Medicare B CONNECTION
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FIRST COAST SERVICE OPTIONS, INC.
A Newsletter for MAC Jurisdiction N Providers
March 2019

In this issue

Medicare Part B clinical laboratory fee schedule: Revised information for laboratories on collecting and reporting data for the private payor rate-based payment system

Provider type affected

This article is for Medicare Part B clinical laboratories who submit claims to Medicare Administrative Contractors (MACs) for services furnished to Medicare beneficiaries.

Provider action needed

This article will assist the laboratory community in meeting the requirements under Section 1834A of the Social Security Act (the Act) for the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). It includes clarifications for determining whether a hospital outreach laboratory meets the requirements to be an "applicable laboratory," the applicable information (that is, private payor rate data) that must be collected and reported to the Centers for Medicare & Medicaid Services (CMS), the entity responsible for reporting applicable information to CMS, the data collection and reporting periods, and the schedule for implementing the next private payor-rate based CLFS update. Also, this revised article includes information about the condensed data reporting option for reporting entities. CMS previously issued additional information about the CLFS data collection system and Advanced Diagnostic Laboratory Tests (ADLTs) through separate instructions.

Background

Section 1834A of the Act, as established by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the CLFS. The CLFS final rule *Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule* (CMS-1621-F) was displayed in the Federal Register on June 17, 2016, and was published on June 23, 2016. The CLFS final rule implemented Section 1834A of the Act.

Under the CLFS final rule, reporting entities must report to CMS certain private payor rate information (applicable

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The *Medicare B Connection* is published monthly by First Coast Service Options Inc.'s Provider Outreach & Education division to provide timely and useful information to Medicare Part B providers.

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Articles included in the *Medicare B Connection* represent formal notice of coverage policies. Policies have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined within to ensure compliance with Medicare coverage and payment guidelines.

About the Medicare B Connection

The *Medicare B Connection* is a comprehensive publication developed by First Coast Service Options Inc. (First Coast) for Part B providers in Florida, Puerto Rico, and the U.S. Virgin Islands and is distributed on a monthly basis.

Important notifications that require communication in between publications will be posted to the First Coast Medicare provider education website at *https://medicare.fcso.com*. In some cases, additional unscheduled special issues may be posted.

Who receives the *Connection*

Anyone may view, print, or download the *Connection* from our provider education website(s). Providers who cannot obtain the *Connection* from the internet are required to register with us to receive a complimentary hardcopy.

Distribution of the *Connection* in hardcopy is limited to providers who have billed at least one Part B claim to First Coast Medicare during the twelve months prior to the release of each issue. Providers meeting these criteria are eligible to receive a complimentary copy of that issue, if a technical barrier exists that prevents them from obtaining it from the internet and they have returned a completed registration form to us.

Registration forms must be submitted annually or when you experience a change in circumstances that impacts your electronic access.

For additional copies, providers may purchase a separate annual subscription (see order form in the back of this issue). All issues published since 1997 may be downloaded from the internet, free of charge.

We use the same mailing address for all correspondence, and cannot designate that the *Connection* be sent to a specific person/department within a provider's office. To ensure continued receipt of all Medicare correspondence, providers must keep their addresses current with the Medicare provider enrollment department. Please remember that address changes must be done using the appropriate CMS-855.

Publication format

The *Connection* is arranged into distinct sections.

- The **Claims** section provides claim submission requirements and tips.
- The **Coverage/Reimbursement** section discusses specific CPT® and HCPCS procedure codes. It is arranged by categories (not specialties). For example, "Mental Health" would present coverage information of interest to psychiatrists, clinical psychologists and clinical social workers, rather than listing articles separately under individual provider specialties. Also presented in this section are changes to the Medicare physician fee schedule, and other pricing issues.

- The section pertaining to **Electronic Data Interchange** (EDI) submission also includes information pertaining to the Health Insurance Portability and Accountability Act (HIPAA).
- The **Local Coverage Determination** section features summaries of new and revised local coverage determinations (LCDs) developed as a result of either local medical review or comprehensive data analysis initiatives.
- The **General Information** section includes fraud and abuse, and national provider identifier topics, plus additional topics not included elsewhere.
- In addition to the above, other sections include:
- **Educational Resources**, and
- **Contact information** for Florida, Puerto Rico, and the U.S. Virgin Islands.

The *Medicare B Connection* represents formal notice of coverage policies

Articles included in each edition represent formal notice that specific coverage policies either have or will take effect on the date given. Providers are expected to read, understand, and abide by the policies outlined in this document to ensure compliance with Medicare coverage and payment guidelines.

Never miss an appeals deadline again

When it comes to submitting a claims appeal request, *timing is everything*. Don't worry – you won't need a desk calendar to count the days to your submission deadline. Try our *"time limit" calculators on our Appeals of claim decisions page*. Each calculator will *automatically calculate* when you must submit your request based upon the date of either the initial claim determination or the preceding appeal level.

Medicare Part B advance beneficiary notices

Medicare Part B allows coverage for services and items deemed medically reasonable and necessary for treatment and diagnosis of the patient.

For some services, to ensure that payment is made only for medically necessary services or items, coverage may be limited based on one or more of the following factors (this list is not inclusive):

- Coverage for a service or item may be allowed only for specific diagnoses/conditions. Always code to the highest level of specificity.
- Coverage for a service or item may be allowed only when documentation supports the medical need for the service or item.
- Coverage for a service or item may be allowed only when its frequency is within the accepted standards of medical practice (i.e., a specified number of services in a specified timeframe for which the service may be covered).

If the provider believes that the service or item may not be covered as medically reasonable and necessary, the patient must be given an acceptable advance notice of Medicare's possible denial of payment if the provider does not want to accept financial responsibility for the service or item. Advance beneficiary notices (ABNs) advise beneficiaries, before items or services actually are furnished, when Medicare is likely to deny payment.

Patient liability notice

The Centers for Medicare & Medicaid Services' (CMS) has developed the Advance Beneficiary Notice of Noncoverage (ABN) (Form CMS-R-131), formerly the "Advance Beneficiary Notice." Section 50 of the *Medicare Claims Processing Manual* provides instructions regarding the notice that these providers issue to beneficiaries in advance of initiating, reducing, or terminating what they believe to be noncovered items or services. The ABN must meet all of the standards found in Chapter 30. Beginning March 1, 2009, the ABN-G and ABN-L was no longer valid; and notifiers must use the revised Advance Beneficiary Notice of Noncoverage (CMS-R-131). Section 50 of the *Medicare Claims Processing Manual* is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf#page=44*.

Reproducible copies of Form CMS-R-131 ABNs (in English and Spanish) and other BNI information may be found at *https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html*.

ABN modifiers

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting modifier GA (waiver of liability statement on file) or GZ (item or service expected to be denied as not reasonable and necessary) with the service or item.

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Modifier GZ may be used in cases where a signed ABN is not obtained from the patient; however, when modifier GZ is billed, the provider assumes financial responsibility if the service or item is denied.

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

GA modifier and appeals

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting the modifier GA (waiver of liability statement on file).

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

Nonassigned claims containing the modifier GA in which the patient has been found liable must have the patient's written consent for an appeal. Refer to the applicable contact section located at the end of this publication for the address in which to send written appeals requests.

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information) for their component applicable laboratories. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, is equal to the weighted median of private payor rates determined for the test, based on the applicable information that laboratories collect during a data collection period and report to CMS during a data reporting period. CMS uses crosswalking or gapfilling methods to establish payment amounts for new Clinical Diagnostic Laboratory Tests (CDLTs) and CDLTs for which CMS receives no applicable information.

CMS published the Physician Fee Schedule (PFS) final rule entitled *Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019 (CMS-1693-F)* November 23, 2018. In this final rule, CMS made two revisions to the regulatory definition of applicable laboratory:

1) Medicare Advantage plan revenues are excluded from total Medicare revenues, the denominator of the majority of Medicare revenues threshold

2) Hospitals that bill for their non-patient laboratory services use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether its hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold.

In addition, for the January 1, 2020, through March 31, 2020 data reporting period, CMS will allow reporting entities the option to condense certain applicable information at the Tax Identification Number (TIN)-level, instead of reporting for each applicable laboratory individually at the National Provider Identifier (NPI) level.

Applicable Laboratory

Section 1834A of the Act defines an applicable laboratory as a laboratory which receives the majority of its Medicare revenues under the CLFS and/or PFS. It also provides the authority to establish a low volume or low expenditure threshold.

Under the revised final policies for the Medicare CLFS, an applicable laboratory is a laboratory as defined under the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of a laboratory (that is, 42 C.F.R. § 493.2) that bills Medicare Part B under its own NPI or for hospital outreach laboratories, bills Medicare Part B on the Form CMS-1450 under bill type 14x. In addition, the laboratory must meet a "majority of Medicare revenues" threshold, that is, in a data collection period it receives more than 50 percent of its Medicare revenues from one or a combination of the CLFS or the PFS. It also must meet a low expenditure threshold, that is, it receives at least $12,500 of its Medicare revenues from the CLFS in a data collection period.

For purposes of determining applicable laboratory status under the CLFS, a hospital outreach laboratory is a hospital-based laboratory that furnishes laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital. A hospital outreach laboratory bills for Medicare Part B services it furnishes to non-hospital patients using the Form CMS-1450 14x Type of Bill (TOB).[1]

[1] The Form CMS-1450 14x is a type of bill as defined by the National Uniform Billing Committee. It is used in hospital claims submission and is associated with hospital laboratory services provided to non-hospital patients.

I. Determination of Applicable Laboratory Status Based on the NPI

This section includes information on how independent laboratories and physician office laboratories that bill Medicare Part B under their own NPI and hospital outreach laboratories that bill Medicare Part B under their own NPI (separate from the hospital's NPI) determine whether they are an applicable laboratory. As discussed later in this article, hospital outreach laboratories that bill Medicare Part B using the hospital's NPI must determine applicable laboratory status based on its revenues attributed to the Form CMS-1450 14x TOB.

