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## Report RL34592

## P.L. 110-275: The Medicare Improvements for Patients and Providers Act of 2008

Hinda Chaikind, Coordinator, Domestic Social Policy Division

July 23, 2008

Abstract. P.L. 110-275, the Medicare Improvements for Patients and Providers Act (MIPPA), is designed to avert a statutory Medicare reduction in payments for physicians and make other changes. MIPPA freezes physician fees at the June 2008 level until January 2009. In January 2009, fees will increase by 1.1%. In 2010, the statutory reduction will again apply, resulting in a 21% reduction in Medicare physician fees, according to the Congressional Budget Office (CBO). CBO estimates that the physician payments provision costs \$9.4 billion (over the 2008-2010 period). Other provisions in the Act will offset these and other costs, so that in total, the provisions in MIPPA will reduce deficits (or increase surpluses) by an estimated \$0.1 billion over the 2008-2013 period and by less than an estimated \$50 million over the 2008-2018 period. The main source for these offsets comes from reductions in spending for (1) the Medicare Advantage program and (2) the physician assistance and quality initiative (PAQI) fund. The Act also makes further changes to Medicare, Medicaid, and other programs under the Social Security Act. This report provides a description of the provisions of MIPPA.



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# **CRS Report for Congress**

# P.L. 110-275: The Medicare Improvements for Patients and Providers Act of 2008

July 23, 2008

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Prepared for Members and Committees of Congress

## P.L. 110-275: The Medicare Improvements for Patients and Providers Act of 2008

#### Summary

P.L. 110-275, the Medicare Improvements for Patients and Providers Act (MIPPA), is designed to avert a statutory Medicare reduction in payments for physicians and make other changes. MIPPA freezes physician fees at the June 2008 level until January 2009. In January 2009, fees will increase by 1.1%. In 2010, the statutory reduction will again apply, resulting in a 21% reduction in Medicare physician fees, according to the Congressional Budget Office (CBO). CBO estimates that the physician payments provision costs \$9.4 billion (over the 2008-2010 period). Other provisions in the Act will offset these and other costs, so that in total, the provisions in MIPPA will reduce deficits (or increase surpluses) by an estimated \$0.1 billion over the 2008-2013 period and by less than an estimated \$50 million over the 2008-2018 period. The main source for these offsets comes from reductions in spending for (1) the Medicare Advantage program and (2) the physician assistance and quality initiative (PAQI) fund. The Act also makes further changes to Medicare, Medicaid, and other programs under the Social Security Act. This report provides a description of the provisions of MIPPA.

MIPPA became law on July 15, 2008, after Congress overrode a presidential veto on H.R. 6331. The bill was originally passed by the House on June 24, 2008, under suspension of the rules by a vote of 355 to 59. On July 9, 2008, the Senate passed the bill without amendment by unanimous consent and the bill was cleared for the White House. On July 15, 2008, President Bush vetoed the bill. On the same day, the House voted 383-41 to override the veto, and the Senate later voted 70-26 to override the veto.

## Contents

Introduction	1
A Brief Description of the Current Programs	
Medicare	2
Medicaid	3
Summary of Provisions in P.L. 110-275	3
Title I - Medicare	
Subtitle A - Beneficiary Improvements	3
Part I - Prevention, Mental Health, and Marketing	
Section 101. Improvements to Coverage of Preventive Services	3
Section 102. Elimination of Discriminatory Copayment Rates for	
Medicare Outpatient Psychiatric Services	4
Section 103. Prohibitions and Limitations on Certain Sales and	
Marketing Activities under Medicare Advantage Plans	
and Prescription Drug Plans	4
Section 104. Improvements to the Medigap Program	
Part II - Low-Income Programs	
Section 111. Extension of Qualifying Individual (QI) Program	5
Section 112. Application of Full Low Income Subsidy (LIS) Assets	
Test under Medicare Savings Program	
Section 113. Eliminating Barriers to Enrollment	5
Section 114. Elimination of Medicare Part D Late Enrollment	
Penalties Paid by Subsidy Eligible Individuals	
Section 115. Eliminating Application of Estate Recovery	5
Section 116. Exemptions from Income and Resources for	
Determination of Eligibility for Low-Income Subsidy	7
Section 117. Judicial Review of Decisions of the Commissioner of	
Social Security under the Medicare Part D Low-Income	_
Subsidy Program	
Section 118. Translation of Model Form	
Section 119. Medicare Enrollment Assistance	
Subtitle B - Provisions Relating to Part A	3
Section 121. Expansion and Extension of the Medicare Rural	0
Hospital Flexibility Program	
Section 122. Rebasing for Sole Community Hospitals	1
Section 123. Demonstration Project on Community Integration Models in Certain Rural Counties	0
Section 124. Extension of the Reclassification of Certain Hospitals . 10	
1	J
Section 125. Revocation of Unique Deeming Authority of the Joint Commission	0
Subtitle C - Provisions Relating to Part B	
Part I - Physicians' Services	
•	J
Section 131. Physician Payment, Efficiency, and Quality Improvements	n
Section 132. Incentives for Electronic Prescribing	
Section 132. Incentives for Electronic Prescribing	
$\beta = \beta =$	-

		Extension of Floor on Medicare Work
	Geograp	bhic Adjustment under the Medicare Physician
	Fee Sch	edule
	Section 135.	Imaging Provisions
	Section 136.	Extension of Treatment of Certain Physician
		gy Services under Medicare
	Section 137.	Accommodation of Physicians Ordered to Active Duty
		rmed Services
		Adjustment for Medicare Mental Health Services 14
		Improvements for Medicare Anesthesia Teaching
		ns
Part	0	yment and Coverage Improvements
		Extension of Exceptions Process for Medicare
		Caps
		Extension of Payment Rule for Brachytherapy
		rapeutic Radiopharmaceuticals
		Speech-Language Pathology Services
		Payment and Coverage Improvements for Patients
		ronic Obstructive Pulmonary Disease and Other
		ons
		Clinical Laboratory Tests 15
		Improved Access to Ambulance Services
		Extension and Expansion of the Medicare Hold Harmless
		on under the Prospective Payment System for
	-	l Outpatient (HOPD) Services for Certain Hospitals 15
		Clarification of Payment for Clinical Laboratory
		rnished by Critical Access Hospitals16
		Adding Certain Entities as Originating Sites for
		t of Telehealth Services
	Section 150.	MedPAC Study and Report on Improving Chronic
		monstration Programs
	Section 151.	Increase of FQHC Payment Limits
	Section 152.	Kidney Disease Education and Awareness Provisions . 17
	Section 153.	Renal Dialysis Provisions
		Delay in and Reform of Medicare DMEPOS
		itive Acquisition Program
Subt		sions Relating to Part C
		Phase-Out of Indirect Medical Education (IME) 20
		Revisions to Requirements for Medicare Advantage
		Fee-for-Service (PFFS) Plans
		Revisions to Quality Improvement Programs
		Revisions Relating to Specialized Medicare Advantage
		r Special Needs Individuals
		Limitation on Out-Of-Pocket Costs for Dual Eligibles
	-	lified Medicare Beneficiaries Enrolled in a
		zed Medicare Advantage Plan for Special
		ndividuals
		Adjustment to the Medicare Advantage Stabilization
		Access to Medicare Reasonable Cost Contract Plans 22
	Section 168.	MedPAC Study and Report on Quality Measures 22

Section 169. MedPAC Study and Report on Medicare	
Advantage Payments	. 22
Subtitle E - Provisions Relating to Part D	. 23
Part I - Improving Pharmacy Access	
Section 171. Prompt Payment by Prescription Drug Plans and	
MA-PD Plans under Part D	. 23
Section 172. Submission of Claims by Pharmacies Located in	
or Contracting with Long-Term Care Pharmacies	. 23
Section 173. Regular Update of Prescription Drug Pricing	
Standard	. 24
Part II - Other Provisions	. 24
Section 175. Inclusion of Barbiturates and Benzodiazepines as	
Covered Part D Drugs	. 24
Section 176. Formulary Requirements With Respect to Certain	
Categories or Classes of Drugs	. 24
Subtitle F - Other Provisions	. 25
Section 181. Use of Part D Data	. 25
Section 182. Revision of Definition of Medically Accepted Indicatio	n
for Drugs	. 25
Section 183. Contract with a Consensus-Based Entity	
Regarding Performance Measurement	. 25
Section 184. Cost-Sharing For Clinical Trials	. 26
Section 185. Addressing Health Care Disparities	
Section 186. Demonstration to Improve Care to Previously	
Uninsured	. 26
Section 187. Office of the Inspector General Report on Compliance	
with and Enforcement of National Standards on Culturally	
and Linguistically Appropriate Services (CLAS) in Medicare	. 27
Section 188. Medicare Improvement Funding	
Section 189. Inclusion of Medicare Providers and Suppliers in	
Federal Payment Levy and Administrative Offset Program	. 28
Title II - Medicaid	. 28
Section 201. Extension of Transitional Medical Assistance	
(TMA) and Abstinence Education Program	. 28
Section 202. Medicaid DSH Extension	
Section 203. Pharmacy Reimbursement under Medicaid	. 29
Section 204. Review of Administrative Claim Determinations	
Section 205. County Medicaid Health Insuring Organizations	. 30
Title III - Miscellaneous	. 30
Section 301. Extension of TANF Supplemental Grants	. 30
Section 302. 70 Percent Federal Matching for Foster Care and	
Adoption Assistance for the District of Columbia	. 30
Section 303. Extension of Special Diabetes Grant Programs	
Section 304. IOM Reports on Best Practices for Conducting	
Systematic Reviews of Clinical Effectiveness Research	
and for Developing Clinical Protocols	. 31

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# P.L. 110-275: The Medicare Improvements for Patients and Providers Act of 2008

### Introduction

P.L. 110-275, the Medicare Improvements for Patients and Providers Act (MIPPA) became law on July 15, 2008, after Congress overrode a Presidential veto on H.R. 6331. The bill was originally passed by the House on June 24, 2008, under suspension of the rules by a vote of 355 to 59. On July 9, 2008, the Senate passed the bill without amendment by unanimous consent after approval was given for cloture by a vote of 69-30. The bill was cleared for the White House. On July 15, 2008 President Bush vetoed the bill. On the same day, the House voted 383-41 to override the veto and the Senate later voted 70-26 to override the veto.

