CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 258	Date: DECEMBER 22, 2006
	Change Request 5443

SUBJECT: Payment Amounts and Policies in the 2007 Medicare Physician Fee Schedule and the Telehealth Originating Site Facility Fee Payment Amount

**I. SUMMARY OF CHANGES:** This change request (CR) contains payment amounts and policies in the 2007 Medicare Physician Fee Schedule and the telehealth originating site facility fee for 2007.

**New / Revised Material** 

Effective Date: January 1, 2007

Implementation Date: January 2, 2007

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:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

#### **IV. ATTACHMENTS:**

**One-Time Notification** 

<sup>\*</sup>Unless otherwise specified, the effective date is the date of service.

### **Attachment – One-Time Notification**

Pub. 100-20 Transmittal: 258 Date: December 22, 2006 Change Request: 5443

SUBJECT: Payment Amounts and Policies in the 2007 Medicare Physician Fee Schedule and the Telehealth Originating Site Facility Fee Payment Amount

Effective Date: January 1, 2007

**Implementation Date: January 2, 2007** 

#### I. GENERAL INFORMATION

**A. Background:** Section 1848(b)(1) of the Social Security Act (the Act) requires the Secretary to establish by regulation before November 1 of each year, fee schedules that establish payment amounts for physicians' services for the subsequent year. We published a document that would affect payments to physicians effective January 1, 2007. (**NOTE:** This final rule also addressed comments received on the separate notice published June 29, 2006, *Five Year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology* (CMS-1521-PN).

Section 1834(m) of the Act establishes the payment amount for the Medicare telehealth originating site facility fee for telehealth services provided from October 1, 2001, through December 31, 2002, at \$20. For telehealth services provided on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased as of the first day of the year by the percentage increase in the Medicare Economic Index (MEI) as defined in \$1842(i)(3) of the Act. The MEI increase for 2007 is 2.1 percent.

**B.** Policy: The Tax Relief and Health Care Act of 2006 set the 2007 conversion factor for physician payment at the same level as in 2006 (\$37.8975), reversing the statutorily mandated 5.0 percent negative update. However, it does not maintain 2007 physician payments at 2006 levels. There are a number of other factors that affect payment rates for 2007.

This year, we completed the 5-year review of physician work relative value units (RVUs) (required by statute to be performed at least once every 5 years) that adjusted the work RVUs for certain services (primarily affecting certain high volume office visits).

Other changes adopted in the physician fee schedule final rule that affect 2007 payment rates include changes in the practice expense RVU-setting methodology, refinements to the practice expense RVUs, re-weighting of geographic adjustment factors, limits on payments for imaging services required by the Deficit Reduction Act, and other annual refinements including coding changes.

See the attachment for a summary of significant issues discussed in CMS-1321-FC and 1317-F, Revisions to Payment Policies and Five-Year Review of Work Relative Value Units Under the Physician Fee Schedules for CY 2007, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; Ambulance Inflation Factor Update for CY 2007 (Informational Only) and other changes mandated by the Tax Relief and Health Care Act of 2006.

For calendar year 2007, the payment amount for HCPCS code "Q3014, telehealth originating site facility fee" is 80 percent of the lesser of the actual charge or \$22.94. The beneficiary is responsible for any unmet deductible amount or coinsurance.

The Medicare telehealth originating site facility fee and MEI increase by the applicable time period is shown below.

Facility Fee	MEI Increase	<u>Period</u>
\$20.00	N/A	10/01/2001 - 12/31/2002
\$20.60	3.0%	01/01/2003 - 12/31/2003
\$21.20	2.9%	01/01/2004 - 12/31/2004
\$21.86	3.1%	01/01/2005 - 12/31/2005
\$22.47	2.8%	01/01/2006 - 12/31/2006
\$22.94	2.1%	01/01/2007 - 12/31/2007

### II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each										
		ap	plic	abl	e co	lun	n)					
		A	D	F	C	D	R	Shared-			OTHER	
		/	M	I	A	M	Η	Sy	sten	n		
		В	Е		R	Е	Η	Ma	ainta	aine	rs	
					R	R	I	F	M	V	С	
		M	M		I	C		I	C	M	W	
		A	A		Е			S	S	S	F	
		C	C		R			S				
5443.1	Carriers and Intermediaries shall pay for the	X		X	X							
	Medicare telehealth originating site facility fee											
	as described by HCPCS code Q3014 at 80% of											
	the lesser of the actual charge or \$22.94.											

#### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B M A	D M E M A	F I	C A R R I E	D M	R	Sy Ma F I S	arecestern ainta	n aine	rs C W F	OTHER
5443.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> 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 one week of the availability of the provider education article. In addition, the provider	X	С	X	X			S				

Number	Requirement	Responsibility (place an "X" in each										
		applicable column)										
		A	D	F	C	D	R	Sh	arec	1-		OTHER
		/	M	I	A	M	Н	Sy	sten	n		
		В	Е		R	Е	Н	Ma	ainta	aine	rs	
					R	R	I	F	M	V	С	
		M	M		I	C		Ι	C	M	W	
		A	A		Е			S	S	S	F	
		C	C		R			S	_			
	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.											

#### 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 the space below:

#### V. CONTACTS

Pre-Implementation Contact(s): Gaysha.Brooks, <u>Gaysha.Brooks@cms.hhs.gov</u>, (410) 786-9649

**Post-Implementation Contact(s):** Appropriate Regional Office

#### VI. FUNDING

- **A.** No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.
- **B.** 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 specified 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.

Attachment

#### **Attachment (Informational Only)**

Summary of Significant Issues Discussed in the 2007 Medicare Physician Fee Schedule Final Rule and Changes Mandated by the Tax Relief and Health Care Act of 2006

#### **Physician Fee Schedule Related Proposals**

#### **Changes Related to Practice Expense RVUs**

Practice expenses are the resources used in furnishing a service (such as office rent, wages of personnel, equipment and supplies). In the final rule--

We address the comments received on the proposed changes to the practice expense methodology that appeared in the proposed notice published June 29, 2006 in the *Federal Register* (CMS-1512-PN). As part of this methodology we will use a bottom—up methodology for direct costs, use supplementary survey data for indirect costs, and eliminate the nonphysician workpool. The nonphysician workpool was a special method that had been used to calculate practice expense RVUs for services with no physician work.

We also discuss acceptance of the American Medical Association (AMA) – Practice Expense Review Committee recommendations for practice expense inputs, pricing of equipment and supplies, and revisions to the global period for certain services and address comments received on these recommendations. We also discuss a policy to continue to pay separately for splint and cast materials.

#### **Inclusion of Work RVUs to Medical Nutrition Therapy Services**

In this rule, we finalize our proposal to adopt work values for CPT codes 97802, 97803, 97804, G0270 and G0271 and address comments received on our proposal.

#### **Medicare Telehealth Services**

We received requests to add certain nursing facility, speech therapy, audiology and physical therapy services to the list of telehealth services. In the final rule, we discussed why these services were not being added to the list.

## <u>Independent Laboratory Billing for the Technical Component of Physician Pathology</u> <u>Services to Hospital Patients</u>

In the final rule, we discuss implementation of the existing regulation allowing payment only to the hospital for the TC of all physician pathology services provided to hospital inpatients and address comments received.

**NOTE:** As mandated by section 104 of the Tax Relief and Health Care Act of 2006, implementation of the existing regulation will be delayed until January 1, 2008.

#### New and Revised CPT/HCPCS codes

In this rule, we address comments received on the interim RVUs for codes that were new for CY 2006 and finalize the RVUS and also announce the interim RVUs for payment under PFS for new codes for CY 2007 (which are subject to comment).