There are four steps in determining whether a laboratory meets the requirements to be an applicable laboratory based on the laboratory's own billing NPI:
(1) Is the laboratory certified under CLIA?
(2) Does the CLIA- certified laboratory bill Medicare Part B under its own NPI?
(3) Does the laboratory meet the majority of Medicare revenues threshold?
(4) Does the laboratory meet the low expenditure threshold?

Step 1: CLIA Certification

The CLIA applies to all laboratories performing testing on human specimens for a health purpose. A laboratory must be a CLIA-certified laboratory to receive Medicare payment. Therefore, the first step in identifying an applicable laboratory is to determine whether the laboratory is CLIA certified. The CLIA regulatory definition of a laboratory is codified in regulation in 42 CFR 493.2. **Note that a facility that receives any CLIA certificate (including a CLIA certificate of waiver) is considered a laboratory as defined in 42 CFR 493.2.**

Step 2: NPI

The second step is to determine whether the CLIA-certified laboratory bills Medicare Part B under its own NPI. The NPI is the standard unique health identifier used by health care providers for billing Medicare and other payors. The National Plan and Provider Enumeration System assigns NPIs, per 45 CFR 162. CMS uses the laboratory's own billing NPI as the mechanism for defining an applicable laboratory.

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Step 3: Majority of Medicare Revenues Threshold

For a CLIA-certified laboratory that bills Medicare Part B under its own NPI, to be an applicable laboratory it must meet the majority of Medicare revenues threshold. A laboratory, by its own billing NPI, meets the majority of Medicare revenues threshold if it receives more than 50 percent of its **total** Medicare revenues from payments under the Medicare CLFS and/or Medicare PFS. The CLFS and PFS are under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To determine whether a laboratory meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims from their MAC received by their own billing NPI during the data collection period. See the Applicable Information Section below for additional information on the concept of final paid claims.

The three steps to determine whether a laboratory meets the majority of Medicare revenues threshold are:

- First, sum the CLFS and PFS payment amounts received by the laboratory's own billing NPI during the data collection period. The revenues from the CLFS include payments for all laboratory services under the CLFS. The revenues from the PFS include all payments from all services paid under the PFS (for instance, laboratory services and services that are not laboratory services such as pathology services, evaluation and management services, and radiology services). The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation.
- Next, sum the total Medicare revenues received by the laboratories own billing NPI during the data collection period. Total Medicare revenues include the sum of all FFS payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation.

Note: Effective January 1, 2019, Medicare Advantage plan payments under Medicare Part C shall not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation.

- Finally, divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues received during the data collection period. We provide additional information on the data collection period below.

If the Medicare revenues received from the CLFS and/or PFS are greater than 50 percent of the total Medicare revenues for the laboratory's billing NPI, the laboratory meets the majority of Medicare revenues threshold.

The majority of Medicare revenues threshold equation is:

If:

$$\frac{\text{Medicare CLFS revenues (for billing NPI) + Medicare PFS revenues (for billing NPI)}}{\text{Total Medicare revenues (for billing NPI)}} \text{ is } >50\%$$

Then: The laboratory meets the majority of Medicare revenues threshold.

Step 4: Low Expenditure Threshold

An applicable laboratory must also meet the low expenditure requirements. A laboratory (as defined under the CLIA regulations) meets the low expenditure threshold if, by its own billing NPI, receives at least $12,500 in Medicare revenues from the CLFS (under Medicare Part B) during the data collection period. To meet the low expenditure threshold, the laboratory must look to its final Medicare paid claims from the MAC received by its own billing NPI during the data collection period.

To determine whether the laboratory meets the low expenditure threshold, sum all final payments for the laboratory's own billing NPI received from Medicare CLFS services during the data collection period (completed under Step 3: Majority of Medicare Revenues Threshold). It is important to note that the low expenditure threshold applies only to **CLFS services**. It does **not** include revenues received under the PFS. In other words, to meet the low expenditure threshold, the laboratory's own billing NPI must receive at least $12,500 under only the CLFS during the data collection period.

The low expenditure threshold equation is:

Medicare CLFS revenues (for billing NPI) ≥ $12,500.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified laboratory's own billing NPI for purposes of determining whether the laboratory is an applicable laboratory:

Example 1: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has its own unique NPI and bills the Medicare Program (and other payors) for laboratory tests separately under each NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to each NPI in the laboratory organization. That is, individually determine whether each laboratory meets the majority of revenues threshold and low expenditure threshold. Even though all five laboratories may be under the same TIN, CMS considers each to be a separate laboratory for purposes

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of determining an applicable laboratory because each bills Medicare Part B for laboratory tests using its own unique NPI.

Example 2: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has the same NPI and bills for laboratory tests under the same NPI for each of its CLIA-certified laboratories. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all CLIA-certified laboratories in the organization that use the same billing NPI. In other words, for purposes of applying the applicable laboratory thresholds, CMS considers all five CLIA-certified laboratories in the laboratory organization to be a single laboratory because they all bill Medicare Part B using the same NPI.

Example 3: A laboratory organization includes five CLIA-certified laboratories. Each CLIA-certified laboratory has its own unique NPI. However, only one laboratory's NPI is used for billing all laboratory tests furnished by all five laboratories in the laboratory organization. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the one NPI used for billing all tests furnished by the laboratory organization.

Example 4: An entity consists of five physician offices and one CLIA-certified laboratory. All five physician offices and the CLIA-certified laboratory have the same NPI and bill for services under the same NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all components of the entity that bill for services under the same NPI. In other words, since the physician offices and CLIA-certified laboratory all have the same NPI and bill Medicare Part B under the same NPI, CMS considers the entity to be a single laboratory for purposes of applying the majority of Medicare revenues threshold and low expenditure threshold.

Example 5: An entity consists of five physician offices and one CLIA-certified laboratory. Each of the five physician offices and the CLIA-certified laboratory have unique NPIs. The laboratory bills for laboratory tests under its own unique NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are only applied to the CLIA-certified laboratory's own billing NPI.

Example 6: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital's NPI. The hospital outreach laboratory bills Medicare Part B for laboratory tests it furnishes to non-hospital patients using its own unique NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory's own unique NPI and not to the hospital's NPI.

Example 7: A hospital includes three CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital outreach laboratory has the same NPI, separate from the hospital's NPI, and bills Medicare Part B separately for laboratory tests under the same NPI for each of its CLIA-certified hospital outreach laboratories. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all CLIA-certified hospital outreach laboratories of the hospital that use the same billing NPI that is separate from the hospital's NPI. In other words, for purposes of applying the applicable laboratory thresholds, CMS considers all three CLIA-certified hospital outreach laboratories of the hospital to be a single laboratory because they all bill Medicare Part B using the same unique billing NPI.

Example 8: A hospital includes three CLIA-certified hospital outreach laboratories. Each CLIA-certified hospital outreach laboratory has its own unique NPI separate from the hospital's NPI. However, the three CLIA-certified outreach laboratories use only one outreach laboratory's NPI for billing all laboratory tests furnished by all three hospital outreach laboratories of the hospital. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the one NPI used for billing all tests furnished by the three hospital outreach laboratories of the hospital.

Example 9: A hospital includes three CLIA-certified hospital outreach laboratories. However, only one (out of the three) has its own unique NPI separate from the hospital's NPI and bills Medicare Part B for laboratory services performed for non-hospital patients using its own unique NPI. Two (out of the three) hospital outreach laboratories bill for laboratory services performed for non-hospital patients using the hospital's NPI. In this example, the hospital outreach laboratory that bills Medicare Part B under its own unique NPI separate from the hospital's NPI uses the Medicare revenues attributed to its own billing NPI to determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold.

The two hospital outreach laboratories that bill for laboratory services performed for non-hospital patients under the hospital's NPI must determine applicable laboratory status based on revenues attributed to the Form CMS-1450 14x TOB. Below, we provide instructions for determining applicable laboratory status for hospital outreach laboratories that bill Medicare Part B using the hospital's NPI.

II. Hospital Outreach Laboratories That Bill Medicare Part B under the Hospital's NPI

Similar to the preceding section, in order for hospital outreach laboratories that bill Medicare Part B using the

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hospital's NPI to be an applicable laboratory, the hospital outreach laboratory must be a laboratory as defined under the CLIA regulatory definition of a laboratory in 42 C.F.R. § 493.2 and meet the majority of Medicare revenues threshold and low expenditure threshold.

However, a hospital outreach laboratory that bills Medicare Part B using the hospital's NPI must determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on revenues attributed to the Form CMS-1450 14x TOB. In other words, when using the CMS Form-1450 14x TOB for determining applicable laboratory status, the majority of Medicare revenues threshold and low expenditure threshold only applies to the hospital outreach laboratory portion of the hospital's NPI, rather than to the NPI of the entire hospital.

Therefore, if a CLIA-certified hospital outreach laboratory that bills Medicare Part B under the hospital's NPI meets the requirements of an applicable laboratory, CMS only considers the hospital outreach laboratory to be an applicable laboratory. The hospital laboratory components furnishing laboratory services to hospital patients are not part of the applicable laboratory determination.

Majority of Medicare Revenues Threshold

To be an applicable laboratory, a hospital outreach laboratory that bills Medicare Part B under the hospital's NPI must meet the majority of Medicare revenues threshold. A hospital outreach laboratory, by its revenues attributed to the Form CMS-1450 14x TOB, meets the majority of Medicare revenues threshold if it receives more than 50 percent of its total Medicare revenues from payments under the Medicare CLFS and/or Medicare PFS. The CLFS and PFS are under Medicare Part B, also known as Original Medicare or Fee-For-Service (FFS) Medicare.

To determine whether the hospital outreach laboratory (that bills using the hospital's NPI) meets the majority of Medicare revenues threshold, the laboratory must look to its final Medicare paid claims from the MAC for the 14x TOB received during the data collection period. See the Applicable Information Section below for additional information on the concept of final paid claims.

