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ORAL ARGUMENT NOT SCHEDULED

March 7, 2013

Via Electronic Case Filing

Mr. Mark J. Langer
Clerk of the Court
U.S. Court of Appeals, D.C. Circuit
333 Constitution Ave., NW
Washington, D.C. 20001

**Re: *Ass'n of Am. Physicians & Surgeons, Inc. v. Sebelius*, No. 13-5003
Notice of Supplemental Authority, FED. R. APP. P. 28(j):**

**Centers for Medicare & Medicaid Services, MLN Matters No:
SE1305, *Full Implementation of Edits on the Ordering Referring
Providers in Medicare Part B, DME, and Part A Home Health
Agency (HHA) Claims (Change Requests 6417, 6421, 6696, and
6856) (Mar. 1, 2013)***

Dear Mr. Langer:

Plaintiffs-appellants Association of American Physicians & Surgeons and Alliance for Natural Health USA hereby notify the Court of the defendants-appellees' release of the above-captioned agency action (copy enclosed), which sets an effective date of May 1, 2013, for implementing certain challenged changes to the procedures for referring orders under the Medicare statute.

In the district court, defendants-appellants "represented to Plaintiffs that, before implementing claims edits that would automatically reject claims for failure to comply with the new regulations, it will provide [Plaintiffs] with sufficient notice to move the Court for preliminary relief," which eliminated the "need to brief a motion for a preliminary injunction with respect to Count IV at this time." Joint Ltr. to Hon. Amy Berman Jackson, 1-2 (June 27, 2010). Defendants-appellants also relied on their commitment as a basis to refute any claims of irreparable harm from the challenged regulations while "Defendants ... have

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delayed the implementation of claims edits that would automatically reject Medicare claims for failure to comply with them.” Reply in Support of Defendants’ Motion to Stay Case Pending Resolution of Appeals Raising Identical Issues, at 8-9 (Docket #50). On March 5, 2013, counsel for plaintiffs-appellants asked counsel for the defendants-appellants whether her clients would be willing to defer further the challenged regulations and advised her that, without a further deferral, the plaintiffs-appellants would seek preliminary relief. Counsel for the defendants-appellees has just advised us that her clients will not further defer the challenged regulations.

Plaintiffs-appellants hereby advise the Court that this appeal now will include a motion for a preliminary injunction. Plaintiffs-appellants will attempt to file their motion as expeditiously as possible.

Respectfully submitted,

/s/ Lawrence J. Joseph
Lawrence J. Joseph
Counsel for Plaintiffs-Appellants

Enclosure

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of March 2013, I have caused the foregoing Notice of Supplemental Authority to be served on the following counsel via the Court's CM/ECF System:

Dana Kaersvang
U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave. NW, Rm 7533
Washington, D.C. 20530
Tel: 202-307-1294
Email: Dana.L.Kaersvang@usdoj.gov

/s/ Lawrence J. Joseph

Lawrence J. Joseph

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



News Flash – In September 2012, the Centers for Medicare & Medicaid Services (CMS) announced the availability of a new electronic mailing list for those who refer Medicare beneficiaries for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Referral agents play a critical role in providing information and services to Medicare beneficiaries. To ensure you give Medicare patients the most current DMEPOS Competitive Bidding Program information, CMS strongly encourages you to review the information sent from this new electronic mailing list. In addition, please share the information you receive from the mailing list and the link to the [“mailing list for referral agents”](#) subscriber webpage with others who refer Medicare beneficiaries for DMEPOS. Thank you for signing up!

MLN Matters® Number: SE1305

Related Change Request (CR) #: 6421, 6417, 6696, 6856

Related CR Release Date: N/A

Effective Date: May 1, 2013

Related CR Transmittal #: R6420TN, R6430TN, R328PI, and R7810TN

Implementation Date: May 1, 2013

Full Implementation of Edits on the Ordering/Referring Providers in Medicare Part B, DME, and Part A Home Health Agency (HHA) Claims (Change Requests 6417, 6421, 6696, and 6856)

Note: This Special Edition MLN Matters® Article is a consolidation and update of prior articles SE1011, SE1201, SE1208, and SE1221. Effective May 1, 2013, the Centers for Medicare & Medicaid Services (CMS) will turn on the Phase 2 denial edits. This means that Medicare will deny claims for services or supplies that require an ordering/referring provider to be identified and that provider is not identified, is not in Medicare's enrollment records, or is not of a specialty type that may order/refer the service/item being billed.

