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Articles contained in this edition are current as of February 29, 2016.
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**Clinical Trials; Device Classification**

The most common types of submissions include:

- **IDE (Investigational device exemption):** The investigational device is allowed to be used in a clinical study in order to collect safety and effectiveness data. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

- **510(k) (Premarket Notification):** Some Class I and most Class II devices require a 510(k). In a 510(k), the sponsor must demonstrate that the new device is “substantially equivalent” to a predicate device in terms of intended use, technological characteristics, and performance testing, as needed.

- **PMA (Premarket Approval):** Most Class III devices require a PMA. A PMA is the most stringent type of premarket submission. Before the FDA approves a PMA, the sponsor must provide valid scientific evidence demonstrating reasonable assurance of safety and effectiveness for the device’s intended use.

- **HDE (Humanitarian Device Exemption):** HDE provides a regulatory path for Class III devices that are intended to benefit patients with rare diseases or conditions. In order for a device to be eligible for an HDE, a sponsor must obtain designation as a Humanitarian Use Device (HUD), which is granted through application to the FDA.

PMAs, HDEs and some 510(k)s require clinical evidence. Prior to initiating a clinical study, the study sponsor may need to obtain approval of an Investigational Device Exemption (IDE) by the FDA. The study will also need to be approved by the appropriate Institutional Review Board (IRB). Clinical studies must comply with all applicable IDE regulations and Good Clinical Practices (GCPs).

If a device requires premarket clearance or premarket approval prior to marketing (i.e., the medical device is not exempt), the device firm must wait until it receives FDA clearance or approval before registering and listing. Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote clearance or approval of the establishment or its products by the FDA.

**NOTE:** When billing CGS for PMA/501K services, you MUST reference the IDE Number on the submission form so that your information can be entered into the Medicare payment systems for claims processing.
Quarterly Provider Update

The Quarterly Provider Update is a comprehensive resource published by the Centers for Medicare & Medicaid Services (CMS) on the first business day of each quarter. It is a listing of all nonregulatory changes to Medicare including transmittals, manual changes, and any other instructions that could affect providers. Regulations and instructions published in the previous quarter are also included in the update. The purpose of the Quarterly Provider Update is to:

- Inform providers about new developments in the Medicare program;
- Assist providers in understanding CMS programs and complying with Medicare regulations and instructions;
- Ensure that providers have time to react and prepare for new requirements;
- Announce new or changing Medicare requirements on a predictable schedule; and
- Communicate the specific days that CMS business will be published in the Federal Register.

To receive notification when regulations and program instructions are added throughout the quarter, go to [https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/CMS-Quarterly-Provider-Updates-Email-Updates.html](https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/CMS-Quarterly-Provider-Updates-Email-Updates.html) to sign up for the Quarterly Provider Update (electronic mailing list).


If you have any questions, please contact a CGS Customer Service Representative by calling the CGS Provider Contact Center at 1.866.276.9558 and choose Option 1.

Kentucky & Ohio

MM9078 Revised: National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers

The Centers for Medicare & Medicaid Services (CMS) has revised the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9078 Revised  
**Related CR Release Date:** December 10, 2015  
**Related CR Transmittal #:** R3421CP and R187NCD  
**Related Change Request (CR) #:** CR 9078  
**Effective Date:** August 13, 2013  
**Implementation Date:** July 6, 2015

**Note:** This article was revised on January 27, 2016, to note that the NCD for Cardiac Pacemakers, “Single Chamber and Dual Chamber Permanent Cardiac Pacemakers” (NCD20.8.3) was effective on August 13, 2013, and remains in effect. In order to address claims processing issues, the Centers for Medicare & Medicaid Services has instructed Medicare Administrative Contractors (MACs) to implement this NCD at the local level until CMS is able to revise the formal claims processing instructions. All aspects of the NCD policy in the “NCD Manual,” Section 20.8.3, remain in effect. Additionally, CMS is temporarily removing the corresponding “Medicare Claims Processing Manual,” Chapter 32, Section 320, and all but two business requirements, to avoid confusion and better clarify that the MACs will use their discretionary authority to process these claims.
Provider Types Affected
This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to MACs for single chamber and dual chamber permanent cardiac pacemaker services provided to Medicare beneficiaries.

Additional Information

If you have questions, please contact your MAC at their toll-free number. The number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work?

Document History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 27, 2016</td>
<td>This article was revised to reflect the revised CR9078 issued on December 10, 2015. The CR was revised to further clarify that the MACs are to implement the NCD at the local level until Medicare system instructions are revised and Medicare system changes are implemented. The CR also included a specific implementation date of January 13, 2016 for local implementation.</td>
</tr>
<tr>
<td>November 13, 2015</td>
<td>All references to the old claims processing instructions were removed from the article.</td>
</tr>
<tr>
<td>October 28, 2015</td>
<td>This article was revised to reflect the revised CR9078 issued on October 26. The CR was revised to direct the MACs to implement the NCD at the local level until Medicare system instructions are revised and Medicare system changes are implemented.</td>
</tr>
<tr>
<td>May 26, 2015</td>
<td>This article was revised to add a reference to MLN Matters® Article MM8525 (<a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8525.pdf">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8525.pdf</a>) which allows payment for nationally covered implanted permanent cardiac pacemakers, single chamber or dual chamber, for the indications outlined in the “Medicare National Coverage Determinations Manual.”</td>
</tr>
</tbody>
</table>

Kentucky & Ohio

**MM9355: New Non-Physician Specialty Code for Dentist**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html

**MLN Matters® Number:** MM9355  
**Related CR Release Date:** January 29, 2016  
**Related CR Transmittal #:** R3447CP and R262FM  
**Related Change Request (CR) #:** CR 9355  
**Effective Date:** July 1, 2016  
**Implementation Date:** July 5, 2016

Provider Types Affected
This MLN Matters® Article is intended for Dentists and certain suppliers submitting claims to Medicare Administrative Contractors (MACs) for dental services provided to Medicare beneficiaries.

Provider Action Needed
Change Request (CR) 9355 announces that the Centers for Medicare & Medicaid Services (CMS) has created a new non-physician specialty code (CS) for Dentist.
Background
Physicians self-designate their Medicare physician specialty on the Medicare enrollment application (CMS-855B, CMS-855I or CMS-855O) or Internet-based Provider Enrollment, Chain and Ownership System (PECOS) when they enroll in the Medicare program. Non-physician practitioners are assigned a Medicare specialty code when they enroll.

The specialty code becomes associated with the claims that the physician or non-physician practitioner submits, and describes the specific/unique types of medicine that they (and certain other suppliers) practice. CMS uses specialty codes for programmatic and claims processing purposes.

Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.

Kentucky & Ohio

MM9390: Update to Pub. 100-08, Chapter 15

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html

MLN Matters® Number: MM9390
Related CR Release Date: February 4, 2016
Related CR Transmittal #: R636PI
Related Change Request (CR) #: CR 9390
Effective Date: March 4, 2016
Implementation Date: March 4, 2016

Provider Types Affected
This MLN Matters® Article is intended for providers, including Home Health Agencies (HHAs), submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed
Change Request (CR) 9390, from which this article was developed, makes several minor revisions to Chapter 15 of the “Medicare Program Integrity Manual.” These changes include, but are not limited to:

1. Clarifying the process for verifying correspondence telephone numbers;
2. Clarifying the process for validating the credentials of technicians of Independent Diagnostic Testing Facilities (IDTFs); and
3. Identifying the timeframe by which approval letters must be sent and to whom they must be sent.

Make sure that your billing staffs are aware of these revisions.
Background
Chapter 15 of the "Medicare Program Integrity Manual" contains instructions regarding the processing of Form CMS-855 applications. CR9390 makes the following key changes:

1. If online verification of an IDTF technician's credentials is not available or cannot be made, the MAC will request a copy of the technician's certification card.
2. The MAC will not request a social security card to verify an individual's identity or social security number.
3. Absent a CMS instruction or directive to the contrary, the MAC will send enrollment approval letters within 5 business days of approving the enrollment application.
4. For all applications other than the Form CMS-855S, the MAC will send development/approval letters/revocation letters, etc., to the contact person if one is listed; otherwise, the contractor may send the letter to the provider or supplier at the provider’s/supplier’s correspondence address or special payments address.

Note: CR9390 does not involve any legislative or regulatory policies and is restricted to changes in operational procedures.

Many of the other Chapter 15 revisions are small, such as inserting single words or short sentences, etc. Others are more significant and those revisions are in the revised Chapter 15, which is attached to CR9390.

Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.

Kentucky & Ohio

MM9403: Screening for the Human Immunodeficiency Virus (HIV) Infection

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html

MLN Matters® Number: MM9403
Related CR Release Date: February 5, 2016
Related CR Transmittal #: R190NCD and R3461CP
Related Change Request (CR) #: CR 9403
Effective Date: April 13, 2015

Implementation Date: March 7, 2016 (non-shared A/B MAC edits); July 5, 2016 (CWF analysis and design); October 3, 2016 (CWF Coding, Testing, Implementation, MCS, FISS Implementation); January 3, 2017 – Requirement 9403-04.9 July 5, 2016 - For CWF and January 1, 2017, for full implementation

Provider Types Affected
This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for human immunodeficiency virus (HIV) infection screening services provided to Medicare beneficiaries.
What You Need to Know
Change Request (CR) 9403 informs MACs that the Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is adequate to conclude that screening of HIV infection for all individuals between the ages of 15-65 years is reasonable and necessary for early detection of HIV, and it is appropriate for individuals entitled to benefits under Part A or enrolled in Part B.

Background
On January 1, 2009, CMS was authorized to add coverage of “additional preventive services” through the National Coverage Determination (NCD) process if certain statutory requirements are met. One of those requirements is that the service(s) be categorized as a grade A (strongly recommends) or grade B (recommends) rating by the United States Preventive Services Task Force (USPSTF) and meets certain other requirements. Previously, the USPSTF strongly recommended screening for all adolescents and adults at increased risk for HIV infection, as well as all pregnant women. The USPSTF made no recommendation for or against routine HIV screening in adolescents and adults not at increased risk for HIV infection. Effective December 8, 2009, CMS issued a final decision supporting the USPSTF recommendations.


In April 2013, the USPSTF updated these recommendations and recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened (Grade A recommendation). The USPSTF also recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown (Grade A recommendation).

CR 9403 instructs that effective for claims with dates of service on and after April 13, 2015, CMS will cover screening for HIV with the appropriate U.S. Food and Drug Administration (FDA)-approved laboratory tests and point-of-care tests, used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the beneficiary’s physician or practitioner within the context of a healthcare setting and performed by an eligible Medicare provider for these services, for beneficiaries who meet one of the following conditions below:

1. Except for pregnant Medicare beneficiaries addressed below, a maximum of one, annual, voluntary screening for all adolescents and adults between the ages of 15 and 65, without regard to perceived risk.

2. Except for pregnant Medicare beneficiaries addressed below, a maximum of one, annual, voluntary screening for adolescents younger than 15 and adults older than 65 who are at increased risk for HIV infection. Increased risk for HIV infection is defined as follows:
   - Men who have sex with men;
   - Men and women having unprotected vaginal or anal intercourse;
   - Past or present injection drug users;
   - Men and women who exchange sex for money or drugs, or have sex partners who do;
   - Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users;
- Persons who have acquired or request testing for other sexually transmitted infectious diseases;
- Persons with a history of blood transfusions between 1978 and 1985;
- Persons who request an HIV test despite reporting no individual risk factors;
- Persons with new sexual partners; or
- Persons who, based on individualized physician interview and examination, are deemed to be at increased risk for HIV infection. The determination of “increased risk” for HIV infection is identified by the health care practitioner who assesses the patient’s history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan. The medical recommendation should be a reflection of the service provided.