The same three steps (as discussed in the previous section) are used to determine whether a hospital outreach laboratory (that bills Medicare Part B under the hospital's NPI) meets the majority of Medicare revenues threshold:

- First, sum the CLFS and PFS payment amounts received by the hospital outreach laboratory attributed to the 14x TOB during the data collection period. The sum of CLFS and PFS revenues is the numerator of the majority of Medicare revenues threshold equation
- Next, sum the total Medicare revenues received by the hospital outreach laboratory under the 14x TOB during the data collection period.

  Total Medicare revenues include the sum of all FFS payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period. The sum of total Medicare revenues is the denominator of the majority of Medicare revenues threshold equation. As noted previously, effective January 1, 2019, Medicare Advantage plan payments under Medicare Part C shall not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation.
- Finally, divide the sum of CLFS and PFS revenues by the sum of total Medicare revenues received during the data collection period. We provide additional information on the data collection period below.

If the Medicare revenues received from the CLFS and/or PFS are greater than 50 percent of the total Medicare revenues received during the data collection period, the hospital outreach laboratory meets the majority of Medicare revenues threshold.

For hospital outreach laboratories that bill Medicare Part B under the hospital's NPI, the majority of Medicare revenues threshold equation is:

If:

Medicare CLFS revenues (based on 14x TOB) + Medicare PFS revenues (based on 14x TOB)

_____ is >50%

Total Medicare revenues (based on 14x TOB)

Then: The laboratory meets the majority of Medicare revenues threshold.

NOTE: Hospital outreach laboratories that bill Medicare Part B under the hospital's NPI, and therefore determine applicable laboratory status based on its Medicare revenues from the 14x TOB, will most likely meet the majority of Medicare revenues threshold. They will most likely meet the majority of Medicare revenues threshold because their Medicare revenues are primarily, if not entirely, derived from the CLFS and or PFS. In other words, the revenues from the CLFS and or PFS services included in the numerator are essentially the same as the total Medicare revenues included in the denominator.

Low Expenditure Threshold

To be an applicable laboratory, a hospital outreach laboratory that bills Medicare Part B under the hospital's NPI must also meet the low expenditure threshold requirement. A CLIA-certified hospital outreach laboratory meets the low expenditure threshold if, by the Form CMS-

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1450 14x TOB, receives at least $12,500 in Medicare revenues from the CLFS (under Medicare Part B) during the data collection period. To meet the low expenditure threshold, the hospital outreach laboratory must look to its final Medicare paid claims from the MAC received under the 14x TOB during the data collection period.

To determine whether the hospital outreach laboratory that bills Medicare Part B under the hospital's NPI meets the low expenditure threshold, sum all final payments attributed to the 14x TOB received from Medicare CLFS services during the data collection period.

It is important to note that the low expenditure threshold applies only to CLFS services. It does not include revenues received under the PFS. In other words, to meet the low expenditure threshold, the hospital outreach laboratory must receive at least $12,500 under only the Medicare CLFS during the data collection period.

These are examples on how the majority of Medicare revenues threshold and low expenditure threshold are applied to the CLIA-certified hospital outreach laboratory using the Form CMS-1450 14x TOB for purposes of determining whether the hospital outreach laboratory is an applicable laboratory:

Example 1: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients bills Medicare Part B using the same NPI as the hospital. In other words, laboratory services performed for non-hospital patients are billed on the Form CMS-1450 14x TOB using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory's Medicare revenues received from the 14x TOB.

Example 2: A CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients has its own unique NPI separate from the hospital's NPI but does not use it to bill Medicare Part B. Instead, the hospital outreach laboratory continues to bill Medicare Part B for laboratory tests it furnishes to non-hospital patients using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to Medicare revenues received from the 14x TOB. In other words, since laboratory services performed for non-hospital patients are billed using the hospital's NPI (and not the hospital outreach laboratory's own unique billing NPI), the majority of Medicare revenues threshold and low expenditure threshold are applied to the hospital outreach laboratory's Medicare revenues received from the 14x TOB.

Example 3: A hospital includes three CLIA-certified hospital outreach laboratories that perform laboratory services for non-hospital patients. Each CLIA-certified hospital outreach laboratory bills Medicare Part B under the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues attributed to the 14x TOB of all CLIA-certified hospital outreach laboratories of the hospital.

In summary, applicable information (as discussed in the next section) from all applicable laboratories must be collected during the data collection period and reported by reporting entities to CMS during the data reporting period. CMS uses the applicable information reported to CMS to establish payment rates under the CLFS. All CLIA-certified laboratories (that is, both applicable laboratories and laboratories that are not applicable laboratories) are subject to the Medicare Part B private payor rate-based CLFS.

Applicable Information

The applicable laboratory along with its reporting entity (we provide more information about reporting entities below) are responsible for collecting applicable information and reporting that data to CMS.

Applicable information includes three major components:
1. The specific HCPCS code associated with the test;
2. The private payor rate for each test for which final payment has been made during the data collection period;
3. The associated volume for each test

Private Payor Defined

The definition of the term "private payor" is:
1. A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act); Or
2. A group health plan as defined in Section 2791(a)(1) of the PHS Act); Or
3. A Medicare Advantage plan under Part C as defined in Section 1859(b)(1) of the Social Security Act (the Act); Or
4. A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m) of the Act).

Note: Applicable information does not include information on tests for which payment is made on a capitated basis, where payments do not reflect specific HCPCS code-level amounts. (See below for additional information on payments made on a capitated basis.) Therefore, private payor rates from Medicaid MCO plans are considered applicable information only to the extent that the individual HCPCS code for the test, private payor rate specific to the test, and the volume paid at the specific rate for the test can be identified.

These specific private payor claims data are **included** as applicable information:

- **Laboratory tests subject to the data collection and reporting requirements**. Applicable information includes the specific HCPCS code for the test, each different private payor rate for the test, and the volume associated with each

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- private payor rate for the test. You can find a list of laboratory tests subject to the data collection and data reporting requirements at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html* and select: *CLFS Applicable Information HCPCS Codes [ZIP, 57KB]*.
- **Final amount paid by a private payor for laboratory tests after all private payor price concessions are applied**. A final paid claim is the final amount paid by a private payor for a laboratory test during the data collection period. If a private payor pays a laboratory for a test but subsequent post-payment activities during the data collection period change that initial payment amount, the final payment is the private payor rate for purposes of determining applicable information. For example, if an initial claim was paid in error 3 months before a data collection period and then the initial claim is corrected, with final payment made by the private payor during the data collection period, the final corrected payment amount for the test is considered the private payor rate for purposes of determining applicable information. However, if an initial claim was paid in error during a data collection period and then corrected, with final paymentmade after the data collection period, the payment amount is not a private payor rate for purposes of applicable information and, therefore, is not reported to CMS.
- **Payments from secondary insurance payors.** Final payments from secondary insurance payors are considered in calculating private payor rates if the final payment was made during the data collection period. The private payor rate is 100 percent of the primary private payors' fee schedule amount which includes the final amount the primary private payor paid for the test, any patient cost sharing responsibilities required by the primary private payor (such as patient deductible and coinsurance amounts) and any payments received from a secondary insurer (if applicable). The important concept here is the reporting entity reports 100 percent of the primary private payors' fee schedule amount for the laboratory test. Reporting entities should not report payments received from secondary insurers separately.
- **Any patient cost sharing amounts, if applicable.** For purposes of applicable information, the private payor rate for a test should include any patient cost sharing responsibilities required by the private payor (for instance, patient deductible and/or coinsurance amounts). In other words, as noted above, the private payor rate is 100 percent of the private payor's fee schedule amount for the test.
- **Multiple payment rates for the same test**. If an applicable laboratory receives more than one payment rate from the same private payor for the same test or more than one payment rate from different private payors for the same test, each unique payment rate along with the associated volume for the test code at each such rate is included as applicable information. In this case, the reporting entity must report each unique payment rate and the associated volume for the test at each such rate.
- **Appeals resolved during the data collection period**. Include payment rates (and the associated volume of tests) for claims under appeal as applicable information if the final payment amount is determined and paid by the private payor during the data collection period. For example, if a laboratory filed an appeal for a test furnished prior to a data collection period and resolved the appeal so that final payment for the test was made during the data collection period, the final rate paid is considered applicable information.
- **Non-contracted amounts for out-of-network laboratories or services.** Applicable information includes private payor rates for out-of-network laboratories if the private payor made final payment for the laboratory test during the data collection period. Non-contracted amounts paid to laboratories include any patient cost sharing amounts (for example, deductible and coinsurance responsibilities, if applicable).

Exclude these specific private payor claims data from applicable information:

- **Private payor rates for laboratory test codes paid only under the PFS**. If a laboratory test code is not paid under the CLFS and is paid under the PFS, the test code, private payor rate, and the test volume associated with the private payor rate is not applicable information.
- **Price concessions applied by a laboratory**. A laboratory's decision to waive a patient's deductible, copay, and/or coinsurance responsibility for a given test(s) must not be factored into the determination of the private payor rate for a test. Although laboratories may provide concessions to patients, it does not reflect the rates paid by private payors. As noted above, the private payor rate is 100 percent of the private payor's fee schedule amount for the test.
- **Information about denied payments.** When a private payor denies payment for a laboratory test, payments of $0.00 are not considered a private payor rate for purposes of determining applicable information under the new CLFS. In other words,

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when the final determination by the private payor during the data collection period is to deny the claim and therefore does not make a payment, do not report $0.00 for a laboratory test code. Report only the final paid claim amount and the associated volume of tests paid at the final paid claim amount.

