Medicare B CONNECTION

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FIRST COAST SERVICE OPTIONS, INC.

A Newsletter for MAC Jurisdiction N Providers

January 2020

In this issue

Provider enrollment application fee amount for CY 2020

On November 12, the Centers for Medicare & Medicaid Services (CMS) issued a notice:

Provider Enrollment Application Fee Amount for Calendar Year 2020 [CMS–6089–N *https://go.usa.gov/xppFM*].

Effective January 1, 2020, the application fee is $595 for institutional providers that are:

- Initially enrolling in the Medicare or Medicaid program or the Children's Health Insurance Program (CHIP);
- Revalidating their Medicare, Medicaid, or CHIP enrollment; or
- Adding a new Medicare practice location.

This fee is required with any enrollment application submitted from January 1 through December 31, 2020.

2020 Medicare Part B Participating Physician and Supplier Directory available after January 30

The Medicare Part B Particpating Physician and Supplier Directory (MEDPARD) conatins names, addresses, telephone numbers, and specialties of physicians and suppliers who have agreed to participate in accepting assignment on all medicare Part B claims for covered items and services. the MEDPARD listing will be available no later than January 30 on the First Coast Medicare provider website at *https://medicare.fcso.com/MEDPARD/*.

Source: Pub 100-04, Transmittal 4455, CR 11493

Contents

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.

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*. 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*.

Reproducible copies of Form CMS-R-131 ABNs (in English and Spanish) and other BNI information may be found *here*.

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.

Medicare Fee-for-Service (FFS) Response to the 2020 Commonwealth of Puerto Rico Earthquakes

Provider type affected

This MLN Matters® Special Edition Article is for providers and suppliers who bill Medicare Fee-For-Service (FFS).

Provider information available

The Secretary of the Department of Health & Human Services declared a Public Health Emergency (PHE) in the Commonwealth of Puerto Rico on January 8, 2020, and authorized waivers and modifications under Section 1135 of the Social Security Act (the Act), retroactive to December 28, 2019, and are in effect for 90 days.

The Centers for Medicare & Medicaid Services (CMS) is issuing blanket waivers consistent with those issued for past PHE declarations. These waivers prevent gaps in access to care for beneficiaries impacted by the disaster/emergency. You do not need to apply for an individual waiver if a blanket waiver is issued.

More Information:

- *Current Emergencies* webpage
- *Instructions* to request an individual waiver if there is no blanket waiver

Background

Section 1135 and Section 1812(f) Waivers

As a result of this PHE, apply the following to claims for which Medicare payment is based on a "formal waiver" including, but not limited to, Section 1135 or Section 1812(f) of the Act:

1. The "DR" (disaster related) condition code for institutional billing, i.e., claims submitted using the ASC X12 837 institutional claims format or paper Form CMS-1450.
2. The "CR" (catastrophe/disaster related) modifier for Part B billing, both institutional and non-institutional, i.e., claims submitted using the ASC X12 837 professional claim format or paper Form CMS-1500 or, for pharmacies, in the NCPDP format.

Medicare FFS Questions & Answers (Q&As) available on the *Waivers and Flexibilities webpage* apply to items and services for Medicare beneficiaries in the current disaster or emergency. These Q&As are displayed in two files:

- Q&As that apply *without any Section 1135* or other formal waiver.
- Q&As apply only *with a Section 1135* waiver or, when applicable, a Section 1812(f) waiver.

Blanket Waivers Issued by CMS

You do not need to apply for the following approved blanket waivers:

Skilled Nursing Facilities (SNFs)

- Section 1812(f): This waiver of the requirement for a 3-day prior hospitalization for coverage of a SNF stay provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who are evacuated, transferred, or otherwise dislocated as a result of the effect of disaster or emergency. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start anew benefit period (Blanket waiver for all impacted facilities)
- 42 CFR 483.20: This waiver provides relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission (Blanket waiver for all impacted facilities).

Home Health Agencies

- 42 CFR 484.20(c)(1): This waiver provides relief to Home Health Agencies on the timeframes related to OASIS Transmission (Blanket waiver for all impacted agencies).
- To ensure the correct processing of home health disaster related claims, Medicare Administrative Contractors (MACs) are allowed to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs).