#### **Provisions Related to the Deficit Reduction Act of 2005 (DRA)**

#### Adjustments of Payment for Imaging Services (DRA Section 5102)

The final rule implements three provisions affecting payment for imaging services under the fee schedule:

- The first provision addresses payment for certain multiple imaging procedures, with full payment for the first procedure, but a 25 percent reduction in payment for additional imaging procedures furnished on contiguous body parts during the same session. This is a smaller reduction for 2007 than had previously been announced in the final rule for the 2006 physician fee schedule for 2007.
- The second limits the payment amount under Medicare physician fee schedule (MPFS) to the outpatient department (OPD) payment amount for the technical component (TC) of certain imaging services. This payment limit is required by the DRA. Under this provision, the physician fee schedule payment amount for furnishing certain imaging procedures can not exceed the amount paid to a hospital outpatient department.
- Finally, payments for imaging services are also affected by revisions to payments for practice expense. CMS is implementing a new methodology for determining practice expense payments for all services including imaging services.

## <u>Addition of Ultrasound Screening for Abdominal Aortic Aneurysm to the "Welcome to Medicare" Benefit (DRA Section 5112)</u>

Section 5112 of the DRA amended section 1861 of the Act to provide for coverage of an ultrasound screening for the early detection of abdominal aortic aneurysms (AAA), effective January 1, 2007, subject to certain eligibility and other limitations. The law mandates this new coverage as a one-time benefit that will only be available to new Part B enrollees who take advantage of the Initial Preventive Physical Examination benefit (referred to as the Welcome to Medicare benefit), and are referred by their physician or other qualified nonphysician practitioner for the new screening. Consistent with the law, we defined the term "eligible beneficiary" to include an individual who (among other things) is included in at least one of the following risk categories: (A) has a family history of an AAA, (B) is a man age 65 to 75 who has smoked at least 100 cigarettes in his lifetime, or (C) is an individual who manifests other risk factors in a benefit category recommended for screening by the United States Preventive Services Task Force for this purpose. We also revised the regulations at 42 CFR 410.16 (a) (7) to add the new ultrasound screening benefit to the list of preventive services for which physicians must provide "education, counseling, and referral" to new beneficiaries under the Welcome to Medicare benefit so that it reflects the additional responsibilities. We created a new HCPCS code (G0389) for this service and payment will be made at the same level as CPT code 76775, the code used to bill for this service when provided as a diagnostic test

## Non-Application of the Part B Deductible for Colorectal Cancer Screening Tests (DRA section 5113)

Current Medicare policy requires that, with limited exceptions, incurred expenses for covered Part B services are subject to, and count toward meeting the Part B annual deductible. Section 5113 of the DRA amends the Act and provides for an exception to the application of the Part B deductible with respect to colorectal cancer screening tests. Beginning January 1, 2007, colorectal cancer screening services as described in section 1861 (pp)(1) of the Act are no longer subject to the Part B deductible. To conform the regulations to this statutory change to the Act, we are revising section 410.160 to include an exception from the Part B annual deductible for colorectal cancer screening services as described in 410.37.

# Addition of Diabetes Outpatient Self-Management Training Services (DSMT) and Medical Nutrition Therapy (MNT) for the Federally Qualified Healthcare Center (FQHC) Program (DRA section 5114)

Section 5114 of the DRA added diabetes self-management training (DSMT) and medical nutrition therapy (MNT) services to the list of Medicare covered and reimbursed services under the FQHC benefit. Effective for services furnished on or after January 1, 2006, FQHCs that are certified providers of DSMT and MNT services can receive per visit payments for covered services furnished by registered dietitians or nutrition professionals. In other words, if all relevant program requirements are met, these services are included under the Medicare FQHC benefit as billable visits. To meet the statutory effective date, we implemented this change through manual instruction however, in order to conform the regulations to the statute, in this final rule we are amending the regulations to expand the scope of FQHC services to include certified providers of DSMT and MNT services and permit DSMT and MNT services to be billed separately from other FQHC services that occur on the same day.

#### **Discussion of Exception to Therapy Caps (DRA Section 5107)**

Section 1833(g)(1) of the Act applies an annual per beneficiary combined cap on outpatient physical therapy and speech-language pathology services and a similar separate cap on outpatient occupational therapy services, with the exception of outpatient hospital services, under Medicare Part B. The DRA provides for an exception process to the therapy cap until December 31, 2006, and states the exception process can be implemented through program instruction rather than through rulemaking. In this rule, we briefly discuss the therapy caps, referencing the DRA provision for an exception process for CY 2006 and announce the therapy cap amount for CY 2007 (\$1,780).

