CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 419	**Date: December 19, 2008**
	Change Request 6349

SUBJECT: Summary of Policies in the 2009 Medicare Physician Fee Schedule (MPFS) and the Telehealth Originating Site Facility Fee Payment Amount

I. SUMMARY OF CHANGES: This Change Request provides a summary of the policies in the 2009 Medicare Physician Fee Schedule and announces the Telehealth Originating Site Facility Fee.

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:
One-Time Notification

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

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 419	Date: December 19, 2008	Change Request: 6349

SUBJECT: Summary of Policies in the 2009 Medicare Physician Fee Schedule (MPFS) and the Telehealth Originating Site Facility Fee Payment Amount

EFFECTIVE DATE: January 1, 2009

IMPLEMENTATION DATE: January 5, 2009

I. GENERAL INFORMATION

A. Background: The purpose of this change request is to provide a summary of the policies in the 2009 MPFS and to announce the telehealth originating site facility fee payment amount. 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. On November 19, 2008 we published the 2009 Physician Fee Schedule that sets payments to physicians effective January 1, 2009.

Section 1834(m) of the Act established 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 CY 2009 is 1.6 percent.

B. Policy: For calendar year 2009, the payment amount for HCPCS code "Q3014, Telehealth originating site facility fee" is 80 percent of the lesser of the actual charge or $23.72. The beneficiary is responsible for any unmet deductible amount or coinsurance.

See the attachment for a summary of issues discussed in CMS-1403-FC, Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6349.1	Medicare contractors shall pay for the Medicare telehealth originating site facility fee as described	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	by HCPCS code Q3014 at 80 percent of the lesser of the actual charge or $23.72.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6349.2	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's 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 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	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): Gaysha Brooks, **Gaysha.Brooks@cms.hhs.gov**, (410) 786-9649

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

A. *For Fiscal Intermediaries and Carriers,* use the following statement:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. *For Medicare Administrative Contractors (MAC),* use the following statement:
The Medicare Administrative Contractor (MAC) is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as changes to the MAC 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 CMS-1403-FC, Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

I. PHYSICIAN FEE SCHEDULE (PFS) RELATED ISSUES

Practice Expense Issues

In the 2009 final rule with comment period, we finalize changes to the practice expenses (PE) for certain codes. These changes were routine in nature and similar to changes made in previous years. The issues include the following:

- Remote Cardiac Monitoring/Equipment Time in Use
- RUC recommendations on PE inputs for certain codes including immunization codes.

Coding Issues

Payment for Preadministration-Related Services for Intravenous Infusion of Immune Globulin

Payment is no longer made under the physician fee schedule for code G0332, for preadministration related services for IVIG infusion, effective January 1, 2009. This code has been deleted from the physician fee schedule database and is no longer recognized for services furnished after December 31, 2008.

Multiple Procedure Payment Reduction (MPPR) for Diagnostic Imaging

It is necessary to periodically update the list of codes subject to the MPPR to reflect new and deleted codes. In this rule, we finalize our CY 2009 proposal to add several additional procedures to the MPPR list. Six procedures represent codes newly created since the MPPR list was established. Four additional procedures were identified as similar to procedures currently subject to the MPPR. We also removed CPT code 76778, a deleted code, from the list. This proposal was also finalized in the final rule with comment period.

Proposed HCPCS code for Prostate Saturation Biopsies

Prostate Saturation Biopsy is a technique that was previously described by Category III CPT code 0137T, Biopsy, prostate, needle, saturation sampling for prostate mapping. Typically, this service entails 40-80 core samples taken from the prostate under general anesthesia. Currently, the biopsies are reviewed by a pathologist and this service is captured under CPT code 88305, Surgical pathology, gross and microscopic examination, which is separately billed by the physician for each core sample taken. CPT Code 88305 has a physician work value of 0.75 and a total nonfacility payment rate of $102.83. We believe that paying individually for review of each core sample submitted grossly overpays for the pathological interpretation and report for this service. Therefore, we proposed to add four G codes to more accurately represent the pathologic evaluation, interpretation, and report for this service. We also proposed that these codes be priced by the Medicare contractor. In this final rule with comment period, we finalize our proposal, but provide assigned values to the four new G codes based upon assumption of the number of cancerous cells.

New and Revised Codes

We received work relative value unit (RVU) recommendations for 128 new and revised CPT codes from the American Medical Association (AMA) Relative Update Committee (RUC) this year. Of the recommendations received, we accepted 114 and disagreed with 14.

The CPT Editorial Panel made significant revisions to the cranial and spinal stereotactic radiosurgery codes and the AMA RUC revalued them. We reduced the work RVUs for these codes in the final rule with comment period by approximately 35 percent because we believe they were valued inappropriately.

The CPT Editorial Panel created 23 new cardiac device codes. We believe that some of the codes are overvalued and should be reduced to maintain consistency between levels of service. We reduced the work RVUs for these codes in the final rule with comment period.

The CPT Editorial Panel revised four pelvic bone fracture codes but the AMA RUC did not recommend any changes to the work RVUs for these codes. We disagreed with this recommendation and created four G codes consistent with CY 2008 descriptors.

The CPT Editorial Panel created 20 CPT codes to replace the G codes for monthly and per diem end-stage renal disease (ESRD) services. We accepted the AMA RUC recommendations for these services. The new CPT codes are listed below:

Deleted G Code	New CPT Code*	Short Descriptor
G0308	90951	Esrd serv, 4 visits p mo, <2
G0309	90952	Esrd serv, 2-3 vsts p mo, <2
G0310	90953	Esrd serv, 1 visit p mo, <2
G0311	90954	Esrd serv, 4 vsts p mo, 2-11
G0312	90955	Esrd srv 2-3 vsts p mo, 2-11
G0313	90956	Esrd srv, 1 visit p mo, 2-11
G0314	90957	Esrd srv, 4 vsts p mo, 12-19
G0315	90958	Esrd srv 2-3 vsts p mo 12-19
G0316	90959	Esrd serv, 1 vst p mo, 12-19
G0317	90960	Esrd srv, 4 visits p mo, 20+
G0318	90961	Esrd srv, 2-3 vsts p mo, 20+
G0319	90962	Esrd serv, 1 visit p mo, 20+
G0320	90963	Esrd home pt, serv p mo, <2
G0321	90964	Esrd home pt serv p mo, 2-11
G0322	90965	Esrd home pt serv p mo 12-19
G0323	90966	Esrd home pt, serv p mo, 20+
G0324	90967	Esrd home pt serv p day, <2
G0325	90968	Esrd home pt srv p day, 2-11
G0326	90969	Esrd home pt srv p day 12-19
G0327	90970	Esrd home pt serv p day, 20+

Physicians and practitioners may receive payment for managing patients on dialysis for less than a full month of care in specific circumstances (as discussed in Publication 100-04, Medicare Claims Processing manual chapter 8, section 140.2). Payment for ESRD related services, less than a full month, is paid on a per diem basis.