Critical Access Hospitals

This action waives the requirements that Critical Access Hospitals limit the number of beds to 25, and that the length of stay be limited to 96 hours. (Blanket waiver for all impacted hospitals)

Housing Acute Care Patients In Excluded Distinct Part Units

CMS has determined it is appropriate to issue a blanket waiver to inpatient prospective payment system (IPPS) hospitals that, as a result of disaster or emergency, need to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatient. The IPPS hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency. (Blanket waiver for all IPPS hospitals located in the affected areas that need to use distinct part beds for acute care patients.)

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Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital

CMS has determined it is appropriate to issue a blanket waiver to IPPS and other acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit. The hospital should continue to bill for inpatient psychiatric services under the inpatient psychiatric facility prospective payment system for such patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.

Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital

CMS has determined it is appropriate to issue a blanket waiver to IPPS and other acute care hospitals with excluded distinct part inpatient rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit. The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for such patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients, and such patients continue to receive intensive rehabilitation services.

Emergency Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for Medicare Beneficiaries Impacted by an Emergency or Disaster

CMS has determined it is appropriate to issue a blanket waiver where Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) is lost, destroyed, irreparably damaged, or otherwise rendered unusable, contractors have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable as a result of the disaster or emergency. For more information refer to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies for Medicare Beneficiaries Impacted by an Emergency or Disaster fact sheet at https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Emergency-DME-Beneficiaries-Hurricanes.pdf.

Extension for Inpatient Prospective Payment System (IPPS) Wage Index Revisions

Allows Hospital Wage Index Development Time Table for hospitals in a disaster or emergency area to request revisions to and provide documentation for their Worksheet S-3 wage data and occupational mix data as included in the preliminary Public Use Files (PUFs), respectively.

CMS has granted an extension for hospitals in the affected area. MACs must receive the revision requests and supporting documentation on or before March 2, 2020. If hospitals encounter difficulty meeting this extended deadline date, hospitals should communicate their concerns to CMS via their MAC, and CMS may consider an additional extension if CMS determines it is warranted.

Medicare Advantage Plan or other Medicare Health Plan Beneficiaries

CMS reminds suppliers that Medicare beneficiaries enrolled in a Medicare Advantage or other Medicare Health Plans should contact their plan directly to find out how it replaces DMEPOS damaged or lost in an emergency or disaster. Beneficiaries who do not have their plan's contact information can contact 1-800-MEDICARE (1-800-633-4227) for assistance.

Replacement Prescription Fills

Medicare payment may be permitted for replacement prescription fills (for a quantity up to the amount originally dispensed) of covered Part B drugs in circumstances where dispensed medication has been lost or otherwise rendered unusable by damage due to the disaster or emergency.

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Additional information

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

The Centers for Disease Control and Prevention released *ICD-10-CM coding advice* to report healthcare encounters in the hurricane aftermath.

Providers may also want to review the CMS Emergency and Preparedness web page at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/EPRO-Home.html*.

Providers may also want to view the *Survey and Certification Frequently Asked Questions* at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html*.

Document history

Date of change	Description
January 10, 2020	Initial article released.

MLN Matters® Number: SE20003
Related CR Release Date: January 10, 2020
Related CR Transmittal Number: N/A
Related Change Request (CR) Number: N/A
Effective Date: N/A
Implementation N/A

New Medicare Beneficiary Identifier (MBI) Get it, Use it

***Note**: We reissued this article on January 2, 2020, to update certain language to show the use of the MBI is fully implemented. This information was previously published in the September 2019 Medicare B Connection, pages 13-15.*

Provider type affected

This Special Edition MLN Matters® Article is 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

Use MBIs for all Medicare transactions. The Centers for Medicare & Medicaid Services (CMS) replaced the Social Security Number (SSN)-based Health Insurance Claim Numbers (HICNs) with the MBI and mailed new Medicare cards to all Medicare beneficiaries. The cards with MBIs offer better identity protection.

With a few exceptions, Medicare will reject claims you submit with Health Insurance Claim Numbers (HICNs). Medicare will reject all eligibility transactions you submit with HICNs.

There are 3 ways you and your office staff can get MBIs:

1. Ask your Medicare patients

Ask your Medicare patients for their new Medicare cards when they come for care. If they don't bring it with them when they come for care, give them the Get Your New Medicare Card flyer in *English* or *Spanish*.