**NOTE:** As mandated by section 201 of the Tax Relief and Health Care Act of 2006, the exception process for therapy caps will be extended until December 31, 2007.

#### **Other Issues**

## <u>Private Contracting-Conforming Change to allow Dietitian and Nutrition Professionals to Opt-Out</u>

The BBA of 1997 amended section 1802 of the Act to permit certain physicians and practitioners to opt-out of Medicare if certain conditions were met, and to provide through private contracts services that would otherwise be covered by Medicare. Subsequently, legislation amended the definition of practitioner located at section 1842(b)(18)(c) of the Act to include registered dietitians or nutrition professionals. Because section 1802(b)(5)(C) of the Act references section 1842(b)(18)(c) of the Act in order to define the term practitioner for purposes of opting out of Medicare, current law permits registered dietitians or nutrition professionals to opt-out of Medicare as well. Because the definition of practitioner located in the current regulations at 42 C.F.R. 405.400 does not include registered dietitians or nutrition professionals, in this final rule we are revising the CFR so that it is consistent with section 1802(b)(5)(C) of the Act.

#### Reassignment on a Contractual Basis -Supplier Access to Billing Records

Section 952 of the MMA expanded the contractual arrangement reassignment exception so that entities, as of December 8, 2003, could bill and receive Medicare payment for services furnished by independent contractors (individual suppliers, such as physicians and non-physician practitioners) furnished off the premises of the entity receiving the reassigned benefits. Prior to this change in the reassignment law, independent contractors were required to furnish services on the premises of the entity receiving the reassigned benefits.

In order for an independent contractor to be able to reassign his or right to bill and receive payment to another entity, section 952 of the MMA requires that both parties must be enrolled in the Medicare program and both parties are subject to specific program integrity safeguards, as the Secretary deems appropriate. The Conference Report to section 952 of the MMA approved the following program integrity safeguards: (1) joint and several liability of any Medicare overpayments; and, (2) access to billing records. These program integrity safeguards became effective on January 1, 2005, and are applicable to the individual supplier furnishing a service and the entity to which the individual supplier is reassigning benefits.

Since the contractual arrangement reassignment exception is applicable to services furnished by independent contractors (such as, physicians or non-physician practitioners who can bill in their own name and billing number), the program integrity safeguards have only been applicable for services furnished by independent contractors that are being reassigned to a Medicare-enrolled entity. However, CMS has received public requests to allow employees the same unrestricted access to billing records that is afforded to independent contractors and specified in the reassignment regulations in section 424.80(d)(2). After reconsidering the issue since publication of the 2005 Physician Fee Schedule final rule, we find no valid reason why employees should not have access to their billing records, and we believe that access to billing records for services furnished by both independent contractors and employees will help monitor the accuracy of the billings made by the entity receiving payment (the reassigned benefits). Effective January 1, 2007, we have amended the reassignment regulations at section 424.80 to state that the individual supplier furnishing a service has unrestricted access to the billings submitted by the entity receiving Medicare payment for services furnished by that supplier, irrespective of whether the supplier is an employee or independent contractor. If an entity refuses to provide the

billing information to the individual supplier furnishing the service, the entity's right to receive reassigned benefits may be revoked in accordance with 42 CFR section 424.82(c)(3).

#### <u>Independent Diagnostic Testing Facilities (IDTFs) – Establishment of IDTF Supplier</u> Standards

We have established additional IDTF supplier standards similar to those used with Durable Medicare Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers. We believe that implementing IDTF supplier standards will improve quality of care and further protect the Medicare Trust Funds from fraud and abuse. Each IDTF must be in compliance with the new supplier standards in order to obtain or maintain Medicare billing privileges. Accordingly, if an IDTF fails to meet one or more standards at the time of enrollment, the application will be denied. If an enrolled IDTF fails to maintain compliance with any of supplier standards, the IDTFs billing privileges will be revoked.