3. A maximum of three voluntary HIV screenings of pregnant Medicare beneficiaries:
   - When the diagnosis of pregnancy is known;
   - During the third trimester; and
   - At labor, if ordered by the woman’s clinician. **NOTE:** There is no co-insurance or deductible for tests paid under the Clinical Laboratory Fee Schedule (CLFS).

**Billing Requirements**

Effective for claims with dates of service on or after April 13, 2015, MACs will recognize new HCPCS code G0475 (HIV antigen/antibody, combination assay, screening) as a new covered service for HIV screening.

**NOTE:** HCPCS G0475 will appear in the January 1, 2017, CLFS; in the January 1, 2016, Integrated Outpatient Code Editor (IOCE); in the January 2016 Outpatient Prospective Payment System (OPPS); and in the January 1, 2016, Medicare Physician Fee Schedule (MPFS). HCPCS Code G0475 will be effective retroactive to April 13, 2015, in the IOCE and OPPS.

### For services from April 13 - September 30, 2015, inclusive, the diagnosis codes are:

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>V22.0</td>
<td>Supervision of normal first pregnancy</td>
</tr>
<tr>
<td>V22.1</td>
<td>Supervision of other normal pregnancy</td>
</tr>
<tr>
<td>V23.9</td>
<td>Supervision of unspecified high-risk pregnancy</td>
</tr>
<tr>
<td>V69.8</td>
<td>Other problems related to lifestyle</td>
</tr>
<tr>
<td>V73.89</td>
<td>Special screening examination for other specified viral diseases</td>
</tr>
<tr>
<td>V69.2</td>
<td>High risk sexual behavior</td>
</tr>
</tbody>
</table>

### For dates of service on or after October 1, 2015, the diagnosis codes are:

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>Long Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z34.00</td>
<td>Encounter for supervision of normal first pregnancy, unspecified trimester</td>
</tr>
<tr>
<td>Z34.01</td>
<td>Encounter for supervision of normal first pregnancy, first trimester</td>
</tr>
<tr>
<td>Z34.02</td>
<td>Encounter for supervision of normal first pregnancy, second trimester</td>
</tr>
<tr>
<td>Z34.03</td>
<td>Encounter for supervision of normal first pregnancy, third trimester</td>
</tr>
<tr>
<td>Z34.80</td>
<td>Encounter for supervision of other normal pregnancy, unspecified trimester</td>
</tr>
<tr>
<td>Z34.81</td>
<td>Encounter for supervision of other normal pregnancy, first trimester</td>
</tr>
<tr>
<td>Z34.82</td>
<td>Encounter for supervision of other normal pregnancy, second trimester</td>
</tr>
<tr>
<td>Z34.83</td>
<td>Encounter for supervision of other normal pregnancy, third trimester</td>
</tr>
<tr>
<td>Z34.90</td>
<td>Encounter for supervision of normal pregnancy, unspecified, unspecified trimester</td>
</tr>
<tr>
<td>Z34.91</td>
<td>Encounter for supervision of normal pregnancy, unspecified, first trimester</td>
</tr>
<tr>
<td>Z34.92</td>
<td>Encounter for supervision of normal pregnancy, second trimester</td>
</tr>
<tr>
<td>Z34.93</td>
<td>Encounter for supervision of normal pregnancy, third trimester</td>
</tr>
<tr>
<td>O09.90</td>
<td>Supervision of high risk pregnancy, unspecified, unspecified trimester</td>
</tr>
</tbody>
</table>
For dates of service on or after October 1, 2015, the diagnosis codes are:

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
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<td>O09.91</td>
<td>Supervision of high risk pregnancy, unspecified, first trimester</td>
</tr>
<tr>
<td>O09.92</td>
<td>Supervision of high risk pregnancy, unspecified, second trimester</td>
</tr>
<tr>
<td>O09.93</td>
<td>Supervision of high risk pregnancy, unspecified, third trimester</td>
</tr>
<tr>
<td>Z72.89</td>
<td>Other problems related to lifestyle</td>
</tr>
<tr>
<td>Z11.4</td>
<td>Encounter for screening for human immunodeficiency virus [HIV]</td>
</tr>
<tr>
<td>Z72.51</td>
<td>High risk heterosexual behavior</td>
</tr>
<tr>
<td>Z72.52</td>
<td>High risk homosexual behavior</td>
</tr>
<tr>
<td>Z72.53</td>
<td>High risk bisexual behavior</td>
</tr>
</tbody>
</table>

On professional claims, the place of service must be either 81 (independent laboratory) or 11 (office).

If claims are received for screenings that exceed the maximum number allowed per year, the claim line item will be denied with the following remittance codes:

- Claim Adjustment Reason Code (CARC) 119: “Benefit maximum for this time period or occurrence has been reached.”
- Remittance Advice Remark Code (RARC) N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at [http://www.cms.gov/mcd/search.asp](http://www.cms.gov/mcd/search.asp) on the CMS website. If you do not have Web access, you may contact the contractor to request a copy of the NCD.”
- Group Code: CO (Contractual Obligation).

Note that the next eligible date for the service will be provided on all Common Working File (CWF) provider query screens (HUQA, HIQA, HIQH, ELGA, ELGH, and PRVN).

Claims with HCPCS Code G0475 for beneficiaries between the ages of 15 and 65 without regard to risk must also be submitted with a primary diagnosis code of either V73.89 (ICD-9) or Z11.4 (ICD-10). If that primary code is not present, the line item will be denied using the following messages:

- CARC 167 – “This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N386 – “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at [http://www.cms.gov/mcd/search.asp](http://www.cms.gov/mcd/search.asp) on the CMS website. If you do not have Web access, you may contact the contractor to request a copy of the NCD.”
- Group Code: CO (Contractual Obligation).

Claims with HCPCS Code G0475 for beneficiaries less than age 15 or greater than age 65 with increased risk must also be submitted with a primary diagnosis code of either V73.89 (ICD-9) or Z11.4 (ICD-10) and a secondary diagnosis code that denotes the high risk. The ICD-9 secondary codes are V69.2 or V69.8. The ICD-10 secondary diagnosis codes are Z72.51, Z72.89, Z72.52, or Z72.53. If that secondary code is not present, the line item will be denied using the following messages:

- CARC 6: “The procedure/revenue code is inconsistent with the patient’s age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N129: “Not eligible due to the patient’s age.”
Group Code: CO (Contractual Obligation).

Effective for claims with dates of service on or after April 13, 2015, MACs will deny line-items on claims for pregnant beneficiaries denoted by a secondary diagnosis code above denoting pregnancy, if HCPCS Code G0475, HIV screening, or CPT code 80081, obstetric panel, and primary diagnosis code V73.89/ Z11.4, as appropriate, are not present on the claim. Such line item denials will result in the following remittance messages:

- **CARC 11:** “The diagnosis is inconsistent with the procedure.
  **Note:** Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

- **RARC N386 – “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at [http://www.cms.gov/mcd/search.asp](http://www.cms.gov/mcd/search.asp) on the CMS website. If you do not have Web access, you may contact the contractor to request a copy of the NCD.”**

Group Code: CO (Contractual Obligation).

Institutional claims for G0475 submitted on Types of Bill (TOB) 12X, 13X, 14X, 22X, and 23X will be paid based on the CLFS with dates of service on or after January 1, 2017. MACs will apply their pricing to claims with dates of service of April 13, 2015, through December 31, 2016. Such claims submitted on TOB 85X will be paid based on reasonable cost for dates of service beginning with April 13, 2015.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html) under - How Does It Work.

**Kentucky & Ohio**

**MM9434: Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing — National Coverage Determination (NCD) 210.2.1**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9434  
**Related CR Release Date:** February 5, 2016  
**Related CR Transmittal #:** R189NCD and R3460CP  
**Related Change Request (CR) #:** CR 9434  
**Effective Date:** July 9, 2015  
**Implementation Date:** July 5, 2016 (CWF analysis and design), October 3, 2016 (CWF Coding, Testing and Implementation, MCS and FISS implementation; January 3, 2017 (requirement 9434-04.8.2), March 7, 2016 (non-sharedMAC edits)}
Provider Types Affected
This MLN Matters® Article is intended for physicians and other providers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed
Change Request (CR) 9434 announces that the Centers for Medicare & Medicaid Services (CMS) has determined that, effective for dates of service on or after July 9, 2015, evidence is sufficient to add Human Papillomavirus (HPV) testing under specified conditions. Make sure that your billing staffs are aware of this change.

Background
Medicare covers a screening pelvic examination and Pap test for all female beneficiaries at 12- or 24-month intervals, based on specific risk factors; however, current Medicare coverage does not include the HPV testing.

Section 1861(ddd) of the Social Security Act (the Act) (see http://www.ssa.gov/OP_Home/ssact/title18/1861.htm) states that CMS may add coverage of “additional preventive services” through the National Coverage Determination (NCD) process. The preventive services must meet all of the following criteria:

1. Reasonable and necessary for the prevention or early detection of illness or disability;
2. Recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and,
3. Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS has reviewed the USPSTF recommendations and supporting evidence for screening for cervical cancer with HPV co-testing, and has determined that the criteria were met. Therefore, effective for claims with dates of service on or after July 9, 2015, CMS will cover screening for cervical cancer with HPV co-testing under the following conditions:

CMS has determined that the evidence is sufficient to add HPV testing once every 5 years as an additional preventive service benefit under the Medicare program, for asymptomatic beneficiaries aged 30 to 65 years in conjunction with the Pap smear test. CMS will cover screening for cervical cancer with the appropriate U.S. Food and Drug Administration (FDA)-approved/cleared laboratory tests, used consistent with FDA-approved labeling, and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations.

A new Healthcare Common Procedure Coding System (HCPCS) code, G0476 (HPV combo assay, CA screen), Type of Service (TOS) 5 (diagnostic lab), has been created for this benefit. This code will:

- Be effective retroactive back to the effective date of July 9, 2015;
- Be included in the January 2016, Integrated Outpatient Code Editor, Outpatient Prospective Payment System, and Medicare Physician Fee Schedule Database;
- Be MAC-priced from July 9, 2015, through December 31, 2016, and during this period code G0476 is paid only when it is billed by a laboratory entity; and,
- Beginning January 1, 2017, this will be priced and paid according to the Clinical Laboratory Fee Schedule (CLFS).

In addition, you should be aware of the following:

1. Your MACs will not apply beneficiary coinsurance and deductibles to claim lines containing HCPCS G0476, HPV screening;
2. Part B MACs shall only accept claims with a Place of Service Code equal to ‘81’, Independent Lab or ‘11’, Office; and

3. Effective for claims with dates of service on or after July 9, 2015, your MACs will deny line-items on claims containing HCPCS G4076, HPV screening, when reported more than once in a 5-year period (at least 4 years and 11 months (59 months total) must elapse from the date of the last screening). The next eligible dates for this service are shown on all Common Working File (CWF) provider query screens (HUQA, HIQA, HIQH, ELGA, ELGH, and PRVN).

When denying a line-item on a claim for this requirement they will use the following messages:

- Claim Adjustment Reason Code (CARC) 119 – “Benefit maximum for this time period or occurrence has been reached;”

- Remittance Advice Remark Code (RARC) N386 – “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.gov/mcd/search.asp. If you do not have Web access, you may contact the contractor to request a copy of the NCD;”

- Group Code “CO” if the claim contains a GZ modifier to denote a signed Advance Beneficiary Notice (ABN) is not on file or with Group Code “PR” (Patient Responsibility) if the claim has a GA modifier to show a signed ABN on file.