Provider Types Affected

This MLN Matters® Special Edition Article is intended for:

- Physicians and non-physician practitioners (including interns, residents, fellows, and those who are employed by the Department of Veterans Affairs (DVA), the Department of Defense (DoD), or the Public Health Service (PHS)) who order or refer items or services for Medicare beneficiaries,

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- Part B providers and suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) who submit claims to carriers, Part A/B Medicare Administrative Contractors (MACs), and DME MACs for items or services that they furnished as the result of an order or a referral, and
- Part A Home Health Agency (HHA) services who submit claims to Regional Home Health Intermediaries (RHHIs), Fiscal Intermediaries (FIs, who still maintain an HHA workload), and Part A/B MACs.
- Optometrists may only order and refer DMEPOS products/services and laboratory and X-Ray services payable under Medicare Part B.

Provider Action Needed

If you order or refer items or services for Medicare beneficiaries and you do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare. You can do this using the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) or by completing the paper enrollment application (CMS-855O). Review the background and additional information below and make sure that your billing staff is aware of these updates.

What Providers Need to Know

Phase 1: Informational messaging: Began October 5, 2009, to alert the billing provider that the identification of the ordering/referring provider is missing, incomplete, or invalid, or that the ordering/referring provider is not eligible to order or refer. The informational message on an adjustment claim that did not pass the edits indicated the claim/service lacked information that was needed for adjudication. **Phase 2: Effective May 1, 2013, CMS will turn on the edits to deny Part B, DME, and Part A HHA claims that fail the ordering/referring provider edits.** Physicians and others who are eligible to order and refer items or services need to establish their Medicare enrollment record and must be of a specialty that is eligible to order and refer.

All enrollment applications, including those submitted over the Internet, require verification of the information reported. Sometimes, Medicare enrollment contractors may request additional information in order to process the enrollment application.

Waiting too long to begin this process could mean that your enrollment application may not be processed prior to the May 1, 2013 implementation date of the ordering/referring Phase 2 provider edits.

Background

The Affordable Care Act, Section 6405, "Physicians Who Order Items or Services are Required to be Medicare Enrolled Physicians or Eligible Professionals," requires physicians or other eligible professionals to be enrolled in the Medicare Program to order or refer items or services for Medicare beneficiaries. Some physicians or other eligible professionals do not and will not send claims to a

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Medicare contractor for the services they furnish and therefore may not be enrolled in the Medicare program. Also, effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the attending physician on the claim if that service or item was the result of an order or referral. Effective May 23, 2008, the unique identifier was determined to be the National Provider Identifier (NPI). The Centers for Medicare & Medicaid Services (CMS) has implemented edits on ordering and referring providers when they are required to be identified in Part B, DME, and Part A HHA claims from Medicare providers or suppliers who furnished items or services as a result of orders or referrals.

Below are examples of some of these types of claims:

- Claims from laboratories for ordered tests;
- Claims from imaging centers for ordered imaging procedures; and
- Claims from suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for ordered DMEPOS.

Only physicians and certain types of non-physician practitioners are eligible to order or refer items or services for Medicare beneficiaries. They are as follows:

- Physicians (doctor of medicine or osteopathy, doctor of dental medicine, doctor of dental surgery, doctor of podiatric medicine, doctor of optometry, optometrists may only order and refer DMEPOS products/services and laboratory and X-Ray services payable under Medicare Part B.)
- Physician Assistants,
- Clinical Nurse Specialists,
- Nurse Practitioners,
- Clinical Psychologists,
- Interns, Residents, and Fellows,
- Certified Nurse Midwives, and
- Clinical Social Workers.

CMS emphasizes that generally Medicare will only reimburse for specific items or services when those items or services are ordered or referred by providers or suppliers authorized by Medicare statute and regulation to do so. Claims that a billing provider or supplier submits in which the ordering/referring provider or supplier is not authorized by statute and regulation will be denied as a non-covered service. The denial will be based on the fact that neither statute nor regulation allows coverage of certain services when ordered or referred by the identified supplier or provider specialty.

CMS would like to highlight the following limitations:

- Chiropractors are not eligible to order or refer supplies or services for Medicare beneficiaries. All services ordered or referred by a chiropractor will be denied.