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. Even if your patients are in a Medicare Advantage Plan, you can look up their MBIs to bill for things like indirect medical education.

You must have your patient's SSN for the search and it may differ from the HICN, which uses the SSN of the primary wage earner. If your Medicare patient doesn't want to give the SSN, tell your patient to log into *mymedicare.gov* to get the MBI.

If the look-up tool returns a last name matching error and the beneficiary's 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

If you previously saw a patient and got a claim payment decision based on a claim submission with a HICN before January 1, 2020, look at that remittance advice. We returned the MBI on every remittance advice when a provider submitted a claim with a valid and active HICN from October 1, 2018 through December 31, 2019.

Background

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) required CMS to remove SSNs from all Medicare cards. CMS replaced the SSN-based HICN with a new, randomly generated MBI. **The new MBI hyphens on the card are for illustration purposes: don't include the hyphens or spaces on transactions.** The MBI

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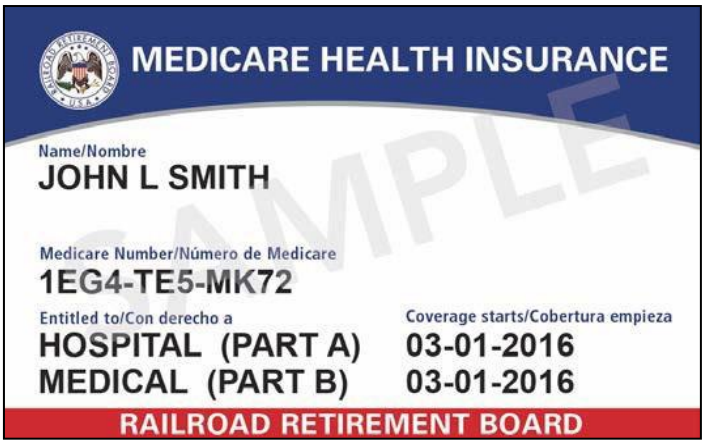
uses numbers 0-9 and all uppercase letters except for S, L, O, I, B, and Z. We exclude these letters to avoid confusion when differentiating some letters and numbers **(for example, between "0" and "O").** Review the *MBI specifications format*.

The Railroad Retirement Board (RRB) also mailed Medicare cards with MBIs. There is a RRB logo in the upper left corner and "Railroad Retirement Board" at the bottom, but you can't tell from looking at the MBI if your patient is eligible for Medicare because they're a railroad retiree. You can identify them by the RRB logo on their card, and we 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 used 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.** Use the MBI on Medicare transactions including Billing, Eligibility Status, and Claim Status. The effective date of the MBI is the date each beneficiary was or is eligible for Medicare. If you don't use the MBI, we will reject claims, with few exceptions. You will get:

- Electronic claims- Reject codes: Claims Status Category Code of A7 (acknowledgment rejected for invalid information), a Claims Status Code of 164 (entity's contract/member number), and an Entity Code of IL (subscriber)
- Paper claims- paper notice; Claim Adjustment Reason Code (CARC) 16 "Claim/service lacks information or has submission/billing error(s)" and 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 change an MBI. An example is if the MBI is compromised. It's possible for your patient to seek care before getting a new card with the new MBI:

If you get a HETS eligibility transaction error code (AAA 72) of "invalid member ID," your patient's MBI may have changed. There are different scenarios for using the old or new MBIs:

FFS claims submissions with:

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

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 MAC's secure MBI lookup tool.

Exceptions

You MUST submit claims using MBIs, no matter what date you performed the service, with a few exceptions:

- Appeals – You can use either HICNs or MBIs for claim appeals and related forms.
- Claim status query – You can use the HICN or MBI to check the status of a claim (276 transactions) 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.

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- Span-date claims – You can use HICNs or MBIs for 11X-Inpatient Hospital, 32X- Home Health (home health final 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, you may submit a claim using either the HICN or the MBI, even if you submit it after December 31, 2019.

Medicare crossover claims

Medicare's Coordination of Benefits Agreement (COBA) trading partners (supplemental insurers, Medigap plans, Medicaid, etc.) must submit the MBI to get Medicare crossover claims. *Exceptions* on use of HICN on outbound Medicare crossover claims will apply.

Remember:

The MBI doesn't change Medicare benefits. **Protect the MBI as Personally Identifiable Information (PII); it is confidential like the HICN**.