4. HCPCS Code G0476 will be paid only for institutional claims submitted on Type of Bill codes (TOB) 12X, 13X, 14X, 22X, 23X, and 85X. Institutional claims on other TOBs will be returned to the provider.

5. Effective for claims with dates of service on or after July 9, 2015, your MACs will deny line-items on claims containing HCPCS G4076, HPV screening, when the beneficiary is less than 30 years of age or older than 65 years of age.

When denying a line-item on claims for this requirement, they will use the following messages:

- CARC 6 – “The procedure/revenue code is inconsistent with the patient’s age. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present;”

- RARC N129 – “Not eligible due to the patient’s age;”

- Group Code “CO” if the claim contains a GZ modifier to denote a signed Advance Beneficiary Notice (ABN) is not on file or with Group Code “PR” (Patient Responsibility) if the claim has a GA modifier to show a signed ABN on file.

6. Effective for claims with dates of service on or after July 9, 2015, you must report the following diagnosis codes when submitting claims for HCPCS G0476:

- ICD-9 (for dates of service prior to October 1, 2015): V73.81, special screening exam, HPV (as primary), and V72.31, routine gynecological exam (as secondary)

- ICD-10: Z11.51, encounter for screening for HPV, and Z01.411, encounter for gynecological exam (general)(routine) with abnormal findings, OR Z01.419, encounter for gynecological exam (general)(routine) without abnormal findings.

Effective on this date, your MACs will deny line-items on claims containing HCPCS Code G0476, HPV screening, when the claim does not contain these codes.

When denying a line-item on claim for this requirement, they will use the following messages:

- CARC 167 – “This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present;”
RARC N386 – “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at [http://www.cms.gov/mcd/search.asp](http://www.cms.gov/mcd/search.asp). If you do not have Web access, you may contact the contractor to request a copy of the NCD;” and

- Group Code CO.


Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html) under - How Does It Work.

Kentucky & Ohio

**MM9454: Accredited Standards Committee (ASC) X12 Healthcare Claims Acknowledgement (277CA) Flat File Update**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9454  
**Related CR Release Date:** February 4, 2016  
**Related CR Transmittal #:** R1609OTN  
**Related Change Request (CR) #:** CR 9454  
**Effective Date:** July 1, 2016  
**Implementation Date:** July 5, 2016

**Provider Types Affected**

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

**What You Need to Know**

Change Request (CR) 9454 updates the Accredited Standards Committee (ASC) X12 Healthcare Claims Acknowledgement (277CA) flat file to allow for larger monetary amounts to meet Medicare’s needs. The 277CA amount fields are currently the same size as the size used for the input files.

**Additional Information**

MM9461: Healthcare Provider Taxonomy Codes (HPTCs) April 2016 Code Set Update

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html

MLN Matters® Number: MM9461
Related CR Release Date: February 19, 2016
Related CR Transmittal #: R3467CP
Related Change Request (CR) #: CR 9461

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

What You Need to Know
Change Request (CR) 9461 instructs MACs to obtain the most recent Healthcare Provider Taxonomy Code (HPTC) set and to update their internal HPTC tables and/or reference files.

Background
The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that covered entities use the standards adopted under this law for electronically transmitting certain health care transactions, including health care claims. The standards include implementation guides which dictate when and how data must be sent, including specifying the code sets which must be used. The institutional and professional claim electronic standard implementation guides (X12 837-I and 837-P) each require use of valid codes contained in the HPTC set when there is a need to report provider type or physician, practitioner, or supplier specialty for a claim.

The National Uniform Claim Committee (NUCC) maintains the HPTC set for standardized classification of health care providers, and updates it twice a year with changes effective April 1 and October 1. These changes include the addition of a new code and addition of definitions to existing codes.

You should note that:

1. Valid HPTCs are those that the NUCC has approved for current use;
2. Terminated codes are not approved for use after a specific date;
3. Newly approved codes are not approved for use prior to the effective date of the code set update in which each new code first appears; and
4. Specialty and/or provider type codes issued by any entity other than the NUCC are not valid.

CR9461 implements the NUCC HPTC code set that is effective on April 1, 2016, and instructs MACs to obtain the most recent HPTC set and use it to update their internal HPTC tables and/
When reviewing the Health Care Provider Taxonomy code set online, you can identify revisions made since the last release by the color code:

- New items are green;
- Modified items are orange; and
- Inactive items are red.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.

Kentucky & Ohio

MM9502: Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html

MLN Matters® Number: MM9502  
Related CR Release Date: N/A  
Related CR Transmittal #: N/A  
Related Change Request (CR) #: N/A  
Effective Date: N/A  
Implementation Date: N/A

Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9502 informs MACs about the Healthcare Common Procedure Coding System (HCPCS) codes for 2016 that are both subject to, and excluded from, CLIA edits; and also includes the HCPCS codes discontinued as of December 31, 2015. Make sure that your billing staffs are aware of these CLIA-related changes for 2016.

Background

The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

The HCPCS codes that are considered a laboratory test under CLIA change each year. Contractors need to be informed about the new HCPCS codes that are both subject to CLIA edits and excluded from CLIA edits.
### Discontinued HCPCS Codes

The HCPCS codes listed in Table 1 below were discontinued on December 31, 2015.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0431</td>
<td>Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter</td>
</tr>
<tr>
<td>G0434</td>
<td>Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter</td>
</tr>
<tr>
<td>G6030</td>
<td>Amitriptyline</td>
</tr>
<tr>
<td>G6031</td>
<td>Benzodiazepines</td>
</tr>
<tr>
<td>G6032</td>
<td>Desipramine</td>
</tr>
<tr>
<td>G6034</td>
<td>Doxepin</td>
</tr>
<tr>
<td>G6035</td>
<td>Gold</td>
</tr>
<tr>
<td>G6036</td>
<td>Assay of imipramine</td>
</tr>
<tr>
<td>G6037</td>
<td>Nortriptyline</td>
</tr>
<tr>
<td>G6038</td>
<td>Salicylate</td>
</tr>
<tr>
<td>G6039</td>
<td>Acetaminophen</td>
</tr>
<tr>
<td>G6040</td>
<td>Alcohol (ethanol); any specimen except breath</td>
</tr>
<tr>
<td>G6041</td>
<td>Alkaloids, urine, quantitative</td>
</tr>
<tr>
<td>G6042</td>
<td>Amphetamine or methamphetamine</td>
</tr>
<tr>
<td>G6043</td>
<td>Barbiturates, not elsewhere specified</td>
</tr>
<tr>
<td>G6044</td>
<td>Cocaine or metabolite</td>
</tr>
<tr>
<td>G6045</td>
<td>Dihydrocodeine</td>
</tr>
<tr>
<td>G6046</td>
<td>Dihydromorphine</td>
</tr>
<tr>
<td>G6047</td>
<td>Dihydrotestosterone</td>
</tr>
<tr>
<td>G6048</td>
<td>Dimethadione</td>
</tr>
<tr>
<td>G6049</td>
<td>Epiandrosterone</td>
</tr>
<tr>
<td>G6050</td>
<td>Ethchlorvynol</td>
</tr>
<tr>
<td>G6051</td>
<td>Flurazepam</td>
</tr>
<tr>
<td>G6052</td>
<td>Meprobamate</td>
</tr>
<tr>
<td>G6053</td>
<td>Methadone</td>
</tr>
<tr>
<td>G6054</td>
<td>Methsuximide</td>
</tr>
<tr>
<td>G6055</td>
<td>Nicotine</td>
</tr>
<tr>
<td>G6056</td>
<td>Opiate(s), drug and metabolites, each procedure</td>
</tr>
<tr>
<td>G6057</td>
<td>Phenothiazine</td>
</tr>
<tr>
<td>G6058</td>
<td>Drug confirmation, each procedure</td>
</tr>
<tr>
<td>82486</td>
<td>Chemical analysis</td>
</tr>
<tr>
<td>82487</td>
<td>Chemical analysis</td>
</tr>
<tr>
<td>82488</td>
<td>Chemical analysis</td>
</tr>
<tr>
<td>82489</td>
<td>Chemical analysis</td>
</tr>
<tr>
<td>82491</td>
<td>Chemical analysis</td>
</tr>
<tr>
<td>82492</td>
<td>Chemical analysis</td>
</tr>
<tr>
<td>82541</td>
<td>Chemical analysis using chromatography technique</td>
</tr>
<tr>
<td>82543</td>
<td>Chemical analysis using chromatography technique</td>
</tr>
<tr>
<td>82544</td>
<td>Chemical analysis using chromatography technique</td>
</tr>
<tr>
<td>83788</td>
<td>Mass spectrometry (laboratory testing method)</td>
</tr>
<tr>
<td>88347</td>
<td>Antibody evaluation</td>
</tr>
<tr>
<td>0103T</td>
<td>Measurement of vitamin B-12 deficiency marker</td>
</tr>
</tbody>
</table>
New HCPCS Codes for 2016

The HCPCS codes listed in table 2, below, are new for 2016 and are subject to CLIA edits. The list does not include new HCPCS codes for waived tests or provider-performed procedures. The HCPCS codes listed below require a facility to have either a:

1. CLIA certificate of registration (certificate type code 9);
2. CLIA certificate of compliance (certificate type code 1); or
3. CLIA certificate of accreditation (certificate type code 3).

The following facilities are not permitted to be paid for these tests:

1. A facility without a valid, current, CLIA certificate;
2. A facility with a current CLIA certificate of waiver (certificate type code 2); or
3. A facility with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4).

Table 2: New HCPCS Codes Subject to CLIA Edits for 2016

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0477</td>
<td>Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service</td>
</tr>
<tr>
<td>G0478</td>
<td>Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) read by instrument-assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service</td>
</tr>
<tr>
<td>G0479</td>
<td>Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LTD, DESI, DART, GHPC, GC mass spectrometry, includes sample validation when performed, per date of service</td>
</tr>
<tr>
<td>G0480</td>
<td>Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed</td>
</tr>
<tr>
<td>G0481</td>
<td>Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed</td>
</tr>
<tr>
<td>G0482</td>
<td>Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed</td>
</tr>
<tr>
<td>G0483</td>
<td>Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed</td>
</tr>
<tr>
<td>80081</td>
<td>Blood test panel for obstetrics ( cbc, differential wbc count, hepatitis b, hiv, rubella, syphilis, antibody screening, rbc, blood typing)</td>
</tr>
<tr>
<td>81162</td>
<td>Gene analysis (breast cancer 1 and 2) full sequence and duplication or deletion variants</td>
</tr>
<tr>
<td>81170</td>
<td>Gene analysis (ABL proto-oncogene 1, non-receptor tyrosine kinase)</td>
</tr>
<tr>
<td>81218</td>
<td>Gene analysis (ccaat/enhancer binding protein [c/ebp], alpha) full gene sequence</td>
</tr>
</tbody>
</table>
Table 2: New HCPCS Codes Subject to CLIA Edits for 2016