MIPPA is designed to avert a statutory Medicare reduction in payments for physicians and make other changes. MIPPA freezes physician fees at the June 2008 level until January 2009. In January 2009, fees will increase by 1.1%. In 2010, the statutory reduction will again apply, resulting in a 21% reduction in Medicare physician payment levels, according to the Congressional Budget Office (CBO). CBO estimates that the physician payments provision cost \$9.4 billion (over the 2008-2010 period).<sup>1</sup> Other provisions in the Act will offset these and other costs, so that in total, the provisions in MIPPA will reduce deficits (or increase surpluses) by an estimated \$0.1 billion over the 2008-2013 period and by less than an estimated \$50 million over the 2008-2018 period. The main source for these offsets comes from reductions in spending for (1) the Medicare Advantage program, and (2) the physician assistance and quality initiative (PAQI) fund.

The Act also makes further changes to Medicare, Medicaid, and other programs under the Social Security Act. For example, MIPPA (1) adds "additional preventive services" to the list of Medicare-covered preventive services; (2) increases the percentage that Medicare generally pays for mental health services and in 2014, outpatient psychiatric services will be paid on the same basis as other Part B services; (3) increases the assets tests applicable under the Medicare Savings program (MSP) to those applicable under the low-income subsidy program under the Medicare Part D prescription drug program; (4) repeals the current law requirement for competitive bidding for clinical laboratory services; (5) makes changes to low-income programs for Medicare beneficiaries, as well as Medicaid; and (6) makes changes to Medicare provisions for hospitals, renal dialysis coverage, and Medicare prescription drug

<sup>&</sup>lt;sup>1</sup> The CBO cost estimate for H.R. 6331 as enacted as P.L. 110-275) is available at [http://www.cbo.gov/ftpdocs/95xx/doc9595/hr6331pgo.pdf]. The total budgetary effect is estimated in the memorandum of the cost estimate, which assumed passage of the Supplemental Appropriations Act of 2008, now P.L. 110-252.

coverage, among others. Finally, MIPPA terminates all contracts under the first round of the Durable Medical Equipment, prosthetics, orthotics, and other medical supplies (DMEPOS) competitive acquisition program, set to start July 1, 2008. It requires the Secretary to re-bid the first round in 2009 and delays the second round of bidding until 2011.

This report provides a description of each of the provisions of MIPPA. In this report, references are also made to the following public laws:

- Balanced Budget Act of 1997 (P.L. 105-33, BBA)
- Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173, MMA)
- Deficit Reduction Act (P.L. 109-171, DRA)
- Tax Relief and Health Care Act of 2006 (P.L. 109-432, TRHCA)
- Medicare, Medicaid, and SCHIP Extension Act of 2007 (P.L. 110-173, MMSEA)

## A Brief Description of the Current Programs

P.L. 110-275 makes changes to the Medicare, and Medicaid programs, briefly described below. More complete and detailed descriptions are available from CRS.<sup>2</sup> It also makes changes to other programs, such as Temporary Assistance for Needy Families (TANF) and Foster Care and Adoption Assistance.

#### Medicare

Medicare is the nation's health insurance program for persons aged 65 and over and certain disabled persons. In FY2008, the program will cover an estimated 44.6 million persons (37.3 million aged and 7.3 million disabled) at a total cost of \$459.4 billion, according to the CBO March 2008 baseline.<sup>3</sup> Federal costs (after deduction of beneficiary premiums and other offsetting receipts) will total \$389.9 billion. In FY2007, federal Medicare spending represented approximately 13% of the total federal budget and 3% of GDP. Medicare is an entitlement program, which means that it is required to pay for all covered services provided to eligible persons, so long as specific criteria are met.

Medicare consists of four distinct parts: Part A (Hospital Insurance, or HI); Part B (Supplementary Medical Insurance, or SMI); Part C (Medicare Advantage, or MA); and Part D (the prescription drug benefit added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA). The program is administered by the Centers for Medicare and Medicaid Services (CMS).

<sup>&</sup>lt;sup>2</sup> See, for example, CRS Report RL33712, *Medicare: A Primer*, by Jennifer O'Sullivan, and CRS Report RL33202, *Medicaid: A Primer*, by Elicia J. Herz.

<sup>&</sup>lt;sup>3</sup> See [http://www.cbo.gov/budget/factsheets/2008b/medicare.pdf].

#### Medicaid

Medicaid is a means-tested entitlement program that finances the delivery of primary and acute medical services as well as long-term care to more than 63 million people at an estimated cost to the federal government of roughly \$206.9 billion, according to the CBO March 2008 baseline. Federal expenditures represent approximately 57% of total costs for the year, with states paying the remainder. Each state designs and administers its own version of Medicaid under broad federal rules. State variability in eligibility, covered services, and how those services are reimbursed and delivered is the rule rather than the exception. In the federal budget, Medicaid is an entitlement program that constitutes a large share of mandatory spending. Federal Medicaid spending is open-ended, with total outlays dependent on the spending levels of state Medicaid programs.

## Summary of Provisions in P.L. 110-275

#### Title I - Medicare

#### Subtitle A - Beneficiary Improvements

#### Part I - Prevention, Mental Health, and Marketing

**Section 101. Improvements to Coverage of Preventive Services.** The provision adds "additional preventive services" to the list of Medicare-covered preventive services. The term "additional preventive services" means services not otherwise described in Medicare law that identify medical conditions or risk factors and that the Secretary determines are (1) reasonable and necessary for the prevention or early detection of an illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force, and (3) appropriate for individuals entitled to Medicare Part A or enrolled in Part B. In making the determinations, the Secretary is required to use the process for making national coverage determinations.<sup>4</sup> As part of the use of such process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into the account the results of such assessment in making such determination.

The provision modifies the list of services covered under the initial preventive physical exam (also known as "Welcome to Medicare") to include measurement of body mass index. It also adds end-of-life planning upon agreement with the individual. End of life planning is defined as verbal or written information regarding an individual's ability to prepare an advance directive in the case that an injury or illness caused the individual to be unable to make health care decisions and whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

<sup>&</sup>lt;sup>4</sup> See [http://www.ahrq.gov/clinic/pocketgd.htm] for a listing of preventive services recommended by the United States Preventive Services Task Force.

The provision waives the deductible for the initial preventive screening exam and extends the eligibility period for this service from the first six months to the first year of Part B enrollment. This section applies to services furnished on or after January 1, 2009.

Section 102. Elimination of Discriminatory Copayment Rates for Medicare Outpatient Psychiatric Services. Medicare Part B generally pays 80% of the approved amount for covered services in excess of the annual deductible. However, Medicare recognizes only 62.5% of covered expenses incurred in connection with the treatment of mental, psychoneurotic and personality disorders of a person who is not a hospital inpatient. As a result, it generally pays 50% (80% X 62.5%) of Medicare's recognized amount for these services. The provision raises the 62.5% level to 68.75% in 2010 and 2011, 75% in 2012, 81.25% in 2013, and 100% in 2014 and subsequent years. When the provision is fully phased-in in 2014, outpatient psychiatric services will be paid on the same basis as other Part B services.

Section 103. Prohibitions and Limitations on Certain Sales and Marketing Activities under Medicare Advantage Plans and Prescription **Drug Plans.** This provision establishes new prohibitions on the marketing activities of Medicare Advantage (MA) plans and Prescription Drug Plans (PDPs) and their agents. Except in instances when the beneficiary initiates contact, plans will be prohibited from soliciting beneficiaries door-to-door or on the phone. Cross-selling of non-health related products, providing meals to prospective enrollees, marketing in areas where health care is delivered (i.e., physician offices or pharmacies), and using sales agents that are not state licensed are also prohibited. The provision requires that by November 15, 2008, the Secretary establish limitations on other plan marketing activities such as co-branding, marketing appointments with prospective enrollees, and agent compensation and training. MA and PDP plans will be required to provide states with information on (1) agent and broker terminations, and (2) at state request, performance and licensing of agents and brokers. Finally, after January 1, 2010, MA and PDP plans will be required to include plan type in all plan names.

**Section 104. Improvements to the Medigap Program.** Many Medicare beneficiaries have individually purchased health insurance policies, commonly referred to as "Medigap" policies that supplement Medicare's coverage. Medigap policies are subject to certain statutory requirements. The law incorporates by reference, as part of the statutory requirements, certain minimum standards established by the National Association of Insurance Commissioners (NAIC) and provides for modification where appropriate to reflect program changes. The provision requires the Secretary to provide for the implementation of the changes in the NAIC model law and regulation approved by the NAIC on March 11, 2007, as modified to reflect the changes in this Act and the Genetic Information Nondiscrimination Act of 2008 (GINA, P.L. 110-233).<sup>5</sup> The provision prohibits a

<sup>&</sup>lt;sup>5</sup> For more information on this NAIC model law, see CRS Report RL31223, *Medicare:* Supplementary 'Medigap' Coverage, by Jennifer O'Sullivan. For more information on GINA, see CRS Report RL34584, The Genetic Information Nondiscrimination Act of 2008 (continued...)

carrier from issuing a new or revised Medigap policy that meets the requirements of the revised NAIC model law and regulations for coverage effective before June 1, 2010. Further, policy issuers will be required to offer at least policies with benefit packages labeled "C" or "F" in addition to the current requirement that issuers offer at least policies designated "A."

#### Part II - Low-Income Programs

**Section 111.** Extension of Qualifying Individual (QI) Program. Certain low-income individuals who are aged or have disabilities, as defined under the Supplemental Security Income (SSI) program, and who are eligible for Medicare are also eligible to have their Medicare Part B premiums paid for by Medicaid under the Medicare Savings Program (MSP). Eligible groups include Qualified Medicare Beneficiaries (QMBs), Specified Low-Income Medicare Beneficiaries (SLMBs), and Qualifying Individuals (QI-1s). QMBs have incomes no greater than 100% of the federal poverty level (FPL) and assets no greater than \$4,000 for an individual and \$6,000 for a couple. SLMBs meet QMB criteria, except that their incomes are greater than 100% of FPL but do not exceed 120% FPL. QI-1s meet the QMB criteria, except that their income is between 120% and 135% of poverty and they are not otherwise eligible for Medicaid. Previously, the QI-1 program was funded through June 2008. The Act extends authorization for the QI-1 program through December 2009.

In general, Medicaid payments are shared between federal and state governments according to a matching formula. Unlike the QMB and SLMB programs, federal spending under the QI-1 program is subject to annual limits. Expenditures under the QI-1 program are paid 100% by the federal government (from the Part B trust fund) up to a state's allocation level. States are required to cover only the number of people which will bring their annual spending on these population groups to their allocation levels. For the period beginning on January 1, 2008, and ending on June 30, 2008, the total allocation amount was \$200 million. The Act extends the allocation of \$200 million from the period of January 1, 2008, through June 30, 2008, to the period of January 1, 2008, through September 30, 2008, and increases the allocation amount for this period to \$300 million. The provision also allocates \$100 million for the period that begins October 1, 2008, and ends December 31, 2009; and allocates \$150 million for the period that begins January 1, 2009 and ends September 30, 2009; and allocates \$150 million for the period that begins October 1, 2009 and ends Network 1, 2009.