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*.

Document history

Date of change	Description
January 2, 2020	We reissued the article to update certain language to show the use of the MBI is fully implemented.
August 19, 2019	We reissued this article to show that all new Medicare cards have been mailed, to encourage providers to use MBIs now to protect patients' identities, to emphasize that providers must use MBIs beginning January 1, 2020, and to explain the rejection codes providers will get if they submit a HICN after January 1, 2020.
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.

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Laboratory/Pathology

Medicare Part B Clinical Laboratory Fee Schedule: Revised Information for Laboratories on Collecting and Reporting Data for the Private Payor Rate-Based Payment System

***Note**: We revised this article on January 8, 2020, to note that for CDLTs that are not ADLTs, the data reporting is delayed by one year and must now be reported from January 1, 2021 through March 31, 2021 (previously January 1, 2020 through March 31, 2020). All references to the 2020 data reporting period have been changed to 2021. We added the "CLFS Data Reporting Period Delayed" Section on page 24 to summarize the changes. All other information remains the same. This information was previously published in the September 2019 Medicare B Connection, pages 18-30.*

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 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, (previously 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.

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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.

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 <u>not</u> 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.

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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:

Medicare CLFS revenues (for billing NPI) + Medicare PFS revenues (for billing NPI)

_____ is >50%

Total Medicare revenues (for billing NPI)

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 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

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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 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

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- 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:

$$\frac{\text{Medicare CLFS revenues (based on 14x TOB)} + \text{Medicare PFS revenues (based on 14x TOB)}}{\text{Total Medicare revenues (based on 14x TOB)}} \text{ is } >50\%$$

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-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

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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 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.

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- **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, 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**

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- **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, 2021, through March 31, 2021 (previously January 1, 2020 through March 31, 2020). CMS will use the next data collection and reporting cycle to determine CLFS payment rates for CY 2022 through CY 2024.

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	1/1/2021 – 3/31/2021	2022 – 2024
1/1/2023 – 6/30/2023	7/1/2023 – 7/31/2023	1/1/2024 – 3/31/2024	2025 – 2027
Continues every third subsequent calendar year	Continues every third subsequent calendar year	Continues every third subsequent calendar year	New CLFS rate every third year

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:

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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 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

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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.

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

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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, 2021 through March 31, 2021 (previously January 1, 2020 through March 31, 2020), reporting entities may condense certain applicable information at the TIN-level, instead 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 2021 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 2021 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

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entity designates one (of its three component applicable laboratories) as the reporting NPI.

TABLE 2a – Example of Individual Applicable Laboratory Reporting for 2021 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 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 2021 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 2021 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
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 2021 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

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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.

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, 2021, through March 31, 2021 (previously January 1, 2020 through March 31, 2020).
- Annual laboratory public meeting for new tests: June/July 2021. 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 2022 CLFS.
- CMS publishes preliminary CLFS rates for CY 2022: Early September 2021. The public will have approximately 30 days, through early October 2021, to submit comments on the preliminary CY 2022 rates.
- CMS makes final CY 2022 CLFS rates available on the CMS website: Early November 2021.
- Implementation date for the next private payor rate-based CLFS update: January 1, 2022.

CLFS Data Reporting Period Delayed – Updated January 8, 2020

For CDLTs that are not ADLTs, the data reporting period is delayed by one year. Applicable information for CDLTs that are not ADLTs that was supposed to be reported from January 1, 2020 through March 31, 2020, must now be reported from January 1, 2021 through March 31, 2021. Reporting entities must report applicable information based on the original data collection period of January 1, 2019 through June 30, 2019. Data reporting for these tests will resume on a three-year cycle, beginning in 2024. (Section 105(a)(1) of the Further Consolidated Appropriations Act of 2020 (FCAA)).

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

Date of change	Description
January 8, 2020	We revised this article to note that for CDLTs that are not ADLTs, the data reporting is delayed by one year and must now be reported from January 1 2021 through March 31, 2021 (previously January 1, 2020 through March 31, 2020). All references to the 2020 data reporting period have been changed to 2021. We added the "CLFS Data Reporting Period Delayed" Section on page 24 to summarize the changes. All other information remains the same
September 5, 2019	We revised this article to delete incorrect information in the section titled Only Applicable Information Attributed to non-Hospital Patients is Reported, which is on page 18. All other information remains the same.
February 27, 2019	Initial article released

MLN Matters® Number: SE19006 *Revised*
Article Release Date: January 8, 2020
Related CR Transmittal Number: N/A
Related Change Request (CR) Number: N/A
Effective Date: N/A
Implementation Date: N/A

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 webpage* 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 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* 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.

