

Regulatory Assurance **Advisor**

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COMMONLY ASKED QUESTIONS

When attempting to change the Number of Uncovered Months (NUNCMO) for a beneficiary from a previous contract with a Plan Change (72) transaction, the submission is rejected with TRC 060. What type of transaction should I submit to correct the beneficiary's record?

If a Plan submits a Plan Change (72) transaction for the Number of Uncovered Months (NUNCMO) via the regular batch process, for a beneficiary who is no longer enrolled in the contract, the Uncovered Months Change Transaction will reject with a Transaction Reply Code (TRC) of "060 Change Rejected, Beneficiary Not Enrolled".

A Plan should submit a Plan Change (72) transaction for NUNCMO via the "retroactive approval process" where the Header date of the Retro file is such that the beneficiary was enrolled in the contract at that time. The transaction will be accepted with a TRC of "141 Uncovered Months Change Accepted" and "177 Change in Late Enrollment Penalty" (if the LEP changed). In these situations, plans are to contact their DPO representative for approval to submit these transactions.

What is the Loss of Subsidy file and when can I anticipate CMS sending this file to Part D Plans?

The Loss of Subsidy file is an annual file sent to all Part D plans identifying beneficiaries who will receive a notice from CMS informing them that effective December 31, 2008, they will lose their Low Income Subsidy (LIS) deemed status.

As with previous years, CMS anticipates sending two files to Part D plans. The first file is sent in September and identifies members who will receive a joint CMS and SSA letter informing them they will no longer be deemed for the following year. The second file will be sent in December and is an updated version of the September file, indicating those beneficiaries who still do not have deemed status for the following year.

For additional information on the LIS eligibility for 2009, Plans can refer to the HPMS memo dated August 5, 2008 from Anthony Culotta entitled "Re-Determination of Low-Income Subsidy Eligibility for 2009".

If a provider has performed a self-audit prior to RAC review and want to extrapolate these findings, will all these claims included in a self-audit be excluded from RAC review?

If a provider self-discloses a payment error and the Claims Processing Contractor confirms that a payment error exists and the sampling/extrapolation methodology used was correct, then these claims will not be reviewed by the RAC. The claims processing contractor will exclude the self-disclosed claims in the RAC data warehouse.

CMS UPDATES

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*Please click on the link below to receive **Transmittal R276PI***

SUBJECT: Deceased Individuals and the Provider Enrollment Process

<http://www.cms.hhs.gov/transmittals/downloads/R276PI.pdf>
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*Please click on the link below to receive **Transmittal R277PI***

SUBJECT: Additional Provider Enrollment Verification and Program Integrity Activities

<http://www.cms.hhs.gov/transmittals/downloads/R277PI.pdf>
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*Please click on the link below to receive **Transmittal R1627CP***

SUBJECT: Calendar Year (CY) 2009 Participation Enrollment and Medicare Participating Physicians and Suppliers Directory (MEDPARD) Procedures

<http://www.cms.hhs.gov/transmittals/downloads/R1627CP.pdf>
.....

CMS UPDATES (CONTINUED)

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1624	Date: OCTOBER 31, 2008
	Change Request 6237

SUBJECT: Reporting National Provider Identifiers (NPI) on Claims for Out-of-Jurisdiction Purchased Mammography Preventive Screening and Diagnostic Services

I. SUMMARY OF CHANGES: This Change Request establishes an exception to the standard reporting of the NPI on certain Medicare fee-for-service claims for purchased mammography screening and diagnostic services. When a provider bills for a mammography screening or diagnostic services that has been purchased from a provider located in another contractor jurisdiction, the billing provider must, in addition to reporting its own NPI on paper or electronically-submitted Medicare claim (as the billing provider), also report its own NPI as the performing provider and annotate the claim with the name, address, and ZIP Code of the performing provider.

New / Revised Material

Effective Date: December 1, 2008

Implementation Date: December 1, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	18/20/20.5/Billing Requirements - Carrier/B MAC Claims

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

CMS UPDATES (CONTINUED)

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1624	Date: October 31, 2008	Change Request: 6237
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SUBJECT: Reporting National Provider Identifiers (NPI) on Claims for Out-of-Jurisdiction Purchased Mammography Preventive Screening and Diagnostic Services

Effective Date: December 1, 2008

Implementation Date: December 1, 2008

I. GENERAL INFORMATION

A. Background: This Transmittal establishes an exception to the standard reporting of the national provider identifier (NPI) on certain Medicare fee-for-service claims for purchased mammography screening and diagnostic services.