Section 112. Application of Full Low Income Subsidy (LIS) Assets Test under Medicare Savings Program. Certain low-income individuals who are aged or have disabilities, as defined under the Supplemental Security Income (SSI) program, and who are eligible for Medicare are also eligible to have their Medicare Part B premiums paid for by Medicaid under the Medicare Savings Program (MSP) and are eligible to receive the Medicare Part D low-income subsidy. Currently, in order for beneficiaries to be eligible for the MSP they must have assets

<sup>&</sup>lt;sup>5</sup> (...continued)

<sup>(</sup>GINA), by Nancy Lee Jones and Amanda K. Sarata.

that are no greater than \$4,000 for an individual and \$6,000 for a couple. The Act alters these asset tests. Beginning January 1, 2010, individuals may qualify under the MSP program if their resource fall below the assets level applicable under the low income subsidy program (LIS) for Medicare Part D. They asset levels are updated annually by increases in the Consumer Price Index (CPI) and rounded to the nearest multiple of \$10. (The 2008 levels are \$6,290 for an individual and \$9,440 for a couple.) MIPPA further modifies the definition of assets to exclude the value of an individual's or couple's life insurance.

Section 113. Eliminating Barriers to Enrollment. The Commissioner of the Social Security Administration (SSA) is required to make low-income subsidy (LIS) determinations for persons applying at SSA offices. The provision extends the outreach requirements currently applicable to the Commissioner of SSA, effective January 2010. The Commissioner will be required, for each individual submitting an application for LIS, requesting an application for LIS, or otherwise identified by the Commissioner as potentially eligible for LIS, to (1) provide information describing the LIS program and the Medicare Savings program ((MSP) which provides Medicaid assistance for Medicare Part B premiums, and for some persons, Medicare cost-sharing charges); (2) provide an application for enrollment under the LIS program; (3) transmit data from such application to the state for purposes of initiating an application for MSP (beginning January 2010), with the applicant's consent; (4) provide information on how the individual may obtain assistance in completing the application and an application under the MSP program, including information on how they may contact the appropriate State health insurance assistance program; and (5) make such application and information available in local social security offices. The Commissioner will be required to provide training to SSA employees who were involved in receiving LIS applications.

The provision provides for reimbursement of SSA costs. The Government Accountability Office (GAO) will be required to conduct a study of the impact of this section on increasing participation in MSP and on states and the SSA. GAO will be required to submit a report by January 1, 2012, to Congress, the Commissioner, and the Secretary.

Section 114. Elimination of Medicare Part D Late Enrollment Penalties Paid by Subsidy Eligible Individuals. A late enrollment penalty is assessed on persons who go for 63 days or longer after the close of their initial Part D enrollment period without creditable prescription drug coverage and subsequently enroll in Part D. CMS has waived this penalty through 2008 for persons deemed eligible for a low-income subsidy after the close of their initial enrollment period. The provision waives late enrollment penalties for persons who are determined to be eligible for a low-income subsidy beginning January 2009.

**Section 115.** Eliminating Application of Estate Recovery. Beneficiaries are allowed to retain certain assets and still qualify for Medicaid. The Medicaid estate recovery program is intended to enable states to recoup these private assets upon a beneficiary's death to recover certain Medicaid expenditures made on behalf of these individuals. Since 1993, Medicaid law has required states to recover, from the estate of the beneficiary, amounts paid by the program for certain long-term care and related services, and given states the option to recover for other services, such as amounts Medicaid paid for Medicare cost-sharing on behalf of dual eligibles who are entitled to Medicare Part A and/or Part B and are eligible for full Medicaid benefits.

States recover amounts paid from the estates of those beneficiaries who (1) were inpatients in a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR) and were not reasonably expected to be discharged from the institution and return home; and (2) received Medicaid assistance for nursing facility services, home and community-based services and related hospital and prescription drug services at age 55 or older. Included in these groups are those who were dual eligibles and were entitled to Medicare Part A and/or Part B and were eligible for full Medicaid benefits.

MIPPA will prohibit states from recovering amounts paid for Medicare cost-sharing on behalf of dual eligibles who are entitled to Medicare Part A and/or Part B and who are eligible for full Medicaid benefits. The provision will take effect as of January 1, 2010.

Section 116. Exemptions from Income and Resources for Determination of Eligibility for Low-Income Subsidy. The definitions of income and assets used for making eligibility determinations for the Part D low-income subsidy (LIS) program generally follow those used for determining eligibility under the Medicare Savings program (which in turn link back to the definitions used for purposes of the Supplemental Security Income program). For purposes of the LIS, the provision excludes from the definition of income, support and maintenance furnished in kind. It also excludes from the definition of resources any part of the value of any life insurance policy. The provision is effective January 1, 2010.

Section 117. Judicial Review of Decisions of the Commissioner of Social Security under the Medicare Part D Low-Income Subsidy Program. A right to a judicial review is added for those found ineligible for LIS by the Commissioner of Social Security.

**Section 118. Translation of Model Form.** Medicaid law requires the Secretary to develop and distribute to the states a simplified application form for use by Medicare Savings applicants in states which elect to use the model form. The provision requires the Secretary to provide for the translation of the model application form into at least 10 languages, other than English, effective January 1, 2010.

**Section 119. Medicare Enrollment Assistance.** Beneficiaries may obtain information on Medicare from a variety of sources including from state health insurance assistance programs (SHIPs). SHIPs are state-based programs that use community-based networks to provide Medicare beneficiaries with local personalized assistance on a wide variety of Medicare and health insurance topics. They receive Federal funding for their activities. The provision will require the Secretary to provide for the transfer of a total of \$7.5 million to the CMS Program Management Account for FY2009 for the purpose of making grants to the states for SHIPs. Two-thirds of the total will be allocated among the states based on the number of

persons in each state with incomes below 150% of poverty who had not enrolled to receive a low income subsidy relative to the total number of such individuals in all states. One third of the total will be allocated among the states based on the number of Part D eligible beneficiaries residing in rural areas in each state relative to the total number of such individuals in all states.

The provision also requires the Secretary, to provide \$7.5 million to the Administration on Aging for FY2009 for the purpose of making grants to the states for area agencies on aging to be used to provide outreach to eligible Medicare beneficiaries. It requires the Secretary to provide for the transfer of a total of \$5.0 million to the Administration on Aging for FY2009 for the purpose of making grants to Aging and Disability Resource Centers (that are established centers on the date of enactment) under the Aging and Disability Resource Center grant program. Each grant will be used to provide outreach to individuals regarding benefits under Part D and the Medicare Savings Program.

#### Subtitle B - Provisions Relating to Part A

Section 121. Expansion and Extension of the Medicare Rural Hospital Flexibility Program. BBA established the Medicare Rural Hospital Flexibility Program which created the critical access hospital (CAH) designation under Medicare and authorized a grant program (FLEX grants) which is administered by the Health Resources and Services Administration (HRSA). There are certain limitations imposed on the use of grant funds for administrative expenses, both at the state and federal level. The grant program has been authorized at \$35 million from FY2005 through FY2008.

With the passage of MIPPA, the purpose of the grant program will be expanded. The Secretary will be able to award grants to States to increase the delivery of mental health services or other health services deemed necessary to meet the needs of veterans of Operation Iraqi Freedom and Operation Enduring Freedom and other residents of rural areas, including rural census tracks, as defined by HRSA. The Secretary will require that the State demonstrate appropriate consultation with the state hospital association, rural hospitals, mental health providers, and other stakeholders.

When awarding grants, the Secretary is required to give special consideration to applications submitted by states where veterans make up a high percentage of the state's total population. This consideration will be given without regard to the number of veterans of Operation Iraqi Freedom and Operation Enduring Freedom living in the areas in which mental health care and other health care services will be delivered. The Director of the Office of Rural Health of the Department of Veterans Affairs will be consulted when awarding grants to states. A state awarded such a grant may use the funds to reimburse providers of services. A state will not be able to expend more than 15% of the grant amount on administrative expenses.

An independent evaluation of the mental and other health grants is required. No later than one year after the date on which the last grant is awarded, the Secretary will submit a report to Congress which will assess the impact of the grants on increasing the delivery of mental health services to veterans living in rural areas, particularly those who served in Operation Iraqi Freedom and Operation Enduring Freedom and to other rural individuals.

HRSA is authorized to spend up to 5% of the total amount appropriated for FLEX grants for each of the fiscal years from 2005 through 2008 on administering the grants. Beginning FY2009, HRSA will be authorized to spend up to 5% of the total amount appropriated for the grant program.

The FLEX grant program will be expanded to provide support for CAHs for quality improvement, quality reporting, performance improvements and benchmarking and will be authorized at \$55 million for each fiscal year from 2009 and 2010. The new rural mental health and other services grants will be authorized at \$50 million for fiscal years 2009 and 2010, money which is available until expended.

An additional grant program is established where eligible CAHs may receive a grant to transition to a skilled nursing or assisted living facility. An eligible CAH is one that has an average daily acute census of less than 0.5 and an average daily swing bed census of greater than 10.0. Matching funds from the state are required. The CAH will surrender its CAH status within 180 days of receiving the grant. These grants cannot exceed \$1 million. There is \$5 million appropriated from the Federal Hospital Insurance Trust Fund for making these grants.

**Section 122.** Rebasing for Sole Community Hospitals. Medicare payments to sole community hospitals (SCHs) for inpatient hospital services are made on the basis of the federal per discharge payment amount or on the basis of its updated hospital-specific per discharge amount from FY1982, FY1987, or FY1996, whichever will result in the largest payment. Under MIPPA, for cost reporting periods beginning on or after January 1, 2009, an SCH will be able to elect payment based on its FY2006 hospital-specific payment amount per discharge. This amount will be increased by the annual update starting for discharges on or after January 1, 2009.

Section 123. Demonstration Project on Community Integration **Models in Certain Rural Counties.** A three-year demonstration project in up to 4 states will be established, beginning October 1, 2009, that will allow states to develop and test a new model for the delivery of health care services for the purpose of better integrating the delivery of acute care, extended care, and other essential health care services. Eligible participants will be Rural Hospital Flexibility Program grantees in a state where at least 65% of the counties have six or few residents per square mile. Eligible entities will apply to participate in the demonstration project. The Secretary will select eligible entities in no more than four states. Each eligible entity will select no more than six eligible counties in the state to participate in the project. An eligible county has six or fewer residents per square mile and must have a facility designated as a CAH on the date of enactment that meets certain criteria. Participating health care providers will be paid at a rate that covers at least the reasonable costs of furnishing acute care, extended care, and other essential health care services. Methods to coordinate the survey and certification process will be tested. Participants and the Secretary will work to revise states' Medicaid payments.