Your Feedback Matters

To ensure that our website meets the needs of our provider community, we carefully analyze your feedback and implement changes to better meet your needs. Discover the results of your feedback on our "*Website enhancements*" page. You'll find the latest enhancements to our provider websites and find out how you can share your thoughts and ideas with First Coast's web team.

Additional Information

Viscosupplementation therapy for knee -- revision to the Part A and Part B Billing and Coding Article

Article ID number: A57256 (Florida, Puerto Rico/U.S. Virgin Islands)

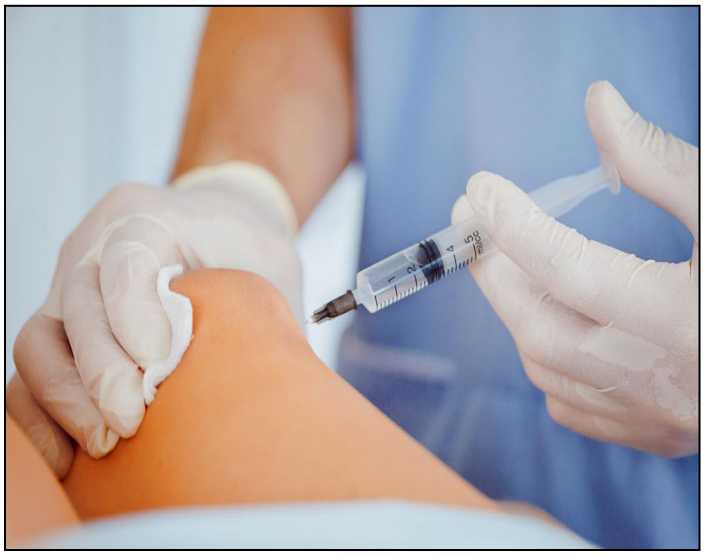
Based on change request (CR) 11564, the status indicators for Healthcare Common Procedure Coding System (HCPCS) codes J7331 and J7332 changed from "E2" to "K". Therefore, they were added to the "CPT®/ HCPCS Codes/ Group 1 Codes" and "ICD-10 Codes that Support Medical Necessity/Group 1 Paragraph" sections of the Billing and Coding article.

Effective date

This billing and coding article revision is effective for services rendered **on or after January 1, 2020**.

LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

A billing and coding article for an LCD 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*.

Independent diagnostic testing facility (IDTF) -- revision to the Part B Billing and Coding Article

Article ID number: A57807 (Florida, Puerto Rico/U.S. Virgin Islands)

Based on further review of the Annual 2020 Healthcare Common Procedure Coding System (HCPCS) Update, HCPCS code G2066 was added. Also, a typographical error was corrected (Current Procedural Terminology [CPT®] code 97516 was changed to CPT® code 95716). In addition, the "Supervising Physician and Interpreting Physician Qualification Requirements" and "Technician Qualification Requirements" sections of the Credentialing Matrix in the billing and coding article were updated for CPT® codes 95700, 95705-95716 and the "Technician Qualification Requirements" section of the Credentialing Matrix was updated for CPT® codes 95717-95726.

Effective date

This billing and coding article revision is effective for services rendered **on or after January 1, 2020**. LCDs are available through the CMS Medicare coverage database at *https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx*.

A billing and coding article for an LCD 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

Medicare Quarterly Updates (Part B)

Date: March 18
Time: 11 a.m. - 12:30 p.m. ET
Type of Event: Webcast

View our complete calendar of events

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 *First Coast University*, 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 *Create 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* for details and newly scheduled educational events (teleconferences, webcasts, etc.).