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- Home Health Agency (HHA) services may only be ordered or referred by a Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), or Doctor of Podiatric Medicine (DPM). Claims for HHA services ordered by any other practitioner specialty will be denied.
- Optometrists may only order and refer DMEPOS products/services, and laboratory and X-Ray services payable under Medicare Part B.

Questions and Answers Relating to the Edits

1. What are the ordering and referring edits?

The edits will determine if the Ordering/Referring Provider (when required to be identified in Part B, DME, and Part A HHA claims) (1) has a current Medicare enrollment record and contains a valid National Provider Identifier (NPI) (the name and NPI must match), and (2) is of a provider type that is eligible to order or refer for Medicare beneficiaries (see list above).

2. Why did Medicare implement these edits?

These edits help protect Medicare beneficiaries and the integrity of the Medicare program.

3. How and when will these edits be implemented?

These edits were implemented in two phases:

Phase 1 -Informational messaging: Began October 5, 2009, to alert the billing provider that the identification of the ordering/referring provider is missing, incomplete, or invalid, or that the ordering/referring provider is not eligible to order or refer. The informational message on an adjustment claim that did not pass the edits indicated the claim/service lacked information that was needed for adjudication. The informational messages used are identified below:

For Part B providers and suppliers who submit claims to carriers:

N264	Missing/incomplete/invalid ordering provider name
N265	Missing/incomplete/invalid ordering provider primary identifier

For adjusted claims, the Claims Adjustment Reason Code (CARC) code 16 (Claim/service lacks information which is needed for adjudication.) is used.

DME suppliers who submit claims to carriers (applicable to 5010 edits):

N544	Alert: Although this was paid, you have billed with a referring/ordering provider that does not match our system record. Unless, corrected, this will not be paid in the future
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For Part A HHA providers who order and refer, the claims system initially processed the claim and added the following remark message:

N272	Missing/incomplete/invalid other payer attending provider identifier
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For adjusted claims the CARC code 16 and/or the RARC code N272 was used.

CMS has taken actions to reduce the number of informational messages.

In December 2009, CMS added the NPIs to more than 200,000 PECOS enrollment records of physicians and non-physician practitioners who are eligible to order and refer but who had not updated their PECOS enrollment records with their NPIs.¹

On January 28, 2010, CMS made available to the public, via the Downloads section of the “Ordering Referring Report” page on the Medicare provider/supplier enrollment website, a file containing the NPIs and the names of physicians and non-physician practitioners who have current enrollment records in PECOS and are of a type/specialty that is eligible to order and refer. The file, called the Ordering Referring Report, lists, in alphabetical order based on last name, the NPI and the name (last name, first name) of the physician or non-physician practitioner. To keep the available information up to date, CMS will replace the Report on a weekly basis. At any given time, only one Report (the most current) will be available for downloading. To learn more about the Report and to download it, go to <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>; click on “Ordering & Referring Information” (on the left). Information about the Report will be displayed.

Phase 2: Effective May 1, 2013, CMS will turn on the Phase 2 edits. In Phase 2, if the ordering/referring provider does not pass the edits, the claim will be denied. This means that the billing provider will not be paid for the items or services that were furnished based on the order or referral. Below are the denial edits for Part B providers and suppliers who submit claims to carriers and/or MACs, including DME MACs:

254D	Referring/Ordering Provider Not Allowed To Refer
255D	Referring/Ordering Provider Mismatch
289D	Referring/Ordering Provider NPI Required

CARC code 16 and/or the RARC code N264 and N265 shall be used for denied or adjusted claims.

¹ NPIs were added only when the matching criteria verified the NPI.

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Below are the denial edits for Part A HHA providers who submit claims:

<p>37236 This reason code will assign when:</p>	<ul style="list-style-type: none"> • The statement "From" date on the claim is on or after the date the phase 2 edits are turned on • The type of bill is '32' or '33' • Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claim is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from EPCOS or the specialty code is not a valid eligible code
<p>37237 This reason code will assign when:</p>	<ul style="list-style-type: none"> • The statement "From" date on the claim is on or after the date the phase 2 edits are turned on • The type of bill is '32' or '33' • The type of bill frequency code is '7' or 'F-P' • Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claims is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from PECOS or the specialty code is not a valid eligible code

Effect of Edits on Providers

I order and refer. How will I know if I need to take any sort of action with respect to these two edits?

In order for the claim from the billing provider (the provider who furnished the item or service) to be paid by Medicare for furnishing the item or service that you ordered or referred, **you, the ordering/referring provider, need to ensure that:**

a. You have a current Medicare enrollment record.