Per diem ESRD-related services should be coded using the ESRD related services (less than full month), per day codes (as described by CPT codes 90967 – 90970) for ESRD-related services furnished in the situations described below.

- Home dialysis patients (less than full month);
- Transient patients – Patients traveling away from home (less than full month);
- Partial month where there was one or more face-to-face visits without a complete assessment of the patient and the patient was either hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient had a transplant.
- Patients who have a permanent change in their MCP physician during the month.

The ESRD-related services (less than full month), per day codes should only be used for the circumstances described above. The per diem codes may not be used for a full month when a complete monthly assessment is not furnished.

Renumbered CPT Codes

Effective for CY 2009, the following CPT codes have been renumbered:

Deleted CPT Code*	New CPT Code*	Short Descriptor
90760	96360	Hydration iv infusion, init
90761	96361	Hydrate iv infusion, add-on
90765	96365	Ther/proph/diag iv inf, init
90766	96366	Ther/proph/diag iv inf addon
90767	96367	Tx/proph/dg addl seq iv inf
90768	96368	Ther/diag concurrent inf
90769	96369	Sc ther infusion, up to 1 hr
90770	96370	Sc ther infusion, addl hr
90771	96371	Sc ther infusion, reset pump
90772	96372	Ther/proph/diag inj, sc/im
90773	96373	Ther/proph/diag inj, ia
90774	96374	Ther/proph/diag inj, iv push
90775	96375	Tx/pro/dx inj new drug addon
90776	96376	Tx/pro/dx inj new drug adon
90779	96379	Ther/prop/diag inj/inf proc
99289	99466	Ped crit care transport
99290	99467	Ped crit care transport addl
99293	99471	Ped critical care, initial
99294	99472	Ped critical care, subsq
99295	99468	Neonate crit care, initial
99296	99469	Neonate crit care, subsq
99298	99478	Ic, lbw inf < 1500 gm subsq
99299	99479	Ic lbw inf 1500-2500 g subsq
99300	99480	Ic inf pbw 2501-5000 g subsq
99431	99460	Init nb em per day, hosp
99432	99461	Init nb em per day, non-fac
99433	99462	Sbsq nb em per day, hosp
99435	99463	Same day nb discharge
99436	99464	Attendance at delivery
99440	99465	Nb resuscitation

Potentially Misvalued Services

In the 2009 PFS NPRM, we identified methods that the American Medical Association Relative Value Update Committee (AMA RUC) could undertake to assist in identifying potentially misvalued services. We suggested the AMA RUC review: the fastest growing procedure codes; the Harvard-valued codes; and direct Practice Expense (PE) inputs.

In this final rule with comment period, we state that we look forward to continuing to work with the AMA RUC and the specialty societies in reviewing these issues and receiving alternative approaches for identifying misvalued codes. In addition, we plan to continue our review of services that could be bundled or made subject to the multiple procedure payment reduction. We decided not to finalize our proposal to update high-cost supplies over $150 every 2 years based on comments received. We will re-visit this issue in the future.

The AMA RUC started a review of potentially misvalued codes using various screens, at the 2008 AMA RUC meetings. These included codes with site of service and high intra-service time anomalies. CMS agreed to accept the valuation for the site of service anomaly codes for CY 2009. However, in the coming months, we plan to continue our review of these codes. We may propose additional changes to these codes to better reflect the resources used in the CY 2010 proposed rule.

Medicare Telehealth Services

In this rule, we finalize our proposal to add HCPCS codes specific to follow-up inpatient consultation delivered via telehealth and clarified that the criteria for these services will be consistent with Medicare policy for consultation services. We also finalize our proposals not to add Diabetes Self-Management Training (DSMT) or critical care services to the list of approved telehealth services.

II. OTHER ISSUES

Part B Drug Issues

In the 2009 PFS proposed rule, we proposed three regulatory changes affecting payment of Part B Drugs under the Average Sales Price (ASP) methodology:

- We proposed to update our regulations to comport with the new volume-weighting ASP calculation methodology established in section 112(a) of the Medicare and Medicaid SCHIP Extension Act (MMSEA) of 2008.
- We proposed conforming changes to our regulations to address the special payment rule for certain single source drugs or biologicals that are treated as multiple source drugs because of the application of the grandfathering provisions of section 1847A of the Act.
- Section 1847A(d)(1) of the Act allows the Secretary to disregard the ASP for a Part B drug or biological that exceeds the WAMP or the AMP for such drug by an applicable threshold percentage. For CY 2009, we proposed to maintain the threshold at 5 percent, absent of data that suggests a change is appropriate.

In this rule, we finalize these proposals related to payment of Part B Drugs under the ASP methodology.

Application of Health Professional Shortage Area (HPSA) Bonus Payment

In this rule, we finalize our proposal to update §414.67 with minor revisions. We clarify that physicians who furnish services in areas that are designated as geographic HPSAs as of December 31 of the prior year but not included on the list of zip codes for automated HPSA bonus payments should use the AQ modifier to receive the HPSA bonus payment.

End-Stage Renal Disease (ESRD) Facility-related Issues

We did not propose any significant changes to the ESRD composite rate payment methodology, but proposed two updates—1) the wage index and transition; and 2) the drug add-on adjustment. Subsequent to the publication of the CY 2009 PFS proposed rule, the Medicare Improvements for Patients and Providers Act (MIPPA) was enacted on July 15, 2008 authorizing (1) a 1 percent increase to the composite payment rate for services furnished on or after January 1, 2009; (2) the establishment of a composite rate that is site neutral to hospital-based and independent dialysis facilities for services furnished on or after January 1, 2009; and (3) the application of a site neutral composite rate with a labor share that is based on the labor share otherwise applied for renal dialysis facilities. In this rule, we finalize our proposals set forth in the CY 2009 PFS proposed rule, as well as the ESRD MIPPA provisions with effective dates of January 1, 2009. The following discussions summarize the changes.

Issue 1: Update to the Wage Index

For CY 2009, we finalize our proposals to: (1) update the wage index using the latest hospital wage data; (2) complete the 4-year transition to the new wage index methodology where ESRD facilities receive 100 percent of the CBSA-based wage-adjusted composite rate; and (3) reduce the wage index floor from 0.75 to 0.70, consistent with reductions made in 2006, 2007, and 2008 updates.

Issue 2: Update to the Drug Add-on Adjustment to the Composite Payment Rate

Section 1881(b)(12)(F) of the Act requires that the Secretary annually increase the drug add-on adjustment to the composite payment rate to account for growth in drug prices and changes in patient level utilization. The drug add-on adjustment for CY 2008 is 15.5 percent of the total composite rate payment. In CY 2008, the Producer Price Index (PPI) for drugs was used to project price growth. In the CY 2009 proposed rule, we proposed to revise the price proxy for ESRD drugs to one based on a trend analysis of ASP pricing. Based on trend analysis of ASP drug prices from 2006, 2007 and 2 quarters of 2008, we projected a decline in ESRD drug prices for CY 2009 of 1.9 percent. Based on a projected price decline of 1.9 percent combined with the projected 1 percent drop in per patient utilization, the proposed growth estimate in total ESRD drug expenditures for CY 2009 was -2.9 percent. However, because the statutory language specifies that only an "increase" in the drug add-on adjustment be reflected, we proposed an update of zero to the drug add-on adjustment for CY 2009.