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® - Special Edition for Monday, December 23, 2019

New Medicare Card Transition Ends Next Week: Claim Reject Codes Beginning January 1

Get paid. Use Medicare Beneficiary Identifiers (MBIs) now. If you do not use MBIs on claims (with a few *exceptions*) after January 1, regardless of the date of service, you will get:

- Electronic claims reject codes: Claims Status Category Code of A7 (acknowledgment rejected for invalid information), a Claims Status Code of 164 (entity's contract/member number), and an Entity Code of IL (subscriber)
- Paper claims notices: Claim Adjustment Reason Code (CARC) 16 "Claim/service lacks information or has submission/billing error(s)" and Remittance Advice Remark Code (RARC) N382 "Missing/ incomplete/invalid patient identifier"

How can you get the MBI? If your patients do not bring their Medicare cards with them:

- Give them the Get Your New Medicare Card flyer in *English* or *Spanish*.
- Use your Medicare Administrative Contractor's look-up tool. *Sign up* for the Portal to use the tool.
- Check the remittance advice. Until December 31, we return the MBI on the remittance advice for every claim with a valid and active Health Insurance Claim Number (HICN).

See the *MLN Matters Article* to learn how to get and use MBIs.

MLN Connects® - Special Edition for Thursday, December 26, 2019

Feedback on Scope of Practice

The Centers for Medicare & Medicaid Services (CMS) is seeking additional input and recommendations regarding elimination of specific Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license.

We are seeking additional feedback in response to part of the President's Executive Order (EO) #13890 on Protecting and Improving Medicare for Our Nation's Seniors. The EO specifically directs HHS to propose a number of reforms to the Medicare program, including ones that eliminate supervision and licensure requirements of the Medicare program that are more stringent than other applicable federal or state laws. These burdensome requirements ultimately limit healthcare professionals, including Physician Assistants (PAs) and Advanced Practice Registered Nurses (APRNs), from practicing at the top of their professional license.

In response to suggestions we have already received regarding supervision, scope of practice, and licensure requirements, CMS has made a number of regulatory changes in several payment rules, including the CY 2020 Physician Fee Schedule, Home Health, and Outpatient Prospective Payment System final rules. These changes include, but are not limited to: redefining physician supervision for services furnished by PAs, allowing therapist assistants to perform maintenance therapy under the Medicare home health benefit and reducing the minimum level of physician supervision required for all hospital outpatient therapeutic services.

We are proud of the work accomplished, and now we need your help in identifying additional Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or which limit health professionals from practicing at the top of their license. If you submitted comments on these topics to our 2019 Request for Information on Reducing Administrative Burden to Put Patients over Paperwork, thank you! We are reviewing those submissions.

We welcome any additional recommendations. Please send your recommendations to *PatientsOverPaperwork@cms.hhs.gov* with the phrase "Scope of Practice" in the subject line by January 17, 2020.

We also continue to welcome your input on ways in which we can reduce unnecessary burden, increase efficiencies and improve the beneficiary experience, and request that input on such topics only be sent to this email address with the phrase "Scope of Practice" in the subject line if they relate to the specific areas in regulation which restrict non-physician providers from practicing to the full extent of their education and training.

MLN Connects® for Thursday, January 9, 2020

MLN Connects® for Thursday, January 9, 2020

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News

- Quality Payment Program: 2018 Performance Data
- Quality Payment Program APM Incentive Payment: Verify Banking Information
- Quality Payment Program: Participation Status Tool Includes Third Snapshot of Data
- Quality Payment Program: Recheck Your Final 2019 MIPS Eligibility
- Quality Payment Program: Check Your Initial 2020 MIPS Eligibility
- Quality Payment Program: Qualified Registries and QCDRs for CY 2020
- Hospice Provider Preview Reports: Review Your Data by January 15
- Feedback on Scope of Practice: Send Recommendations by January 17
- Promoting Interoperability Programs: Deadline to Submit 2019 Data is March 2
- Quality Payment Program: MIPS 2019 Data Submission Period Open through March 31
- Hospitals: New Beneficiary Notices (IM, DND, and MOON) Required April 1
- Hospital Outpatient Departments: Prior Authorization Process Begins July 1
- Home Health Compare: Preview Reports for April Refresh
- Clinical Laboratory Data Reporting Delayed
- ICD-10-CM Browser Tool
- Provider Enrollment Application Fee Amount for CY 2020
- Nursing Home Quality Initiative: Draft 2020 MDS Item Sets
- Hospice Quality Reporting Program News
- Qualified Medicare Beneficiary Billing Requirements
- Get Your Patients Off to a Healthy Start in 2020
- Looking for Educational Materials?