- **Unresolved appeals.** Where a laboratory test claim is still under review by the private payor or is under appeal during a data collection period, the amount that has already been paid is not considered a final payment rate and therefore is not considered applicable information. Additionally, if the appeal was settled during the data collection period but final payment was not made by the private payor until after the data collection period, the payment amount cannot be used for a private payor rate and therefore is excluded from applicable information.
- **Payments made on a capitated basis.** Generally, a capitated payment is made for health care services based on a set amount for each enrolled beneficiary in the plan for a given period, regardless of whether the beneficiary receives services during the period covered by the payment. Payment is typically made on a capitated basis under a managed care arrangement. As there is no way to determine payment specifically for a given test, it cannot be reported as applicable information. Therefore, applicable information does not include information about a test for which payment is made on a capitated basis.
- **Payments where the associated test volume cannot be determined.** As discussed above, the associated volume of tests performed corresponding to each private payor rate is a component of the definition of applicable information. Where the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payor's remittance, CMS does not consider those payment amounts as applicable information and you should not report them to CMS.
- **Remittances where the payor has grouped individual HCPCS code payments into an encounter or claim level payment.** When a private payor groups payments for individual HCPCS codes into a single encounter or claim-level payment that is not represented by another HCPCS code, those payments are not applicable information. In other words, if a laboratory bills individual HCPCS codes and the payor bundles the individual HCPCS codes into groups not represented by other HCPCS codes, the payor's bundled payment amount is not considered applicable information.

Note: In general, if a laboratory cannot correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information. Estimated private payor rates and volumes are also not considered applicable information.

Schedule for data collection and reporting

The next data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) is from January 1, 2019, through June 30, 2019. A 6-month review and validation period follows the data collection period and precedes the data reporting period (the period where applicable information must be submitted to CMS).

During the 6-month review and validation period between the end of the data collection period and the beginning of the data reporting period, laboratories and reporting entities should assess whether the applicable laboratory thresholds are met. That is, determine whether each laboratory component of the reporting entity meets the majority of Medicare revenues threshold and low expenditure threshold from final Medicare paid claims received during the data collection period. Applicable laboratories and their reporting entity should also use this time to review and validate applicable information (private payor data) before it is reported to CMS.

The next data reporting period (the period where applicable information for an applicable laboratory is reported to CMS) is from January 1, 2020, through March 31, 2020. CMS will use the next data collection and reporting cycle to determine CLFS payment rates for CY 2021 through CY 2023.

This table illustrates the next data collection and reporting periods for CDLTs.

Data Collection and Reporting Periods for CDLTs

Data Collection Period	Six-Month Review and Validation Period	Data Reporting Period	Used for CLFS Rate Years
1/1/2019 – 6/30/2019	7/1/2019 – 12/31/2019	1/1/2020 – 3/31/2020	2021 – 2023
Continues every third subsequent calendar year	Continues every third subsequent calendar year	Continues every third subsequent calendar year	New CLFS rate every third year

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While reporting is required every 3 years for CDLTs (that are not ADLTs), reporting entities must report applicable information annually for ADLTs, except for ADLTs in an initial data collection period (in which case a reporting entity will report by the end of the second quarter of the new ADLT initial period). We have issued additional information about ADLTs through separate instructions.

Reporting Entity

The TIN-level entity reports applicable information individually for all its laboratory components that are applicable laboratories. As noted above, an applicable laboratory is a CLIA-certified laboratory and, using its billing NPI or the 14x TOB (in the case of a hospital outreach laboratory that bills Medicare Part B under the hospital's NPI), meets the majority of Medicare revenues threshold and low expenditure threshold. Please note that we discuss a condensed data reporting option later in this section.

I. Reporting for an Applicable Laboratory That Bills Medicare Part B Under its Own NPI

This section provides examples of reporting entities reporting applicable information for independent laboratories and physician office laboratories that bill Medicare Part B under their own NPI and hospital outreach laboratories that bill Medicare Part B under their own NPI (separate from the hospital's NPI). The examples below illustrate reporting entities that must report applicable information individually for all NPI-level components that are applicable laboratories:

Example 1: A TIN-level entity consists of five CLIA-certified laboratories. Each laboratory bills using its own unique NPI and all five CLIA-certified laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of five unique applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that is an applicable laboratory (not collectively for all NPIs that are applicable laboratories under the TIN). The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for five applicable laboratories.

Example 2: A TIN-level entity consists of five CLIA-certified laboratories, each billing for services under its own unique NPI. However, only three of the laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold while the remaining two laboratories do not individually meet the low expenditure threshold. In other words, two of the five CLIA-certified laboratories receive less than $12,500 of revenue under the CLFS during the data collection period. This TIN-level entity consists of three unique applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that is an applicable laboratory, but will not report information on the two individual NPIs of the laboratories that are not applicable laboratories. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for three applicable laboratories.

Example 3: A TIN-level entity consists of five CLIA-certified laboratories and each laboratory has the same NPI and bills Medicare Part B under the same NPI. Collectively, the five CLIA-certified laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one applicable laboratory. In this case, the reporting entity reports applicable information for all laboratories associated with the same NPI as a single applicable laboratory. In other words, in this example, CMS considers the five CLIA-certified laboratories as one applicable laboratory for purposes of reporting applicable information because they all have the same NPI and all bill Medicare Part B under the same NPI.

Example 4: A TIN-level entity includes three CLIA-certified hospital outreach laboratories. Each hospital outreach laboratory bills using its own unique NPI (separate from the hospital's NPI) and all three CLIA-certified hospital outreach laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of three applicable laboratories. In this case, the reporting entity reports applicable information associated with each individual NPI that is an applicable laboratory (not collectively for all NPIs that are applicable laboratories under the TIN). The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for three applicable laboratories.

Example 5: A TIN-level entity consists of three CLIA-certified hospital outreach laboratories, each billing for services under its own unique NPI (separate from the hospital's NPI). However, only two of the laboratories individually meet both the majority of Medicare revenues threshold and low expenditure threshold while the remaining laboratory does not individually meet the low expenditure threshold. In other words, one of the three CLIA-certified hospital outreach laboratories receives less than $12,500 in revenues from the CLFS during the data collection period. This TIN-level entity consists of two applicable laboratories. In this case, the reporting entity will report applicable information associated with each individual NPI that is an applicable laboratory, but will not report information on the one individual NPI of the laboratory that is not an applicable laboratory. The reporting entity separates the applicable information by each NPI and submits applicable information during the data reporting period for two applicable laboratories.

Example 6: A TIN-level entity includes three CLIA-certified hospital outreach laboratories and all three laboratories

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have the same unique NPI and bill Medicare Part B under the same unique NPI (separate from the hospital's NPI). Collectively, the three CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one applicable laboratory. In this case, the reporting entity reports applicable information for all three hospital outreach laboratories associated with the same NPI as a single applicable laboratory. In other words, in this example, CMS considers the three CLIA-certified hospital outreach laboratories as one applicable laboratory for purposes of reporting applicable information because they all have the same NPI (separate from the hospital's NPI) and all bill Medicare Part B under the same NPI.

Note: For a hospital outreach laboratory that bills Medicare Part B under its own unique billing NPI (separate from the hospital's NPI), the reporting entity reports applicable information by the hospital outreach laboratory's own unique billing NPI.

II. Reporting for Hospital Outreach Laboratories That Bill Medicare Part B Under the Hospital's NPI

This section provides examples of reporting entities reporting applicable information for hospital outreach laboratories that bill Medicare Part B under the hospital's NPI. The examples below illustrate reporting entities that must report applicable information for hospital outreach laboratories that bill Medicare Part B under the hospital's NPI that are applicable laboratories:

Example 1: A TIN-level entity includes a CLIA-certified hospital outreach laboratory that performs laboratory services for non-hospital patients and bills Medicare Part B using the hospital's NPI. Based on its Medicare revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold and low expenditure threshold and therefore is an applicable laboratory. In this example, the reporting entity reports applicable information for its hospital outreach laboratory that bills Medicare Part B under the hospital's NPI.

Example 2: A TIN-level entity consists of three CLIA-certified hospital outreach laboratories and each laboratory bills Medicare Part B under the hospital's NPI. Collectively, the three CLIA-certified hospital outreach laboratories meet the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of one applicable laboratory. In this example, the reporting entity collectively reports applicable information for its three hospital outreach laboratories that bill Medicare Part B under the hospital's NPI.

Example 3: A TIN-level entity includes three CLIA-certified hospital outreach laboratories. Two (out of the three) hospital outreach laboratories bill for laboratory services performed for non-hospital patients using the hospital's NPI. Collectively, the two CLIA-certified hospital outreach laboratories that bill using the hospital's NPI meet the majority of Medicare revenues threshold and low expenditure threshold. However, one (out of the three) bills Medicare Part B for laboratory services performed for non-hospital patients using its own unique NPI (separate from the hospital's NPI) and meets the majority of Medicare revenues threshold and low expenditure threshold. This TIN-level entity consists of two applicable laboratories.

In this example, the reporting entity reports applicable information for the hospital outreach laboratories that bill Medicare Part B for non-hospital patients under the hospital's NPI separately from the hospital outreach laboratory that bills Medicare Part B under its own unique NPI.

Note: The reporting entity must report applicable information for hospital outreach laboratories that are applicable laboratories based on the NPI used for billing Medicare Part B. That is, for hospital outreach laboratories that bill Medicare Part B under the hospital's NPI, (and therefore determines applicable laboratory status based on its Medicare revenues attributed to the 14x TOB) the reporting entity reports applicable information by the **hospital's NPI**.

Only Applicable Information Attributed to non-Hospital Patients is Reported

As discussed previously in this publication, a CLIA certified hospital outreach laboratory that bills Medicare Part B using the hospital's NPI must determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold based on its Medicare revenues attributed to the Form CMS-1450 14x TOB. If a CLIA-certified hospital outreach laboratory that bills Medicare Part B under the hospital's NPI meets the requirements of an applicable laboratory, only the hospital outreach laboratory component of the hospital laboratory (that is, laboratory tests furnished to non-hospital patients) is considered an applicable laboratory. Therefore, report only applicable information attributed to the laboratory's non-hospital patients to CMS.