In this final rule we recommend changing the proxy used in measuring ESRD drug price growth from the PPI to ASP, as proposed. After consultation with CMS/Office of the Actuary, we agree with commenters regarding the use of 2007 data to predict patient level utilization and will establish this estimate at zero. Therefore, using the latest data, the combined utilization and drug price change projection for CY 2009 is -1.8 percent. Despite this projected negative value, we will recommend implementing a zero update to the drug add-on adjustment for CY 2009. We believe that this approach is consistent with the plain reading of the statute. The zero percent update to the drug add-on payment and implementation of the MIPPA one percent increase effective January 1, 2009 revises the drug add-on adjustment from 15.5 percent to 15.2 percent for CY 2009

Independent Diagnostic Testing Facilities (IDTF)

The following is a summary of the IDTF provisions in the final rule:

Require mobile IDTFs to enroll and bill for the services furnished by the mobile IDTF.
As part of this final rule, we are requiring all mobile units furnishing diagnostic testing services to Medicare beneficiaries to enroll in the Medicare program. In addition, all mobile units furnishing diagnostic testing services will be required to bill for services unless the service is furnished under arrangement with a hospital. When services are furnished under arrangement, the hospital will continue to bill for the diagnostic testing services.

Physician and Nonphysician Enrollment Safeguards

The following is a summary of the enrollment provisions in the final rule:

1. Limit retrospective payments to physicians and nonphysician practitioners and physician and nonphysician practitioner organizations.
We establish the effective date of billing privileges for physicians and nonphysician practitioners and physician or nonphysician practitioner organizations as the later of: (1) the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date an enrolled physician or nonphysician practitioner first started furnishing services at a new practice location. This provision permits physicians and nonphysician practitioners to retrospectively bill for services furnished up to 30 days prior to the effective date of enrollment if the physician or nonphysician practitioner meets all program requirements, even if the initial enrollment application is rejected or denied as long as the application is ultimately approved. In addition, physicians and non-physician practitioners will be permitted to retrospectively bill for services furnished up to 90 days prior to the effective date if the physician or non-physician practitioner meets all program requirements and there is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§5121-5206 (Stafford Act).

2. Prohibit physicians and nonphysician practitioners, as well as owners, authorized officials, and delegated officials of a physician or nonphysician practitioner organization from obtaining additional billing privileges if their current billing privileges are suspended or an overpayment is pending.
We adopted this provision of the proposed rule without modification because, as a health plan, Medicare must be able to limit future payments to those individuals and organizations where there is a payment risk.

3. Require all providers and suppliers, including individual practitioners, to maintain ordering and referring documentation for 7 years from the date of service.
We adopted this revision of the proposed provision by requiring all providers and suppliers, including individual practitioners, to maintain ordering and referring documentation for 7 years from the date of service.

4. Require physician and nonphysician organizations, physicians and nonphysician practitioners, and IDTFs to submit all outstanding claims within 60 days of the revocation date.
We adopted a revision of the proposed provision by requiring all physicians, nonphysician practitioners, and physician or nonphysician practitioner organizations to submit all outstanding claims within 60 days of the effective date of revocation. Since physicians, nonphysician practitioners and physician and nonphysician organizations are already afforded approximately 30 days notice before the effective date of revocation, we believe that almost 90 days is more than sufficient time to submit any outstanding claims.

5. Require physicians and nonphysician practitioners and physician and nonphysician practitioner organizations to notify their Medicare contractor of a change of ownership, final adverse action, or change of location that impacts a payment amount within 30 days. Failure to notify the designated contractor of these changes may result in an overpayment from the date of the reportable event.

We adopted this provision from the proposed rule without modification because it is essential that physicians and nonphysician practitioners report certain changes in a timely manner. Since a final adverse action (for example, license suspension/revocation, Federal debarment/exclusion, or felony conviction) may impact future payments, we believe that physicians and nonphysician practitioners must report these changes timely and that an overpayment would result from the date of the reportable event if the reportable event precluded further payments. We also believe that physicians and nonphysician practitioners and physician and nonphysician practitioner organizations must report changes in practice location and ownership in a timely manner as these events may effect payment.

6. We solicited comments regarding whether we should consider revoking billing privileges or taking some other administrative action when a physician or nonphysician practitioner has a Federal tax delinquency that cannot be levied through the Federal Payment Levy Program (FPLP).

In this final rule with comment period, we state that we will consider these comments in developing any future rulemaking proposal; however, we continue to maintain that physicians and nonphysician practitioners resolve any existing Federal tax delinquency before enrolling in the Medicare program.

Amendment to the Exemption for Computer-Generated Facsimile Transmission from the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for Transmitting Prescription and Certain Prescription-Related Information for Part D Eligible Individuals

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) mandated the adoption of standards for the electronic transmission of prescriptions and certain other information for covered drugs prescribed under the Medicare Part D drug program. The November 2005 e-prescribing final rule adopted a set of foundation standards for e-prescribing Part D covered drugs for Part D eligible individuals. The 2005 final rule also established an exemption to the requirement to use the NCPDP SCRIPT standard for entities that transmit prescriptions or prescription-related information by means of computer-generated facsimiles (faxes generated by one computer and electronically transmitted to another computer or fax machine which prints out or displays an image of the prescription or prescription-related information). The exemption was intended to allow providers and dispensers time to upgrade to software that utilizes the NCPDP SCRIPT standard, rather than forcing them to revert to paper prescriptions. The CY 2008 PFS rule partially lifted this exemption, effective January 2009.

We proposed to further amend this exemption in the CY 2009 PFS proposed rule; however, in light of industry comments and the impact of the e-prescribing provisions of MIPPA, in this final rule we restore the computer-generated fax exemption in its entirety as of January 1, 2009. We also eliminate the computer-generated fax exemption on January 1, 2012, once the MIPPA e-prescribing program disincentives take effect. We need to give MIPPA every chance to succeed, and partially lifting the exemption now would create confusion over what constitutes e-prescribing and could impact patient care.

Comprehensive Outpatient Rehabilitation Facilities (CORFs) and Rehabilitation Agency (RA) Issues

In this final rule, we finalize our proposed changes for CORFs and RAs for clarity and to better reflect current nomenclature. These changes include:

- Revising the definitions for different categories of respiratory therapists to reflect current professional standards and nomenclature to ensure that only those therapists who have achieved the appropriate level of certification provide care to CORF patients;
- Revising the CORF personnel requirements to align with other regulations in Part 485 by referencing the home health agency personnel requirements;
- Amending the duties of a CORF physician to include medical supervision of nonphysician staff;
- Clarifying that a patient's home may serve as an "alternate location" at which CORF services can be provided;
- Adding a definition for an extension location of a RA;
- Deleting the requirement that RAs retain a physician on call in case of an emergency;
- Deleting the requirement that a RA provide social or vocational services; and
- Making a technical correction by removing reference to a RA section that no longer exists.