Compliance

- Chiropractic Services: Comply with Medicare Billing Requirements

Events

- Quality Payment Program: QCDR Measures Webinar — January 13
- ESRD Quality Incentive Program: CY 2020 ESRD PPS Final Rule Call — January 14
- Listening Sessions on MAC Opportunities to Enhance Provider Experience — January 15, 22, or 29

MLN Matters® Articles

- Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 – Laboratory Date of Service Policy
- IVIG Demonstration: Payment Update for 2020
- January 2020 Update of the Ambulatory Surgical Center (ASC) Payment System
- Manual Update to Publication (Pub.) 100-04, Chapter 20, to Revise the Subsection 10 - Where to Bill Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Parenteral and Enteral Nutrition (PEN) Items and Services
- Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Medicare Benefit Policy Manual Chapter 13 Update
- New Medicare Beneficiary Identifier (MBI) Get It, Use It — Reissued
- Home Health Patient-Driven Groupings Model (PDGM) -Split Implementation — Revised

Publications

- MLN Catalog – January 2020 Edition
- Quality Payment Program and MIPS Resources
- Diabetes Resources
- Hospice Payment System — Revised
- Medicare Diabetes Prevention and Diabetes Self-Management Training — Revised
- Provider Compliance Tips for Hospital Based Hospice — Revised

Multimedia

- eCQM: CMS Measure Collaboration Workspace

MLN Connects® for Thursday, January 16, 2020

MLN Connects® for Thursday, January 16, 2020

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News

- CMS Reduces Psychiatric Hospital Burden with New Survey Process
- Quality Payment Program: MIPS 2020 Payment Adjustments
- Quality Payment Program: New MIPS Participation Framework for 2021 Performance Period
- Part A Providers: Talk to a QIC Adjudicator About Your Appeal
- Comparative Billing Reports: Access via CBR Portal
- January is Cervical Health Awareness Month

Compliance

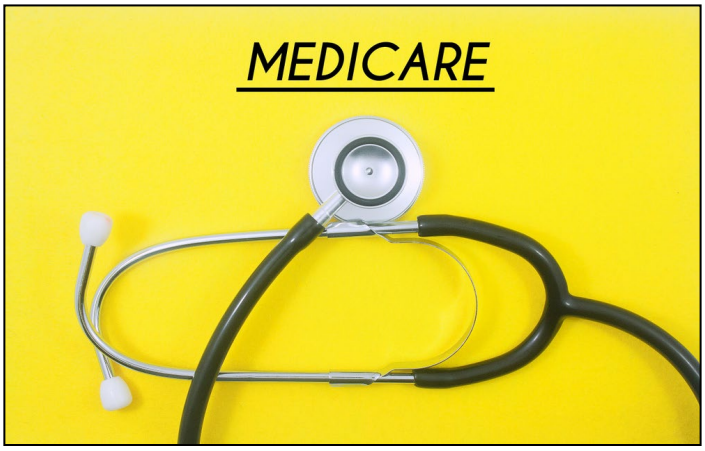
- Bill Correctly for Polysomnography Services

Events

- Listening Sessions on MAC Opportunities to Enhance Provider Experience — January 22 or 29
- Quality Payment Program: MIPS for 2020 Performance Period Webinar — January 22

MLN Matters® Articles

- Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging- Approval of Using the K3 Segment for Institutional Encounters
- Medicare Fee-for-Service (FFS) Response to the 2020 Commonwealth of Puerto Rico Earthquakes
- January 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.0
- Manual Updates Related to Calendar Year (CY) 2020 Home Health Payment Policy Changes, Maintenance Therapy, and Remote Patient Monitoring
- Medicare Part B Clinical Laboratory Fee Schedule:



- Revised Information for Laboratories on Collecting and Reporting Data for the Private Payor Rate-Based Payment System — Revised
- Medicare Part B Home Infusion Therapy Services with the Use of Durable Medical Equipment — Revised
- Add Dates of Service (DOS) for Pneumococcal Pneumonia Vaccination (PPV) Health Care Procedure Code System (HCPCS) Codes (90670, 90732), and Remove Next Eligible Dates for PPV HCPCS — Revised
- CY 2020 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule — Revised
- Updates to CR 11152 Implementation of the Skilled Nursing Facility (SNF) Patient Driven Payment Model (PDPM)

Publications

- Provider Compliance Tips for Polysomnography (Sleep Studies) - Revised

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