The reporting entity for the hospital outreach laboratory that bills Medicare Part B under the hospital's NPI, and therefore determines applicable laboratory status based on Medicare revenues attributed to the 14x TOB, may **not** report applicable information for other parts of a hospital's laboratory business such as testing performed for hospital outpatients or hospital inpatients.

In circumstances in which a private payor does not require a hospital outreach laboratory to use the Form CMS-1450 14x TOB, the hospital must distinguish between private payor fee for service payments (and the associated volume) made for laboratory tests furnished to non-patients (the applicable laboratory) from private payor fee for service payments (and associated test volume) for laboratory tests furnished to hospital patients.

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Even if a private payor's rate is the same for a given laboratory test code in each setting, that is, the outreach laboratory setting for non-patients, outpatient hospital setting for hospital outpatients and the inpatient hospital setting for hospital inpatients, only the *volume* of services for hospital outreach laboratory services (non-hospital patient laboratory testing) is permitted to be reported to CMS.

It is the hospital's responsibility to identify, collect and report the separately payable private payor rates (and the volume of tests paid at those rates) that are associated with only the outreach laboratory portion of the hospital's laboratory business.

Example 1: A private payor does not require the Form CMS-1450 14x TOB for hospital outreach laboratory services. The private payor's final paid claim amount during the data collection period for the HCPCS code of a test is $20 for both hospital outpatients and non-hospital patients. The volume of services paid at $20 for tests furnished to hospital outpatients is 200 and the volume of services paid at $20 for tests furnished to non-hospital patients is 250. In this example, the reporting entity reports the HCPCS code for the test, payment rate $20, volume 250. Do not report the volume associated with tests furnished to hospital patients (200).

Example 2: A private payor does not require the Form CMS-1450 14x TOB for hospital outreach laboratory services. The private payor pays one rate for tests furnished to hospital patients and pays a different rate for testing furnished for non-hospital patients. The private payor's final paid claim amount during the data collection period for the HCPCS code of a test is $20 for hospital outpatients and $18 for non-hospital patients. The volume of services paid at $20 for tests furnished to hospital outpatients is 200 and the volume of services paid at $18 for tests furnished to non-hospital patients is 250. In this example, the reporting entity reports the HCPCS code for the test, payment rate $18 with a volume of 250. Do not report the payment rate for hospital patients of $20 and volume paid at that rate (200).

III. Additional Reporting Instructions That Apply to All Applicable Laboratories

This section provides additional reporting instructions for reporting entities reporting applicable information for its component applicable laboratory(s).

Reporting Entity Must Ensure Accurate Collection and Reporting of Applicable Information

The TIN-level entity along with its applicable laboratory(s) should establish their own approach for ensuring that the TIN-level entity can report applicable information to CMS. To that end, applicable laboratories and their reporting entity should determine the best approach to collect applicable information from final paid claims data and for submitting applicable information to CMS during the data reporting period.

Voluntary Reporting is Not Permitted

The reporting entity reports only applicable information for laboratory components that are applicable laboratories (that is, laboratories that meet the definition of an applicable laboratory). Reporting entities do **not** report applicable information for laboratories that do not meet the definition of an applicable laboratory.

Example 1: A TIN-level entity consists of four NPI-level entities. Three of the NPI-level entities meet the definition of an applicable laboratory, and one NPI-level entity does not meet the definition of an applicable laboratory. In this example, the reporting entity reports applicable information to CMS for **only** the three NPI-level entities that are applicable laboratories.

Example 2: A TIN-level entity includes one hospital outreach laboratory that bills Medicare Part B under the hospital's NPI. Based on revenues attributed to the Form CMS-1450 14x TOB, the hospital outreach laboratory meets the majority of Medicare revenues threshold but does not meet the low expenditure threshold. In other words, the hospital outreach laboratory does not receive at least $12,500 in revenues from the Medicare CLFS during the data collection period. Therefore, the hospital outreach laboratory does not meet the definition of an applicable laboratory. In this example, the reporting entity does **not** report applicable information to CMS for its hospital outreach laboratory.

Reporting Applicable Information is Not Discretionary

Reporting entities must report all applicable information for its laboratory components that are applicable laboratories. Reporting entities do **not** have the discretion to selectively omit reporting certain applicable information.

Example: An applicable laboratory has various final paid claims for laboratory tests from the data collection period that are only in "hard copy" paper format. The reporting entity along with its applicable laboratory perceives that reporting applicable information derived from the paper claims has minimal impact on the final payment rate calculated for the tests. In this case, the reporting entity **cannot** selectively omit reporting applicable information due to the perception that reporting such applicable information may not influence the final weighted median private payor rates for a given test. In this example, the reporting entity must report the applicable information obtained from the "paper-based" claims to CMS during the data reporting period.

IV. Condensed Data Reporting Option

For the next data reporting period, that is January 1, 2020, through March 31, 2020, reporting entities may condense certain applicable information at the TIN-level, instead

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of reporting individually for each component that is an applicable laboratory. You may use the condensed data reporting option when more than one applicable laboratory under the TIN is paid at the same private payor rate for a specific HCPCS code.

For example, if three of the reporting entity's corresponding applicable laboratories are paid the same private payor rate for a specific HCPCS code, the reporting entity may report one record of data showing the HCPCS code, the payment rate, and the associated volume, across all three applicable laboratories, rather than reporting three separate records (that is, one for each component applicable laboratory). In other words, the reporting entity may combine the volume paid at the same private payor rate for the same HCPCS code for its component applicable laboratories.

Under the condensed data reporting option, the reporting entity must select one NPI as the reporting NPI. That is, the reporting entity will designate one applicable laboratory's NPI as the reporting NPI for each instance of condensed reporting. The reporting entity can select any NPI under the TIN that meets the definition of an applicable laboratory and designate that NPI as the reporting NPI for reporting the condensed applicable information.

Note that each unique private payor rate for each laboratory test code must be reported to CMS during the data reporting period. The condensed data reporting option is only permitted when a specific laboratory test code is paid at the same private payor rate to more than one applicable laboratory under the same TIN. Unique private payor rates paid to only one applicable laboratory under the TIN, and the volume paid at such rate(s), must be reported individually by applicable laboratory.

Reporting entities have the option of condensing the volume paid at the same private payor rate for a specific HCPCS code during a data collection period across its components that are applicable laboratories. However, if the reporting entity prefers to report applicable information individually for each of its component applicable laboratories, they may continue to do so.

To illustrate how reporting entities may report condensed applicable information when three different applicable laboratories under the same TIN are paid the same private payor rate for the same laboratory test code during a data collection period, see the comparative examples below. These examples are meant to show the difference between the individual applicable laboratory data reporting method that is, by each component that is an applicable laboratory, and the condensed data reporting method and are not intended to be representative of every possible scenario.

TABLE 1a – Example of Individual Applicable Laboratory Reporting for 2020 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	$15.00	400
2	Lab Test Code (1)	$15.00	300
3	Lab Test Code (1)	$15.00	200

In this example of the individual applicable laboratory data reporting method, three applicable laboratories are paid the same private payor rate for "Lab Test Code 1". Therefore, the reporting entity reports applicable information individually for each of its component applicable laboratories.

TABLE 1b- Example of Condensed Reporting for 2020 Data Submission (TIN-Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	$15.00	900

This example illustrates how the scenario presented in Table **1a** would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN-Level). The reporting entity designates one (of its three component applicable laboratories) as the reporting NPI.

TABLE 2a – Example of Individual Applicable Laboratory Reporting for 2020 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	$15.00	400
1	Lab Test Code (1)	$17.00	100
2	Lab Test Code (1)	$15.00	300
2	Lab Test Code (1)	$17.00	150
3	Lab Test Code (1)	$15.00	200
3	Lab Test Code (1)	$17.00	75

In this example of the individual applicable laboratory data reporting method, three applicable laboratories are paid a private payor rate of $15 for "Lab Test Code 1" and the same three applicable laboratories are also paid

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a private payor rate of $17 for "Lab Test Code 1." In this example, the reporting entity reports each HCPCS code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

TABLE 2b- Example of Condensed Reporting for 2020 Data Submission (TIN-Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	$15.00	900
Designated NPI for Condensed Reporting	Lab Test Code (1)	$17.00	325

This example illustrates how the scenario presented in Table **2a** would be reported under the condensed data reporting method. The reporting entity reports applicable information by combining the volume paid at the same private payor rate for the same HCPCS code at the reporting entity level (TIN-Level). In other words, the private payor rate of $15 and associated volume is combined and the private payor rate of $17.00 and associated volume is combined.

TABLE 3a – Example of Individual Applicable Laboratory Reporting for 2020 Data Submission

NPI	HCPCS Code	Payment Rate	Volume
1	Lab Test Code (1)	$15.00	400
1	Lab Test Code (1)	$17.00	100
1	Lab Test Code (1)	$18.50	50
2	Lab Test Code (1)	$15.00	300
2	Lab Test Code (1)	$17.00	150
2	Lab Test Code (1)	$19.50	40
3	Lab Test Code (1)	$15.00	200
3	Lab Test Code (1)	$17.00	75
3	Lab Test Code (1)	$20.00	30

In this example of the individual applicable laboratory data reporting method, three applicable laboratories are paid a private payor rate of $15 for "Lab Test Code 1" and the same three applicable laboratories are also paid a private payor rate of $17 for "Lab Test Code 1". In addition, one of the three applicable laboratories is paid a private payor rate of $18.50, another applicable laboratory is paid a private payor rate of $19.50, and another applicable laboratory is paid a private payor rate of $20 for "Lab Test Code 1". The reporting entity reports the HCPCS code and each unique private payor rate and the volume paid at each unique private payor rate individually for each of its component applicable laboratories.