CORF Social and Psychological Services HCPCS code G0409

In this rule, we finalize our proposal to create the CORF specific G code which describes the unique social and psychological services provided by CORF staff. We also finalize our proposal to remove the application of the mental health limitation to CORF services.

Anti-Markup Provisions

Section 1842(n)(1) of the Social Security Act (the Act) requires us to impose a payment limitation on certain diagnostic tests where the physician performing or supervising the test does not share a practice with the billing physician or other supplier. This statutory provision was codified in §414.50 of our regulations to apply an "anti-markup" payment limitation to the technical component (TC) of a diagnostic test (other than a clinical diagnostic laboratory test) that is purchased from an outside supplier. In this final rule with comment period (73 FR 69799), we finalize changes to §414.50, including alternative methods to satisfy the statutory requirement that, in order to avoid application of an anti-markup payment limitation on a diagnostic test, the physician who performs or supervises the diagnostic test must share a practice with the billing physician or other supplier. Because the revisions to the regulations in §414.50 would apply an anti-markup payment limitation on purchased diagnostic tests (because they are, by nature, not performed by a physician who shares a practice with the billing physician or other supplier), we eliminated this duplicative category of tests to which the payment limitation would apply. Thus, we removed all references to the term "purchased diagnostic test."

The anti-markup payment limitation will not apply if the performing physician "shares a practice" with the billing physician or other supplier. As set forth in §414.50(a)(2), there are two alternative methods for determining whether a performing/supervising physician shares a practice with the billing physician or other supplier. Under the first alternative, if the performing physician (that is, the physician who supervises the TC or performs the PC, or both) furnishes substantially all (at least 75 percent) of his or her professional services through the billing physician or other supplier, none of the physician's diagnostic testing services will be subject to the anti-markup payment limitation. If the performing physician does not meet the "substantially all services" requirement, a "site of service" analysis may be applied on a test-by-test basis to determine whether the anti-markup payment limitation applies. Under this "site of service" test, only TCs conducted and supervised in and PCs performed in the "office of the billing physician or other supplier" by a physician owner, employee or independent contractor of the billing physician or other supplier will avoid application of the anti-markup payment limitation. The

"office of the billing physician or other supplier" is any medical office space, regardless of the number of locations, in which the ordering physician or other ordering supplier regularly furnishes patient care, and includes space where the billing physician or other supplier furnishes diagnostic testing, if the space is located in the "same building" (as defined in §411.351) in which the ordering physician regularly furnishes patient care. If the billing physician or other supplier is a physician organization (as defined in §411.351), the "office of the billing physician or other supplier" is space in which the ordering physician provides substantially the full range of patient care services that the ordering physician generally provides. With respect to the TC, the performing supplier is the physician who supervised the TC, and with respect to the PC, the performing supplier is the physician who performed the PC.

In cases where a physician does not share a practice with the billing physician or other supplier, either under the "substantially all services" or "site of service" test, the anti-markup payment limitation will apply. Payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

(i) The performing supplier's net charge to the billing physician or other supplier.
(ii) The billing physician or other supplier's actual charge.
(iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly (§414.50(a)(1)).

The net charge must be determined without regard to any charge that reflects the cost of equipment or space leased to the performing supplier by the billing physician or other supplier (§414.50(a)(2)(i)).

2009 Physician Quality Reporting Initiative (PQRI) and Electronic Prescribing Incentive Requirements

The Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) requires the Secretary to select measures for 2009 PQRI through rule making and to establish alternative reporting criteria and alternative reporting periods for reporting measures groups and for registry-based reporting. The Medicare Patients and Provider Act of 2008 (MIPPA) made the PQRI program permanent and authorized an Electronic Prescribing (e-prescribing) Incentive program. The 2009 PQRI and e-prescribing incentive program requirements in the final CY PFS rule include the following:

1. 2009 PQRI Quality Measures

- Removes the e-prescribing measure (measure #125) as required by MIPPA.
- Final number of 2009 PQRI quality measures is 153.
- Includes 18 measures reportable only through registries

2. Reporting Options

- 2009 PQRI reporting period is the entire year for 2009, as specified by MIPPA.
- 2 alternative reporting periods: Jan 1, 2009 – Dec 31, 2009; and Jul 1, 2009 – Dec 31, 2009 for measures groups and registry-based reporting.
- Reporting criteria for claims-based reporting of individual measures: 80% of applicable Medicare Part B FFS patients for at least 3 PQRI measures (or 1-2 measures if fewer than 3 apply). These criteria will apply to the Jan 1, 2009 – Dec 31, 2009 reporting period. The Jul 1, 2009-Dec 31, 2009 reporting period is not an option for claims-based reporting of individual measures.
- Reporting criteria for claims-based reporting of measures groups: 1) For the Jan 1, 2009 – Dec 31, 2009 reporting period: a) 30 consecutive Medicare Part B FFS patients to whom all measures of 1 measures group apply, OR b) 80% of applicable Medicare Part B

FFS patients to whom all measures of 1 measures group apply with a minimum of 30 patients; OR 2) For the Jul 1, 2009 – Dec 31, 2009 reporting period: 80% of applicable Medicare Part B FFS patients to whom all measures of 1 measures group apply, with a minimum of 15 patients.

3. **Measures Groups**
   - 7 measures groups, which include 1) Diabetes Mellitus, 2) Chronic Kidney Disease, 3) Preventive Care, 4) Coronary Artery Bypass Graft (CABG) Surgery, 5) Rheumatoid Arthritis, 6) Perioperative Care, and 7) Back Pain with the Back Pain Measures Group reportable solely as a measures group and not by individual measures.
4. **Clinical Registry Data Reporting**
   - Begin accepting PQRI measures data from clinical data registries starting Jan 1, 2010 for services performed in 2009;
   - Conduct another registry self-nomination;
   - Reporting Periods: Jan 1, 2009 – Dec 31, 2009; and Jul 1, 2009 – Dec 31, 2009.
   - Reporting criteria for registry-based reporting of individual measures: 80% of applicable Medicare Part B FFS patients to whom at least 3 individual measures apply (criteria apply for either reporting period).
   - Reporting criteria for registry-based reporting of measures groups: 1) For the Jan 1, 2009 – Dec 31, 2009 reporting period: a) 30 consecutive patients to whom all measures of 1 measures group apply, OR b) 80% of applicable Medicare Part B FFS patients to whom all measures of 1 measures group apply with a minimum of 30 patients; OR 2) For the Jul 1, 2009 – Dec 31, 2009 reporting period: 80% of applicable Medicare Part B FFS patients to whom all measures of 1 measures group apply with a minimum of 15 patients.
   - Registries qualified to submit data on behalf of their eligible professionals in 2008 not required to self-nominate again for 2009 unless they are unsuccessful at submitting 2008 data by Mar 31, 2009.
5. **EHR data reporting**
   - Extend EHR testing process into 2009 and conduct a self-nomination process for EHR vendors and testing to qualify EHR vendors to submit quality data to CMS data warehouse and potential submission of clinical quality data extracted from EHRs for future PQRI.
6. **2009 PQRI Satisfactory Reporting Incentive**
   - Eligible professionals who satisfactorily report quality measures are eligible to receive an incentive of 2% of estimated allowable charges submitted not later than 2 months after the end of the reporting period for 2009 PQRI.
7. **Uses of PQRI Information**
   - For 2009 PQRI submitted data, we plan to the post the names of individual eligible professionals who 1) satisfactorily report quality measures for the 2009 PQRI and/or 2) are successful electronic prescribers for the 2009 e-prescribing incentive program, following completion of 2009 incentive payments.
8. **E-Prescribing Incentive Program**
   - Implement new 2% incentive payment (i.e., 2% of estimated allowable charges submitted not later than 2 months after the end of the reporting period) for successful electronic prescribers in 2009
   - In 2009, we are adopting one e-prescribing measure (Measure #125) for e-prescribing incentive program, reportable only through the Medicare claims process. Updates to measure specifications will be posted no later than Dec 31, 2008. The Part D standards for electronic prescribing, which are incorporated in the measure specifications for the e-prescribing measure, are referenced.