#### <u>Payment for Renal Dialysis Services Furnished by End Stage Renal Disease (ESRD)</u> <u>Facilities - Wage Index Update</u>

In 2006, CMS implemented a number of changes to the wage index adjustment to the composite payment rate. These included moving from the 1980 metropolitan statistical (MSA) designations to the new core based statistical area (CBSA) designations; revising the labor portion of the composite payment rate based on the ESRD market basket; eliminating the wage index cap; gradually decreasing the wage index floor from 0.9 to 0.85 in 2006 and to 0.8 in 2007; and providing for a 4-year transition to the new wage index methodology. Year one of the transition is a 75/25 blend of the old MSA-based wage index and the new CBSA-based wage index, respectively. In the final rule, we are continuing with the process finalized last year for annually updating the ESRD wage index adjustment. That is, update the wage data and continue with the second year of the wage index transition, which would reduce the floor to 0.8 and use a 50/50 blended wage index.

## <u>Payment for Renal Dialysis Services Furnished by ESRD Facilities - Update to the Drug Add-on Adjustment to the Composite Payment Rate</u>

Section 623 of MMA established the drug add-on adjustment to the composite payment rate to account for the difference between payment amounts for separately billable drugs under pre-MMA payments and the new payment methodology established under that section of the statute. In addition, beginning in 2006, the MMA requires that CMS annually update the drug add-on adjustment to reflect the estimated growth in ESRD drug expenditures from the previous year. The current add-on adjustment is 14.5 percent and includes a 1.4 percent update for 2006. The 14.5 percent adjustment reflects an average per treatment adjustment of \$18.88. In the final rule for the CY 2007 add-on adjustment, we used the producer price index (PPI) for drugs as a proxy for ESRD drug pricing growth and to estimate the growth in per treatment utilization of separately billable ESRD drugs by isolating utilization from the historical data from 2004 and 2005 and projecting utilization growth for 2007. For CY 2007 the drug add-on adjustment to the composite payment rate is 0.5 percent. As a result, the drug add-on adjustment to the composite payment rate for 2007 will increase from 14.5 percent to 15.1 percent (1.145 x 1.005).

#### **Coverage of Bone Mass Measurement Tests**

In an interim final rule (IFC) published in the Federal Register on June 24, 1998, we implemented section 4106 of the Balanced Budget Act of 1997 (BBA) by establishing a new

regulatory section, 42 CFR 410.31 (Bone Mass Measurement: Conditions for Coverage and Frequency Standards), effective July 1, 1998. Based on these comments, as well as review of a 2004 report issued by the Surgeon General (Bone Health and Osteoporosis) and other available evidence, we are making the following changes to these 1998 regulations:

- Non-cover the single-photon absorptiometry (SPA) device for performing BMMs. SPA is generally regarded as an obsolete technology that is not as accurate and reliable as other BMM techniques.
- Limit coverage of confirmatory baseline BMMs to those furnished by a central DXA
  device for axial skeleton if the initial measurement is not performed this way. This
  change will ensure that more accurate and reliable BMMs are performed for our
  beneficiaries.
- Limit coverage of BMMs used for monitoring individuals receiving FDA-approved drug therapies for osteoporosis to those performed with a central DXA device for axial skeleton. As with the previous change, this will ensure that these measurements for monitoring are as accurate and reliable as possible.
- Reduce the dosage eligibility requirement for beneficiaries receiving (or expecting to receive) steroid therapy from an average of 7.5 mg to 5.0 mg of prednisone, or greater per day for more than 3 months. This change is based on comments received previously and our review of the current evidence.
- Add a new subsection that would allow us to use the NCD process to identify alternative bone mass measurement systems that could be covered for monitoring individuals receiving osteoporosis drug therapy and performing confirmatory baseline measurements.

<u>Codes (Designated Health Services) Subject to the Physician Self-Referral Prohibition</u>
In this rule we update the list codes subject to the physician self-referral prohibition to account for changes in the CPT and HCPCS for CY 2007.

#### Payment of bad debts

In this final rule we codify in the regulations Medicare's longstanding policy that payment of bad debts associated with services paid under a fee schedule/charge-based system is not allowable.

#### **Payments for Part B Drugs**

We have provided more specific language on services fees in the regulation text and have clarified that the service fee guidance applies regardless of whether an entity takes title to the product. We provide additional guidance concerning service fees in several areas including appropriate methods for determining fair market value and whether fees are passed on, and the treatment of fees paid to Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs).