TABLE 3b- Example of Condensed Reporting for 2020 Data Submission (TIN-Level)

Reporting NPI	HCPCS Code	Payment Rate	Volume
Designated NPI for Condensed Reporting	Lab Test Code (1)	$15.00	900
1 Designated NPI for Condensed Reporting	Lab Test Code (1)	$17.00	325
1	Lab Test Code (1)	$18.50	50
2	Lab Test Code (1)	$19.50	40
3	Lab Test Code (1)	$20.00	30

This example illustrates how the scenario presented in Table **3a** would be reported under the condensed data reporting method. As discussed previously, the reporting entity must report each unique private payor rate for each specific HCPCS code and the associated volume paid at each such rate. Since some private payor rates are paid to only one applicable laboratory under the TIN, a combination of the condensed data reporting method and individual applicable laboratory reporting is used to report applicable information.

The condensed data reporting method may be used when more than one applicable laboratory under the TIN is paid the same private payor rate for a specific laboratory test code. In this example, the volume among the three applicable laboratories for the private payor rate of $15.00 may be combined and the volume among the three applicable laboratories for the private payor rate of $17.00 may be combined.

However, condensed reporting would **not** be permitted for the unique private payor rates for "Lab Test Code 1" that are paid to only one applicable laboratory under the same TIN. Therefore, the private payor rate of $18.50 paid to "NPI 1"; the private payor rate of $19.50 paid to "NPI 2"; the private payor rate of $20.00 paid to "NPI 3" and the associated volume paid at each of these unique private payor rates must be reported individually for each applicable laboratory.

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Implementation Schedule

This is the schedule for implementing the next private payor rate-based CLFS update:

- Data collection period for determining CY 2021 CLFS payment rates: January 1, 2019, through June 30, 2019.
- Data reporting period for reporting entities to report private payor rate data to CMS for determining CY 2021 CLFS payment rates: January 1, 2020, through March 31, 2020.
- Annual laboratory public meeting for new tests: June/July 2020. CMS will use crosswalking or gapfilling to set rates for new tests and existing tests for which there is no private payor data collected for the CY 2021 CLFS.
- CMS publishes preliminary CLFS rates for CY 2021: Early September 2020. The public will have approximately 30 days, through early October 2020, to submit comments on the preliminary CY 2021 rates.
- CMS makes final CY 2021 CLFS rates available on the CMS website: Early November 2020.
- Implementation date for the next private payor rate-based CLFS update: January 1, 2021.

Additional information

For more information about the private payor rate-based payment system including a summary of the private payor rate-based CLFS, the CLFS final rule, related press release and fact sheet, frequently asked questions on our final policies, a PowerPoint slide presentation of the private payor rate-based CLFS and ADLTs, visit *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html*.

The CLFS final rule entitled Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule (CMS-1621-F) is available at *https://www.gpo.gov/fdsys/pkg/FR-2016-06-23/pdf/2016-14531.pdf*.

The PFS final rule entitled Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019 (CMS-1693-F) is available at *https://www.govinfo.gov/content/pkg/FR-2018-11-23/pdf/2018-24170.pdf*.

If you have questions about requirements for the private payor rate-based CLFS, please email them to the CLFS Inquiries mailbox at *CLFS_Inquiries@cms.hhs.gov*.

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

Document history

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Modification of the MCS claims processing system logic for modifier 59, XE, XS, XP, and XU involving the National Correct Coding Initiative (NCCI) procedure to procedure (PTP) column one and column two codes

Provider type affected

This MLN Matters® Article is for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider action needed

CR11168 informs MACs about changes to National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) edits which consist of column one and column two codes. Make sure that your billing staffs are aware of these changes.

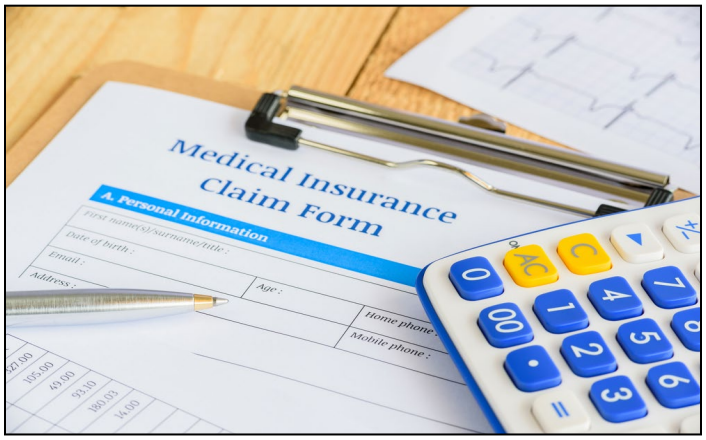
Background

Modifiers 59, XE, XS, XP, and XU are among the NCCI-associated modifiers. The Multi-Carrier System (MCS) currently requires that modifiers 59, XE, XS, XP, or XU be appended to the column two code of a PTP edit to bypass the edit. With the implementation of CR 11168, Medicare will allow modifiers 59, XE, XS, XP, or XU on column one and column two codes to bypass the edit.

Additional information

The official instruction, CR 11168, issued to your MAC regarding this change is available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R2259OTN.pdf*.

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



Document history

Date of change	Description
February 19, 2019	Initial article released.

MLN Matters® Number: MM11168
Related CR Release Date: February 15, 2019
Related CR Transmittal Number: R2259OTN
Related Change Request (CR) Number: 11168
Effective Date: July 1, 2019
Implementation Date: July 1, 2019

Your feedback matters

Your opinion is important to us. If you haven't already completed the MAC Satisfaction Indicator (MSI) survey, please take a moment to complete it now. Share your experience with the services we provide. It will take about 10 minutes. You can access the survey by clicking here.

New Medicare beneficiary identifier (MBI) get it, use it

***Note**: This article was revised on March 6, 2019, to add language that the MBI look-up tool can be used to obtain an MBI even for patients in a Medicare Advantage Plan.All other information remains the same. This information was previously published in the December 2018 Medicare A Connection, pages 10-11.*

Provider type affected

This Special Edition MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment MACs (DME MACs) and Home Health and Hospice MACs, for services provided to Medicare beneficiaries.

Provider action needed

The Centers for Medicare & Medicaid Services (CMS) is mailing the new Medicare cards with the MBI in phases by *geographic location*. Here are 3 ways you and your office staff can get MBIs:

1. Ask your Medicare patients

Ask your Medicare patients for their new Medicare card when they come for care. If they haven't received a new card at the completion of their geographic mailing wave, give them the "Still Waiting for Your New Card?" handout (in *English* or *Spanish*) or refer them to 1-800-Medicare (1-800-633-4227).

2. Use the MAC's secure MBI look-up tool

You can look up MBIs for your Medicare patients when they don't or can't give them. *Sign up* for the Portal to use the tool. You can use this tool even after the end of the transition period – it doesn't end on December 31, 2019. Even if your patient is in a Medicare Advantage Plan, you can look up the MBI to bill for things like indirect medical education.

Your patient's Social Security Number (SSN) is required for the search and may differ from their Health Insurance Claim Number (HICN), which uses the SSN of the primary wage earner. If your Medicare patients do not want to give their SSN, they can log into *mymedicare.gov* to get their MBI.

If the look-up tool returns a last name matching error and the beneficiary last name includes a suffix, such as Jr. Sr. or III, try searching without and with the suffix as part of the last name.

3. Check the remittance advice

Starting in October 2018 through the end of the transition period, we'll also return the MBI on every remittance advice when you submit claims with valid and active HICNs.

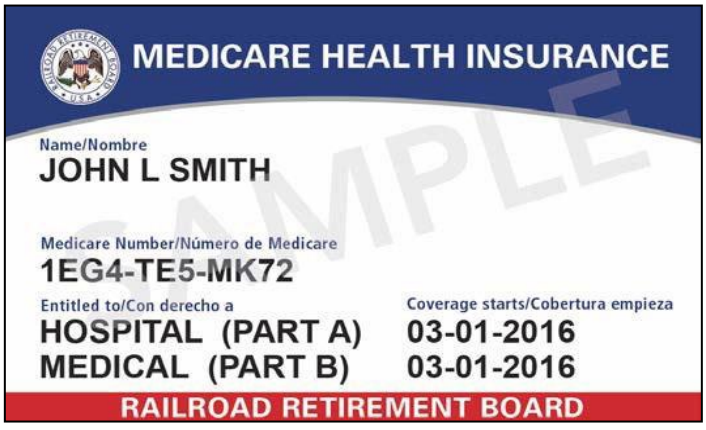
You can start using the MBIs even if the other health care providers and hospitals who also treat your patients haven't. When the transition period ends on December 31, 2019, you must use the MBI for most transactions.

Background

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to remove Social Security Numbers from all Medicare cards by April 2019. A new, randomly generated Medicare Beneficiary Identifier, or MBI, is replacing the SSN-based HICN. The new MBI is noticeably different than the HICN. **Just like with the HICN, the MBI hyphens on the card are for illustration purposes: don't include the hyphens or spaces on transactions.** The MBI uses numbers 0-9 and all uppercase letters except for S, L, O, I, B, and Z. We exclude these letters to avoid confusion when differentiating some letters and numbers **(e.g., between "0" and "O").**

The Railroad Retirement Board (RRB) is also mailing new Medicare cards with the MBI. The RRB logo will be in the upper left corner and "Railroad Retirement Board" at the bottom, but you can't tell from looking at the MBI if your patients are eligible for Medicare because they're railroad retirees. You'll be able to identify them by the RRB logo on their card, and we'll return a "Railroad Retirement Medicare Beneficiary" message on the Fee-For-Service (FFS) MBI eligibility transaction response.

RRB issued Medicare card



Use the MBI the same way you use the HICN today.