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>81219</td>
<td>Gene analysis (calreticulin), common variants</td>
</tr>
<tr>
<td>81272</td>
<td>Gene analysis (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog), targeted sequence</td>
</tr>
<tr>
<td>81273</td>
<td>Gene analysis (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog), D816 variants</td>
</tr>
<tr>
<td>81276</td>
<td>Gene analysis (Kirsten rat sarcoma viral oncogene homolog), additional variants;</td>
</tr>
<tr>
<td>81311</td>
<td>Gene analysis for cancer (neuroblastoma)</td>
</tr>
<tr>
<td>81314</td>
<td>Gene analysis ((platelet-derived growth factor receptor, alpha polypeptide) targeted sequence</td>
</tr>
<tr>
<td>81412</td>
<td>Test for detecting genes for disorders related to Ashkenazi Jews</td>
</tr>
<tr>
<td>81432</td>
<td>Gene analysis (breast and related cancers), genomic sequence</td>
</tr>
<tr>
<td>81433</td>
<td>Gene analysis (breast and related cancers), duplication or deletion variants</td>
</tr>
<tr>
<td>81434</td>
<td>Gene analysis (retinal disorders), genomic sequence</td>
</tr>
<tr>
<td>81437</td>
<td>Gene analysis (neuroendocrine tumors), genomic sequence</td>
</tr>
<tr>
<td>81438</td>
<td>Gene analysis (neuroendocrine tumors), duplication and deletion variants</td>
</tr>
<tr>
<td>81442</td>
<td>Gene analysis (noonan syndrome) genomic sequence analysis</td>
</tr>
<tr>
<td>81490</td>
<td>Test for detecting genes associated with rheumatoid arthritis using immunoassay technique</td>
</tr>
<tr>
<td>81493</td>
<td>Test for detecting genes associated with heart vessels diseases</td>
</tr>
<tr>
<td>81525</td>
<td>Gene analysis (colon related cancer)</td>
</tr>
<tr>
<td>81528</td>
<td>Gene analysis (colorectal cancer)</td>
</tr>
<tr>
<td>81535</td>
<td>Culture of live tumor cells and chemotherapy drug response by staining</td>
</tr>
<tr>
<td>81536</td>
<td>Culture of live tumor cells and chemotherapy drug response by staining</td>
</tr>
<tr>
<td>81538</td>
<td>Testing of lung tumor cells for prediction of survival</td>
</tr>
<tr>
<td>81540</td>
<td>Gene analysis (cancer)</td>
</tr>
<tr>
<td>81545</td>
<td>Gene analysis (thyroid cancer)</td>
</tr>
<tr>
<td>81595</td>
<td>Test for detecting genes associated with heart diseases</td>
</tr>
<tr>
<td>88350</td>
<td>Antibody evaluation</td>
</tr>
<tr>
<td>0009M</td>
<td>Fetal aneuploidy (trisomy 21, and 18) dna sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy</td>
</tr>
<tr>
<td>0010M</td>
<td>Oncology (high-grade prostate cancer), biochemical assay of four proteins (total psa, free psa, intact psa and human kallidrein 2 (hk2)) plus patient age, digital rectal examination status, and no history of positive prostate biopsy, utilizing plasma, prognostic algorithm reported as a probability score</td>
</tr>
</tbody>
</table>

MACs will not search their files to either retract payment for claims already paid or retroactively pay claims, but will adjust claims that brought to their attention.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html) under - How Does It Work.
MM9515: New Waived Tests

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html

MLN Matters® Number: MM9515 Related Change Request (CR) #: CR 9515
Related CR Release Date: January 15, 2016 Effective Date: April 1, 2016
Related CR Transmittal #: R3440CP Implementation Date: April 4, 2016

Provider Types Affected
This MLN Matters® Article is intended for clinical diagnostic laboratory providers submitting clinical diagnostic laboratory claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed
The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

The Current Procedural Terminology (CPT) codes that the Centers for Medicare & Medicaid Services (CMS) consider to be laboratory tests under CLIA (and thus requiring certification) change each year. Change Request (CR) 9515 informs the MACs about the latest new CPT codes that are subject to CLIA edits. Make sure your billing staffs are aware of the latest CLIA-related changes.

Background
Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The CPT codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests with CPT codes 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651 do not require a QW modifier to be recognized as a waived test. The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

- 83036QW, August 10, 2015, PTS Diagnostics A1C + Professional Use;
- 82274QW, G0328QW, September 14, 2015, Tanner Scientific iFOB One Step Rapid Test;
- 87502QW, September 18, 2015, Roche Molecular, cobas Liat System (cobas Liat Influenza A/B Assay);
- G0434QW [from October 27, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test Cup;
- G0434QW [from October 27, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Clarity Diagnostics LLC, Clarity Multi-Drug Urine Test DipCard;
- G0434QW [from November 10, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Cup Test;
- G0434QW [from November 10, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], W.H.P.M., Inc. First Sign® Drug of Abuse Butalbital Dip Card Test;
- G0434QW [from November 10, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], W.H.P.M., Inc. First Sign® Drug of Abuse Morphine Dip Card Test;
• G0434QW [from November 13, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], UCP Biosciences, Inc. U-Cup Drug Test Cards;
• G0434QW [from November 13, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], UCP Biosciences, Inc. U-Card Drug Test Cups; and
• G0434QW [from December 14, 2015 to December 31, 2015] and G0477QW [on and after January 1, 2016], Tanner Scientific, Platinum Line® Multi-Panel Drug Test Cup.

The HCPCS code G0434 [Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter] was discontinued on 12/31/2015. The new HCPCS code G0477 [Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service] was effective 1/1/2016. HCPCS code G0477QW describes the waived testing previously assigned code G0434QW. All tests in the attachment to CR9515 that previously had HCPCS G0434QW are now assigned G0477QW.

You should be aware that your MAC will not search their files, to either retract payment or retroactively pay claims; however, they should adjust such claims that you bring to their attention.

Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html) under - How Does It Work.

Kentucky & Ohio

**MM9531: Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) - April Calendar Year (CY) 2016 Update**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9531  
**Related CR Release Date:** February 19, 2016  
**Effective Date:** April 1, 2016  
**Related CR Transmittal #:** R3469CP  
**Implementation Date:** April 4, 2016

**Provider Types Affected**
This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

**Provider Action Needed**
Change Request (CR) 9531 amends payment files that were issued to your MAC based upon the CY 2016 Medicare Physician Fee Schedule (MPFS) Final Rule published in the Federal Register on November 16, 2015. These payment files are to be effective for services furnished
between January 1, 2016, and December 31, 2016. Please make sure your billing staff is aware of these changes.

**Background**

Section 1848(c)(4) of the Social Security Act authorizes the Secretary to establish ancillary policies necessary to implement relative values for physicians’ services.

MACs will not search their files to either retract payment for claims already paid or to retroactively pay claims, however, they will adjust claims that you bring to their attention.

The key changes for the April update that are effective as of January 1, 2016 are as follows:

- CPT/HCPCS code G0464 is assigned a procedure status of I;
- Code 10030 is assigned Global period days of 000;
- Code 77014 is assigned a PC/TC Indicator of 1; and
- Code 80055 is assigned a procedure status of X.

Other changes that are effective for services performed on or after April 1, 2016 are as follows:

- Code G9678 is assigned a procedure status of X;
- G9481 (Remote E/M new pt 10mins) has a PE RVU = 0, all other MPFS indicators/values = code 99201;
- G9482 (Remote E/M new pt 20mins) has a PE RVU = 0, all other MPFS indicators/values = 99202;
- G9483 (Remote E/M new pt 30mins) has a PE RVU = 0, all other MPFS indicators/values = 99203;
- G9484 (Remote E/M new pt 45mins) has a PE RVU = 0, all other MPFS indicators/values = 99204;
- G9485 (Remote E/M new pt 60mins) has a PE RVU = 0, all other MPFS indicators/values = 99205;
- G9486 (Remote E/M est. pt 10mins) has a PE RVU = 0, all other MPFS indicators/values = 99212;
- G9487 (Remote E/M est. pt 15mins) has a PE RVU = 0, all other MPFS indicators/values = 99213;
- G9488 (Remote E/M est. pt 25mins) has a PE RVU = 0, all other MPFS indicators/values = 99214;
- G9489 (Remote E/M est. pt 40mins) has a PE RVU = 0, all other MPFS indicators/values = 99215; and
- G9490 (Joint replac mod home visit) with all MPFS indicators & RVUs = those of G9187.

Codes G9481-G9490 are new and are assigned Type of Service of 1. See the MNL Matters article MM9533 at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9533.pdf for further details of these new codes.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.
MM9533: Comprehensive Care for Joint Replacement Model (CJR) Provider Education

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html

MLN Matters® Number: MM9533  Related Change Request (CR) #: CR 9533
Related CR Release Date: February 19, 2016  Effective Date: April 1, 2016
Related CR Transmittal #: R140DEMO  Implementation Date: April 4, 2016

Provider Types Affected
This MLN Matters® Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for Comprehensive CJR services provided to Medicare beneficiaries.

What You Need to Know
Change Request (CR) 9533 supplies information to providers about the CJR model. The intent of the CJR model is to promote quality and financial accountability for episodes of care surrounding a Lower-Extremity Joint Replacement (LEJR) or reattachment of a lower extremity procedure. CJR will test whether bundled payments to certain acute care hospitals for LEJR episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. Make sure that your billing staffs are aware of these changes.

Background
Section 1115A of the Social Security Act (the Act) authorizes the Centers for Medicare & Medicaid Services (CMS) to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children’s Health Insurance Program beneficiaries. Under this authority, CMS published a rule to implement a new five year payment model called the Comprehensive Care for Joint Replacement (CJR) model on April 1, 2016.

Under the CJR model, acute care hospitals in certain selected geographic areas will take on quality and payment accountability for retrospectively calculated bundled payments for LEJR episodes. Episodes will begin with admission to an acute care hospital for an LEJR procedure that is paid under the Inpatient Prospective Payment System (IPPS) through Medical Severity Diagnosis-Related Group (MS-DRG) 469 (Major joint replacement or reattachment of lower extremity with MCC) or 470 (Major joint replacement or reattachment of lower extremity without MCC) and end 90 days after the date of discharge from the hospital.

Key Points of CR9533
CJR Episodes of Care
LEJR procedures are currently paid under the IPPS through: MS-DRG 469 or MS-DRG 470. The episode will include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge. The day of discharge is counted as the first day of the 90-day bundle.

CJR Participant Hospitals
The model requires all hospitals paid under the IPPS in selected geographic areas to participate in the CJR model, with limited exceptions. A list of the selected geographic areas and participant hospitals is available at https://innovation.cms.gov/initiatives/cjr on the Internet. Participant hospitals initiate episodes when an LEJR procedure is performed.
within the hospital and will be at financial risk for the cost of the services included in the bundle. Eligible beneficiaries who elect to receive care at these hospitals will automatically be included in the model.

CJR Model Beneficiary Inclusion Criteria
Medicare beneficiaries whose care will be included in the CJR model must meet the following criteria upon admission to the anchor hospitalization:

- The beneficiary is enrolled in Medicare Part A and Part B;
- The beneficiary’s eligibility for Medicare is not on the basis of the End-Stage Renal Disease benefit;
- The beneficiary is not enrolled in any managed care plan;
- The beneficiary is not covered under a United Mine Workers of America health plan; and
- Medicare is the primary payer.

If at any time during the episode the beneficiary no longer meets all of these criteria, the episode is canceled.

CJR Performance Years
CMS will implement the CJR model for 5 performance years, as detailed in the table below. Performance years for the model correlate to calendar years with the exception of performance year 1, which is April 1, 2016, through December 31, 2016.