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate the adoption of a standard unique health identifier for health care providers. The NPI final rule, published on January 23, 2004, establishes the NPI as this standard. All entities covered under HIPAA must comply with the requirements of the NPI final rule (45 CFR Part 162, CMS-0045-F). Covered health care providers, suppliers and health plans (other than small plans) are required to use the NPI effective May 23, 2008. Specifically, every provider must report its NPI on a paper or electronically-submitted Medicare fee-for-service claim.

Certain Medicare-covered services may be forwarded by the billing provider to another provider for performance by such other provider. In such a circumstance, the forwarded service is “purchased” by the billing provider who must not only report its own NPI (as the billing provider) but also annotate the claim with the performing provider’s NPI. However, when the performing provider is located in a contractor jurisdiction different from that of the billing provider, the contractor will not have a record of the performing provider’s NPI. In this latter circumstance, the billing provider is permitted to annotate its own NPI as the performing provider’s NPI in order for the claim to be adjudicated by Medicare. However, it should be noted that the billing provider has the responsibility to keep on record the performing provider’s NPI in the clinical records for auditing purposes.

In reviewing the Medicare Program’s business needs, it was determined that the foregoing described reporting convention had not previously been established for out-of-jurisdiction purchased mammography screening and diagnostic services. This Transmittal establishes this convention for such services.

B. Policy: When a provider bills for a mammography screening or diagnostic service that has been purchased from a provider located in another contractor jurisdiction, the billing provider must, in addition to reporting its own NPI on a paper or electronically-submitted Medicare claim (as the billing provider), also report its own NPI as the performing provider and annotate the claim with the name, address, and ZIP Code of the performing provider.

N.B.: In this Transmittal, the term “provider” shall be construed to also mean “physician or other supplier” if the context requires such alternative meaning.

II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

CMS UPDATES (CONTINUED)

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6237.1	Carriers/AB MACs shall accept the billing provider's NPI in lieu of the performing provider's NPI if it is reported on a claim for out-of-jurisdiction purchased mammography screening or diagnostic service.	X			X						
6237.2	Carriers/AB MACs shall return as unprocessable a claim on out-of- jurisdiction purchased mammography screening or diagnostic service when submitted without a NPI or the name, address, and ZIP Code of the performing provider.	X			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6237.3	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLN MattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

CMS UPDATES (CONTINUED)

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wendy Knarr at Wendy.Knarr@cms.hhs.gov or dial Relay #711 and have agent dial 410-786-0843 and/or Eric Coulson at Eric.Coulson@cms.hhs.gov or (410) 786-3352.

Post-Implementation Contact(s): Your appropriate RO

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

CMS UPDATES (CONTINUED)

20.5 - Billing Requirements – Carrier/B MAC Claims

(Rev. 1624; Issued: 10-31-08; Effective/Implementation Date: 12-01-08)

Contractors use the weekly-updated file to verify that the billing facility is certified by the FDA to perform mammography services, and has the appropriate certification to perform the type of mammogram billed (film and/or digital). Carriers/B MACs match the FDA assigned, 6-digit mammography certification number on the claim to the FDA mammography certification number appearing on the file for the billing facility.

Carriers/B MACs complete the following activities in processing mammography claims:

- If the claim does not contain the facility's 6-digit certification number, or if a 6-digit certification number is not reported in item 32 of the Form CMS-1500 for paper claims, or in the 2400 loop (REF 02 segment, where 01=EW segment) of the ASC X12N 837 professional claim format, version 4010A1, for electronic claims, then carriers/B MACs return the claim as unprocessable.
- If the claim contains a 6-digit certification number that is reported in the proper field or segment (as specified in the previous bullet) but such number does not correspond to the number specified in the MQSA file for the facility, then carriers/B MACs deny the claim.
- When a film mammography HCPCS code is on a claim, the claim is checked for a "1" film indicator.
- If a film mammography HCPCS code comes in on a claim and the facility is certified for film mammography, the claim is paid if all other relevant Medicare criteria are met.
- If a film mammography HCPCS code is on a claim and the facility is certified for digital mammography only, the claim is denied.
- When a digital mammography HCPCS code is on a claim, the claim is checked for "2" digital indicator.
- If a digital mammography HCPCS code is on a claim and the facility is certified for digital mammography, the claim is paid if all other relevant Medicare criteria are met.
- If a digital mammography HCPCS code is on a claim and the facility is certified for film mammography only, the claim is denied.
- Process the claim to the point of payment based on the information provided on the claim and in carrier claims history.
- Identify the claim as a screening mammography claim by the CPT-4 code listed in field 24D and the diagnosis code(s) listed in field 21 of Form CMS-1500.

CMS UPDATES (CONTINUED)

- Assign physician specialty code 45 to facilities that are certified to perform only screening mammography.
- Ensure that entities that bill globally for screening mammography contain a blank in modifier position #1.
- Ensure that entities that bill for the technical component use only HCPCS modifier “-TC.”
- Ensure that physicians who bill the professional component separately use HCPCS modifier “-26.”
- Send the mammography modifier to CWF in the first modifier position on the claim. If more than one modifier is necessary, e.g., if the service was performed in a rural Health Manpower Shortage Area (HMSA) facility, instruct providers to bill the mammography modifier in modifier position 1 and the rural (or other) modifier in modifier position 2.
- Ensure all those who are qualified include the 6-digit FDA-assigned certification number of the screening center in field 32 of Form CMS-1500 and in the REF02 segment (where 01 = EW segment) of the 2400 loop for the ASC X12N 837 professional claim format, version 4010A1. Carriers/B MACs retain this number in their provider files.
- Waive Part B deductible and apply coinsurance for a screening mammography.
- Add diagnosis code V76.12 if a claim comes in for screening mammography without a diagnosis and the carrier file data shows this is appropriate. If there are other diagnoses on the claim, but not code V76.12, add it. (Do not change or overlay code V76.12 but ADD it). At a minimum, edit for age, frequency, and place of service (POS).
- After May 23, 2008, accept the screening mammography facility’s NPI number in place of the attending/referring physician NPI number for self-referred mammography claims.
- *When a mammography claim is billed as a purchased service and the service is purchased from another billing jurisdiction, the provider must submit their own NPI with the name, address, and ZIP Code of the performing physician/supplier.*
- *Refer to Pub. 100-04, chapter 1, section 10.1.1.1., for claims processing instructions for payment jurisdiction on Form CMS-1500 and electronic form ANSI X12 837P.*

CMS UPDATES (CONTINUED)

NOTE: Beginning October 1, 2003, carriers/B MACs are no longer permitted to add the ICD-9 code for a screening mammography when the screening mammography claim has no diagnosis code. Screening mammography claims with no diagnosis code must be returned as unprocessable for assigned claims. For unassigned claims, deny the claim.

Carrier Provider Education

- Educate providers that when a screening mammography turns to a diagnostic mammography on the same day for the same beneficiary, add the “-GG” modifier to the diagnostic code and bill both codes on the same claim. Both services are reimbursable by Medicare.
- Educate providers that they cannot bill an add-on code without also billing for the appropriate mammography code. If just the add-on code is billed, the service will be denied. Both the add-on code and the appropriate mammography code should be on the same claim.
- Educate providers to submit their own NPI in place of an attending/referring physician NPI in cases where screening mammography services are self-referred.

CMS UPDATES (CONTINUED)

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1625	Date: October 31, 2008
	Change Request 6254

SUBJECT: 2009 Annual Update to the Therapy Code List

I. SUMMARY OF CHANGES: This instruction updates the list of codes that sometimes or always describe therapy services. The attached Recurring Update Notification applies to chapter 5, section 20.