The demonstration will be administered jointly by the Office of Rural Health Policy (ORHP) in HRSA and CMS.

The Secretary will ensure that the aggregate Medicare expenditures under the project do not exceed the amount that would have been expended without the project and will provide for the transfer of necessary funds from the Medicare trust funds. There will be \$800,000 authorized to be appropriated to ORHP for each of the fiscal years 2010, 2011, and 2112, which will remain available for the project's duration.

No later than two years after the demonstration's implementation date, ORHP in coordination with CMS, will submit a status report to Congress with initial recommendations. A final report with recommendations for legislation and for administrative action is due no later than one year after the project's completion.

**Section 124. Extension of the Reclassification of Certain Hospitals.** Section 508 of MMA provided \$900 million for a one-time, three year geographic reclassification of certain hospitals who were otherwise unable to qualify for administrative reclassification to areas with higher wage index values. These reclassifications were subsequently extended to September 30, 2008. MMSEA extended certain hospital reclassifications made through the Secretary's authority to make exceptions and adjustments during the FY2005 rulemaking process until September 30, 2008. This provision extends the Section 508 and the special exception reclassifications until September 30, 2009.

**Section 125. Revocation of Unique Deeming Authority of the Joint Commission.** In order to receive Medicare payments, Medicare providers and suppliers must meet certain health and safety requirements specified in statute. Alternatively, a provider can be deemed to meet these requirements if it has been accredited by an approved national accreditation body. This provision will revoke the unique authority granted the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to accredit hospitals. Hospitals, like other Medicare provider entities, will be accredited by national accrediting organizations approved by the Secretary. This provision will take effect 24 months after the legislation is enacted and will not affect those hospitals currently being accredited or under accreditation by JCAHO. The provision does not remove the unique authority granted the American Osteopathic Association (AOA) to accredit provider entities for participation in the program.

#### Subtitle C - Provisions Relating to Part B

#### Part I - Physicians' Services

Section 131. Physician Payment, Efficiency, and Quality Improvements. Medicare payments for services of physicians and certain nonphysician practitioners are made on the basis of a fee schedule. The fee schedule assigns relative values to services that reflect physician work (i.e., time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variation in costs. The adjusted relative values are then converted into a dollar payment amounts by a conversion

#### CRS-11

factor. The law specifies a formula for calculating the annual update to the conversion factors. This formula would have resulted in a 10.1% cut effective January 1, 2009. However, Section 101 of the MMSEA increased the update to the conversion factor for Medicare physician payment by 0.5% compared with 2007 rates for the first six months of 2008. The update formula would have required a reduction in the conversion factor of 10.6% for services provided between July 1 and December 31, 2008, and by additional amounts annually for at least several years thereafter. This provision averts this reduction and extends the 0.5% increase in the physician fee schedule that was set to expire on June 30, 2008, through the end of 2008. For 2009, the update to the conversion factor will be 1.1%. The conversion factor for 2010 and subsequent years will be computed as if this modification had never applied.

The Tax Relief and Health Care Act of 2006 (P.L. 109-432, TRHCA) created the physician assistance and quality initiative (PAQI) Fund, which is to be available to the Secretary of HHS for physician payment and quality improvement initiatives. The MMSEA, as well as provisions in the Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act of 2008 (division G of the Consolidated Appropriations Act of 2008) modified the amounts that will be available in the PAQI Fund and the years in which the monies can be spent. This provision in MIPPA together with a provision in the Supplemental Appropriations Act, 2008 (P.L. 110-252), further modifies the amounts available for the PAQI Fund by removing \$4.96 billion from the fund in 2013-2015 and returning these amounts to the Medicare Part A and Part B Trust Funds, to be made available for other purposes.

The physician quality reporting system, which currently runs only through 2009, is extended through 2010. Eligible professionals who provide covered professional services will be eligible for the incentive payment if (1) there are quality measures that have been established under the physician reporting system that are applicable to any services furnished by such professional for the reporting period; and (2) the eligible professional satisfactorily submits data to the Secretary on the quality measures. These providers, in addition to the amount otherwise paid under Medicare, will also be paid an incentive payment equal to 1.5% for 2008 and 2.0% for 2009 and 2010 of the allowed Medicare charges for all such covered professional services furnished by the eligible professional. The provision also defines satisfactory reporting of measures for group practices and includes qualified audiologists as eligible professionals for purposes of Medicare payment, beginning in 2009.

Both MedPAC and GAO have recently recommended providing information to physicians on their resource use. MedPAC asserts that physicians would be able to assess their practice styles, evaluate whether they tend to use more resources than their peers or what evidence-based research (if available) recommends, and revise practice styles as appropriate. MedPAC notes that in certain instances, the private sector use of feedback has led to a small downward trend in resource use. The GAO noted that certain public and private health care purchasers routinely evaluate physicians in their networks using measures of efficiency and other factors and that the purchasers it studied linked their evaluation results to a range of incentives to encourage efficiency. This provision of MIPPA will establish a physician feedback program with the intent to improve efficiency and to control costs. Under the Physician Feedback Program, to be implemented by January 1, 2009, the Secretary will use Medicare claims data to provide confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. The resources to be considered in this program may be measured on an episode basis, on a per capita basis, or on both an episode and a per capita basis. The GAO will conduct a study of the Physician Feedback Program as described above, including the implementation of the Program, and will submit a report to Congress by March 1, 2011 containing the results of the study, together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

Finally, the provision requires the Secretary of Health and Human Services to develop a plan to transition to a value-based purchasing program for payment under the Medicare program for covered professional services. Not later than May 1, 2010, the Secretary of Health and Human Services will submit a report to Congress containing the plan, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

**Section 132.** Incentives for Electronic Prescribing. The provision establishes incentives for electronic prescribing in the Medicare program. For 2009 through 2013, Medicare professionals providing covered services to Medicare beneficiaries and who are successful electronic prescribers will receive an incentive payment of 2.0% for 2009 and 2010, 1.0% for 2011 and 2012, and 0.5% for 2013. Providers who do not have a sufficient volume of qualifying services will be excluded from the program, as will those for whom the Secretary determines that compliance would be a significant hardship (such as for an eligible professional who practices in a rural area without sufficient Internet access). Not later than September 1, 2012, the GAO will submit to Congress a report on the implementation of the incentives for electronic prescribing established by this section.

**Section 133. Expanding Access to Primary Care Services.** The provision gives the Secretary the authority to expand the duration and scope of the Medical Home Demonstration Project if the expansion will meet either of the following conditions: (1) the expansion of the project is expected to improve the quality of patient care without increasing spending under Medicare, or (2) the expansion of the project is expected to reduce spending under the Medicare program without reducing the quality of patient care. To fund any potential expansion of the demonstration project, \$100 million will be made available from the Federal Supplementary Medical Insurance Trust Fund.

The provision changes the application of the budget-neutrality adjustor used in the calculation of Medicare physician fee schedule reimbursement from the relative value units to the conversion factor, beginning with 2009.

Section 134. Extension of Floor on Medicare Work Geographic Adjustment under the Medicare Physician Fee Schedule. Medicare makes payment for physician services under the fee schedule. Three factors enter into the calculation of the fee schedule payment amount: the relative value for the service, a geographic adjustment and a national dollar conversion factor. The geographic adjustments are indexes that reflect cost differences among areas compared to the national average in a "market basket" of goods. A value of 1.00 represents an average across all areas. The law placed a temporary floor of 1.00 on the geographic work adjustment for January 2004-June 2008. The provision extends, through December, 2009, the period that the floor is set at 1.00. In addition, beginning January 1, 2009, it raises the work geographic adjustment to 1.5 in Alaska if the index will otherwise be less than 1.5.

**Section 135. Imaging Provisions.** The provision specifies that beginning January 1, 2012, payment may only be made under the physician fee schedule for the technical component of advanced diagnostic imaging services furnished by a supplier if such supplier is accredited by an accreditation organization. Advanced diagnostic imaging services are defined as including diagnostic magnetic resonance imaging, computed tomography, and certain other services as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

The accreditation organization must be designated by the Secretary who will be required to consider specified factors both in designating an accreditation organization and in reviewing and modifying the list of designated organizations. The Secretary will be required to establish procedures to ensure that the criteria used by an accreditation organization to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services is specific to each imaging modality.

The provision requires the Secretary to establish a two-year demonstration project using specified models to collect data regarding physician compliance with appropriateness criteria for advanced diagnostic imaging services. The Secretary may focus the demonstration project, such as on services that account for a large amount of Medicare expenditures, services that have recently experienced a high rate of growth, or services for which appropriateness criteria exist. The Secretary, in consultation with medical specialty societies and other stakeholders, will select criteria with respect to the clinical appropriateness of advanced diagnostic imaging for use in the demonstration. The Secretary will develop mechanisms to provide feedback reports to physicians participating in the project. In addition, the Secretary is required to evaluate the demonstration project and submit a report to Congress containing the results of the evaluation together with recommendations for legislative and administrative action.

The GAO is required to conduct a study by imaging modality of the new accreditation requirement and any other relevant questions involving access to and the value of advanced diagnostic imaging services for beneficiaries.

Section 136. Extension of Treatment of Certain Physician Pathology Services under Medicare. Legislation enacted in 1997 specified that independent labs that had agreements with hospitals on July 22, 1999 to bill directly for the technical component of pathology services could continue to do so in 2001 and 2002. The provision has been periodically extended, most recently through June 30, 2008. MIPPA further extends this provision through December 31, 2009.

Section 137. Accommodation of Physicians Ordered to Active Duty in the Armed Services. Medicare payment may be made to a physician for services furnished by a second physician to patients of the first physician, provided certain conditions are met. In general, the services cannot be provided by the second physician for more than 60 days. The law permits, for services provided prior to June 30, 2008, reciprocal billing over a longer period in cases where the first physician was called or ordered to active duty as a member of a reserve component of the Armed Forces. The provision will make the accommodation permanent.

**Section 138.** Adjustment for Medicare Mental Health Services. Medicare pays for mental health services under the physician fee schedule. The provision increases the fee schedule amount otherwise applicable for certain specified mental health services by 5% for the period July 2008 - December 2009.