- "Successful electronic prescriber" defined as an eligible professional who reports the e-prescribing measure in at least 50% of the applicable cases.
- Reporting period for the 2009 e-prescribing incentive: Jan 1, 2009 – Dec 31, 2009.
- In order to be considered an eligible professional for purposes of the e-prescribing incentive for 2009, the e-prescribing measure denominator codes must apply to at least 10 % of the total of allowed charges for all such covered services furnished by the eligible professional.

9. Other Pertinent MIPPA Provisions that will be implemented for 2009 PQRI

- Definition of "eligible professional" expanded to include qualified audiologists.

Educational Requirements for Nurse Practitioners (NPs) and Clinical Nurse Specialists(CNSs)

In this rule, we finalize our proposal to recognize the doctor of nursing practice (DNP) degree and also state that we will continue to study the evolution of the DNP degree to ensure that it continues to be consistent with our program requirements. In addition, we finalize a proposed technical correction to the NP regulatory qualifications that will clarify that the requirement for a master's degree in nursing is the minimum educational level for newly enrolled NPs and CNSs independently treating Medicare beneficiaries.

Portable X-Ray Issue

In the CY 2009 PFS proposed rule, we proposed to revise §486.104 (Qualifications, orientation, and health of technical personnel) of the Conditions for Coverage (CfC) for Portable X-Ray services to reflect the existing professional standards of practice and training requirements. The CFCs are authorized under section 1861(s)(3) of the Act and were first adopted January 1969. The proposal was based on recommendations from the Center for Medicaid and State Operations (CMSO), which received reports of the potential for adverse job actions as a result of the current rule's inaccuracy. We proposed the following revisions to the CFCs:

- To revise the qualification requirements for x-ray personnel in §486.104 (a)(1), (a)(2), and (a)(3), which rely on credentialing activities from the Council on Education of the American Medical Association (CEAMA) and the American Osteopathic Association (AOA). These organizations no longer approve formal training programs for x-ray technology and have not done so since 1992.
- To reflect that the Joint Review Committee on Education in Radiologic Technology (JRCERT) is now the only accrediting entity recognized by the United States Department of Education (USDE) that approves x-ray technology programs.
- To reflect that x-ray technology programs are no longer based on program duration, but on program requirements. Prior to 1992, the curriculum for x-ray technology programs was based on a duration of 24 months.

In this final rule, we finalize the revisions as proposed and also:

- Delete references to schools approved by the CEAMA or the AOA for those receiving training after 1992;
- Add JRCERT as an accrediting body for x-ray technology schools;
- Delete the requirement for formal training of not less than 24 months in duration, since this criterion is not part of the criteria established by entities that evaluate and approve x-ray technology programs since 1993; and
- Add a new paragraph to address those who completed their training after July 1, 1966 but before January 1, 1993, the time period during which CEAMA and the AOA were approving training programs.

Other Issues

1. Continuous Positive Air Pressure (CPAP) Prohibition

On March 13, 2008, we published a national coverage determination (NCD) that expands coverage of CPAP devices to beneficiaries whose obstructive sleep apnea (OSA) has been diagnosed by specified home sleep testing. Prior Medicare policy had covered CPAP devices only for beneficiaries whom OSA had been diagnosed by facility-based attended polysomnography. During the NCD public comment period, we received many comments expressing concern that financial incentives could lead to abusive testing practices that may harm Medicare beneficiaries and the Medicare program. Because of these concerns, we proposed to implement a provision that would remove a significant financial incentive for abusive practice.

We proposed to prohibit DME supplier payment for a CPAP device if the provider of a sleep test that is used to diagnose OSA in a Medicare beneficiary is the DME supplier or an affiliate of the supplier of the CPAP machine used to treat the beneficiary's sleep apnea. The proposed prohibition applied to all sleep testing from attended facility based polysomnography (PSG) to unattended home sleep testing (HST).

In this final rule, we finalize the proposal at this time with a narrower scope that would effectively exclude attended facility-based PSG from the prohibition, and solicit public input on accreditation models that might support future exceptions.

2. Beneficiary signatures for Nonemergency Ambulance Claims

In this rule, we finalize the following revisions to the beneficiary signature requirements in §424.36:

- Expand the exception in §424.36(b)(6) to include nonemergency ambulance transports in situations where the beneficiary is incapable of signing a claim form and there is no one authorized to sign on behalf of the beneficiary available or willing to sign.
- Amend §424.36(a) to clarify that providers and suppliers must make reasonable efforts to obtain the beneficiary's signature before relying on one of the exceptions in §424.36(b)(1) through (b)(5) (as proposed).
- Amend §424.36(a) to define "claim," for purposes of the beneficiary signature requirements, as the claim form itself or a form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary (as proposed).
- Clarify that secondary forms of verification do not require a signature from a facility representative, provided that the information collected is an official facility record that documents the name of the beneficiary and the date and the time that the beneficiary was received by that facility.
- Not making the regulation retroactive to January 1, 2008, and not creating an exception to the signature requirement rules for good faith attempts to comply.
- Not abolishing the signature requirement rules entirely as suggested by many of the commenters.

3. Revision to the "Appeals of CMS or CMS contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges" Final Rule

The Office of Management and Budget (OMB) requested that CMS establish the effective revocation date as the date of a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the date a practice location is determined to be not operational by

CMS or our contractor. For these types of revocations, a physician or nonphysician practitioner would not be allowed to bill for services after the date of the reportable event.

In this final rule, we adopt this provision without modification because while we discontinue billing privileges based on the date of the reportable event, physicians and nonphysician practitioners are afforded appeal rights.