In order for a fee to be considered a bona fide service fee for ASP reporting purposes, the following conditions must be met:

- -The fee paid must be for a bona fide, itemized service that is actually performed on behalf of the manufacturer;
- -The manufacturer would otherwise perform or contract for the service in the absence of the service arrangement;
- The fee represents fair market value; and

- The fee is not passed on in whole or in part to a client or customer of any entity.

In the final rule, we clarify that a manufacturer can presume, if all other criteria are met, that a fee satisfies the "not passed on" criterion and would be excluded from the ASP calculation. These clarifications are intended to reduce manufacturers' reporting burden. We also clarify that fees paid to GPOs and PBMs that meet the bona fide service fee definition are excluded from the ASP calculation. We also state that we will consider issuing additional guidance on the treatment of payments to entities that do not take title to products for ASP purposes.

#### **Treatment of Bundled Price Concession in the ASP Calculation**

In the final rule, we indicate that we are not establishing a specific methodology that manufacturers must use for the treatment of bundled price concessions for purposes of the ASP calculation at this time.

The final rule also emphasizes that we expect manufacturers of drugs reimbursed by Medicare Part B to comply with all applicable laws, regulations, and legal decisions including, but not limited to the Stark law, other relevant anti-kickback laws, antitrust laws, and laws governing fair trade practices.

#### **Technical ASP and Drug Payment Issues**

- Finalizing ASP Reporting Rule. We published an interim final rule with comment (IFC) on Average Sales Price (ASP) reporting in April 2004 and we finalized that rule in the 2007 PFS Final Rule with comment.
- Clotting Furnishing Fee. Each year, the Secretary is required to make certain statutory updates related to Part B drug payment policy. The clotting factor furnishing fee is updated annually based on growth in the consumer price index. For 2007, the clotting factor furnishing fee will be \$0.152 per unit, a 4.1 percent increase from 2006.
- Substituting Alternate Rate for ASP Based on OIG Studies. Each year, the Secretary is also required to establish a threshold to be used by the OIG in their studies comparing the average manufacturer price and the widely available market price with the ASP. The current threshold is 5 percent, and in the final rule we finalized our proposal to maintain the threshold at 5 percent for 2007.

Public Consultation for Medicare Payment for New Clinical Diagnostic Laboratory Tests
Pursuant to section 942(b) of the Medicare Modernization Act (MMA), the final rule codifies an open-to-the public meeting process to establish fees for new clinical laboratory tests. Section 942(b) of the MMA adds specific procedures that CMS must perform each year. The procedures include: publishing a notice for a public meeting, convening a public meeting, making available to the public (through the Internet or other appropriate mechanism) a list of proposed fees for new codes for clinical laboratory tests, receiving comments on the proposed fees, and making available to the public (through the Internet) a list of final fees. CMS has already been following this process for a number of years and will continue the process for public consultation to establish new clinical laboratory test fees.

#### **Technical Refinements to the Clinical Laboratory Fee Schedule**

Technical refinements to the clinical laboratory fee schedule in the final rule include:

- A discussion of the need for payment to foster the provision of quality care and the prevention of avoidable health care costs.
- CMS reiterated that Medicare separately pays for a blood glucose test only when the service meets all of the conditions of payment for a test payable under the clinical laboratory fee schedule including that the test must be ordered by the physician who is treating the beneficiary and the physician must use the results in the management of the beneficiary's specific medical condition. Our regulation states that for payment to be made for a blood glucose test under Medicare Part B, a physician must certify that each test is medically necessary and that a standing order for many tests over a time period is not sufficient documentation. Payment for nursing care glucose monitoring is encompassed under Medicare Part A and other payment methods.
- CMS is codifying its longstanding date of service policy for specimens that have been in program instructions. In addition, CMS amended the policy to permit conditions by which a specimen may be obtained from storage in less than 30 days and qualify for separate payment under the clinical laboratory fee schedule if a number of conditions are met. The amendment addresses certain tissue specimens for post hospital care cancer treatment.