Section 139. Improvements for Medicare Anesthesia Teaching Programs. Anesthesia services may be personally performed by the anesthesiologist or the anesthesiologist may medically direct up to four concurrent anesthesia cases. When the anesthesiologist medically directs a case, the payment for the physician's medical direction service is 50% of the amount otherwise recognized if the anesthesiologist personally performed the service. The provision establishes a special payment rule with respect to physicians' services furnished on or after January 1, 2010. In the case of teaching anesthesiologists involved in a single anesthesia case or two concurrent anesthesia cases, the payment amount will be 100% of the fee schedule amount otherwise applicable if the anesthesia services were personally performed by the teaching anesthesiologist alone. This payment provision will only apply if (1) the teaching anesthesiologist was present during all critical or key portions of the anesthesia service or procedure involved; and (2) the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist had entered into an arrangement) was immediately available to furnish anesthesia services during the entire procedure. Further, the provision requires the Secretary to make appropriate payment adjustments for items and services furnished by teaching certified registered nurse anesthetists.

#### Part II - Other Payment and Coverage Improvements

Section 141. Extension of Exceptions Process for Medicare Therapy Caps. The law places annual per beneficiary payment limits for all outpatient therapy services provided by non-hospital providers. There are two beneficiary limits. The first is a \$1,810 (in 2008) per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second is a \$1,810 (in 2008) per beneficiary annual cap for all outpatient occupational therapy services. The law required the Secretary to implement an exceptions process for 2006, 2007, and the first half of 2008 for cases in which the provision of additional therapy services was determined to be medically necessary. The provision extends the exceptions process through 2009.

Section 142. Extension of Payment Rule for Brachytherapy and Therapeutic Radiopharmaceuticals. MMA required Medicare's outpatient prospective payment system to make separate payments for specified brachytherapy sources. Subsequent legislation established that the separate payment would be made using hospitals' charges adjusted to their costs until January 1, 2008. MMSEA extended this payment method for brachytherapy services until July 1, 2008 and established these type of payments for therapeutic radiopharmaceuticals for services provided on or after January 1, 2008, and before July 1, 2008. This provision extends cost reimbursement for brachytherapy and therapeutic radiopharmaceuticals until January 1, 2010.

**Section 143.** Speech-Language Pathology Services. The provision establishes a separate definition for outpatient speech-language pathology services and permits speech-language pathologists practicing independently to bill Part B subject to the same conditions applicable to physical and occupational therapists in independent practice. The provision is effective July 1, 2009.

Section 144. Payment and Coverage Improvements for Patients with Chronic Obstructive Pulmonary Disease and Other Conditions. The provision will include, within the definition of covered medical and other health services, items and services furnished under a cardiac rehabilitation program or under a pulmonary rehabilitation program, subject to specified conditions. The provision will be effective January 1, 2010.

This provision repeals the requirement that medical equipment suppliers transfer the title for oxygen equipment to the beneficiary after a 36 months rental period, effective January 1, 2009; suppliers will retain ownership of the equipment but will continue to furnish the equipment to the beneficiary during the period of medical need.

**Section 145.** Clinical Laboratory Tests. The provision repeals the requirement for competitive bidding for clinical laboratory services. In addition, it specifies that the clinical laboratory fee schedule update, otherwise slated to occur each year, will be reduced each year from 2009 through 2013 by 0.5 percentage points.

**Section 146.** Improved Access to Ambulance Services. The provision increases payments for ground ambulance transports originating in rural areas or rural census tracts by 3% and the payments for such transports originating in other areas by 2% for the period July 1, 2008 - December 31, 2009. The provision also specifies that any area designated as rural for the purposes of making payments for air ambulance services on December 31, 2006, will be treated as rural for the purpose of making air ambulance payments during the period July 1, 2008-December 31, 2009.

Section 147. Extension and Expansion of the Medicare Hold Harmless Provision under the Prospective Payment System for Hospital Outpatient (HOPD) Services for Certain Hospitals. Small rural hospitals (with no more than 100 beds) that are not sole community hospitals (SCHs) can receive additional Medicare payments if their outpatient prospective payment system (OPPS) payments are less than those under the prior reimbursement system. For calendar year (CY) 2006, these hospitals received 95% of the difference, 90% of the difference in CY2007 and 85% of the difference in CY2008. The provision establishes that small rural hospitals will receive 85% of the payment difference in CY2009. SCHs with not more than 100 beds will receive 85% of the payment difference for covered HOPD services furnished on or after January 1, 2009, and before January 1, 2010.

Section 148. Clarification of Payment for Clinical Laboratory Tests Furnished by Critical Access Hospitals. Medicare outpatient clinical laboratory services are generally paid based on a fee schedule. Clinical diagnostic laboratory services provided to patients who receive services directly from critical access hospitals (CAHs) on an outpatient basis are paid 101% of reasonable costs. Clinical laboratory services provided by CAHs to those who are not patients are paid on the basis of the Medicare fee schedule. In no instance are Medicare beneficiaries liable for any coinsurance or deductible amounts. Generally, clinical laboratory services provided to skilled nursing facility (SNF) patients (who are Medicare beneficiaries that are covered under Medicare Part A) are paid under consolidated billing as part of the SNF-PPS. Under this provision, starting for services furnished on July 1, 2009, clinical diagnostic laboratory services furnished by a CAH will be reimbursed as outpatient hospital services at 101% of costs without regard to whether the individual who receives the service is physically present in the CAH, or in a skilled nursing home or a clinic (including a rural health clinic) that is operated by a CAH at the time the specimen is collected.

Section 149. Adding Certain Entities as Originating Sites for Payment of Telehealth Services. Originating sites are defined as the site where a Medicare provider delivers the telehealth service to the patient. The following are qualified as originating sites: (1) office of a physician or physician practitioner; (2) a critical access hospital; (3) a rural health clinic; (4) a federally qualified health center, and (5) a hospital. The provision adds: (1) a hospital-based or critical access hospital based renal dialysis center (including satellites), (2) a skilled nursing facility, and (3) a community health center to the list of originating sites for payment of telehealth services, effective on January 1, 2009.

Section 150. MedPAC Study and Report on Improving Chronic Care Demonstration Programs. The Medicare Payment Advisory Commission (MedPAC) will be required to conduct a study and provide a report to Congress no later than June 15, 2009, on the feasibility and advisability of establishing a Medicare Chronic Care Practice Research Network to serve as a standing network of providers testing new models of care coordination and other care approaches for chronically ill beneficiaries, including the initiation, operation, evaluation, and if appropriate, expansion of such models to the broader Medicare patient population. They will also be required to make recommendations for appropriate legislative and administrative action.

**Section 151. Increase of FQHC Payment Limits.** The provision will increase the payment limits otherwise applicable for federally qualified health centers (FQHCs) in 2010 by \$5 for each patient visit. In subsequent years the previous year's amount will be increased by the increase in the Medicare economic index (MEI). The provision also requires the GAO to study whether the structure for FQHC payments adequately reimburses FQHCs for care furnished to Medicare beneficiaries.

**Section 152. Kidney Disease Education and Awareness Provisions.** A new section is added to the Public Health Service Act, allowing the Secretary to establish pilot projects for chronic kidney disease to (1) increase awareness; (2) increase screening; and (3) enhance surveillance systems to better assess prevalence and incidence. The Secretary will select at least 3 states in which to conduct pilot projects, for no longer than five years, beginning on January 1, 2009. GAO will conduct an evaluation and report to Congress not later than 12 months after completion of the pilot projects. There are authorized to be appropriated such sums as may be necessary to carry out this provision.

Medicare coverage is expanded to include coverage for kidney disease education services, defined as education services (1) for an individual with stage IV chronic kidney disease who requires dialysis or a kidney transplant; (2) furnished upon the referral of the physician managing the individual's kidney condition or by a qualified person; (3) designed to provide comprehensive information regarding managing co-morbidities, including delaying the need for dialysis, prevention of uremic complications, and options for renal replacement therapy; and (4) designed to meet an individual's needs and provide an opportunity to participate in the choice of therapy. The Secretary will set standards for the educational services. Individuals will be eligible for no more than six sessions of kidney disease education services, effective for services furnished on or after January 1, 2010.

**Section 153. Renal Dialysis Provisions.** The composite rate for dialysis services furnished on or after January 1, 2009, and before January 1, 2010, will be increased by 1% above the December 31, 2008 amount. Beginning January 1, 2010, the composite rate will be increased by 1% above the December 31, 2009 amount.

Beginning January 1, 2009, the payment rate for dialysis services will be "site neutral" and in applying the geographic index to providers of services, the labor share will be based on the labor share otherwise applied for renal dialysis facilities. Adjustments will no longer be made to the composite rate for hospital-based dialysis facilities to reflect higher overhead costs.

Beginning January 1, 2011, the Secretary will implement a bundled payment system making a single payment for Medicare renal dialysis services, ensuring that the estimated total payment for 2011 for Medicare renal dialysis services will equal 98% of payments that would have been made if the bundled payment system had not been implemented. The term "renal dialysis services" will include (1) items and services which were included in the composite rate as of December 31, 2010; (2) erythropoiesis stimulating agents (ESAs) or any other oral form of such agents furnished to individuals for the treatment of End Stage Renal Disease (ESRD); (3) other drugs and biologicals for which payment was made separately (before bundling), and any oral equivalent form of such drug or biological; and (4) diagnostic laboratory tests and other items and services" will not include vaccines.

Payments will include adjustments for (1) case mix; (2) high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of ESAs necessary for anemia management; (3) the extent that costs in rural, low-volume facilities exceed the costs incurred by other facilities,

with a minimum payment adjustment of 10% for services furnished between January 1, 2011, and January 1, 2014; and (4) other items as determined by the Secretary.

The bundled payments system will be phased-in equally over four years, (fully implemented by January 1, 2014). A provider of dialysis services or facility will be allowed to make a one-time election to be excluded from the phase-in and be paid entirely based on the bundled payment system. Estimated total payments during the phase-in will equal the estimated total payments that would otherwise occur.

Beginning in 2012, the Secretary will annually increase the bundled payment amounts by an ESRD market basket increase factor appropriate for a bundled payment system for renal dialysis minus 1 percentage point. For the portion of the payment based on the old composite rate system, the composite rate will be updated by the ESRD market basket increase factor minus 1 percentage point.

The demonstration established in the MMA for a bundled case-mix adjusted payment system for ESRD services is repealed.

Beginning in January 1, 2012, providers of renal dialysis services and renal dialysis facilities will be subject to quality incentive requirements and they will be subject to a reduction of up to 2% if they do not meet the requirements. The requirements will include measures on (1) anemia management and dialysis adequacy; (2) to the extent feasible, patient satisfaction; and (3) other areas.

The Secretary will develop a methodology to assess the total performance of each provider or facility, referred to as the "total performance score." Any reductions in payments will apply a larger reduction to those achieving the lowest scores. The Secretary will make performance information available to the public, provide certificates to be displayed in patient areas, and will allow the provider or facility the opportunity to review the information, prior to it being made public.

No later than March 1, 2013, GAO must submit a report to Congress on the implementation of the payment system and the quality initiatives.