II. PROVISIONS FROM THE MEDICARE IMPROVEMENTS FOR PATIENTS AND PROVIDERS ACT OF 2008 (MIPPA)

Section 101: Improvements to Coverage of Preventive Services

Background and Provisions

When Medicare was established, little was known about preventive care and early detection. As a result, Medicare did not cover prevention and was fundamentally a program for treating the ill. Before the enactment of the MIPPA, the statute was thought to limit Medicare coverage of preventive services because of the reasonable and necessary exclusion in section 1862(a)(1)(A) of the Act, which excludes payment for any item or service that is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Also, section 1862(a)(7) of the Act specifically excludes from coverage routine physical checkups. These two statutory provisions taken together resulted in the longstanding Medicare policy interpretation that, except as otherwise provided in the law, payment for diagnostic examinations or evaluations must be preceded by signs, symptoms, complaint, or a personal history of a medical problem. The Congress has, over the last decade, added individual preventive benefits to the Medicare program. The preventive or screening services currently covered under Medicare include the following:

- Pneumococcal, influenza, and hepatitis B vaccinations.
- Pap smear.
- Pelvic examination.
- Mammography.
- Screening of colorectal cancer, prostate cancer, glaucoma, cardiovascular, diabetes, ultrasound abdominal aortic aneurysms.
- Bone mass measurement.
- The initial preventive physical examination (IPPE).

Section 101 of the MIPPA created a new benefit category—additional preventive services—and modified the IPPE benefit. Like the current preventive services we cover, the new services are excluded from the reasonable and necessary (R&N) determinations under section 1862(a)(1)(A) of the Act that we normally use under the NCD process. In other words, we can not use R&N under section 1861(a) of the Act to determine that a specific screening benefit is not covered. However, in most cases, the Congress did authorize us to add additional tests we deem appropriate under the screening benefit.

For additional preventive services, the Congress created a new R&N standard within the benefit category under section 1861(ddd) of the Act: "reasonable and necessary for the prevention or early detection of an illness or disability". Under this provision, we may add another preventive service if it meets the R&N standard, the US Preventive Services Task Force "strongly recommends (grade A) or "recommends" (grade B) the service, and we find it appropriate for Medicare beneficiaries. We must use the NCD process to make that coverage determination. In addition, the statute allows consideration of costs within that NCD (as it also did for colorectal cancer screening and prostate cancer screening).

In this rule, we revise the regulations to reflect these statutory changes.

Payment for the IPPE

The MMA provided for one IPPE per beneficiary per lifetime. A beneficiary is eligible when first enrolling in Medicare Part B on or after January 1, 2005, and receives the IPPE benefit within the first 6 months of the effective date of the initial Part B coverage period. If the physician or qualified NPP is not able to perform both the examination and the screening EKG, an arrangement may be made to ensure that another physician or entity performs the screening EKG and reports the EKG separately using the appropriate existing HCPCS G code(s). MIPPA made several changes to the IPPE including expanding the IPPE benefit period to not later than 12 months after an individual's first coverage period begins under Medicare Part B. (Other changes to this benefit were included in segment 1 of the rule.) The following is a summary of the payment changes resulting from section 101 of the MIPPA:

- The Deductible Change with MIPPA**:** The Medicare deductible does not apply to the IPPE if performed on or after January 1, 2009 within the beneficiary's 12-month initial enrollment period of Medicare Part B. The waived deductible is applicable to the IPPE service only. Medicare will pay for one IPPE per beneficiary per lifetime. The Medicare deductible for the IPPE performed before January 1, 2009 (G0344) applies. Co-insurance applies irrespective of codes or date of the IPPE. The waived deductible for the IPPE, effective January 1, 2009, does not apply to the screening EKG. We have revised §410.16 to reflect this change.

- New G Codes Needed with MIPPA Implementation**:** We revised the G codes for both the IPPE and EKG to reflect the changes in the legislation. The EKG codes will reflect a once-in-a lifetime screening with a referral from an IPPE. We retained the current work RVUs associated with the previous codes. We do not believe that the additional required components (end of life planning and individual body mass index) result in additional physician work or affect the PEs of a physician.

Section 131: Physician Payment, Efficiency, and Quality Improvements and Section 132: Incentives for Electronic Prescribing

Section 131(a) of the MIPPA amended section 1848(d)(8) of the Act to extend the 6-month increase in the CY 2008 conversion factor (CF) to the entire year and added section 1848(d)(9) of the Act which provided that the update to the single CF for CY 2009 shall be 1.1 percent. This subsection further specified that the CFs for CY 2010 and subsequent years must be computed as if these increases had never applied.

The MMSEA requires the Secretary for 2009 to select measures for PQRI through rulemaking for purposes of reporting data on quality measures for services furnished during 2009. In addition, for 2009 the Secretary is to establish alternative reporting criteria and alternative reporting periods for reporting measures groups and for registry-based reporting. For eligible professionals who satisfactorily report data on quality measures, the Secretary is required to make an incentive payment of 1.5 percent of Part B estimated allowed charges for the relevant reporting periods for 2007 and 2008. There was no current authority for an incentive payment for 2009 when the proposed rule was published. Section 131 of the MIPPA requires the Secretary to make incentive payments for eligible professionals who satisfactorily report for 2009 and contains other provisions that affect PQRI for 2009.

The following is a discussion of the specific MIPPA provisions followed by our implementation (in italics) in the final rule with comment period.

Section 131(b)

- For 2009 and for subsequent years, for each quality measure (including an electronic prescribing quality measure) adopted by the Secretary, eligible professionals must have had the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish. *This will not impact the measures since all measures included a public comment period during development and NQF endorsement.*
- Eligible professionals who satisfactorily report quality measures shall be paid a 2 percent incentive of estimated allowable charges submitted not later than 2 months after the end of the reporting period for 2009 quality measures. T*his application of MIPPA is included in this final rule with comment period. This is the same method for calculation of the bonus payment as for CY 2007 and CY 2008 except that the bonus payment is 2 percent of charges for the reporting period, not 1.5 percent.*
- Eligible professionals shall be paid 2 percent incentive of estimated allowable charges submitted not later than 2 months after the end of the reporting period for 2009 electronic prescribing measure. *We added a new provision in this final rule with comment period to implement the new 2 percent incentive bonus payment for successful e-prescribing. The e-prescribing measure referred to in statute is the measure included in 2008 PQRI and was proposed for continuation for the 2009 PQRI. In the proposed PFS rule we provided that the measure specifications were subject to modification until December 31, 2008 and would be posted on the CMS Web site. MIPPA also allows specification code changes to the e-prescribing measure. We note in this final rule with comment period that all specification updates will be completed no later than December 31, 2008, consistent with the PQRI quality measures.*
- E-Prescribing measures must not be included in the quality measures. *Although we proposed the e-prescribing as one of the quality measures for 2009, the MIPPPA requires that this be removed for the quality measures incentive payment. We are not including the e-prescribing measure in the finalized quality measures for 2009, but will adopt the measure independently for purposes of the incentive for successful electronic prescribers.*
- The Secretary shall post on the CMS Web site a list of names of the eligible professionals who satisfactorily submitted data on quality measures and who are successful electronic prescribers. No date is stated in legislation. *In this final rule, we state our intention to initiate the internet posting as required under MIPPA for the 2008 and 2009 PQRI.*
  - *For 2007 PQRI, we plan to post the names of individual eligible professionals who submitted quality data for 2007 PQRI measures without regard to whether the eligible professionals qualified for satisfactory reporting.*
  - *For 2008 PQRI, we currently plan to post the names of individual eligible professionals who satisfactorily report quality measures for the 2008 PQRI, following completion of the incentive payments for 2008 (scheduled for July, 2009).*
  - *For 2009 PQRI, we will post the list of names of the individual eligible professionals who satisfactorily report quality measures and those who are successful electronic prescribers for the 2009 PQRI, following completion of the incentive payments for 2009 (planned for July, 2010).*
- Defines the reporting period for 2009 to be the entire year. *This is consistent with the proposed rule for individual measures, which we will finalize. Under existing authority (MIEA-TRHCA), we finalize alternative reporting periods and alternative reporting criteria.*
- Includes qualified audiologist in the definition of an eligible professional. *We are adding qualified audiologists to the list of eligible professionals.*
- No effect on 2007 or 2008 payments for section 131 of the MIPPA. *This is noted in this final rule with comment period.*
- The Secretary shall implement a physician feedback program not later than January 1, 2009, to use claims data (and may use other data) to provide confidential reports to