NEW/REVISED MATERIAL

EFFECTIVE DATE: JANUARY 1, 2009

IMPLEMENTATION DATE: JANUARY 5, 2009

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

**Unless otherwise specified, the effective date is the date of service.*

CMS UPDATES (CONTINUED)

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1625	Date: October 31, 2008	Change Request: 6254
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SUBJECT: 2009 Annual Update to the Therapy Code List

Effective Date: January 1, 2009

Implementation Date: January 5, 2009

I. GENERAL INFORMATION

A. Background: Section 1834(k)(5) of the Act requires that all claims for outpatient rehabilitation therapy services and all comprehensive outpatient rehabilitation facility services be reported using a uniform coding system. The Healthcare Common Procedure Coding System/Current Procedural Terminology, 2009 Edition (HCPCS/CPT-4) is the coding system used for the reporting of these services.

This instruction updates the list of codes that sometimes or always describe therapy services. The additions, changes, and deletions to the therapy code list reflect those made in the CY 2008 and 2009 Healthcare Common Procedure Coding System and Current Procedural Terminology, Fourth Edition (HCPCS/CPT-4).

B. Policy: This CR updates the therapy code list with two “sometimes” therapy codes for CY 2009. Note that these codes always represent therapy services when performed by therapists and require the use of a therapy modifier.

- 95992** – Standard Canalith repositioning procedure(s) (eg, Epley maneuver, Semont maneuver), per day.
- 0183T** – Low frequency, non-contact, non-thermal ultrasound, including topical applications(s), when performed, wound assessment, and instruction(s) for ongoing care, per day.

NOTE: If billed by a hospital subject to OPPS for an outpatient service, CPT code 0183T will be paid under the OPPS when the service is not performed by a qualified therapist and it is inappropriate to bill the service under a therapy plan of care. In addition, no MPFS amount exists for this code. The carrier determines the coverage and pricing for this code. Therefore, the FI contacts the carrier to obtain the appropriate fee schedule amount.

II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

Number	Requirement	Responsibility (place an “X” in each applicable column)									
		A / B M A C	D M A C	F I	C A R E R	R H I	Shared-System Maintainers				OTHER
						F I S	M C S	V M S	C W F		
6254.1	Medicare contractors shall change any policies or local edits that are not consistent with the policies or list of codes provided in this change request.	X		X	X	X					
6254.2	Medicare contractors shall be aware that CPT codes 95992 and 0183T have been added as “sometimes therapy” to the	X		X	X	X	X	X			OCE COBC

CMS UPDATES (CONTINUED)

new 2009 therapy code list.									
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III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHE R
							F I S S	M C S	V M S	C W F	
6254.3	<p>A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>	X		X	X	X					

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Jason Kerr, Jason.Kerr@cms.hhs.gov (for FI/A/B MAC billing), Leslie Trazzi; Leslie.Trazzi@cms.hhs.gov (for carrier/A/B MAC billing), and Pam West; Pamela.West@cms.hhs.gov (for therapy policy)

Post-Implementation Contact(s): Appropriate regional office
http://www.cms.hhs.gov/RegionalOffices/01_Overview.asp

VI. FUNDING

CMS UPDATES (CONTINUED)

A. For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their current operating budgets.

B. For Medicare Administrative Contractors (MACs):

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

CMS UPDATES (CONTINUED)

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1626	Date: October 31, 2008
	Change Request 6218

SUBJECT: Announcement of Medicare Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Payment Rate Increases

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the calendar year (CY) 2009 Payment Rate Increases for Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC) services. The attached RUN applies to Chapter 9, section 20.1 of the IOM.

New / Revised Material

Effective Date: January 1, 2009

Implementation Date: January 5, 2009

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	Chapter / Section / Subsection / Title
N/A	

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

**Unless otherwise specified, the effective date is the date of service.*

CMS UPDATES (CONTINUED)

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1626	Date: October 31, 2008	Change Request: 6218
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SUBJECT: Announcement of Medicare Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Payment Rate Increases.

Effective Date: January 1, 2009

Implementation Date: January 5, 2009

I. GENERAL INFORMATION

This Recurring Update Notification provides instructions for the calendar year (CY) 2009 Payment Rate Increases for Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC) services.

A. Background:

RHCs:

The RHC upper payment limit per visit is increased from \$75.63 to \$76.84 effective January 1, 2009, through December 31, 2009 (i.e., CY 2009). The 2009 rate reflects a 1.6 percent increase over the 2008 payment limit in accordance with the rate of increase in the Medicare Economic Index (MEI) as authorized by §1833(f) of the Social Security Act.