- If you are not sure you are enrolled in Medicare, you may:
 - i. Check the Ordering Referring Report and if you are on that report, you have a current enrollment record in Medicare and it contains your NPI;
 - ii. Contact your designated Medicare enrollment contractor and ask if you have an enrollment record in Medicare and it contains the NPI; or

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- iii. Use Internet-based PECOS to look for your Medicare enrollment record (if no record is displayed, you do not have an enrollment record in Medicare).
- iv. If you choose iii, please read the information on the Medicare provider/supplier enrollment web page about Internet-based PECOS before you begin.

b. If you do not have an enrollment record in Medicare.

- You need to submit **either an electronic application through the use of internet-based PECOS or a paper enrollment application** to Medicare.
 - i. **For paper applications** - fill it out, sign and date it, and mail it, along with any required supporting paper documentation, to your designated Medicare enrollment contractor.
 - ii. **For electronic applications** – complete the online submittal process and either e-sign or mail a printed, signed, and dated Certification Statement and digitally submit any required supporting paper documentation to your designated Medicare enrollment contractor.
 - iii. In either case, the designated enrollment contractor cannot begin working on your application until it has received the signed and dated Certification Statement.
 - iv. If you will be using Internet-based PECOS, please visit the Medicare provider/supplier enrollment web page to learn more about the web-based system before you attempt to use it. Go to <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>, click on “Internet-based PECOS” on the left-hand side, and read the information that has been posted there. Download and read the documents in the Downloads Section on that page that relate to physicians and non-physician practitioners. A link to Internet-based PECOS is included on that web page.
 - v. If you order or refer items or services for Medicare beneficiaries and you do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare. You can do this using Internet-based PECOS or by completing the paper enrollment application (CMS-8550). Enrollment applications are available via internet-based PECOS or .pdf for downloading from the CMS forms page (<http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/index.html>).

c. You are an opt-out physician and would like to order and refer services. What should you do?

If you are a physician who has opted out of Medicare, you may order items or services for Medicare beneficiaries by submitting an opt-out affidavit to a Medicare contractor within your specific jurisdiction. Your opt-out information must be current (an affidavit must be completed every 2 years, and the NPI is required on the affidavit).

d. You are of a type/specialty that can order or refer items or services for Medicare beneficiaries.

When you enrolled in Medicare, you indicated your Medicare specialty. **Any** physician specialty (Chiropractors are excluded) and **only** the non-physician practitioner specialties listed above in this article are eligible to order or refer in the Medicare program.

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e. **I bill Medicare for items and services that were ordered or referred. How can I be sure that my claims for these items and services will pass the Ordering/Referring Provider edits?**

- You need to ensure that the physicians and non-physician practitioners from whom you accept orders and referrals have current Medicare enrollment records and are of a type/specialty that is eligible to order or refer in the Medicare program. If you are not sure that the physician or non-physician practitioner who is ordering or referring items or services meets those criteria, it is recommended that you check the Ordering Referring Report described earlier in this article.
- Ensure you are correctly spelling the Ordering/Referring Provider's name.
- If you furnished items or services from an order or referral from someone on the Ordering Referring Report, your claim should pass the Ordering/Referring Provider edits.
- The Ordering Referring Report will be replaced weekly to ensure it is current. It is possible that you may receive an order or a referral from a physician or non-physician practitioner who is not listed in the Ordering Referring Report but who may be listed on the next Report.

f. **Make sure your claims are properly completed.**

- Do not use "nicknames" on the claim, as their use could cause the claim to fail the edits.
- Do not enter a credential (e.g., "Dr.") in a name field.
- On paper claims (CMS-1500), in item 17, you should enter the Ordering/Referring Provider's first name first, and last name second (e.g., John Smith).
- Ensure that the name and the NPI you enter for the Ordering/Referring Provider belong to a physician or non-physician practitioner and not to an organization, such as a group practice that employs the physician or non-physician practitioner who generated the order or referral.
- Make sure that the qualifier in the electronic claim (X12N 837P 4010A1) 2310A NM102 loop is a 1 (person). Organizations (qualifier 2) cannot order and refer.

If there are additional questions about the informational messages, Billing Providers should contact their local carrier, A/B MAC, or DME MAC.