See **MEDICARE**, page 20

MEDICARE

from page 19

Put the MBI in the same field where you've always put the HICN. This also applies to reporting informational only and no-pay claims. **Don't use hyphens or spaces with the MBI to avoid rejection of your claim.** The MBI will replace the HICN on Medicare transactions including Billing, Eligibility Status, and Claim Status. The effective date of the MBI, like the old HICN, is the date each beneficiary was or is eligible for Medicare. Until December 31, 2019, you can use either the HICN or the MBI in the same field where you've always put the HICN. After that the remittance advice will tell you if we rejected claims because the MBI wasn't used. It will include Claim Adjustment Reason Code (CARC) 16, "Claim/service lacks information or has submission/billing error(s)." along with Remittance Advice Remark Code (RARC) N382 "Missing/ incomplete/invalid patient identifier".

The beneficiary or their authorized representative can request an MBI change. CMS can also initiate a change to an MBI. An example is if the MBI is compromised. There are different scenarios for using the old or new MBIs:

FFS claims submissions with:

- Dates of service before the MBI change date – use the old or new MBI.
- Span-date claims with a "From Date" before the MBI change date – use the old or new MBI.
- Dates of service that are entirely on or after the effective date of the MBI change – use the new MBI.

FFS eligibility transactions when the:

- Inquiry uses new MBI – we'll return all eligibility data.
- Inquiry uses the old MBI and request date or date range overlap the active period for the old MBI – we'll return all eligibility data. We'll also return the old MBI termination date.
- Inquiry uses the old MBI and request date or date range are entirely on or after the effective date of the new MBI – we'll return an error code (AAA 72) of "invalid member ID."

When the MBI changes, we ask the beneficiary to share the new MBI with you. You can also get the MBI from your MACs secure MBI lookup tool.

Protect the MBI as personally identifiable information (PII); it is confidential like the HICN.

Submit all HICN-based claims by the end of the transition period, December 31, 2019. On January 1, 2020, even for dates of services before this date, you must use MBIs for all transactions; there are a few exceptions when you can use either the HICN or MBI:

- **Appeals** – You can use either the HICN or MBI for claim appeals and related forms.
- **Claim status query** – You can use HICNs or MBIs to check the status of a claim (276transactions) if the earliest date of service on the claim is before January 1, 2020. If you are checking the status of a claim with a date of service on or after January 1, 2020, you must use the MBI.
- **Span-date claims** – You can use the HICN or the MBI for 11x-inpatient hospital, 32x-home health (home health claims and request for anticipated payments [RAPs]) and 41x-religious non-medical health care institution claims if the "From Date" is before the end of the transition period (December 31, 2019). If a patient starts getting services in an inpatient hospital, home health, or religious non-medical health care institution before December 31, 2019, but stops getting those services after December 31, 2019, you may submit a claim using either the HICN or the MBI, even if you submit it after December 31, 2019. Since you submit home health claims for a 60-day payment episode, you can send in the episode's RAP with either the HICN or the MBI, but after the transition period ends on December 31, 2019, you have to use the MBI when you send in the final claim that goes with it.

The MBI does not change Medicare benefits. Medicare beneficiaries may start using their new Medicare cards and MBIs as soon as they get them. Use MBIs as soon as your patients share them. The new cards are effective the date beneficiaries are eligible for Medicare.

Medicare advantage and prescription drug plans continue to assign and use their own identifiers on their health insurance cards. For patients in these plans, continue to ask for and use the plans' health insurance cards.

Additional information

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

To sign up for your MAC's secure portal MBI look-up tool, visit *https://www.cms.gov/Medicare/New-Medicare-Card/Providers/MACs-Provider-Portals-by-State.pdf*.

The MBI format specifications, which provide more details on the construct of the MBI, are available at *https://www.cms.gov/Medicare/New-Medicare-Card/Understanding-the-MBI.pdf*.

A fact sheet discussing the transition to the MBI and the new cards is available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TransitiontoNewMedicareNumbersandCards-909365.pdf*.

See **MEDICARE**, page 21

MEDICARE

from page 20

Document history

Date of change	Description
March 6, 2019	We revised this article to add language that the MBI look-up tool can be used to obtain an MBI even for patients in a Medicare Advantage Plan. All other information remains the same.
December 10, 2018	The article was revised to update the language regarding when MACs can return an MBI through the MBI look up tool (page 1). All other information remains the same.
July 11, 2018	This article was revised to provide additional information regarding the format of the MBI not using letters S, L, O, I, B, and Z (page 2).
June 25, 2018	This article was revised to provide additional information regarding the ways your staff can get MBIs (*Provider action needed* section).
June 21, 2018	The article was revised to emphasize the need to submit the MBI without hyphens or spaces to avoid rejection of your claim. All other information remains the same.
May 25, 2018	Initial article released.

MLN Matters® Number: SE18006 *Revised*
Related CR Release Date: March 6, 2019
Related CR Transmittal Number: N/A
Related Change Request (CR) Number: N/A
Effective Date: N/A
Implementation N/A

Disclaimer: This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT® only copyright 2017 American Medical Association.

CMS National Provider Compliance Conference

Tuesday, May 7, 8 a.m.-5:30 p.m. MT and Wednesday, May 8, 8 a.m.-1 p.m. MT

Location: Sheraton Denver Downtown Hotel, Denver, CO

Registration is now open for the CMS National Provider Compliance Conference at the Sheraton Denver Downtown Hotel.

Join us for this inaugural conference, featuring expert presentations on Medicare Fee-for-Service (FFS) claims. Don't miss out on this unique learning and networking opportunity for anyone who processes Medicare Part A and Part B, Home Health and Hospice, and Durable Medical Equipment (DME) claims.

This is an in-person event only and limited spots are available. *Register today*.

Processing Issues

Claim rejections associated with reference lab and anti-markup payment limitations

Issue

The Centers for Medicare & Medicaid Services (CMS) has notified Medicare administrative contractors (MACs) of an issue concerning invalid rejections of some laboratory service claims associated with reference lab and anti-markup payment limitation services.

Resolution

CMS has instructed MACs to disable edits associated with these services effective March 12, 2019. MACs shall also adjust claims when brought to their attention.

Status/date resolved

Open.

Provider action

Providers and suppliers who have claims that rejected in error for this editing may resubmit their previously returned claims after March 12.

Current processing issues

Here is a link to a table of *current processing issues* for both Part A and Part B.

Mohs surgery with no separate excision

Issue

A system edit erroneously excluded covered diagnosis codes for Mohs surgery with no separate excision.

Resolution

Medicare administrative contractors (MACs) will adjust affected claims.

Status/date resolved

Open. Adjustments will begin no later than March 29, 2019.

Provider action

None.

Current processing issues

Here is a link to a table of *current processing issues* for both Part A and Part B.

Keep updated...

Use the tools and useful information found on *medicare.fcso.com* to stay updated on changes associated with the Medicare program.

This section of *Medicare B 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

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.

Find out first: Subscribe to First Coast *eNews*

Subscribe to First Coast Service Options *eNews*, to learn the latest Medicare news and critical program changes affecting the provider community. Join as many lists as you wish, in English or Spanish, and customize your subscription to fit your specific needs, line of business, specialty, or topics of interest. So, *subscribe to eNews, and stay informed.*

Revisions to LCDs

Revisions to sections of multiple Part B LCDs

LCD ID number: L33833 and L37800 (Florida, Puerto Rico/U.S. Virgin Islands)

Based on change request (CR) 10951, the following local coverage determinations (LCDs) were revised to update the internet only manual (IOM) citations in the "Centers for Medicare & Medicaid Services (CMS) National Coverage Policy" section of the LCDs to be consistent with the IOM publications.

L33833 – surgical treatment of nails

L37800 – allergen immunotherapy

In addition, based on CR 10901, the "CMS National Coverage Policy", "Limitations", and "Provider Qualifications" sections of the allergen immunotherapy LCD were revised to update the section number for Publication 100-08, Chapter 13 from Section 13.5.1 to Section 13.5.4.

Effective date

The revisions to the LCDs related to CR 10951 are effective for claims processed **on or after February 19, 2019**, for services rendered **on or after December 11, 2018.** The revision to the LCD 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*.

Intravenous immune globulin -- revision to the Part A and Part B LCD

LCD ID number: L34007 (Florida, Puerto Rico/ U.S. Virgin Islands)

Based on reconsideration requests of the local coverage determination (LCD) for intravenous immune globulin, the LCD was revised to update the "Coverage Indications, Limitations, and/or Medical Necessity" and "Utilization Guidelines" sections of the LCD to include the Food and Drug Administration (FDA) and off label dosage recommendation indications.

Effective date

This LCD revision is effective for services rendered **on or after February 19, 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*.

Where do I find...

Looking for something specific and don't know where to find it? Find out how to perform routine tasks or locate information that visitors frequently visit our site to accomplish or find. Check out the "Where do I find" page.

Revisions to multiple Part A and Part B LCDs

LCD ID number: L37398, L37697, L36504, L37561, L33751 and L37166 (Florida, Puerto Rico/U.S. Virgin Islands)

Based on change request (CR) 10951 the following local coverage determinations (LCDs) were revised to update the internet only manual (IOM) citations in the "Centers for Medicare & Medicaid Services (CMS) National Coverage Policy" section of the LCDs to be consistent with the CMS IOM Publications.

L37398 - Electroretinography (ERG)

L37697 - Emergency and Non-Emergency Ground Ambulance Services

L36504 - Hyperbaric Oxygen (HBO) Therapy

L37561 - Cystatin C Measurement

L33751 - Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI)

L37166 - Wound Care

In addition, based on CR 10901, the "Utilization Guidelines" and "Limitations" sections of the following LCDs were revised to update the section number for Publication 100-08, Chapter 13 from Section 13.5.1 to Section 13.5.4 and add this IOM publication to the "CMS National Coverage Policy" section of the LCD.

L36504 - Hyperbaric Oxygen (HBO) Therapy

L37561 - Cystatin C Measurement

L37166 - Wound Care

Effective date

The revisions to the LCDs related to CR 10951 are effective for claims processed **on or after February 19, 2019**, for services rendered **on or after December 11, 2018.** The revisions to the LCDs related to CR 10901 are 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*.