Section 154. Delay in and Reform of Medicare DMEPOS Competitive Acquisition Program. Medicare generally pays for most durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) on the basis of a fee schedule. MMA required the Secretary to establish a DMEPOS Competitive Acquisition Program for specified medical equipment in specified areas; the Competitive Acquisition Program is to be phased-in and will replace the Medicare fee schedule. This provision terminates all contracts awarded for the first round of the Program and requires the Secretary to re-bid the first round in 2009. Damages for the delay could be paid from the Part B Trust Fund. Suppliers will be precluded from seeking administrative or judicial review of the terminations. Puerto Rico, negative pressure wound therapy, and complex rehabilitative power wheelchairs will be excluded from the competition.

The second round of bidding and expansion of the program beyond the original 80 locations will be delayed by two years to 2011. National mail order items, however, could be implemented after 2010. After the first two rounds, but prior to

#### **CRS-19**

2015, the Secretary will be prohibited from expanding competitive acquisition into (1) rural areas, (2) metropolitan statistical areas (MSAs) of fewer than 250,000 if not previously selected, and (3) areas with low population density within MSAs that are otherwise selected for competitive acquisition. The Inspector General (IG) will be required to assess the program through post-award audits, surveys, or other means. The Secretary will be required to notify bidders if certain financial documents were missing and allow the bidders to resubmit those documents by a specified date.

To pay for the program delay, the fee schedule update in 2009 will be reduced by 9.5% for all round 1 items, services and accessories. The reduction will apply to all areas, not just competitive acquisition areas. For items or services that were not part of round 1, the fee schedule update in 2009 will be the increase in the consumer price index (CPI), as required by law. For 2010 through 2013, the fee schedule update will be the increase in the CPI for all items and services outside competitive bidding areas. For 2014, the update will be the increase in the CPI plus 2 percentage points for items and services that (1) had received a 9.5% reduction in 2009, (2) had not received a payment adjustment based on the Secretary's authority to adjust payments outside of competitive areas based on data from competitive acquisition, and (3) were not part of a competitive bidding area. For all others, the 2014 update will be the increase in the CPI.

The provision will delay (from January 1, 2009 to January 1, 2011) the Secretary's authority to use information from the competitive acquisition program to adjust the payments in areas that are not competitive acquisition areas. Prior to exercising this authority, the Secretary is required promulgate regulations describing the method to be used in adjusting rates.

The provision will require suppliers (directly or as subcontractors) to submit evidence of accreditation by October 1, 2009. The Secretary will be given authority to exempt certain professionals from the accreditation requirement. Contracted suppliers will be required to inform the Secretary of the identity of each subcontractor and whether the subcontractor met accreditation requirements.

The Secretary will be required to create a competitive acquisition ombudsman within CMS to respond to complaints and inquiries made by suppliers and individuals.

The provision will exempt off-the-shelf orthotics and other DME and supplies from competitive acquisition when furnished by a physician or other practitioner (as defined by the Secretary) to their own patients as part of their professional services, or by a hospital to its own patients during an admission or on the date of discharge. The provision will expand the definition of physician with respect to the requirement that the Secretary establish standards on the types or classes of items requiring a face-to-face examination as a condition of coverage.

Starting in the second round of the program, the suppliers will be required to demonstrate that their bid covers over 50% of all types of diabetic test strips in use. The IG will determine the types of diabetic test strips that could be used to make this determination, and submit the report prior to the start of the second round of the program.

The Secretary will be required to evaluate the Healthcare Common Procedure Coding System (HCPCS) for negative pressure wound therapy.

Various reports and requirements will be delayed to conform with the delay in the bidding schedule. The scope of one required GAO report will be expanded.

The Secretary will be required to transfer \$20 million for FY2008 and \$25 million for each of FY2009 through 2012 from the Part B Trust Fund to the CMS Program Management Account as additional funding to implement the provisions of the Act. These provisions are effective June 30, 2008.

#### Subtitle D - Provisions Relating to Part C

**Section 161.** Phase-Out of Indirect Medical Education (IME). Beginning in 2010, the Medicare Advantage benchmarks for every county will be adjusted to phase-out the cost of indirect medical education (IME). The amount phased-out each year will be based on a ratio of (1) a specified percentage (0.60% in the first year), relative to (2) the proportion of per capita costs in original Medicare in the county that IME costs represent. The effect of the ratio is to phase-out a higher proportion of IME costs in areas where IME makes up a smaller percentage of per capita spending in original Medicare. After 2010, the numerator phase-out percentage will be increased by 0.60 percentage points each year. This provision will not apply to the benchmarks for plans in the PACE program (Programs of All-Inclusive Care for the Elderly).

Section 162. Revisions to Requirements for Medicare Advantage Private Fee-for-Service (PFFS) Plans. Prior to enactment of MIPPA, MA coordinated care plans were required to meet medical access requirements by forming networks of contracted providers; PFFS plans could meet access requirements either by establishing payment rates for providers that were not less than rates paid under original Medicare or by developing contracts and agreements with a sufficient number and range of providers within a category to provide covered services under the terms of the plan. The Act makes some access requirements for some PFFS plans move closer to the access requirements for coordinated care plans. Starting in 2010, any PFFS plan that chooses to contract with a category of providers is required to meet the same general access to services requirements applicable to coordinated care plans.

Starting in 2011, PFFS plans sponsored by employers or unions are required to establish contracted networks of providers to meet access requirements. Non-employer sponsored MA PFFS plans are required to establish contracted networks of providers in network areas defined as areas having at least two plans with networks (such as health maintenance organizations [HMOs], provider sponsored organizations [PSOs], or local preferred provider organizations [PPOs]). In areas without at least two network-based plans, the non-employer PFFS plans retain the ability to establish access requirements through establishing payment rates that are not less than those under original Medicare.

Section 163. Revisions to Quality Improvement Programs. With the enactment of MIPPA, beginning January 1, 2010, PFFS and Medical Savings

Account (MSA) plans are required to have a quality improvement program similar to other MA plans. Starting in 2011, data collection, reporting, and analysis requirements for PFFS and MSA plans may not exceed the requirements for local PPO plans, which are limited to those data from providers in the plan's contracted network, but not from out-of-network providers. In 2010, the data requirements for PFFS and MSA plans are limited to administrative data, but must be collected from both in-network and out-of-network providers. MIPPA removes the requirement that the Secretary establish separate data collection requirements for MA regional plans; it requires regional and local PPO plans to adhere to the same data collection requirements.

Section 164. Revisions Relating to Specialized Medicare Advantage Plans for Special Needs Individuals. This provision extends the time current Special Needs Plans (SNPs) may restrict enrollment to special needs individuals and extends the moratorium on the Secretary's authority to designate new SNPs until January 1, 2011. Starting January 1, 2010, all new enrollees in a SNP will be required to meet the definition of a special needs individual.

Additional requirements are specified for all three types of SNPs: Institutional, Medicaid, and Chronic Care. For institutional SNPs, individuals living in the community who may need an institutional level of care are not eligible to enroll in the SNP unless it is determined by an entity other than the SNP using a state assessment tool, that the individual needs an institutional level of care.

Medicaid SNPs are required to have a contract with the State to provide Medicaid benefits, or arrange for benefits to be provided; Medicaid SNPs that do not comply with the contracting requirement will be permitted to participate in 2010, but will not be allowed to expand their service area. Further, Medicaid SNPs are required to provide prospective enrollees with descriptions of benefits and cost sharing under the Medicaid program and which are be covered by the SNP.

Chronic Care SNPs are required to comply with a revised definition of a Chronic Care SNP; the Secretary is also required to convene a panel of clinical advisors to determine which conditions meet the definition of a severe and disabling chronic condition.

The Act requires all SNPs to comply with certain care management requirements such as having an appropriate network of providers, performing enrollee health assessments, and arranging for interdisciplinary teams to manage care for enrollees. By no later than January 1, 2010, SNPs are required to collect and report data related to the care management requirements. To ensure compliance with the care management requirements, the Secretary is required to conduct a review of SNPs in conjunction with its periodic financial audit of MA plans. Plans would be expected to comply with these new requirements beginning January 1, 2010.

Section 165. Limitation on Out-Of-Pocket Costs for Dual Eligibles and Qualified Medicare Beneficiaries Enrolled in a Specialized Medicare Advantage Plan for Special Needs Individuals. Effective January 1, 2010, Medicaid Special Needs Plans (SNPs) serving beneficiaries eligible for full benefits under Medicaid, or limited benefits under the Qualified Medicare Beneficiary program, are prohibited from charging cost-sharing in excess of what would be permitted under Medicaid.

Section 166. Adjustment to the Medicare Advantage Stabilization Fund. The MMA created the MA Regional Plan Stabilization Fund with an initial level of \$10 billion. Subsequent legislation reduced this amount to \$1.79 billion. Also, currently a portion of the savings accrued in the regional plan bidding process is added to the Fund. MIPPA reduces the initial funding to one dollar. Money from the regional plan bidding process continues to flow into the Fund. Expenditures are delayed one year, until 2014.

**Section 167.** Access to Medicare Reasonable Cost Contract Plans. Reasonable Cost Contract Plans are MA plans that are reimbursed by Medicare for the actual cost of providing services to enrollees. Prior to MIPPA, these plans were allowed to operate indefinitely unless there were two other MA plans of the same type that operated for the entire year in the cost contract's service area. The Act extends for one year — from January 1, 2009, to January 1, 2010 — the length of time reasonable cost plans may continue operating regardless of any other MA plans serving the area. It specifies that to prohibit the cost plan from participating after January 1, 2010, the two plans in the service area must be offered by different organizations. Finally, MIPPA modifies the minimum enrollment requirements for local or regional plans operating within the cost plan's service area.

GAO is required to submit a report to Congress on the reasons why cost-based plans may be unable to become MA plans, together with recommendations for legislation and administrative action as appropriate by December 31, 2009.

**Section 168. MedPAC Study and Report on Quality Measures.** The Medicare Payment Advisory Commission (MedPAC) is required to conduct a study on how comparable measures of performance and patient experience can be collected and reported by 2011 for MA and original Medicare. Not later than March 31, 2010, MedPAC is required to submit a report to Congress containing the results of the study, together with recommendations for legislation and administrative action as appropriate.

Section 169. MedPAC Study and Report on Medicare Advantage Payments. MedPAC is required to conduct a study on the correlation between MA costs of providing Medicare coverage (as reflected in plan bids) and county level, per-capita spending in the original fee-for-service (FFS) program. The study is required to include differences by plan type and geographic area. Based on the results of this study, and other data, MedPAC is required to examine (1) alternatives to county-level payments and (2) the accuracy and completeness of county-level estimates of spending in original Medicare. Not later than March 31, 2010, MedPAC is required to submit a report to Congress containing the results of the study, together with recommendations for improving estimates, legislation and administrative action as appropriate.