FQHCs:

The FQHC upper payment limit per visit for urban FQHCs is increased from \$117.41 to \$119.29 effective January 1, 2009, through December 31, 2009 (i.e., CY 2009), and the maximum Medicare payment limit per visit for rural FQHCs is increased from \$100.96 to \$102.58 effective January 1, 2009, through December 31, 2009 (i.e. CY 2009). The 2009 FQHC rates reflect a 1.6 percent increase over the 2008 rates, in accordance with the rate of increase in the MEI.

B. Policy:

This effective date of January 1, 2009, is necessary in order to update RHC and FQHC payment rates in accordance with §1833(f) of the Social Security Act. To avoid unnecessary administrative burden, the contractor shall not retroactively adjust individual RHC/FQHC bills paid at previous upper payment limits.

The contractor does, however, retain the discretion to make adjustments to the interim payment rate or a lump sum adjustment to total payments already made to take into account any excess or deficiency in payments to date.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)						
		A	D	F	C	R	Shared-System Maintainers	OTHE R
		/	M	I	A	H		
		B	E		R	H		

CMS UPDATES (CONTINUED)

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Glenn McGuirk, (410) 786-5723, Glenn.McGuirk@cms.hhs.gov

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Carriers*, and *Regional Home Health Carriers (RHHIs)* use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*, use the following statement:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

MEDICAL LEARNING, INC. UPDATES

NDC REPORTING RULES CHALLENGED IN COURT: Possible Implications for All Hospitals

By JANIS OPPELT
MedLearn Editor

A trade organization representing more than 400 safety net hospitals has challenged the legality of a Medicaid regulation requiring hospitals to report national drug code (NDC) identifiers for drugs administered in outpatient departments.

The Deficit Reduction Act (DRA) of 2005 mandated that the Centers for Medicare & Medicaid Services (CMS) make major changes related to reporting, billing, and calculating rebates and reimbursements received for physician-administered Medicaid drugs. The rule was issued after the U.S. Government Accountability Office (GAO) and the Department of Health & Human Services Office of the Inspector General (OIG) found that states were artificially inflating prices by using the traditional average wholesale price (AWP) to set reimbursement levels.

Beginning July 1, 2008, in order to receive reimbursement, hospital outpatient departments and physicians have been required to include NDCs when submitting claims for all single-source and certain multiple-source physician-administered drugs.

340B Trade Group Challenges Legality

On August 21, Safety Net Hospitals for Pharmaceutical Access (SNHPA) and the University Medical Center of Southern Nevada (UMCSN) filed a claim in federal court against the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS). SNHPA's member hospitals participate in the 340B federal drug discount program and serve largely indigent populations.

SNHPA seeks to have the court abolish CMS's drug code reporting requirement for hospitals. The organization argues that CMS has

misinterpreted a provision in the Deficit Reduction Act of 2005 that calls for NDC reporting by physician offices and other providers so that the government can collect rebates from drug manufacturers under the Medicaid program.

According to SNHPA, lawmakers did not intend for this provision to apply to outpatient hospital settings, and CMS is in error by imposing reporting regulations on them. Not only is the regulation contrary to federal law, claims SNHPA, it has proven costly and impractical to administer for its member hospitals.

HHS and CMS have 60 days to respond to SNHPA's and UMCSN's complaint. After the government files its response, a federal judge will address the merits of the claim.

Implications for All Hospitals

The suit has possible implications for all hospitals, not only 340B hospitals that serve Medicaid patients.

"If we prevail, a likely outcome is that all hospitals would be exempted from the NDC reporting provisions," stated William von Oehsen, SNHPA's president and general counsel.

SNHPA is seeking co-plaintiffs or hospitals with cases to support the litigation. For more information, contact Stuart Gordon at stuart.gordon@safetynetrx.org.

Information Source: August 21, 2008, SNHPA press release, "Safety Net Hospitals Turn to Federal Court to Block Unlawful Reporting Mandate," available at http://www.safetynetrx.org/public/documents/news_release_8_21_08.cfm.