#### **Discussion Items**

#### **Geographic Practice Cost Indices (GPCIs)**

Section 1848(e)(1)(A) of the Act requires us to develop separate GPCIs to measure resource cost differences among localities compared to the national average for each of the three fee schedule components. In this final rule, we briefly discuss the expiration of the MMA mandated work GPCI floor of 1.0 as well as the regulatory timeframe for updating the GPCIs.

**NOTE:** As mandated by section 102 of the Tax Relief and Health Care Act of 2006, application of the 1.0 floor in the work GPCI for any locality for which the index is less than 1.0 (based upon the GPCIs announced in the December 1, 2006 *Federal Register*) will be extended until December 31, 2007. Practice expense GPCIs and malpractice GPCIs are not affected by this provision.

#### **Certification of Advanced Practice Nurses**

We are delaying our decision about whether to include the National Board on Certification of Hospice and Palliative Care Nurses (NBCHPN) under the manual instruction listing of recognized national certifying bodies for NPs and clinical nurse specialists (CNSs) until we have had more time to examine and investigate the comments that we received about this issue.

#### **Discussion of Chiropractic Services Demonstration**

In the final rule, we include a discussion on the chiropractic services demonstration and our intent to ensure the chiropractic demonstration is budget neutral in terms of Medicare payments to chiropractors.

We also discuss the Department's efforts with respect to promoting the effective use of health information technology and the health care information transparency technology.

#### **Ambulance Fee Schedule**

This final rule will improve the accuracy of payments under the ambulance fee schedule and incorporate changes in geographic adjustments based on the most recent census data. The final rule announces an Ambulance Inflation Factor (AIF) for CY 2007 of 4.3 percent. The final rule will also resolve three issues that have arisen since April 1, 2002, when CMS began phasing in the ambulance fee schedule. They are:

- Revising the designation of areas as urban or rural to incorporate changes made by the Office of Management and Budget to the Metropolitan Statistical Areas (MSAs), to reflect the 2000 census data;
- Replacing the Goldsmith Modification (identifying rural census tracts within MSAs) with the most recent version based on Rural Urban Commuting Areas (RUCAs);
- Discontinuing formal annual review of "low billers" (providers or suppliers billing at less than the fee schedule amount) and air ambulances to determine whether adjustments are needed in the ambulance fee schedule conversion factor (CF).

The final rule adopts the new Metropolitan Statistical Area (MSA) definitions developed by the Office of Management and Budget (OMB) based on 2000 census data. Currently, Medicare uses MSAs based on 1990 census data to differentiate between rural and urban areas for purposes of ambulance payment. CMS has already made similar revisions in geographic designations for the Inpatient Prospective Payment System, and other Medicare payment systems that include rural adjustments. The 2000 census data reflect both urban-to-rural and rural-to-urban shifts across the nation, but, overall, there were more urban areas in the 2000 census than in the 1990 census. Thus, the final rule will lead to some redistribution of aggregate Medicare payments among ambulance services since trips originating in a rural area are generally paid at a higher rate than urban trips. However, in areas newly-designated as urban, an ambulance company would be expected to have a greater volume of business; thus, it would be paid for more ambulance trips.

As an extension of the new geographic definitions, CMS will update the Goldsmith Modification with new Rural-Urban Commuting Area Codes (RUCAs) utilized by OMB. The existing Goldsmith Modification recognizes rural census tracts within Large Area Metropolitan Counties (LAMCs), based on population density and commuting patterns. In contrast, the RUCAs are based on a broader range of data, and allow recognition of rural census tracts within any metropolitan county.

#### **Payment for Administration of Part D Vaccines**

As mandated by section 202 of the Tax Relief and Health Care Act of 2006, effective January 1, 2007, Medicare will cover administration of vaccines that are covered under Part D of the program. This is covered under section 1860D-2(e) of the Social Security Act (42 U.S.C 1395w-102 (e)). The administration of a vaccine is described in section 1861(s) (10) (B) The law stipulates the administration of the vaccine shall be paid under Part B of title XVIII of the Act. A new G code (G0377) has been created for the administration of Part D vaccines. Payment for G0377 will be crosswalked to CPT code 90471 and will be effective for one year.

