<td>We revised the article to reflect the revised CR 10901 issued on January 11. In the article, we added language to show that MACs have the discretion to host multi-jurisdictional CACs. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.</td>
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<tr>
<td>October 3, 2018</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

MLN Matters® Number: MM10901 Revised
Related CR Release Date: January 11, 2019
Related CR Transmittal Number: R854PI
Related Change Request (CR) Number: 10901
Effective Date: October 3, 2018
Implementation Date: January 8, 2019

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Upcoming provider outreach and educational events

Medicare quarterly updates (Part A)

Date: Tuesday, March 19
Time: 10:00 a.m. - 11:30 a.m.
Type of Event: Webcast

https://medicare.fcso.com/Events/0425417.asp

Note: Unless otherwise indicated, designated times for educational events are stated as ET, and the focus is to Florida, Puerto Rico, and the U.S. Virgin Islands.

Two easy ways to register

Online – Visit our provider training website at https://gm1.geolearning.com/geonext/fcso/opensite.geo, log on to your account and select the course you wish to register. Class materials are available under “My Courses” no later than one day before the event.

First-time User? Set up an account by completing Request User Account Form online. Providers who do not have yet a national provider identifier may enter “99999” in the NPI field. You will receive logon information within 72 hours of your request.

Fax – Providers without internet access may request a fax registration form through our Registration Hotline at 1-904-791-8103. Class materials will be faxed to you the day of the event.

Please Note:

- Pre-registration is required for all teleconferences, webcasts and in-person educational seminars.
- Dates and times are subject to change prior to opening of event registration.

Registrant’s Name: __________________________________________________________________________
Registrant’s Title: __________________________________________________________________________
Provider’s Name: ____________________________________________________________________________
Telephone Number: _____________________________ Fax Number: __________________________________
Email Address: _____________________________________________________________________________
Provider Address: ___________________________________________________________________________
City, State, ZIP Code: ________________________________________________________________________

Keep checking our website, medicare.fcso.com, for details and newly scheduled educational events (teleconferences, webcasts, etc.) or call the First Coast Provider Education Registration Hotline at 1-904-791-8103 to learn more about our newest training opportunities for providers.

Never miss a training opportunity

If you or your colleagues were unable to attend one of our past Medicare educational webcasts, you still have the opportunity to learn about the topics covered during the training session. Visit the First Coast Medicare training website, download the recording of the event, and listen to the webcast when you have the time.

Take advantage of 24-hour access to free online training

In addition to live training events, we also offer you the advantage of self-paced, free online courses that will allow you and your staff to train when and where it is most convenient for you. In addition, our comprehensive course catalog allows you to find the Medicare training that fits your specific needs, and several of our online courses offer CEUs. Learn more on the First Coast Medicare training website and explore our catalog of online courses.
The Centers for Medicare & Medicaid Services (CMS) MLN Connects® is an official Medicare Learning Network® (MLN) – branded product that contains a week’s worth of news for Medicare fee-for-service (FFS) providers. CMS sends these messages weekly to national health industry provider associations, who then disseminates the MLN Connects® to its membership as appropriate.

MLN Connects® for January 3, 2019

MLN Connects® for Thursday, January 3, 2019

News & Announcements

- Medicare Shared Savings Program: Final Rule Creates Pathways to Success
- Physician Compare Preview Period Extended to January 7
- Hospice Provider Preview Reports: Review Your Data by January 9
- Medicare Shared Savings Program: Submit Notice of Intent to Apply by January 18
- Laboratory Date of Service Exception Policy: Enforcement Discretion Exercised until July 1
- Quality Payment Program: 2019 Resources
- eCQM Resource: The Collaborative Measure Development Workspace
- Medicare Enrollment Application Fee for CY 2019
- Delivery of Initial Prescriptions of Immunosuppressive Drugs
- Antipsychotic Drug Use in Nursing Homes: Trend Update
- Get Your Patients Off to a Healthy Start in 2019

Provider Compliance

- Coding for Specimen Validity Testing Billed in Combination with Urine Drug Testing — Reminder

Claims, Pricers & Codes

- Medicare Diabetes Prevention Program: Valid Claims

Upcoming Events

- ESRD Quality Incentive Program: CY 2019 ESRD

PPS Final Rule Call — January 15
- Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates Call — January 22
- Home Health Patient-Driven Groupings Model Call — February 12

Medicare Learning Network Publications & Multimedia

- Claim Status Category and Codes Update MLN Matters Article — New
- Ensuring Only the Active Billing Hospice Can Submit a Revocation MLN Matters Article — New
- Guidance for MACs Processing BFCC QIO 2MN SSR Determinations MLN Matters Article — New
- I/OCE Version 20.0: January 2019 MLN Matters Article — New
- FISS/DDE: New Search Features MLN Matters Article — New
- Quality Payment Program in 2018: Group Participation Web-Based Training — New
- SNF PPS Call: Audio Recording and Transcript — New
- IRF PPS Call: Audio Recording and Transcript — Revised
- New Physician Specialty Code for Undersea and Hyperbaric Medicine MLN Matters Article — Revised
- Repetitive, Scheduled Non-emergent Ambulance Prior Authorization Model MLN Matters Article — Revised
- Looking for Educational Materials?