MEDICAL LEARNING, INC. UPDATES

FDA IDENTIFIES 20 DRUGS WITH POTENTIAL SAFETY ISSUES: Uses New Adverse Event Reporting System to Identify

By JANIS OPPELT
MedLearn Editor

The Food & Drug Administration (FDA) has created a new database called the Adverse Event Reporting System (AERS). In accordance with Title IX, Section 921 of the Federal Drug Administration Amendments Act of 2007 it is posting data that comes from adverse events and medication errors voluntarily reported by health-care professionals and consumers. Drug manufacturers are required to forward any adverse event reports that they receive to the FDA. The agency then uses AERS data to support its post-marketing safety surveillance program for approved drugs and biologic products. The FDA may decide to further evaluate drugs that appear in the AERS database and, depending on evaluation results, may take regulatory action to enhance product safety such as updating product labeling. The results will be reported on a quarterly basis.

From data gathered between January and March 2008, the FDA identified 20 drugs exhibiting potential signals of serious risk. In the table on this page, you will find the latest additions to the AERS database, which the FDA made public in September.

Note that a drug's appearance on the AERS list does not imply a causal relationship between the drug and the cited risk. FDA further emphasizes that it is not suggesting patients stop taking, or providers stop prescribing, those drugs on the AERS list. The list is designed to serve as an alert to pharmacists, healthcare providers, and consumers of reports of adverse events or errors associated with the drugs.

Information Source: For more on this topic, see http://www.fda.gov/cder/aers/potential_signals/potential_signals_2008Q1.htm#top.

Potential Signals of Serious Risks/New Safety Information Identified by the AERS January–March 2008

Product Names	Potential Signals
Arginine Hydrochloride Injection (R-Gene 10)	Pediatric overdose due to labeling/packaging confusion
Desflurane (Suprane)	Cardiac arrest
Duloxetine (Cymbalta)	Urinary retention
Etravirine (Intelence)	Hemarthrosis
Fluorouracil Cream (Carac) and Ketoconazole Cream (Kuric)	Adverse events due to name confusion
Heparin	Anaphylactic-type reactions
Icodextrin (Extraneal)	Hypoglycemia
Insulin U-500 (Humulin R)	Dosing confusion
Ivermectin (Stromectol) and Warfarin	Drug interaction
Lapatinib (Tykerb)	Hepatotoxicity
Lenalidomide (Revlimid)	Stevens Johnson syndrome
Natalizumab (Tysabri)	Skin melanomas
Nitroglycerin (Nitrostat)	Overdose due to labeling confusion
Octreotide Acetate Depot (Sandostatin LAR)	Ileus
Oxycodone Hydrochloride Controlled-Release (Oxycontin)	Drug misuse, abuse and overdose
Perflutren Lipid Microsphere (Definity)	Cardiopulmonary reactions
Phenytoin Injection (Dilantin)	Purple glove syndrome
Quetiapine (Seroquel)	Overdose due to sample pack labeling confusion
Telbivudine (Tyzeka)	Peripheral neuropathy
Tumor Necrosis Factor (TNF) Blockers	Cancers in children and young adults

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MEDICAL LEARNING, INC. UPDATES

PHARMACOGENOMIC TESTING FOR WARFARIN:

Is it medically necessary for Medicare patients?

By JANIS OPPELT
MedLearn Editor

The Centers for Medicare & Medicaid Services (CMS) opened a national coverage analysis (NCA) to decide if the use of pharmacogenomic testing for warfarin is reasonable and necessary for Medicare beneficiaries. Patients who are usually candidates for warfarin therapy include those with mechanical heart valves, those experiencing atrial fibrillation after a cerebrovascular event or those who have other thromboembolic risk factors. Each patient's response to warfarin therapy varies and can be influenced by a number of factors, such as diet, other drugs, and heredity.

Pharmacogenomics explores how an individual's genetic makeup affects the body's

response to drugs. CMS cites the scarcity of evidence available on the reliability of this testing for aiding treatment decisions and improving health outcomes. As part of the NCA, CMS is conducting a thorough review of existing scientific information and considering public comment before making its decision on whether or not to cover pharmacogenomic testing under Medicare. A decision is expected in February 2009.

Information Source: The NCA tracking sheet is available at <https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?from2=viewtrackingsheet.asp&id=2246>.

»» Comments, Questions?

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