CJR Episode Reconciliation Activities
CMS will continue paying hospitals and other providers and suppliers according to the usual Medicare fee-for-service payment systems during all performance years. After completion of a performance year, Medicare will compare or “reconcile” actual claims paid for a beneficiary during the 90 day episode to an established target price. The target price is an expected amount for the total cost of care of the episode. Hospitals will receive separate target prices to reflect expected spending for episodes assigned to MS-DRGs 469 and 470, as well as hip fracture status. If the actual spending is lower than the target price, the difference will be paid to the hospital, subject to certain adjustments, such as for quality. This payment will be called a reconciliation payment. If actual spending is higher than the target price, hospitals will be responsible for repayment of the difference to Medicare, subject to certain adjustments, such as for quality.

Identifying CJR Claims
To validate the retroactive identification of CJR episodes, CMS is associating the Demonstration Code 75 with the CJR initiative. This code will also be utilized in future CRs to operationalize a waiver of the three-day stay requirement for covered Skilled Nursing Facility (SNF) services, effective for CJR episodes beginning on or after January 1, 2017.

Medicare will automatically apply the CJR demonstration code to claims meeting the criteria for inclusion in the demonstration. Participant hospitals need not include demonstration code 75 on their claims. Instructions for submission of claims for SNF services rendered to beneficiaries in a CJR episode of care will be communicated once the waiver of the three-day stay requirement is operationalized.

Waivers and Amendments of Medicare Program Rules
The CJR model waives certain existing payment system requirements to provide additional flexibilities to hospitals participating in CJR, as well as other providers that furnish services to beneficiaries in CJR episodes. The purpose of such flexibilities would be to increase LEJR episode quality and decrease episode spending or provider and supplier internal costs, The CJR model waives certain existing payment system requirements to provide additional flexibilities to hospitals participating in CJR, as well as other providers that furnish services to beneficiaries in CJR episodes. The purpose of such flexibilities would be to increase LEJR
episode quality and decrease episode spending or provider and supplier internal costs, or both, and to provide better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries.

**Post-Discharge Home Visits**

In order for Medicare to pay for home health services, a beneficiary must be determined to be "home bound." A beneficiary is considered to be confined to the home if the beneficiary has a condition, due to an illness or injury, that restricts his or her ability to leave home except with the assistance of another individual or the aid of a supportive device (that is, crutches, a cane, a wheelchair or a walker) or if the beneficiary has a condition such that leaving his or her home is medically contraindicated. Additional information regarding the homebound requirement is available in the "Medicare Benefit Policy Manual," Chapter 7 ([https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf)), Home Health Services, Section 30.1.1, Patient Confined to the Home.


For those CJR beneficiaries who could benefit from home visits by licensed clinical staff for purposes of assessment and monitoring of their clinical condition, care coordination, and improving adherence with treatment, CMS will waive the "incident to" direct physician supervision requirement to allow a beneficiary who does not qualify for Medicare home health services to receive post-discharge visits in his or her home or place of residence any time during the episode, subject to the following conditions:

- Licensed clinical staff will provide the service under the general supervision of a physician or NPP. These staff can come from a private physician office or may be either an employee or a contractor of the participant hospital.
- Services will be billed under the MPFS by the supervising physician or NPP or by the hospital or other party to which the supervising physician has reassigned his or her billing rights.
- Up to 9 post discharge home visits can be billed and paid per beneficiary during each CJR episode, defined as the 90-day period following the anchor hospitalization.
- The service cannot be furnished to a CJR beneficiary who has qualified, or would qualify, for home health services when the visit was furnished.
- All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

As described in the "Medicare Claims Processing Manual," Chapter 12 ([https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf)), Sections 40-40.4, Medicare policy generally does not allow for separate billing and payment for a postoperative visit furnished during the global period of a surgery when it is related to recovery from the surgery. However, for CJR, CMS will allow the surgeon or other practitioners to bill and be paid separately for a post-discharge home visit that was furnished in accordance with these conditions. All other Medicare rules for global surgery billing during the 90 day post-operative period continue to apply.

CMS expects that the post-discharge home visits by licensed clinical staff could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, and care management to improve beneficiary connections to community and other services.
The service will be billed under the MPFS with a HCPCS G-code (G9490) specific to the CJR post-discharge home visit, as listed in Attachment A. The post-discharge home visit HCPCS code will be payable for CJR model beneficiaries beginning April 1, 2016, the start date of the first CJR model performance year. Claims submitted for post-discharge home visits for the CJR model will be accepted only when the claim contains the CJR specific HCPCS G-Code. Although CMS is associating the Demonstration Code 75 with the CJR initiative, no demonstration code is needed or required on Part B claims submitted with the post-discharge home visit HCPCS G-Code.

Additional information on billing and payment for the post-discharge home visit HCPCS G-Code will be available in the April 2016 release of the MPFS Recurring Update. Future updates to the relative value units (RVUs) and payment for this HCPCS code will be included in the MPFS final rules and recurring updates each year.

Billing and Payment for Telehealth Services

Medicare policy covers and pays for telehealth services when beneficiaries are located in specific geographic areas. Within those geographic areas, beneficiaries must be located in one of the health care settings that are specified in the statute as eligible originating sites. The service must be on the list of approved Medicare telehealth services. Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Additional information regarding Medicare telehealth services is available in the “Medicare Benefit Policy Manual,” Chapter 15 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf), Section 270 and the “Medicare Claims Processing Manual,” Chapter 12 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf), Section 190.

Under CJR, CMS will allow a beneficiary in a CJR episode in any geographic area to receive services via telehealth. CMS also will allow a home or place of residence to be an originating site for beneficiaries in a CJR episode. This will allow payment of claims for telehealth services delivered to beneficiaries at eligible originating sites or at their residence, regardless of the geographic location of the beneficiary. CMS will waive these telehealth requirements, subject to the following conditions:

- Telehealth services cannot substitute for in-person home health visits for patients under a home health episode of care.
- Telehealth services performed by social workers for patients under a home health episode of care will not be covered under the CJR model.
- The telehealth geographic area waiver and the allowance of home as an originating site under the CJR model does not apply for instances where a physician or allowed NPP is performing a face-to-face encounter for the purposes of certifying patient eligibility for the Medicare home health benefit.
- The principal diagnosis code reported on the telehealth claim cannot be one that is specifically excluded from the CJR episode definition.
- If the beneficiary is at home, the physician cannot furnish any telehealth service with a descriptor that precludes delivering the service in the home (for example, a hospital visit code).
- If the physician is furnishing an evaluation and management visit via telehealth to a beneficiary at home, the visit must be billed by one of nine unique HCPCS G-codes developed for the CJR model that reflect the home setting.
- For CJR telehealth home visits billed with HCPCS codes G9484, G9485, G9488, and G9489, the physician must document in the medical record that auxiliary licensed clinical staff were available on site in the patient’s home during the visit or document the reason that such a high-level visit would not require such personnel.
Physicians billing distant site telehealth services under these waivers must include the GT modifier on the claim, which attests that the service was furnished in accordance with all relevant coverage and payment requirements.

The facility fee paid by Medicare to an originating site for a telehealth service will be waived if the service was originated in the beneficiary’s home.

The telehealth home visits will be billed under the MPFS with one of nine HCPCS G-code specific to the CJR telehealth home visits. Those codes are G9481, G9482, G9483, G9484, G9485, G9586, G9487, G9488, and G9499. Attachment A of CR9533 provides the long descriptors of these codes. The telehealth home visit HCPCS codes will be payable for CJR model beneficiaries beginning April 1, 2016, the start date of the first CJR model performance year. Claims submitted for telehealth home visits for the CJR model will be accepted only when the claim contains one of nine of the CJR specific HCPCS G-Code. Although CMS is associating the Demonstration Code 75 with the CJR initiative, no demonstration code is needed or required on Part B claims submitted with the post-discharge home visit HCPCS G-Code. Additional information on billing and payment for the telehealth home visit HCPCS G-Codes will be available in the April 2016 release of the MPFS Recurring Update. Future updates to the RVUs and payment for these HCPCS codes will be included in the MPFS final rules and recurring updates each year.

Additional Information


If you have any questions, please contact your MAC at their toll-free number. That number is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html) under - How Does It Work.

**Kentucky & Ohio**

**MM9536: April 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files**

The Centers for Medicare & Medicaid Services (CMS) has issued the following Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html)

**MLN Matters® Number:** MM9536  
**Related CR Release Date:** February 4, 2016  
**Related CR Transmittal #:** R3450CP  
**Effective Date:** April 1, 2016  
**Implementation Date:** April 1, 2016

**Provider Types Affected**

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment MACs (DME MACs) and Home Health & Hospice MACs (HH&H MACs), for Part B drugs provided to Medicare beneficiaries.

**Provider Action Needed**

Medicare will use the April 2016 quarterly Average Sales Price (ASP) and Not Otherwise Classified (NOC) pricing files to determine the payment limit for claims for separately payable
Medicare Part B drugs processed or reprocessed on or after April 4, 2016, with dates of services from April 1, 2016, through June 30, 2016.

Change Request (CR) 9536 instructs MACs to implement the April 2016 ASP Medicare Part B drug pricing file for Medicare Part B drugs, and if they are released by the Centers for Medicare & Medicaid Services (CMS), to also implement the revised January 2016, October 2015, July 2015, and April 2015 files. Make sure your billing personnel are aware of these changes.

Background
The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP and NOC drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions that are in the “Medicare Claims Processing Manual,” Chapter 4 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf), Section 50.

The following table shows how the files will be applied.

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<thead>
<tr>
<th>Files</th>
<th>Effective Date for Dates of Service</th>
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<tr>
<td>April 2016 ASP and ASP NOC</td>
<td>April 1, 2016, through June 30, 2016</td>
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<tr>
<td>January 2016 ASP and ASP NOC</td>
<td>January 1, 2016, through March 31, 2016</td>
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<tr>
<td>October 2015 ASP and ASP NOC</td>
<td>October 1, 2015, through December 31, 2015</td>
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<tr>
<td>July 2015 ASP and ASP NOC</td>
<td>July 1, 2015, through September 30, 2015</td>
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<tr>
<td>April 2015 ASP and ASP NOC</td>
<td>April 1, 2015, through June 30, 2015</td>
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Additional Information

If you have any questions, please contact your MAC at their toll-free number. That number is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html under - How Does It Work.

Kentucky & Ohio
SE1128 Revised: Prohibition on Balance Billing Dually Eligible Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program

The Centers for Medicare & Medicaid Services (CMS) has revised the following Special Edition Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html

MLN Matters® Number: SE1128 Revised
Related CR Release Date: N/A
Related CR Transmittal #: N/A
Related Change Request (CR) #: N/A
Effective Date: N/A
Implementation Date: N/A

Note: This article was revised on February 4, 2016, to include updated information for 2016 and a correction to the second sentence in paragraph 2 under Important Clarifications Concerning QMB Balance Billing Law on page 3. All other information is the same.
Provider Types Affected
This article pertains to all Medicare physicians, providers and suppliers, including those serving beneficiaries enrolled in original Medicare or a Medicare Advantage plan.

What you Need to Know
STOP – Impact to You
This Special Edition MLN Matters® Article from the Centers for Medicare & Medicaid Services (CMS) reminds all Medicare providers that they may not bill beneficiaries enrolled in the QMB program for Medicare cost-sharing (such charges are known as “balance billing”). QMB is a Medicare Savings Program that exempts Medicare beneficiaries from Medicare cost-sharing liability.

CAUTION – What You Need to Know
The QMB program is a State Medicaid benefit that covers Medicare deductibles, coinsurance, and copayments, subject to State payment limits. (States may limit their liability to providers for Medicare deductibles, coinsurance and copayments under certain circumstances.) Medicare providers may not balance bill QMB individuals for Medicare cost-sharing, regardless of whether the State reimburses providers for the full Medicare cost-sharing amounts. Further, all original Medicare and MA providers — not only those that accept Medicaid—must refrain from charging QMB individuals for Medicare cost-sharing. Providers who inappropriately balance bill QMB individuals are subject to sanctions.