physicians (and as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care under the Act. The Secretary shall provide education and outreach under the program. *This is not applicable to PQRI. However, we have an existing feedback report for quality.*

Section 132

- Eligible professionals who are successful electronic prescribers shall be paid 2 percent incentive of estimated allowable charges submitted not later than 2 months after the end of the reporting period for 2009 successful electronic prescribing. *We are adding a new section on the provisions of section 132 to identify the electronic prescribing measure which is the current PQRI Measure #125.*
- A "successful electronic prescriber" is defined under section 1848(m)(3)(B)(ii) of the Act as an eligible professional who reports the e-prescribing measure in at least 50 percent of the cases in which the measure is reportable by the professional. Although the Secretary is given authority to assess successful electronic prescribing using either data reported by eligible professionals using electronic prescribing quality measures or using Part D prescription data, we will use the former for 2009. *We will set forth the statutory criteria for successful electronic prescriber as reporting the measure in 50 percent of applicable cases. We will not discuss the alternative criteria for successful electronic prescribing based on submission of a sufficient number of prescriptions under Part D. These alternative criteria may be used in the future, after 2009.*
- There is also a limitation of the applicability of the e-prescribing incentive. For CY 2009, in order to be considered an eligible professional for purposes of the e-prescribing incentive, the e-prescribing measure denominator codes must apply to at least 10 percent of the total of allowed charges for all such covered services furnished by the eligible professional. *We note this limitation for e-prescribing in this final rule with comment period.*
- To the extent practicable the Secretary shall ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D Electronic Prescribing Program Standards for electronic prescribing. *We refer to the Part D Regulation definition of electronic prescribing which is included in the Electronic Prescribing measure.*
- The reporting period for electronic prescribing is a period specified by the Secretary. We will make the reporting period the entire year. A shorter time period would result in a smaller incentive bonus since charges on which bonus is based is tied to the reporting period. No effect on 2007 or 2008 payments for section 132 of the MIPPA.

Section 131(c): Physician Resource Use Reports

Section 131(c) of the MIPPA requires the Secretary to establish and implement by January 1, 2008, a physician feedback program using Medicare claims data and other data to provide confidential feedback reports to physicians (and as determined by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to Medicare beneficiaries. If determined appropriate by the Secretary, the Secretary may also include information on quality of care furnished to Medicare beneficiaries by the physician (or group of physicians) in the reports.

In April 2008, we launched a phased pilot program to develop physician resource use measures and confidential feedback reports. The goals of the pilot program are: (1) to develop meaningful, actionable, and fair measures of resource use for physician practices with the ultimate goal of using the measures in our value-based purchasing (VBP) initiatives; and (2) to provide feedback and education to encourage more efficient provision of services.

Design of Pilot Program

We are currently testing various methodology and design options for constructing resource utilization reports. To inform future phases of the pilot program, we are soliciting comments in this final rule with comment period on the following issues:

- Use of both per capita and episode-based resource use measures.
- Risk adjustment of resource use scores.
- Attribution of cost to physicians/practitioners.
- Benchmarks for peer comparison.

Section 133(b): Budget Neutrality and the PFS Conversion Factor (CF)

Section 133(b) of MIPPA states, "(b) APPLICATION OF BUDGET-NEUTRALITY ADJUSTOR TO CONVERSION FACTOR.—…….effective for fee schedules established beginning with 2009, with respect to the 5-year review of work RVUs used in fee schedules for 2007 and 2008, in lieu of continuing to apply BN adjustments required under clause (ii) for 2007 and 2008 to work RVUs, the Secretary shall apply such budget-neutrality adjustments to the conversion factor otherwise determined for years beginning with 2009." Therefore, section 133(b) of the MIPPA requires that the Secretary, in a budget neutral manner, shift the -12 percent separate work payment adjustment to the conversion factor (CF). Because work represents just over half of payments, shifting the -12 percent separate work payment adjustment to apply to the CF requires a reduction to the CF of approximately -6 percent. The resulting CY 2009 CF will be lower than the CY 2008 CF.

Section 133(b) of the MIPPA has no overall impact on physician payments. The payment impact on most specialties is modest (+/- 1 percent) since most specialties have generally similar work, PE, and malpractice payment distributions. Specialties that are heavily PE dependent, such as diagnostic testing facilities (-5 percent) and portable x-ray suppliers (-4 percent) are impacted the most.

Section 134: Extension of Floor on Medicare Work Geographic Adjustment under the Medicare Physician Fee Schedule

Section 134 of the MIPPA extends the 1.0 floor on the geographic adjustment to the physician work component of the fee schedule from July 1, 2008 through December 31, 2009. This section also sets a permanent 1.5 floor on the geographic adjustment for the physician work component in Alaska, beginning with January 1, 2009.

Section 136: Treatment of Certain Physician Pathology Services Under Medicare

Section 136 of the MIPPA extends from July 1, 2008 through December 31, 2009, separate (unbundled) payment of the TC of physician pathology services furnished to hospital inpatients and outpatients by independent laboratories.

Section 141: Extension of Exceptions Process for Medicare Therapy Caps

Section 141 of the MIPPA extends the exceptions process for therapy caps from July 1, 2008 through December 31, 2009.

CY 2009 Therapy Cap Amount

In addition, we announced the per beneficiary therapy cap for CY 2009. As required by section 1833(g)(2) of the Act, the cap is equal to the preceding year's cap increased by the percentage increase in the Medicare Economic Index (MEI) (except that if an increase for a year is not a

multiple of $10, it is rounded to the nearest multiple of $10). For CY 2008, the cap was $1810. For CY 2009, the cap will be $1840.

Section 143: Speech Language Pathology (SLP) Services

Section 143 of the MIPPA authorizes CMS to enroll speech-language pathologists (SLPs) as suppliers of services and to bill for services provided in private practice settings as of July 1, 2009.