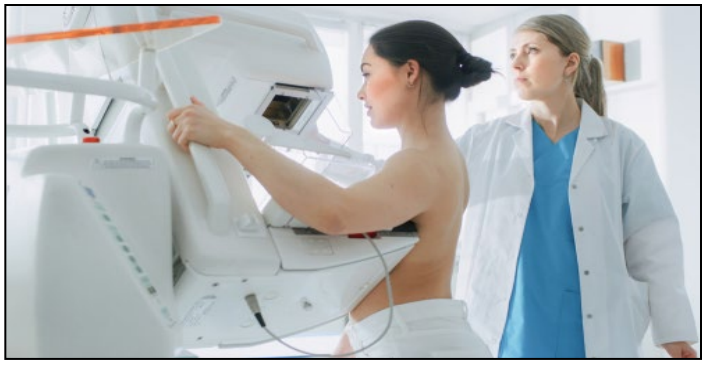
Screening and diagnostic mammography -- revision to the Part A and Part B LCD

LCD ID number: L36342 (Florida, Puerto Rico/ U.S. Virgin Islands)

Based on change request (CR) 11005 (International Classification of Diseases, 10th Revision [ICD-10] and Other Coding Revisions to National Coverage Determinations [NCDs]), the screening and diagnostic mammography local coverage determination (LCD) was updated to add ICD-10-CM diagnosis codes N63.10 and N63.20 to the "ICD-10 Codes that Support Medical Necessity" section of the LCD for procedure codes 77065, 77066, and G0279.

Effective date

This LCD revision is effective for claims processed **on or after April 1, 2019**, for services rendered **on or after October 1, 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*.

Upcoming provider outreach and educational events

Gaining access to SPOT

Date: Wednesday, April 10
Time: 11:30 a.m. - 1:30 p.m. ET
Type of Event: Webcast

https://medicare.fcso.com/Events/0428397.asp

Medicare Speaks 2019: Keeping you updated and informed

Date: Wednesday, April 24
Time: 9:00 a.m. - noon ET
Type of Event: Face-to-face

https://medicare.fcso.com/Events/0428397.asp

Date: Thursday, April 25
Time: 9:00 a.m. - noon ET
Type of Event: Face-to-face

https://medicare.fcso.com/Events/0430789.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, *https://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 the 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.

CMS MLN Connects®

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 February 21, 2019

MLN Connects® for February 21, 2019

View this edition as a PDF

News & Announcements

- CMS: Beyond the Policy — New Podcast
- CAR T-cell Therapy: CMS Proposes Coverage with Evidence Development
- SNF Provider Preview Reports: Review Your Data by March 4
- IRF-PAI Clinical Help Desk: New Address for Questions
- SNF PPS Patient Driven Payment Model: Updated Resources
- Promoting Interoperability Program: 2019 Resources
- Hospital Quality Reporting: Updated QRDA I Schematron

Provider Compliance

- Payment for Outpatient Services Provided to Beneficiaries Who Are Inpatients of Other Facilities — Reminder

Upcoming Events

- MIPS: 2019 QCDR Measure Development and Review Webinar Series — February 28 and March 5
- Home Health Quality Reporting Program In-Person Training — March 5 and 6
- Dementia Care & Psychotropic Medication Tracking Tool Call — March 12
- Open Payments: Transparency and You Call — March 13
- SNF Value-Based Purchasing Program: Phase One Review and Corrections Call — March 20

Medicare Learning Network Publications & Multimedia

- New HHAs Placed in a Provisional Period of Enhanced Oversight MLN Matters Article — New
- Quality Payment Program: 2017 MIPS Performance Feedback Web-Based Training Course — New
- Appeals Call: Audio Recording and Transcript — New
- LCDs MLN Matters Article — Revised
- How to Use the Medicare National Correct Coding Initiative Tools Booklet — Revised
- How to Use the Medicare Coverage Database Booklet — Revised
- Advance Care Planning Fact Sheet — Reminder

Medicare Learning Network®

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*.

MLN Connects® for February 28, 2019

MLN Connects® for February 28, 2019

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News & Announcements

- Interoperability and Patient Access to Health Data: New Proposals
- Opioid Prescribing Mapping Tool Improved with Medicaid and Rural Data
- Hospice Compare Refresh
- Data on Geographic Variation in the Medicare Program
- 2017 CMS Program Statistics
- Quality Payment Program: Payment Adjustment Resource
- Choosing a Primary Clinician in MyMedicare.gov: New Video for Your Patients

Provider Compliance

- Laboratory Blood Counts: Provider Compliance Tips — Reminder

Upcoming Events

- Interoperability and Patient Access Proposed Rule Listening Session — March 5
- Dementia Care & Psychotropic Medication Tracking Tool Call — March 12
- Open Payments: Transparency and You Call — March 13
- SNF Value-Based Purchasing Program: Phase One Review and Corrections Call — March 20
- Submitting Your Medicare Part A Cost Report Electronically Webcast — March 28

Medicare Learning Network Publications & Multimedia

- HPTCs Code Set: April 2019 Update MLN Matters Article — New
- DMEPOS Fee Schedule: April 2019 Update MLN Matters Article — New
- NCCI: Modification of MCS Logic for Modifiers Involving PTP MLN Matters Article — New
- Home Health PDGM MLN Matters Article — Revised
- Organ Acquisition Charges Not Included in IPPS Payment MLN Matters Article — Revised
- Medical Documentation: Exchanging the List of eMDR via esMD MLN Matters Article — Revised
- How to Use the Medicare Coverage Database Booklet — Revised
- SNF Billing Reference Booklet — Revised
- Clinical Laboratory Fee Schedule Fact Sheet — Revised

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MLN Connects® for March 7, 2019

MLN Connects® for March 7, 2019

View this edition as a PDF

News & Announcements

- Reducing Opioid Misuse Letter
- New Medicare Card: Need an MBI?
- CMS Improving Nursing Home Compare in April
- Comparing Hospital Quality: CMS Updates Consumer Resources
- Promoting Interoperability Programs: Attestation Deadline Extended to March 14
- CY 2018 eCQM Data: Submission Deadline Extended to March 14
- Hospice Provider Preview Reports: Review Your Data by March 31
- LTCH Provider Preview Reports: Review Your Data by April 3
- IRF Provider Preview Reports: Review Your Data by April 3
- Interoperability and Patient Access to Health Data: Comments on New Proposals due May 3
- Clinical Diagnostic Laboratories: New Resources about the Private Payor Rate-Based CLFS
- SNF Provider Threshold Report
- 2019 QRDA I Voc.xml File
- Whole Hospital Approach to Mass Casualties
- Medicare Beneficiaries at a Glance Infographic
- Help Your Patients Make Informed Food Choice

Provider Compliance

- Bill Correctly for Device Replacement Procedures — Reminder

Claims, Pricers & Codes

- Laboratory Panel Billing Requirements
- Average Sales Price Files: April 2019
- Medicare Diabetes Prevention Program: Valid Claims

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MLN Connects® for March 14, 2019

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News

- New Medicare Card: 67% of Claims Submitted with MBI
- DMEPOS Competitive Bidding: Get ready for Round 2021
- Protecting the Health and Safety of all Americans
- LTCH Compare Refresh
- IRF Compare Refresh
- March is National Colorectal Cancer Awareness Month

Compliance

- Hospital Beds and Accessories: Provider Compliance Tips

Events

- Data Interoperability across the Continuum: CMS Data Element Library Call — March 19
- SNF Value-Based Purchasing Program: Phase One Review and Corrections Call — March 20
- Submitting Your Medicare Part A Cost Report Electronically Webcast — March 28

MLN Matters® Articles

- New MBI: Get It, Use It — Revised
- NGACO Model Post Discharge Home Visit HCPCS — Revised

Publications

- PECOS FAQs — Revised
- PECOS Technical Assistance Contact Information — Revised

Multimedia

- Quality Payment Program: 2017 MIPS Performance Feedback Web-Based Training Course

MLN

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Upcoming Events

- Dementia Care & Psychotropic Medication Tracking Tool Call — March 12
- Open Payments: Transparency and You Call — March 13
- Data Interoperability across the Continuum: CMS Data Element Library Call — March 19
- SNF Value-Based Purchasing Program: Phase One Review and Corrections Call — March 20
- Submitting Your Medicare Part A Cost Report Electronically Webcast — March 28

Medicare Learning Network Publications & Multimedia

- CLFS: Collecting and Reporting Data for the Private Payor Rate-Based Payment System MLN Matters Article — New
- CLIA Edits: HCPCS Codes Subject to and Excluded MLN Matters Article — New
- Home Health Call: Audio Recording and Transcript — New
- E/M When Performed with Superficial Radiation Treatment MLN Matters Article — Revised
- Implantable Defibrillators: NCD 20.4 MLN Matters Article — Revised
- RA Messaging: 20-Hour Weekly Minimum for PHP Services MLN Matters Article — Revised
- AWV, IPPE, and Routine Physical – Know the Differences Educational Tool — Reminder
- Diabetes Self-Management Training Accrediting Organizations Fact Sheet — Reminder
- Diagnosis Coding: Using the ICD-10-CM Web-Based Training Course — Reminder
- Dual Eligible Beneficiaries under Medicare and Medicaid Booklet — Reminder
- Procedure Coding: Using the ICD-10-PCS Web-Based Training — Reminder

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Jacksonville, FL 32231-0019

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P.O. Box 2360
Jacksonville, FL 32231-0018

Redetermination of overpayments
Overpayment Redetermination, Review Request
P.O Box 45248
Jacksonville, FL 32232-5248

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Redeterminations

Medicare Part B Redetermination
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Jacksonville, FL 32232-5024

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Medicare EDI, 4C
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Jacksonville, FL 32231-4071

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Jacksonville, FL 32232-5056

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Jacksonville, FL 32232-5300

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