GO – What You Need to Do
Refer to the Background and Additional Information Sections of this article for further details and resources about this guidance. Please ensure that you and your staffs are aware of the federal balance billing law and policies regarding QMB individuals. Contact the Medicaid Agency in the States in which you practice to learn about ways to identify QMB patients in your State and procedures applicable to Medicaid reimbursement for their Medicare cost-sharing. If you are a Medicare Advantage provider, you may also contact the MA plan for more information. Finally, all Medicare providers should ensure that their billing software and administrative staff exempt QMB individuals from Medicare cost-sharing billing and related collection efforts.

Background
This article provides CMS guidance to Medicare providers to help them avoid inappropriately billing QMBs for Medicare cost-sharing, including deductibles, coinsurance, and copayments. This practice is known as “balance billing.”

Balance Billing of QMBs Is Prohibited by Federal Law

QMB is a Medicaid program for Medicare beneficiaries that exempts them from liability for Medicare cost-sharing. State Medicaid programs may pay providers for Medicare deductibles, coinsurance and copayments. However, as permitted by federal law, States can limit provider reimbursement for Medicare cost-sharing under certain circumstances. See the chart at the end of this article for more information about the QMB benefit.

Medicare providers must accept the Medicare payment and Medicaid payment (if any) as payment in full for services rendered to a QMB beneficiary. Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions. (See Sections 1902(n)(3)(C); 1905(p)(3); 1866(a)(1)(A); 1848(g)(3)(A) of the Social Security Act.)
Inappropriate Balance Billing Persists

Despite federal law, erroneous balance billing of QMB individuals persists. Many beneficiaries are unaware of the billing restrictions (or concerned about undermining provider relationships) and simply pay the cost-sharing amounts. Others may experience undue distress when unpaid bills are referred to collection agencies. See Access to Care Issues Among Qualified Medicare Beneficiaries (QMB), Centers for Medicare & Medicaid Services July 2015 at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/Access_to_Care_Issues_Among_Qualified_Medicare_Beneficiaries.pdf on the CMS website.

Important Clarifications Concerning QMB Balance Billing Law

Be aware of the following policy clarifications to ensure compliance with QMB balance billing requirements. First, know that all original Medicare and MA providers — not only those that accept Medicaid — must abide by the balance billing prohibitions.

In addition, QMB individuals retain their protection from balance billing when they cross state lines to receive care. Providers cannot charge QMB individuals even if the patient’s QMB benefit is provided by a different State than the State in which care is rendered.

Finally, note that QMBs cannot choose to “waive” their QMB status and pay Medicare cost-sharing. The federal statute referenced above supersedes Section 3490.14 of the “State Medicaid Manual,” which is no longer in effect.

Ways to Improve Processes Related to QMBs

Proactive steps to identify QMB individuals you serve and to communicate with State Medicaid Agencies (and Medicare Advantage plans if applicable), can promote compliance with QMB balance billing prohibitions.

1. Determine effective means to identify QMB individuals among your patients. Find out what cards are issued to QMB individuals so you can in turn ask all your patients if they have them. Learn if you can query state systems to verify QMB enrollment among your patients. If you are a Medicare Advantage provider contact the plan to determine how to identify the plan’s QMB enrollees.

2. Discern what billing processes apply to seek reimbursement for Medicare cost-sharing from the States in which you operate. Different processes may apply to original Medicare and MA services provided to QMB beneficiaries. For original Medicare claims, nearly all states have electronic crossover processes through the Medicare Benefits Coordination & Recovery Center (BCRC) to automatically receive Medicare-adjudicated claims.
   - If a claim is automatically crossed over to another payer, such as Medicaid, it is customarily noted on the Medicare Remittance Advice.
   - Understand the processes you need to follow to request reimbursement for Medicare cost-sharing amounts if they are owed by your State. You may need to complete a State Provider Registration Process and be entered into the State payment system to bill the State.

3. Make sure that your billing software and administrative staff exempt QMB individuals from Medicare cost-sharing billing and related collection efforts.
QMB Eligibility and Benefits

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<tr>
<th>Dual Eligibility</th>
<th>Eligibility Criteria</th>
<th>Benefits</th>
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| Qualified Medicare Beneficiary (QMB only) | • Resources cannot exceed $7,280 for a single individual or $10,930 in 2015 for an individual living with a spouse and no other dependents.  
• Income cannot exceed 100% of the Federal Poverty Level (FPL) + $22 ($1,001/month – Individual $1,348/month – Couple in 2015).  
Note: These guidelines are a federal floor. Under Section 1902(r)(2) of the Social Security Act, states can effectively raise these limits above these baseline federal standards. | Medicaid Pays Medicare Part A and B premiums, deductibles, co-insurance and co-pays to the extent required by the State Medicaid Plan.  
• Exempts beneficiaries from Medicare cost-sharing charges  
• The State may choose to pay the Medicare Advantage (Part C) premium. |
| QMB Plus | • Meets all of the standards for QMB eligibility as described above, but also meets the financial criteria for full Medicaid coverage | Provides all benefits available to QMBs, as well as all benefits available under the State Plan to a fully eligible Medicaid recipient |

**Additional Information**

For more information about dual eligible categories and benefits, please visit [http://www.medicare.gov/Publications/Pubs/pdf/10126.pdf](http://www.medicare.gov/Publications/Pubs/pdf/10126.pdf) on the Internet. Also, for more information about QMBs and other individuals who are dually eligible to receive Medicare and Medicaid benefits, please refer to the Medicare Learning Network® publication titled "Medicaid Coverage of Medicare Beneficiaries (Dual Eligibles)," which is available on the CMS website.

For general Medicaid information, please visit the Medicaid webpage at [http://www.medicaid.gov/index.html](http://www.medicaid.gov/index.html) on the CMS website.

**Document History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 4, 2016</td>
<td>The article was revised on February 4, 2016, to include updated information for 2016 and a correction to the second sentence in paragraph 2 under <em>Important Clarifications Concerning QMB Balance Billing Law</em> on page 3.</td>
</tr>
<tr>
<td>February 1, 2016</td>
<td>The article was revised to include updated information for 2016 and a clarifying note regarding eligibility criteria in the table on page 4.</td>
</tr>
<tr>
<td>March 28, 2014</td>
<td>The article was revised on to change the name of the Coordination of Benefits Contractor (COBC) to Benefits Coordination &amp; Recovery Center (BCRC).</td>
</tr>
</tbody>
</table>

**Kentucky & Ohio**

**SE1417 Revised: Implementation of Fingerprint-Based Background Checks**


**MLN Matters® Number:** SE1417 Revised  
**Related Change Request (CR) #:** N/A  
**Effective Date:** N/A  
**Implementation Date:** N/A

**Note:** This article was revised on January 27, 2016, to update language in the article and to emphasize affected providers and suppliers in the Caution Section.

**Provider Types Affected**

This MLN Matters® Special Edition article is intended for all providers and suppliers who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.
Provider Action Needed

STOP – Impact to You
This Special Edition article is being provided by the Centers for Medicare & Medicaid Services (CMS) to announce the implementation of fingerprint-based background checks as part of enhanced enrollment screening provisions contained in Section 6401 of the Affordable Care Act.

CAUTION – What You Need to Know
Fingerprint-based background checks are generally completed on individuals with a 5 percent or greater ownership interest in a provider or supplier that falls under the high risk category. A 5 percent or greater owner includes any individual that has any partnership (general or limited) in a high risk provider or supplier. Note that the high level of risk category applies to providers and suppliers who are newly enrolling Durable Medicare Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers or Home Health Agencies (HHA). It also applies to providers and suppliers who have been elevated to the high risk category. CMS may adjust a particular provider or supplier’s screening level from “limited” to “high” or “moderate” to “high” if any of the following occur:

- CMS has imposed a payment suspension within the last 10 years;
- Has been excluded from Medicare by the OIG;
- Has had billing privileges revoked by CMS within the previous 10 years;
- Has been excluded from any Federal Health Care program;
- Has been subject to any final adverse action, in the previous 10 years;
- Has been terminated or is otherwise precluded from billing Medicaid; or

CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.

GO – What You Need to Do
See the Background and Additional Information Sections of this article for further details.

Background
As part of the enhanced enrollment screening provisions contained in the Affordable Care Act (see http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf), the Centers for Medicare & Medicaid Services (CMS) implemented fingerprint-based background checks. The fingerprint-based background checks will be used to detect bad actors who are attempting to enroll in the Medicare program and to remove those currently enrolled. Once fully implemented, the fingerprint-based background check will be completed on all individuals with a 5 percent or greater ownership interest in a provider or supplier that falls under the high risk category. A 5 percent or greater owner includes any individual that has any partnership (general or limited) in a provider or supplier. Fingerprint-based background checks are also required for any provider or supplier who has been elevated to the high risk category for any of the following reasons:

- CMS has imposed a payment suspension within the last 10 years;
- Has been excluded from Medicare by the OIG;
- Has had billing privileges revoked by CMS within the previous 10 years;
- Has been excluded from any Federal Health Care program;
- Has been subject to any final adverse action, in the previous 10 years;
- Has been terminated or is otherwise precluded from billing Medicaid; or
CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.


Note: The fingerprint-based background checks will be applied to providers and suppliers in the high level of risk category, which includes newly enrolling Durable Medicare Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, Home Health Agencies (HHA) and providers and suppliers who have been elevated to the high risk category in accordance with enrollment screening regulations.

The fingerprint-based background check implementation has been phased in beginning in 2014. Affected providers and suppliers will receive notification of the fingerprint requirements from their MAC. The MAC will send a notification letter to the affected providers or suppliers listing all 5 percent or greater owners who are required to be fingerprinted. The notification letter will be mailed to the provider or supplier’s correspondence address and the special payments address on file with Medicare. Generally, an individual will be required to be fingerprinted only once, but CMS reserves the right to request additional fingerprints if needed.

The relevant individuals will have 30 days from the date of the notification letter to be fingerprinted. If the provider or supplier finds a discrepancy in the ownership listing, the provider or supplier should contact their MAC immediately to communicate the discrepancy and take the appropriate action to update the enrollment record to correctly reflect the ownership information.

The notification letter will identify contact information for the Fingerprint-Based Background Check Contractor (FBBC). The relevant individual(s) are required to contact the FBBC prior to being fingerprinted to ensure the fingerprints are accurately submitted to the Federal Bureau of Investigation (FBI) and results are properly returned to CMS. Providers/suppliers may contact the FBBC by telephone or by accessing the FBBC’s website. Contact information for the FBBC will be provided in the notification letter received from the MAC. Once contacted, the FBBC will provide at least three fingerprint locations convenient to the relevant individual’s location. One of these locations will be a local, state, or federal law enforcement facility.

The relevant individuals who are required to undergo the fingerprint-based background check will incur the cost of having their fingerprints taken, and the cost may vary depending on location. Once an individual has submitted his/her fingerprints, if that individual is subsequently required to undergo a fingerprint-based background check in accordance with 42 CFR 424.518(c), CMS will, to the extent possible, rerun the fingerprint-based background check rather than requiring resubmission of fingerprints. You can review 42 CFR 424.518(c) at http://www.ecfr.gov/cgi-bin/text-idx?SID=f14b263d1175a355d736e9f38f3a6baf&node=42:3.0.1.11.12.5.11&rgn=div8 on the Internet.