Billing Providers should be aware that claims that are denied because they failed the Ordering/Referring Provider would not expose the Medicare beneficiary to liability. Therefore, **an Advance Beneficiary Notice is not appropriate.**

g. **What if my claim is denied inappropriately?**

If your claim did not initially pass the Ordering/Referring provider edits, you may file an appeal through the standard claims appeals process.

Additional Guidance

1. **Terminology:** Part B claims use the term "ordering/referring provider" to denote the person who ordered, referred, or certified an item or service reported in that claim. The final rule uses technically

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correct terms: 1) a provider "orders" non-physician items or services for the beneficiary, such as DMEPOS, clinical laboratory services, or imaging services and 2) a provider "certifies" home health services to a beneficiary. The terms "ordered" "referred" and "certified" are often used interchangeably within the health care industry. Since it would be cumbersome to be technically correct, CMS will continue to use the term "ordered/referred" in materials directed to a broad provider audience.

2. **Orders or referrals by interns or residents:** The IFC mandated that all interns and residents who order and refer specify the name and NPI of a teaching physician (i.e., the name and NPI of the teaching physician would have been required on the claim for service(s)). The final rule states that State-licensed residents may enroll to order and/or refer and may be listed on claims. Claims for covered items and services from un-licensed interns and residents must still specify the name and NPI of the teaching physician. However, if States provide provisional licenses or otherwise permit residents to order and refer services, CMS will allow interns and residents to enroll to order and refer, consistent with State law.
3. **Orders or referrals by physicians and non-physician practitioners who are of a type/specialty that is eligible to order and refer who work for the Department of Veterans Affairs (DVA), the Public Health Service (PHS), or the Department of Defense(DoD)/Tricare:** These physicians and non-physician practitioners will need to enroll in Medicare in order to continue to order or refer items or services for Medicare beneficiaries. They may do so by filling out the paper CMS-855O or they may use Internet-based PECOS. They will not be submitting claims to Medicare for services they furnish to Medicare beneficiaries.
4. **Orders or referrals by dentists:** Most dental services are not covered by Medicare; therefore, most dentists do not enroll in Medicare. Dentists are a specialty that is eligible to order and refer items or services for Medicare beneficiaries (e.g., to send specimens to a laboratory for testing). To do so, they must be enrolled in Medicare. They may enroll by filling out the paper CMS-855O or they may use Internet-based PECOS. They will not be submitting claims to Medicare for services they furnish to Medicare beneficiaries.

Additional Information

For more information about the Medicare enrollment process, visit <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html> or contact the designated Medicare contractor for your State. Medicare provider enrollment contact information for each State can be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/Contact_list.pdf on the CMS website.

The Medicare Learning Network® (MLN) fact sheet titled, "Medicare Enrollment Guidelines for Ordering/Referring Provider," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network->

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[MLN/MLNProducts/downloads/MedEnroll_OrderReferProv_factSheet_ICN906223.pdf](#) on the CMS website.

Note: You must obtain a National Provider Identifier (NPI) prior to enrolling in Medicare. Your NPI is a required field on your enrollment application. Applying for the NPI is a separate process from Medicare enrollment. To obtain an NPI, you may apply online at <https://nppes.cms.hhs.gov/NPPES/Welcome.do> on the CMS website. For more information about NPI enumeration, visit <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvdentStand/index.html> on the CMS website.

MLN Matters® Article MM7097, "Eligible Physicians and Non-Physician Practitioners Who Need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Items and Services for Medicare Beneficiaries," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7097.pdf> on the CMS website.

MLN Matters® Article MM6417, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Claims Processed by Medicare Carriers and Part B Medicare Administrative Contractors (MACs)," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6417.pdf> on the CMS website.

MLN Matters® Article MM6421, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers' Claims Processed by Durable Medical Equipment Medicare Administrative Contractors (DME MACs)," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6421.pdf> on the CMS website;

MLN Matters® Article MM6129, "New Requirement for Ordering/Referring Information on Ambulatory Surgical Center (ASC) Claims for Diagnostic Services," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6129.pdf> on the CMS website.

MLN Matters Article, MM6856, "Expansion of the Current Scope for Attending Physician Providers for free-standing and provider-based Home Health Agency (HHA) Claims processed by Medicare Regional Home Health Intermediaries (RHHIs), is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6856.pdf> on the CMS website.

If you have questions, please contact your Medicare Carrier, Part A/B MAC, or DME MAC, at their toll-free numbers, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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