Section 144(b): Repeal of Title for O2 Equipment

Oxygen and oxygen equipment are paid based on a fee schedule in accordance with section 1834(a)(5) of the Act. The Deficit Reduction Act (DRA) of 2005 limited monthly payments for oxygen and oxygen equipment to 36 months of continuous use, after which the equipment title transferred to the beneficiary. As part of the DRA rulemaking effort, we established beneficiary safeguards to ensure that suppliers would continue to maintain and service beneficiary-owned oxygen equipment after the 36-month cap. The safeguards include payment for periodic (every 6 months) routine maintenance of beneficiary-owned oxygen equipment, payment for pickup of beneficiary-owned oxygen tanks that are no longer needed, and rules for furnishing or replacing oxygen equipment during the 36-month payment period. Section 144(b) of the MIPPA repeals the transfer of ownership provision established by the DRA and establishes three new subparagraphs under 1834(a)(5)(F) addressing payment and rules after the 36 month payment cap.

1. Section 1834(a)(5)(F)(ii)(I) of the Act: Furnishing Oxygen Equipment After the Cap

The MIPPA repeals the transfer of ownership provision, allowing suppliers to retain ownership of the equipment. This section requires the supplier who furnished the oxygen equipment during the 36th month of continuous use to continue furnishing the equipment for any period of medical necessity until the beneficiary elects to obtain replacement equipment because the reasonable useful lifetime for the equipment has expired. We are proposing to revise our regulations to reflect this change. We are also proposing to delete §414.210(e)(3) of our regulations which is now obsolete and unnecessary, permitted payment for pick up and safe disposal of beneficiary-owned oxygen tanks that are no longer needed.

2. Section 1834(a)(5)(F)(ii)(II) of the Act: Oxygen Contents

This section requires that payment be made after the cap for oxygen contents used with gaseous or liquid oxygen equipment. The supplier that is responsible for continuing to furnish the gaseous or liquid oxygen equipment (tanks) in accordance with section 1834(a)(5)(F)(ii)(I) of the Act would be paid on a monthly basis for furnishing the contents used with the equipment. We are proposing to revise §414.226(a)(2) to include this provision.

3. Section 1834(a)(5)(F)(ii)(III) of the Act: Maintenance and Servicing of Oxygen Equipment

This section permits payment for maintenance and servicing of oxygen equipment after the cap if the Secretary determines such payments (for parts and labor not covered under a warranty) are reasonable and necessary. Oxygen equipment is very dependable, low maintenance equipment, and the quality standards require that suppliers furnish quality products. However, in order to reduce potential harm to beneficiaries that might result due to malfunctioning equipment, we believe it is reasonable and necessary to pay for periodic maintenance and servicing of oxygen concentrators and transfilling equipment after the cap to ensure safe operation of the equipment. We are revising §414.210(e)(2) to pay for periodic maintenance and servicing of supplier-owned oxygen concentrators and transfilling equipment after the cap in the same manner that these payments would have applied to maintenance and servicing of beneficiary-owned equipment. This section provides for payment every 6 months, beginning 6 months after the 36-month cap,

for 30 minutes of labor for general maintenance and servicing of the equipment. Payment will only be made for actual incidents of maintenance and servicing where the supplier visits the beneficiary's home to inspect the equipment and provide any necessary maintenance and servicing. Payment will not be made for replacement of parts for supplier-owned equipment. Maintenance and servicing of supplier-owned liquid or gaseous equipment (tanks, cylinders, regulators, etc.) is the responsibility of the supplier, who should be furnishing equipment in good working order at the time that they are delivering the oxygen contents paid for in accordance with section 1834(a)(5)(F)(ii)(II) of the Act. This would not present a cost to Medicare since we currently pay for maintenance and servicing.

Note: The rules and requirements at §414.226(g)(1) through (3) that apply to suppliers during the 36-month payment period relating to furnishing oxygen and oxygen equipment and replacing oxygen equipment in §414.210(e)(2) will remain in effect. Unless special circumstances apply, §414.226(g)(1) requires the supplier who furnished the oxygen equipment in the first month to continue furnishing the oxygen equipment for the entire 36-month period. Section 414.226(g)(2) prevents suppliers from switching equipment during the 36-month period (for example, from concentrator to liquid in month 36 so that they can continue to be paid for contents after the cap). As is the case with §414.226(g)(1), special exceptions to this rule may apply. Since the supplier's responsibility for furnishing oxygen equipment now extends beyond the 36-month rental period, we are revising §414.226(g)(2) to extend the period during which equipment switches are limited through the end of the reasonable useful lifetime of the equipment. Finally, §414.226(g)(1) requires the supplier to disclose their intentions for accepting assignment of claims during the 36 month rental period.

Section 145: Clinical Laboratory Tests

Section 145 of the MIPPA sets the clinical laboratory fee schedule update at CPI-U minus 0.5 percentage point for CY 2009 through CY 2013.

The update for 2009 is 4.5 percent. For purposes of calculating the CLFS update, we use the CPI-U that covers the period from June to June of each year.

Section 146: Improved Access to Ambulance Services.

Section 146 of the MIPPA establishes increased payments for ground ambulance services from July 1, 2008 through December 31, 2009 of 3 percent for services originating in a rural area and 2 percent for services originating in a non-rural area. Such increased payments would not affect payment calculations for subsequent years. It also establishes a 1½ year "hold harmless" period (July 1, 2008 through December 31, 2009) for air ambulance services originating in an area that was switched from rural to urban under new geographic classifications that took effect January 1, 2007. Such areas would continue to be designated as rural (and thus eligible for rural payment treatment) during this period.

Section 149: Adding Certain Entities as Originating Sites for Payment of Telehealth

The MIPPA recognizes the following additional originating sites, effective for services furnished on or after January 1, 2009: a hospital-based or CAH-based renal dialysis center (including satellites); a skilled nursing facility (SNF); and a community mental health center (CMHC).

Section 153: End Stage Renal Disease (ESRD) Provisions

Section 153 of the MIPPA increases the composite rate by 1.0 percent for ESRD services furnished during CY 2009 and increases such composite rates by another 1.0 percent for services furnished on or after January 1, 2010. It requires that the composite rate paid to hospital-based

facilities be the same rate as paid to independent renal dialysis facilities for services furnished beginning on January 1, 2009. (Other ESRD provisions of this section are effective later.)

In this final rule with comment period, we indicate that MIPPA increased the composite rate by 1.0 percent for ESRD services furnished during 2009. This requires us to update the drug add-on adjustment separately in the rule. We also discuss the MIPPA provision that requires that the composite rate paid to hospital-based facilities be the same rate as paid to independent renal dialysis facilities for services furnished on or after January 1, 2009. Since the current method of payment will not be available after January 1, 2009, we are revising §413.174 which describes the methodology that differentiates ESRD composite payments rates between hospital-based and independent facilities. The site neutral composite rate shall reflect the labor share based on the labor share otherwise applied for renal dialysis facilities.