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MLN Connects® for January 10, 2019

News & Announcements

- Medicare Shared Savings Program: Submit Notice of Intent to Apply by January 18
- New Medicare Card: Transition Period Ends December 31
- January is Cervical Health Awareness Month

Provider Compliance

- Proper Use of the KX Modifier for Part B Immunosuppressive Drug Claims — Reminder

Upcoming Events

- ESRD Quality Incentive Program: CY 2019 ESRD PPS Final Rule Call — January 15
- Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates Call — January 22
- New Electronic System for Provider Reimbursement Review Board Appeals Call — February 5
- Home Health Patient-Driven Groupings Model Call — February 12
- Home Health Rural Add-on Payment MLN Matters Article — Revised
- Implantable Defibrillators: NCD 20.4 MLN Matters Article — Revised
- Medicare Billing: Form CMS-1500 and the 837 Professional Web-Based Training Course — Revised

MLN Connects® -- Special Edition for January 16, 2019

New Medicare Card Mailing Complete, 58% of Claims Submitted with MBI

CMS finished mailing new Medicare cards to people with Medicare across all mailing waves, including Wave 7 states and territories and also to people with Medicare Parts A&B who live in Canada and Mexico.

Medicare patients are using their new cards in doctor’s offices and other health care facilities. For the week ending January 11, 2019, fee-for-service health care providers submitted 58% of claims with new Medicare Beneficiary Identifiers (MBIs), showing that many of you are already successfully submitting claims with MBIs. While you can continue using the former Social Security Number-based Health Insurance Claim Numbers during the transition period, we encourage you to use the new MBIs for all Medicare transactions.

To ensure that you have access to your patients’ new numbers, you can individually look up MBIs if you have access to your Medicare Administrative Contractor’s secure provider portal. Likewise, your patients can access their new Medicare numbers or print official cards within their secure MyMedicare.gov accounts.

If your Medicare patients say they did not get a card, instruct them to:

- Look for unopened mail. We mailed new Medicare cards in a plain white envelope from the Department of Health and Human Services.
- Sign into MyMedicare.gov to get their new numbers or print official cards. They need to create an account if they do not already have one.
- Call 1-800-MEDICARE (1-800-633-4227), so we can help them get their new cards.
- Continue to use their current cards to get health care services. They can use their old cards until December 31, 2019.

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MLN Connects® for January 17, 2019

News & Announcements

- Medicare Shared Savings Program: Submit Notice of Intent to Apply by January 18
- Hospice Quality Reporting Program: Quality Measure User’s Manual
- Qualified Medicare Beneficiary Billing Requirements
- Medicare Diabetes Prevention Program: Become a Medicare Enrolled Supplier
- Glaucoma Awareness Month: Make a Resolution for Healthy Vision

Provider Compliance

- Hospice Election Statements Lack Required Information or Have Other Vulnerabilities — Reminder

Upcoming Events

- Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates Call — January 22
- Comparative Billing Report Webinar on Intensity-Modulated Radiation Therapy Webinar — January 24
- New Electronic System for Provider Reimbursement Review Board Appeals Call — February 5
- Home Health Patient-Driven Groupings Model Call — February 12
- New Part D Opioid Overutilization Policies Call — February 14

Medicare Learning Network Publications & Multimedia

- 2019 DMEPOS HCPCS Code Jurisdiction List MLN Matters Article — New
- DMEPOS CBP: Quarterly Update MLN Matters Article — New
- NCCI PTP Edits: Quarterly Update MLN Matters Article — New
- Medicare Claims Processing Manual MLN Matters Article — New
- Clinical Lab Fee Schedule: Medicare Travel Allowance Fees MLN Matters Article — New
- New Waived Tests MLN Matters Article — New
- ICD-10 and Other Coding Revisions to NCDs MLN Matters Article — Revised
- Local Coverage Determinations MLN Matters Article — Revised
- Skilled Nursing Facility ABN MLN Matters Article — Revised
- Medicare Preventive Services Educational Tool — Revised
- Remittance Advice: An Overview Booklet — Revised

The Medicare Learning Network® (MLN) is the home for education, information, and resources for the health care professional community. The MLN provides access to CMS Program information you need, when you need it, so you can focus more on providing care to your patients. Find out what the MLN has to offer you and your staff at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html.
First Coast Service Options
Phone Numbers
(Note: Specific geographic contact information is noted when phone numbers and addresses are different for providers in Florida, U.S. Virgin Islands or Puerto Rico.