#### Subtitle E - Provisions Relating to Part D

#### Part I - Improving Pharmacy Access

Section 171. Prompt Payment by Prescription Drug Plans and **MA-PD Plans under Part D.** For plan years beginning on or after January 1, 2010, the negotiated contracts between pharmacies and Medicare Part D prescription drug plans (PDP sponsors or MA-PD plans) will be required to provide that payment will be issued, mailed, or otherwise transmitted with respect to all "clean claims" submitted by pharmacies within the "applicable number of calendar days" after the date on which the claim is received. This requirement will not apply to pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility. "Clean claims" are defined as those claims that have no defect or impropriety such as the lack of any required substantiating documentation, or any circumstances requiring special treatment that prevents timely payment from being made. Claims submitted electronically will be considered to have been received on the date on which the claim is transferred. Claims not submitted electronically will be considered to have been received on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission. The term "applicable number of calendar days" will be defined as 14 days for claims submitted electronically and 30 days for claims submitted otherwise.

If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days after a clean claim is received, the PDP sponsor or MA-PD plan will be required to pay interest to the pharmacy that submitted the claim. This interest charge will not be counted against the administrative costs of a PDP sponsor or MA-PD plan or treated as allowable risk corridor costs. The Secretary may provide that a PDP sponsor or MA-PD plan will not be charged interest in cases with exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

A claim will be deemed to be clean if the PDP sponsor or MA-PD plan does not provide notice of any deficiency in the claim within 10 days of the date of receipt, for claims submitted electronically, and, otherwise, within 15 days of the date of receipt. If the PDP sponsor or MA-PD plan determines that the submitted claim is not a clean claim, the PDP sponsor or MA-PD plan will be required to notify the claimant, specifying all defects or improprieties in the claim and listing all additional information or documents necessary for the proper processing and payment of the claim. If the sponsor or plan does not notify the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received, the claim will be deemed a clean claim. If a PDP sponsor or MA-PD plan does not pay or contest a claim within the applicable number of days after the date of receipt, the claim will be deemed a clean claim and will be required to be paid. PDP sponsors or MA-PD plans will be required to pay all clean claims (and remittance) submitted electronically by electronic transfer of funds if the pharmacy so requests or has requested previously.

#### Section 172. Submission of Claims by Pharmacies Located in or Contracting with Long-Term Care Pharmacies. For plan years beginning on

or after January 1, 2010, contracts between PDP sponsors and pharmacies located in or contracting with long-term care facilities will be required to provide that the pharmacy has between 30 and 90 days to submit claims for reimbursement.

Section 173. Regular Update of Prescription Drug Pricing Standard. For plan years beginning on or after January 1, 2009, contracts between pharmacies and PDP sponsors or MA-PD plans that use the cost of a drug as the standard for reimbursement of pharmacies will be required to provide that the sponsor update the standard at least every seven days, to accurately reflect the market price of acquiring the drug.

#### Part II - Other Provisions

Section 175. Inclusion of Barbiturates and Benzodiazepines as Covered Part D Drugs. Prescription drug plans and MA-PD plans are not currently required to include barbiturates or benzodiazepines in their formularies. For prescriptions dispensed on or after January 1, 2013, plans will be required to include benzodiazepines in their formularies. Barbiturates will also be required to be included in formularies for the indications of epilepsy, cancer, or chronic mental health disorder.

Section 176. Formulary Requirements With Respect to Certain Categories or Classes of Drugs. Under Medicare Part D, formularies of prescription drug plans and MA-PD plans must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories and classes. CMS has required plans to cover all or substantially all drugs in the following six classes: anticonvulsants, antineoplastics, antiretrovirals, antidepressants, antipsychotics, and immunosuppressives. CMS stated that it instituted the policy because it felt it necessary to ensure that Medicare beneficiaries reliant on these drugs will not be substantially discouraged from enrolling with Part D plans and to mitigate the risks and complications associated with interruption of therapy for vulnerable populations.

Beginning with plan year 2010, the Secretary will be required to identify categories and classes of drugs (which may be different from the six classes required by CMS) for which (1) restricted access to the category or class will have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class; and (2) there is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer.

Prescription drug plan (PDP) sponsors will be required to include all covered Part D drugs in the categories and classes identified by the Secretary. However, the Secretary may establish a formal exceptions process that ensures that any exception is based upon scientific evidence and medical standards of practice (which for antiretroviral medications must be consistent with HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents), and includes a public notice and comment period.

#### Subtitle F - Other Provisions

Section 181. Use of Part D Data. In order to maintain the confidentiality of sensitive data, and to protect trade secrets, MMA placed restrictions on Medicare Part D data and limited access only for specific purposes. On May 27, 2008, the CMS issued a final rule that would allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. Some organizations who submitted comments on the rule questioned the CMS's authority to use the Part D data for other than payment purposes. This provision in MIPPA grants CMS authority to use and share data from the Medicare Part D program by amending Section 1860D-12(b)(3)(D) of the Social Security Act (42 U.S.C. 1395w-112(b)(3)(D)). As a result of this modification, information provided to the Secretary in the administration of the Part D program may be used for the purposes of improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate), and shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

Section 182. Revision of Definition of Medically Accepted Indication for Drugs. The term medically accepted indication includes any use which has been approved by the Food and Drug Administration (FDA). The term also includes another use if the drug itself has been approved by the FDA and the use has been supported by one or more citations (or approved for inclusion) in one or more compendia specified in the law or other authoritative compendia identified by the Secretary, unless the Secretary determines that the use is not medically appropriate or the use is identified as not indicated in one or more compendia. The Secretary may revise the list of compendia as appropriate. CMS has proposed a formal process for accepting and acting on requests for changes to the list of compendia.

On and after January 1, 2010, no compendia will be permitted to be included on the Secretary's list of compendia unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests. For plan years beginning on or after January 1, 2009, the Secretary will be required to include the compendia used in the Medicaid program in the list of compendia, provided that the compendia for the Medicaid program has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests on and after January 1, 2010. If the compendia for the Medicaid program do not meet these criteria, the Secretary will be required to revise the compendia for the Medicaid program accordingly. In the case of a covered part D drug to be used in an anticancer chemotherapeutic regimen, PDPs and MA-PDs will have the authority to determine, based upon guidance provided by the Secretary, whether such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified by the Secretary.

Section 183. Contract with a Consensus-Based Entity Regarding Performance Measurement. This provision will enable the Secretary to contract with an organization that will develop and endorse health care quality measures. For this purpose, up to \$10 million from the Medicare Part A and Part B Trust Funds will be made available for the period of fiscal years 2009 through 2012. The provision also includes the Sense of the Senate that the contract with the consensus-based entity should not be construed as diminishing the significant contributions of the Boards of Medicine, the quality alliances, and other clinical and technical experts for efforts to measure and improve the quality of health care services. The GAO will conduct studies on the performance of the consensus-based entity and report on (1) its duties under the contract and (2) the costs incurred by the entity in performing such duties. These reports will be due not later than 18 months and 36 months after the effective date of the first contract, together with recommendations for such legislation and administrative action as the Comptroller General determined appropriate.

**Section 184. Cost-Sharing For Clinical Trials.** This provision gives the Secretary the authority to develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary. These are payments which would be necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

Section 185. Addressing Health Care Disparities. The provision gives the Secretary the authority to initiate data collection and analysis efforts to address health care disparities across race, ethnicity, and gender. The Secretary will prepare several reports that will (1) identify approaches (including defining methodologies) for identifying and collecting and evaluating data on health care disparities on the basis of race, ethnicity, and gender for the original Medicare fee-for-service program, and (2) include recommendations on the most effective strategies and approaches to reporting Health Effectiveness Data and Information Set (HEDIS) quality measures and other nationally recognized quality performance measures, as appropriate, on the basis of race, ethnicity, and gender. Not later than four years after enactment, and four years thereafter, the Secretary will submit to Congress a report that includes recommendations for improving the identification of health care disparities for Medicare beneficiaries based on analyses of the data collected as described above. Not later than 24 months after the date of the enactment of this section, the Secretary will implement the approaches identified in this report for the ongoing, accurate, and timely collection and evaluation of data on health care disparities on the basis of race, ethnicity, and gender.

**Section 186.** Demonstration to Improve Care to Previously Uninsured. Within one year after enactment, the Secretary will establish a demonstration project to determine the greatest needs and most effective methods of outreach to Medicare beneficiaries who were previously uninsured. The demonstration will be in no fewer than 10 sites, and will include state health insurance assistance programs, community health centers, community-based organizations, community health workers, and other service providers under Medicare Parts A, B, and C. The Secretary will conduct the demonstration project for a period of two years and will submit a report to Congress not later than one year after completion that will include (1) an analysis of the effectiveness of outreach activities targeting beneficiaries who were previously uninsured, and (2) the effect of the outreach on beneficiary access to care, utilization of services, efficiency and cost-effectiveness of health care delivery, patient satisfaction, and select health outcomes.

Section 187. Office of the Inspector General Report on Compliance with and Enforcement of National Standards on Culturally and Linguistically Appropriate Services (CLAS) in Medicare. The National Standards on Culturally and Linguistically Appropriate Services (CLAS) were published in the Federal Register on December 22, 2000 (Vol. 65, No. 247, pp. 80865-80879) as national standards for adoption or adaptation by stakeholder organizations and agencies. The CLAS standards are primarily directed at health care organizations and were initially derived from an analysis of current practice and policy on cultural competence. The CLAS standards are intended to provide a common understanding and consistent definitions of culturally and linguistically appropriate services in health care, and to offer a practical framework for the implementation of services and organizational structures that can help health care organizations and providers be responsive to the cultural and linguistic issues presented by diverse populations.

Not later than two years after enactment, the HHS Inspector General will prepare and publish a report on (1) the extent to which Medicare providers and plans are complying with the Office for Civil Rights' Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons and the Office of Minority Health's Culturally and Linguistically Appropriate Services Standards in health care, and (2) a description of the costs associated with or savings related to the provision of language services. The report will include recommendations on improving compliance with CLAS Standards and recommendations on improving enforcement of CLAS Standards. Not later than one year after the date of publication of the report, the Department of Health and Human Services will implement changes responsive to any deficiencies identified in the report.

**Section 188. Medicare Improvement Funding.** The Secretary will establish a Medicare Improvement Fund that will be available to the Secretary to make improvements under the original fee-for-service program under Parts A and B for Medicare beneficiaries. MIPPA, together with a provision in the Supplemental Appropriations Act, 2008 (P.L. 110-252), makes \$2.22 billion from the Part A and B Trust Funds available for services furnished during FY2014 and an additional \$19.9 billion available for fiscal years 2014 through 2017.