Fingerprinting can be completed on the FD-258 form or electronically at certain locations. CMS strongly encourages all required applicants to provide electronic fingerprints, but CMS will accept the FD-258 card instead. If the FD-258 form is submitted, the FBBC will convert the paper form to electronic submission to the FBI. You can review the FD-258 form at https://www.fbi.gov/about-us/cjis/identity-history-summary-checks/fd-258-1 on the Internet.

Once the fingerprint process is complete, the fingerprints will be forwarded to the FBI for processing. Within 24 hours of receipt, the FBI will compile the background history based on the fingerprints and will share the results with the FBBC. CMS, through the FBBC, will assess the law enforcement data provided for the fingerprinted individuals. The FBBC will review each
record and provide a fitness recommendation to CMS. CMS will assess the recommendation and make a final determination.

- All fingerprint data will be stored according to:
  - Federal requirements;
  - FBI Security and Management Control Outsourcing Standards for Channelers and Non-Channelers; and
  - The FBI Criminal Justice Information Services (CJIS) Security Policy.

The FBBC will maintain Federal Information Systems Management Act (FISMA) certification and comply with the FBI (CJIS) Security Policy. All data will be secured in accordance with the Privacy Act of 1974 and the FBI CJIS Security Policy.

CMS will rely on existing authority to deny enrollment applications and revoke existing Medicare billing privileges per 42 CFR §424.530(a) and §424.535(a) (http://www.ecfr.gov/cgi-bin/text-idx?SID=f14b263d117fa355d736e9f38f3a6ba&node=42:3.0.1.1.11.12.5.15&rgn=div8) if an individual who maintains a 5 percent or greater direct or indirect ownership interest in a provider or supplier has submitted an enrollment application that contains false or misleading information. Providers or suppliers will be notified by CMS if the assessment of the fingerprint based background check results in the denial of its enrollment application or revocation of its existing Medicare billing privileges.

**Additional Information**

If you have any questions, please contact your MAC at their toll-free number, which may be found at [http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html](http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html) on the CMS website.

**Document History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>January 27, 2016</td>
<td>The article was revised to update language in the article and to emphasize affected providers and suppliers in the Caution Section.</td>
</tr>
</tbody>
</table>

**Kentucky & Ohio**

**SE1425 Revised: Extension of Provider Enrollment Moratoria for Home Health Agencies and Part B Ambulance Suppliers**

The Centers for Medicare & Medicaid Services (CMS) has revised the following Special Edition Medicare Learning Network® (MLN) Matters article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html)

MLN Matters® Number: SE1425 Revised Related Change Request (CR) #: N/A
Related CR Release Date: N/A Effective Date: N/A
Related CR Transmittal #: N/A Implementation Date: N/A

**Note:** This article was revised on February 2, 2016, to reflect an extension of the temporary moratoria for an additional 6 months, as noted in the article. All other information remains the same.

**Provider Types Affected**

This MLN Matters® Article is intended for home health agencies, home health agency sub-units, and part B ground ambulance suppliers in certain geographic areas of Florida, Illinois, Michigan,
Texas, Pennsylvania and New Jersey that provide services to Medicare, Medicaid and CHIP beneficiaries.

**Provider Action Needed**

**STOP – Impact to You**

Effective January 29, 2016, the temporary moratoria on new home health agencies, home health agency sub-units, and part B ground ambulance suppliers are being extended for an additional 6 months in certain geographic locations.

**CAUTION – What You Need to Know**

During the 6-month temporary moratoria, initial provider enrollment applications and change of information applications to add additional practice locations, received from home health agencies, home health agency sub-units, and Part B ground ambulance suppliers in the moratoria counties will be denied. Application fees that are paid for applications that are denied due to the temporary moratoria will be refunded.

**GO – What You Need to Do**

Effective January 29, 2016, home health agencies, home health agency sub-units, and part B ground ambulance suppliers should not submit initial enrollment applications or change of information applications to add additional practice locations until the 6-month moratoria has expired. CMS will announce in the Federal Register when the moratorium has been lifted, extended, or changed.

**Background**

In accordance with 42 CFR §424.570(c), the Centers for Medicare & Medicaid Services (CMS) may impose a moratorium on the enrollment of new Medicare providers and suppliers of a specific type or the establishment of new practice locations in a particular geographic area.

On January 29, 2016, CMS announced, in a Federal Register notice ([http://federalregister.gov/a/2016-01835](http://federalregister.gov/a/2016-01835)), the extension of temporary moratoria on the enrollment of new home health agencies, home health agency sub-units and part B ambulance suppliers in designated geographic locations.

The moratoria initially became effective on July 30, 2013, and the implementation was announced in the Federal Register which may be accessed on the internet at: [https://federalregister.gov/a/2013-18394](https://federalregister.gov/a/2013-18394). The moratoria were expanded on January 30, 2014, and the expansion was announced in the Federal Register which may be accessed at: [https://federalregister.gov/a/2014-02166](https://federalregister.gov/a/2014-02166).

**Moratoria Extension**

Effective January 29, 2016, the temporary moratorium on new home health agencies and home health agency sub-units is being extended for an additional 6 months in the areas stated in Table 1, below.

<table>
<thead>
<tr>
<th>City and State</th>
<th>Counties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fort Lauderdale, FL</td>
<td>Broward</td>
</tr>
<tr>
<td>Miami, FL</td>
<td>Miami-Dade, Monroe</td>
</tr>
<tr>
<td>Detroit, MI</td>
<td>Macomb, Monroe, Oakland, Washtenaw, Wayne</td>
</tr>
<tr>
<td>Dallas, TX</td>
<td>Collin, Dallas, Denton, Ellis, Kaufman, Rockwall, Tarrant</td>
</tr>
<tr>
<td>Houston, TX</td>
<td>Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, Waller</td>
</tr>
<tr>
<td>Chicago, IL</td>
<td>Cook, DuPage, Kane, Lake, McHenry, Will</td>
</tr>
</tbody>
</table>

In addition, the temporary moratorium on new part B ground ambulance suppliers is being extended for an additional 6 months in the areas stated in Table 2, below.
Table 2: Part B Ambulance Suppliers Under 6-month Temporary Moratorium

<table>
<thead>
<tr>
<th>City and State</th>
<th>Counties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Houston, TX</td>
<td>Harris Brazoria</td>
</tr>
<tr>
<td></td>
<td>Chambers</td>
</tr>
<tr>
<td></td>
<td>Fort Bend</td>
</tr>
<tr>
<td></td>
<td>Galveston</td>
</tr>
<tr>
<td></td>
<td>Liberty</td>
</tr>
<tr>
<td></td>
<td>Montgomery</td>
</tr>
<tr>
<td></td>
<td>Waller</td>
</tr>
<tr>
<td>Philadelphia, PA</td>
<td>Bucks (PA)</td>
</tr>
<tr>
<td></td>
<td>Delaware (PA)</td>
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<tr>
<td></td>
<td>Montgomery (PA)</td>
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<td>Philadelphia (PA)</td>
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<td></td>
<td>Burlington (NJ)</td>
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<tr>
<td></td>
<td>Camden (NJ)</td>
</tr>
<tr>
<td></td>
<td>Gloucester (NJ)</td>
</tr>
</tbody>
</table>

Initial provider enrollment applications and change of information applications to add additional practice locations received from home health agencies, home health agency sub-units, and Part B ground ambulance suppliers in the above listed counties will be denied in accordance with 42 CFR §424.570(c). Application fees that are paid for applications that are denied due to the temporary moratoria will be refunded.

**Note:** Home health agencies, home health agency sub-units, and Part B ground ambulance suppliers are afforded appeal rights. However, the scope of review will be limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. CMS’ basis for imposing a temporary moratorium is not subject to review.

**Additional Information**


If you have any questions, please contact your MAC at their toll-free number, which is available at [http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html](http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html) on the CMS website.

**Kentucky & Ohio**

**SE1605: Provider Enrollment Revalidation – Cycle 2**

The Centers for Medicare & Medicaid Services (CMS) has issued the following *Special Edition Medicare Learning Network® (MLN) Matters* article. This MLN Matters article and other CMS articles can be found on the CMS website at: [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/2015-MLN-Matters-Articles.html)

**MLN Matters® Number:** SE1605  
**Related CR Release Date:** N/A  
**Related CR Transmittal #:** N/A  
**Related Change Request (CR) #:** N/A  
**Effective Date:** N/A  
**Implementation Date:** N/A

**Provider Types Affected**

This Medicare Learning Network (MLN) Matters® Special Edition Article is intended for all providers and suppliers who are enrolled in Medicare and required to revalidate through their Medicare Administrative Contractors (MACs), including Home Health & Hospice MACs (HH&H MACs), Medicare Carriers, Fiscal Intermediaries, and the National Supplier Clearinghouse (NSC). These contractors are collectively referred to as MACs in this article.

**Provider Action Needed**

**STOP – Impact to You**

Section 6401 (a) of the Affordable Care Act established a requirement for all enrolled providers/suppliers to revalidate their Medicare enrollment information under new enrollment screening criteria. The Centers for Medicare & Medicaid Services (CMS) has completed its initial round of revalidations and will be resuming regular revalidation cycles in accordance with 42 CFR §424.515. In an effort to streamline the revalidation process and reduce provider/supplier
burden, CMS has implemented several revalidation processing improvements that are captured within this article.

**CAUTION – What You Need to Know**

**Special Note:** The Medicare provider enrollment revalidation effort does not change other aspects of the enrollment process. Providers/suppliers should continue to submit changes (for example, changes of ownership, change in practice location or reassignments, final adverse action, changes in authorized or delegated officials or, any other changes) as they always have. If you also receive a request for revalidation from the MAC, respond separately to that request.

**GO – What You Need to Do**

1. Check [http://go.cms.gov/MedicareRevalidation](http://go.cms.gov/MedicareRevalidation) for the provider/suppliers due for revalidation;

2. If the provider/supplier has a due date listed, CMS encourages you to submit your revalidation within six months of your due date or when you receive notification from your MAC to revalidate. When either of these occur:

   - Submit a revalidation application through Internet-based PECOS located at [https://pecos.cms.hhs.gov/pecos/login.do](https://pecos.cms.hhs.gov/pecos/login.do), the fastest and most efficient way to submit your revalidation information. Electronically sign the revalidation application and upload your supporting documentation or sign the paper certification statement and mail it along with your supporting documentation to your MAC; or
   
   - Complete the appropriate CMS-855 application available at [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html);
   
   - If applicable, pay your fee by going to [https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do](https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do); and
   
   - Respond to all development requests from your MAC timely to avoid a hold on your Medicare payments and possible deactivation of your Medicare billing privileges.

**Background**

Section 6401 (a) of the Affordable Care Act established a requirement for all enrolled providers/suppliers to revalidate their Medicare enrollment information under new enrollment screening criteria. CMS has completed its initial round of revalidations and will be resuming regular revalidation cycles in accordance with 42 CFR §424.515. This cycle of revalidation applies to those providers/suppliers that are currently and actively enrolled.

**What's ahead for your next Medicare enrollment revalidation?**

**Established Due Dates for Revalidation**

CMS has established due dates by which the provider/supplier’s revalidation application must reach the MAC in order for them to remain in compliance with Medicare’s provider enrollment requirements. The due dates will generally be on the last day of a month (for example, June 30, July 31 or August 31). Submit your revalidation application to your MAC within 6 months of your due date to avoid a hold on your Medicare payments and possible deactivation of your Medicare billing privileges. Generally, this due date will remain with the provider/supplier throughout subsequent revalidation cycles.