Customer service
Monday to Friday
8:00 a.m. to 4:00 p.m
888-664-4112 (FL/USVI)
877-908-8433 (Puerto Rico)
877-660-1759 (TDD-FL/USVI)
888-216-8261 (TDD-Puerto Rico)

Electronic data interchange
888-670-0940 (FL/USVI)
888-875-9779 (Puerto Rico)

Interactive Voice Response
877-602-8816

Provider education/outreach
Event registration hotline
904-791-8103

Overpayments
904-791-8123

SPOT Help Desk
FCSOSPOTHelp@fcso.com
855-416-4199

Websites
medicare.fcso.com
medicareespanol.fcso.com

First Coast Service Options Addresses
Claims/correspondence
Florida/ U.S. Virgin Islands
Medicare Part A Customer Service
P. O. Box 2711
Jacksonville, FL 32231-0021

Puerto Rico
First Coast Service Options Inc.
P. O. Box 45003
Jacksonville, FL 32232-5003

Medicare EDI
Electronic claim filing
Direct Data Entry
P. O. Box 44071
Jacksonville, FL 32231-4071

Fraud and abuse
Complaint Processing Unit
P. O. Box 45087

FOIA requests
Provider audit/reimbursement
(relative to cost reports and audits)
Attr: FOIA PARD – 16T
P. O. Box 45268
Jacksonville, FL 32232-5268

General Inquiries
Online Form (Click here)
Email: EDOC-CS-FLINQA@fcso.com

Local coverage determinations
Medical Policy and Procedures – 19T
P. O. Box 2078
Jacksonville, FL 32231-0048

Medicare secondary payer (MSP)
Medicare Secondary Payer
P. O. Box 2711
Jacksonville, FL 32231-0021

Hospital audits
MSP – Hospital Review
P. O. Box 45267
Jacksonville, FL 32232-5267

MSPRC DPP debt recovery, auto accident settlements/lawsuits, liabilities
Auto/Liability – 17T
P. O. Box 44179
Jacksonville, FL 32231-4179

Overpayment collections and debt recovery
Repayment, cost reports, receipts and acceptances, tentative settlement determinations, provider statistical and reimbursement reports, cost report settlement, TEFRA target limit and SNF routine cost limit exceptions
Provider Audit and Reimbursement
P. O. Box 45268
Jacksonville, FL 32232-5268

Credit balance reports
First Coast Service Options Inc.
P. O. Box 45011
Jacksonville, FL 32232-5011

Post-pay medical review
First Coast Service Options Inc.
P. O. Box 44159
Jacksonville, FL 32231-4159

Provider enrollment
CMS-855 Applications
P. O. Box 3409
Mechanicsburg, PA 17055-1849

Special or overnight deliveries
Provider Enrollment
2020 Technology Parkway Suite 100
Mechanicsburg, PA 17055-1849

Redetermination
Florida:
Medicare Part A Redetermination/Appeals
P. O. Box 3409
Jacksonville, FL 32232-5053

U.S. Virgin Islands:
First Coast Service Options Inc
P. O. Box 45097
Jacksonville, FL 32232-5097

Puerto Rico
First Coast Service Options Inc.
P. O. Box 45028
Jacksonville, FL 32232-5028

Special delivery/courier services
First Coast Service Options Inc.
532 Riverside Avenue
Jacksonville, FL 32202-4914

Other Medicare carriers and intermediaries
DME regional carrier (DMERC)
DME, orthotic, prosthetic device, take-home supply, oral anti-cancer drug claims
CGS Administrators, LLC
P. O. Box 20010
Nashville, Tennessee 37202

Railroad Medicare
Palmetto GBA
P. O. Box 10066
Augusta, GA 30999-0001

Regional home health/hospice intermediary
Palmetto GBA
Medicare Part A
34650 US HWY 19N
Palm Harbor, FL 34684

Contact CMS
Centers for Medicare & Medicaid Services (CMS)
(https://www.cms.gov/)
Centers for Medicare & Medicaid Services, Division of Financial Management and Fee for Service Operations
ROATLFM@CMS.HHS.GOV

Office of Inspector General (OIG)
Medicare fraud hotline
800-HHS-TIPS (800-447-8477)

Beneficiary customer service
1-800-MEDICARE (1-800-633-4227)
Hearing and speech impaired (TDD)
1-800-754-7820