**2007 Coding Issue**For 2007, the following CPT codes have been renumbered:

	T	
Old CPT Code	Renumbered to	Short Descriptor
15831	15847	EXCISE EXCESSIVE SKIN TISSUE
19140	19300	REMOVAL OF BREAST TISSUE
19160	19301	PARTICAL MASTECTOMY
19162	19302	P-MASTECTOMY W/LN REMOVAL
19180	19303	MAST, SIMPLE, COMPLETE
19182	19304	MAST, SUBQ
19200	19305	MAST, RADICAL
19220	19306	MAST, RAD, URBAN TYPE
19240	19307	MAST, MOD RAD
27315	27325	NEURECTOMY, HAMSTRING
27320	27326	NEURECTOMY, POPLITEAL
28030	28055	NEURECTOMY, FOOT
47716	47719	FUSION OF BILE DUCT CYST
48005	48105	RESECT/DEBRIDE PANCREAS
48180	48548	FUSE PANCREAS AND BOWEL

40005	40.400	DEMOVE FOREIGN BODY ADROMEN
49085	49402	REMOVE FOREIGN BODY, ADBOMEN
54820	54865	EXPLORE EPIDIDYMIS
55859	55875	TRANSPERI NEEDLE PLACE, PROS
56720	56442	HYMENOTOMY
57820	57558	D&C OF CERVICAL STUMP
37020	37330	Dag of GERMIONE GLOWIN
67350	67346	BIOPSY, EYE MUSCLE
75998	77001	FLUOROGUIDE FOR VEIN DEVICE
76003	77002	NEEDLE LOCALIZATION BY XRAY
76005	77003	FLUOROGUIDE FOR SPINE INJECT
76006	77071	X-RAY STRESS VIEW
70000	77071	X TO CT CT COO VIEW
76012	72291	PERQ VERTEBROPLASTY, FLUOR
76013	72292	PERQ VERTEBROPLASTY, CT
76020	77072	X-RAYS FOR BONE AGE
76040	77073	X-RAYS, BONE LENGTH STUDIES
76061	77074	X-RAYS, BONE SURVEY, LIMITED
7,0001	77014	
76062	77075	X-RAYS, BONE SURVEY COMPLETE
76065	77076	X-RAYS, BONE SURVEY, INFANT
76066	77077	JOINT SURVEY, SINGLE VIEW
76070	77078	CT BONE DENSITY, AXIAL

76071	77079	CT BONE DENSITY, PERIPHERAL
76075	77080	DXA BONE DENSITY, AXIAL
76076	77081	DXA BONE DENSITY/PERIPHERAL
76077	77082	DXA BONE DENSITY, VERT FX
76078	77083	RADIOGRAPHIC ABSORPTIOMETRY
76082	77051	COMPUTER DX MAMMOGRAM ADD- ON
76083	77052	COMP SCREEN MAMMOGRAM ADD- ON
76086	77053	X-RAY OF MAMMARY DUCT
76088	77054	X-RAY OF MAMMARY DUCTS
76090	77055	MAMMOGRAM, ONE BREAST
76091	77056	MAMMOGRAM, BOTH BREASTS
76092	77057	MAMMOGRAM, SCREENING
76093	77058	MRI, ONE BREAST
76094	77059	MRI, BOTH BREASTS
76095	77033	STEREOTACT GUIDE FOR BRST BX
76096	77032	GUIDANCE FOR NEEDLE, BREAST
76355	77011	CT SCAN FOR LOCALIZATION
76360	77012	CT SCAN FOR NEEDLE BIOPSY
76362	77013	CT GUIDE FOR TISSUE ABLATION

76370	77014	CT SCAN FOR THERAPY GUIDE
70202	77004	MR GUIDANCE FOR NEEDLE PLACE
76393	77021	WIR GUIDANCE FOR NEEDLE PLACE
		MDI FOR TISSUE ARI ATION
76394	77022	MRI FOR TISSUE ABLATION
76400	77084	MAGNETIC IMAGE, BONE MARROW
76986	76998	US GUIDE, INTRAOP