For purposes of carrying out the provisions of, and amendments made by, this Act, in addition to any other amounts provided in such provisions and amendments, additional funds will be made available to CMS. For fiscal years 2009 through 2013, the Secretary of Health and Human Services will transfer \$140 million from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund to the CMS Program Management Account. The amounts drawn from the funds will be in the same proportion as for Medicare managed care payments (Medicare Advantage), that is, in a proportion that reflects the relative

weight that benefits under part A and under part B represent of the actuarial value of the total benefits.

Section 189. Inclusion of Medicare Providers and Suppliers in Federal Payment Levy and Administrative Offset Program. The Federal Payment Levy Program (FPLP) authorizes the Internal Revenue Service (IRS) to collect overdue taxes through a continuous levy on federal payments made to delinquent taxpayers. This provision will require that CMS process all payments through the FPLP by September 30, 2011.

#### Title II - Medicaid

Section 201. Extension of Transitional Medical Assistance (TMA) and Abstinence Education Program. States are required to continue Medicaid benefits for certain low-income families who will otherwise lose coverage because of changes in their income (e.g., an increase in hours of employment). This continuation is called transitional medical assistance (TMA). Permanent law requires four months of TMA, and Section 1925 of the Social Security Act (which has a sunset date) requires up to 12 months for families who will otherwise lose coverage for work-related reasons. Since 2001, Section 1925 TMA requirements have been funded through a series of short-term extensions, most recently through June 30, 2008.

P.L. 104-193, the 1996 welfare reform law, provided \$250 million in federal funds specifically for an abstinence education program (\$50 million per year for each of five years, FY1998-FY2002). Funds for this program (referred to as the Title V Abstinence Education block grant) must be requested by states when they solicit Title V Maternal and Child Health block grant funds and must be used exclusively for teaching abstinence. Although it has not been reauthorized, the latest temporary extension continued funding through June 30, 2008.

The provision will extend Section 1925 TMA requirements and the abstinence education program through June 30, 2009, with funding at the level provided through the third quarter of FY2008.

**Section 202.** Medicaid DSH Extension. When establishing hospital payment rates, state Medicaid programs are required to recognize the situation of hospitals that provide a disproportionate share of care to low-income patients with special needs. Such "disproportionate share hospital (DSH) payments" are subject to statewide allotment caps. Allotments for Tennessee and Hawaii, however, are equal to zero because the states operate their state Medicaid programs under the provisions of a Section 1115 research and demonstration waiver. Such research and demonstration waivers allow for states to waive various provisions of Medicaid law specified in Title XIX of SSA (such as the requirement to make disproportionate share payments) to conduct demonstrations as long as the demonstrations are likely to assist in promoting the objectives of the Medicaid program.

Congress has enacted special DSH provisions for Tennessee and Hawaii in the past. Both states received a special allotment for FY2007 and part of FY2008. Tennessee's allotment amount was set at \$30 million for FY2007, and the same

amount was prorated for the applicable portion of FY2008. Hawaii's allotment was set at \$10 million for 2007 and similarly prorated for FY2008. Both states have, in addition, been allowed to submit state plan amendments describing their methodologies for distributing such payments for the Secretary's approval.

The provision will extend the special DSH allotment arrangements for Tennessee and Hawaii through a portion of FY2010. Allotment amounts will be equal to \$30 million for Tennessee for each full year — 2008 and 2009 — and one-quarter of that amount will be available for the first quarter of FY2010. Hawaii's \$10 million allotment will be extended for each full fiscal year — 2008 and 2009 — and \$2.5 million will be available for the first quarter of FY2010.

Section 203. Pharmacy Reimbursement under Medicaid. State Medicaid programs set the prices paid to pharmacies for Medicaid outpatient drugs. Federal reimbursements for those drugs, however, are limited to a federal upper limit (FUL). The DRA established that FULs applying to drugs available from multiple sources (generic drugs, for the most part) be re-calculated by CMS to be equal to 250% of the average manufacturer's price (AMP, the average price paid by wholesalers to manufacturers) as reported to CMS by the manufacturers. Upon full implementation of the DRA provisions, AMPs are to become publicly available. Important components of the new FUL formula have been issued in a final rule in July of 2007. The rule defines a number of terms related to drug pricing under Medicaid, including definitions impacted by DRA provisions such as AMP, multiple source drugs, and nominal prices. The rule has been contested, and CMS is prohibited from implementing its provisions until the court hears the case and makes a final determination of its legality. In the interim, FUL formulas remain calculated by CMS as equal to 150% of the published price for the least costly therapeutic equivalent.

The provision will retain, through September 30, 2009, the FUL formulas for federal reimbursement of multiple source drugs as described in federal regulations in effect as of December 21, 2006 (42 CFR 447). Under those instructions, FULS are calculated to be equal to 150% of the published price for the least costly therapeutic equivalent. In addition, the Secretary will not be permitted to make AMP prices publicly available prior to such date.

**Section 204. Review of Administrative Claim Determinations.** The federal government and the states share in the cost of Medicaid expenditures that states incur for services provided to Medicaid beneficiaries and for the administration of their Medicaid programs. States submit quarterly expense reports in order to receive federal reimbursement for a share of these costs. If the Department of Heath and Human Services (HHS) believes that a state's claim for federal financial participation (FFP) for state expenditures is improper or erroneous, it may disallow the claim. Disputes that pertain to disallowances of FFP in Medicaid expenditures are heard by the HHS, Departmental Appeals Board (the Board) in accordance with specified procedures.

The provision will establish new timelines and procedures for the administrative review of disallowances of federal financial participation under Medicaid. In the case where the Secretary disallows FFP for a state claim under Medicaid, the state will be permitted to receive a reconsideration of the disallowance (or a reconsideration of an unfavorable reconsideration of a disallowance) if the state files an appeal with the Board within 60 days after receiving notice. The provision will also permit States to obtain judicial review by filing an action in any United States District Court located within the appealing state, or if several States jointly appeal, in any United States District Court that is located within any State that is a party to the appeal. Judicial review will be permitted only in the case that (1) no motion for reconsideration was filed during the 60-day period after the state received notice of the disallowance of FFP under Medicaid, or (2) if the State filed a motion for an appeal, during the 60 day period that begins on the date of the Board's decision on such motion.

**Section 205. County Medicaid Health Insuring Organizations.** In general, Medicaid managed care organizations are subject to contracting requirements described in section 1903(m)(2)(A) of the Social Security Act. However, certain county-operated managed care plans in California that serve Medicaid beneficiaries, which are referred to as "county organized health systems" or "health insuring organizations" (HIOs), are exempt from these contracting requirements. The Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272) grandfathered the 1903(m)(2)(A) exemption for HIOs operating before January 1, 1986. In addition, the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) provided an exemption for up to three county-operated HIOs in California that became operational on or after January 1, 1986, provided that certain requirements were met. For example, the three entities could enroll no more than 10% of all Medicaid beneficiaries in California, later raised to 14% by MMSEA.

The provision will add an exemption for HIOs operated by Ventura County and Merced County, and will raise the allowable percentage of beneficiaries to 16%.

#### **Title III - Miscellaneous**

**Section 301. Extension of TANF Supplemental Grants.** Temporary Assistance for Needy Families (TANF) provides supplemental grants for 17 states with exceptionally high population growth in the early 1990s, historic (pre-1996) welfare grants per poor person lower than 35 percent of the national average, or a combination of above average population growth and below average historic welfare grants per poor person. Grants were authorized at \$800 million over FY1998 through FY2001, and annual grants grew from \$79 million in FY1998 to \$319 million in FY2001. Congress froze supplemental grants at the \$319 million annual level when it extended supplemental grants for FY2002 and subsequent years. DRA provided the last extension of supplemental grants, continuing their funding through FY2008. (Other TANF grants are funded through FY2010.) This provision extends supplemental grants at the \$319 million level through FY2009. In FY2009, each of the 17 qualifying states will receive the same supplemental grant amount as it did in FY2008.

Section 302. 70 Percent Federal Matching for Foster Care and Adoption Assistance for the District of Columbia. Under Title IV-E of the Social Security Act, states are entitled to receive federal reimbursement for a portion of the cost of each foster care maintenance payment or adoption assistance payment

#### CRS-31

provided on behalf of an eligible child. The federal reimbursement rate for these payments is equal to each state's Federal Medical Assistance Percentage (FMAP) rate as defined under Title XIX. In general, Title XIX provides that a state's FMAP (including the District of Columbia's FMAP) is calculated annually and may range from 50%-83% based on the state's per capita income. (States with higher per capita income receive a lower reimbursement rate and vice versa.) However, for purposes of the Medicaid program and the State Children's Health Insurance Program (SCHIP), only, Title XIX sets the District of Columbia's FMAP at 70%.

This provision will entitle the District of Columbia to receive federal reimbursement for its eligible foster care maintenance and adoption assistance payments at 70% (by amending Title IV-E to fix the District of Columbia's FMAP at that rate for those payments). It will make this change effective beginning with the first day of the first quarter of FY2009.

**Section 303.** Extension of Special Diabetes Grant Programs. As specified in the Public Health Service Act, the Secretary, directly or through grants, must provide for research into the prevention and cure of Type I diabetes (Section 330B), and must make grants for providing services for the prevention and treatment of diabetes among American Indians and Alaskan Natives (Section 330C). For each grant program, appropriations are set at \$150 million per year during the period FY2004 through FY2009. An evaluation is required for each program. For both programs, MIPPA will provide appropriations of \$150 million per year for FY2010 and FY2011. It will also re-designate the final report in current law that was due in January 2007 to be a second interim report (an initial interim report was due in January, 2000), and will add a new final report that will be due not later than January 1, 2011.

IOM Reports on Best Practices for Conducting Section 304. Systematic Reviews of Clinical Effectiveness Research and for Developing Clinical Protocols. Within 60 days after the date of enactment of this Act, the Secretary will be required to enter into a contract with the IOM to conduct (1) a study on the best methods used in developing clinical practice guidelines, and (2) a study to identify the methodological standards for conducting systematic reviews of clinical effectiveness research on health and health care. The purpose of these studies is to ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent. Not later than 18 months after the effective date of the contract, the IOM will be required to submit a report to the Secretary and the appropriate committees of Congress, that contains the results of the studies and recommendations for legislation and administrative action. The contract with the IOM will require that stakeholders with expertise in making clinical recommendations participate on the panel responsible for study (1), and stakeholders with expertise in conducting clinical effectiveness research participate on the panel responsible for study (2).

To carry out these studies, this provision appropriates, out of any funds in the Treasury not otherwise appropriated, \$3 million for FY2009 and FY2010.