- The list will be available at [http://go.cms.gov/MedicareRevalidation](http://go.cms.gov/MedicareRevalidation) and will include all enrolled providers/suppliers. Those due for revalidation will display a revalidation due date, all other providers/suppliers not up for revalidation will display a “TBD” (To Be Determined) in the due date field. In addition, a crosswalk to the organizations that the individual provider reassigns benefits will also be available at [http://go.cms.gov/MedicareRevalidation](http://go.cms.gov/MedicareRevalidation) on the CMS website.
IMPORTANT: The list identifies billing providers/suppliers only that are required to revalidate. If you are enrolled solely to order, certify, and/or prescribe via the CMS-855O application or have opted out of Medicare, you will not be asked to revalidate and will not be reflected on the list.

- Due dates are established based on your last successful revalidation or initial enrollment (approximately 3 years for DME suppliers and 5 years for all other providers/suppliers).
- In addition, the MAC will send a revalidation notice within 2-3 months prior to your revalidation due date either by e-mail (to e-mail addresses reported on your prior applications) or regular mail (at least two of your reported addresses: correspondence, special payments and/or your primary practice address) indicating the provider/supplier’s due date.

Revalidation notices sent via e-mail will indicate “URGENT: Medicare Provider Enrollment Revalidation Request” in the subject line to differentiate from other emails. If all of the e-mails addresses on file are returned as undeliverable, your MAC will send a paper revalidation notice to at least two of your reported addresses: correspondence, special payments and/or primary practice address.

**NOTE:** Providers/suppliers who are within 2 months of their listed due dates on [http://go.cms.gov/MedicareRevalidation](http://go.cms.gov/MedicareRevalidation) but have not received a notice from their MAC to revalidate, are encouraged to submit their revalidation application.

- To assist with submitting complete revalidation applications, revalidation notices for individual group members, will list the identifying information of the organizations that the individual reassigns benefits.

**Large Group Coordination**

Large groups (200+ members) accepting reassigned benefits from providers/suppliers identified on the CMS list will receive a letter from their MACs listing the providers linked to their group that are required to revalidate for the upcoming 6 month period. A spreadsheet detailing the applicable provider’s Name, National Provider Identifier (NPI) and Specialty will also be provided. CMS encourages the groups to work with their practicing practitioners to ensure that the revalidation application is submitted prior to the due date. We encourage all groups to work together as only one application from each provider/supplier is required, but the provider must list all groups they are reassigning to on the revalidation application submitted for processing. MACs will have dedicated provider enrollment staff to assist in the large group revalidations.

Groups with less than 200 reassignments will not receive a letter or spreadsheet from their MAC, but can utilize PECOS or the CMS list available on [http://go.cms.gov/MedicareRevalidation](http://go.cms.gov/MedicareRevalidation) to determine their provider/supplier’s revalidation due dates.

**Unsolicited Revalidation Submissions**

All unsolicited revalidation applications submitted more than 6 months in advance of the provider/supplier’s due date will be returned

- What is an unsolicited revalidation?
  - If you are not due for revalidation in the current 6 month period, your due date will be listed as “TBD” (To Be Determined). This means that you do not yet have a due date for revalidation. **Please do not submit a revalidation application if there is NOT a listed due date.**
  - Any off-cycle or ad hoc revalidations specifically requested by CMS or the MAC are not considered unsolicited revalidations.
  - If your intention is to submit a change to your provider enrollment record, you must submit a ‘change of information’ application using the appropriate CMS-855 form.
Submitting Your Revalidation Application

**IMPORTANT:** Each provider/supplier is required to revalidate their entire Medicare enrollment record.

A provider/supplier’s enrollment record includes information such as the provider’s individual practice locations and every group that benefits are reassigned (that is, the group submits claims and receives payments directly for services provided). This means the provider/supplier is recertifying and revalidating all of the information in the enrollment record, including all assigned NPIs and Provider Transaction Access Numbers (PTANs).

If you are an individual who reassigns benefits to more than one group or entity, you must include all organizations to which you reassign your benefits on one revalidation application. If you have someone else completing your revalidation application for you, encourage coordination with all entities to which you reassign benefits to ensure your reassignments remain intact.

The fastest and most efficient way to submit your revalidation information is by using the Internet-based PECOS.

To revalidate via the Internet-based PECOS, go to [https://pecos.cms.hhs.gov/pecos/login.do](https://pecos.cms.hhs.gov/pecos/login.do). PECOS allows you to review information currently on file and update and submit your revalidation via the Internet. Once completed, YOU MUST electronically sign the revalidation application and upload any supporting documents or print, sign, date, and mail the paper certification statement along with all required supporting documentation to your appropriate MAC IMMEDIATELY.

PECOS ensures accurate and timelier processing of all types of enrollment applications, including revalidation applications. It provides a far superior alternative to the antiquated paper application process.

To locate the paper enrollment applications, refer to [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html) on the CMS website.

**Getting Access to PECOS:**

To use PECOS, you must get approved to access the system with the proper credentials which are obtained through the Identity and Access Management System, commonly referred to as “I&A”. The I&A system ensures you are properly set up to submit PECOS applications. Once you have established an I&A account you can then use PECOS to submit your revalidation application as well as other enrollment application submissions.


If you have questions regarding filling out your application via PECOS, please contact the MAC that sent you the revalidation notice. You may also find a list of MAC’s at [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/contact_list.pdf](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/contact_list.pdf) on the CMS website.

For questions about accessing PECOS (such as login, forgot username/password) or I&A, contact the External User Services (EUS) help desk at 1.866.484.8049 or at [EUSSupport@cgi.com](mailto:EUSSupport@cgi.com).

**Deactivations Due to Non-Response to Revalidation or Development Requests**

It is important that you submit a complete revalidation application by your requested due date and you respond to all development requests from your MACs timely. **Failure to submit a**
complete revalidation application or respond timely to development requests will result in possible deactivation of your Medicare enrollment.

If your application is received substantially after the due date, or if you provide additional requested information substantially after the due date (including an allotted time period for US or other mail receipt) your provider enrollment record may be deactivated. Providers/suppliers deactivated will be required to submit a new full and complete application in order to reestablish their provider enrollment record and related Medicare billing privileges. The provider/supplier will maintain their original PTAN; however, an interruption in billing will occur during the period of deactivation resulting in a gap in coverage.

**NOTE:** The reactivation date after a period of deactivation will be based on the receipt date of the new full and complete application. Retroactive billing privileges back to the period of deactivation will not be granted. Services provided to Medicare patients during the period between deactivation and reactivation are the provider’s liability.

### Revalidation Timeline and Example

Providers/suppliers may use the following table/chart as a guide for the sequence of events through the revalidation progression.

<table>
<thead>
<tr>
<th>Action</th>
<th>Timeframe</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revalidation list posted</td>
<td>Approximately 6 months prior to due date</td>
<td>March 30, 2016</td>
</tr>
<tr>
<td>Issue large group notifications</td>
<td>Approximately 6 months prior to due date</td>
<td>March 30, 2016</td>
</tr>
<tr>
<td>MAC sends email/letter notification</td>
<td>75 – 90 days prior to due date</td>
<td>July 2 - 17, 2016</td>
</tr>
<tr>
<td>MAC sends letter for undeliverable e-mails</td>
<td>75 – 90 days prior to due date</td>
<td>July 2 - 17, 2016</td>
</tr>
<tr>
<td>Revalidation due date</td>
<td></td>
<td>September 30, 2016</td>
</tr>
<tr>
<td>Apply payment hold/issue reminder letter (group members)</td>
<td>Within 25 days after due date</td>
<td>October 25, 2016</td>
</tr>
<tr>
<td>Deactivate</td>
<td>60 – 75 days after due date</td>
<td></td>
</tr>
</tbody>
</table>

### Application Fees

Institutional providers of medical or other items or services and suppliers are required to submit an application fee for revalidations. The application fee is $554.00 for Calendar Year (CY) 2016. CMS has defined “institutional provider” to mean any provider or supplier that submits an application via PECOS or a paper Medicare enrollment application using the CMS-855A, CMS-855B (except physician and non-physician practitioner organizations), or CMS-855S forms.

All institutional providers (that is, all providers except physicians, non-physicians practitioners, physician group practices and non-physician practitioner group practices) and suppliers who respond to a revalidation request must submit the 2016 enrollment fee (reference 42 CFR 424.514) with their revalidation application. You may submit your fee by ACH debit, or credit card. To pay your application fee, go to [https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do](https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do) and submit payment as directed. A confirmation screen will display indicating that payment was successfully made. This confirmation screen is your receipt and you should print it for your records. CMS strongly recommends that you include this receipt with your uploaded documents on PECOS or mail it to the MAC along with the Certification Statement for the enrollment application. CMS will notify the MAC that the application fee has been paid. Revalidations are processed only when fees have cleared.

**SUMMARY:**

- CMS will post the revalidation due dates for the upcoming revalidation cycle on [http://go.cms.gov/MedicareRevalidation](http://go.cms.gov/MedicareRevalidation) for all providers/suppliers. This list will be refreshed periodically. Check this list regularly for updates.

- MACs will continue to send revalidation notices (either by e-mail or mail) within 2-3 months prior to your revalidation due date. When responding to revalidation requests, be sure to revalidate your entire Medicare enrollment record, including all reassignment
and practice locations. If you have multiple reassignments/billing structures, you must coordinate the revalidation application submission with all parties.

- If a revalidation application is received but incomplete, the MACs will develop for the missing information. If the missing information is not received within 30 days of the request, the MACs will deactivate the provider/supplier’s billing privileges.
- If a revalidation application is not received by the due date, the MAC may place a hold on your Medicare payments and deactivate your Medicare billing privileges.
- If billing privileges are deactivated, a reactivation will result in the same PTAN but an interruption in billing during the period of deactivation. This will result in a gap in coverage.
- If the revalidation application is approved, the provider/supplier will be revalidated and no further action is needed.

Additional Information
To find out whether a provider/supplier has been mailed a revalidation notice go to http://go.cms.gov/MedicareRevalidation on the CMS website. A sample revalidation letter is available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/SampleRevalidationLetter.pdf on the CMS website. A revalidation checklist is available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Revalidations.html

For more information about the enrollment process and required fees, refer to MLN Matters® Article MM7350, which is available at the CMS website. http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7350.pdf on the CMS website.

For more information about the application fee payment process, refer to MLN Matters Article SE1130, which is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1130.pdf on the CMS website.

The MLN fact sheet titled “The Basics of Internet-based Provider Enrollment, Chain and Ownership System (PECOS) for Provider and Supplier Organizations” is designed to provide education to provider and supplier organizations on how to use Internet-based PECOS to enroll in the Medicare Program and is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedEnroll_PECOS_ProviderSup_FactSheet_ICN903767.pdf on the CMS website.

To access PECOS, your Authorized Official must register with the PECOS Identification and Authentication system. To register for the first time go to https://pecos.cms.hhs.gov/pecos/PecosIAConfirm.do?transferReason=CreateLogin to create an account.

For additional information about the enrollment process and Internet-based PECOS, please visit the Medicare Provider-Supplier Enrollment webpage at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html on the CMS website.

If you have questions, contact your MAC. Medicare provider enrollment contact information for each State can be found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/contact_list.pdf on the CMS website.

Kentucky & Ohio

News Flash Items

- NEW product from the Medicare Learning Network® (MLN)
  - Provider Compliance Tips for Computed Tomography (CT) Scans (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-
Revised products from the Medicare Learning Network® (MLN)