Summary of Selected Sections of the
Medicare Improvements for
Patients and Providers Act of 2008
Crowell & Moring’s  
Summary of Selected Sections of the  
*Medicare Improvements for Patients and Providers*  
*Act of 2008*  

**Acronyms and Abbreviations**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLAS</td>
<td>Culturally and Linguistically Appropriate Services</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
</tr>
<tr>
<td>DMEPOS</td>
<td>Durable Medical Equipment, Prosthetics, Orthotics and Supplies</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FFY</td>
<td>Federal Fiscal Year</td>
</tr>
<tr>
<td>FFP</td>
<td>Federal Financial Participation</td>
</tr>
<tr>
<td>FPLP</td>
<td>Federal Payment Levy Program</td>
</tr>
<tr>
<td>FQHCs</td>
<td>Federally Qualified Health Centers</td>
</tr>
<tr>
<td>GAO</td>
<td>General Accountability Office</td>
</tr>
<tr>
<td>HOPD</td>
<td>Hospital Outpatient Department</td>
</tr>
<tr>
<td>HRSA</td>
<td>Health Resources and Services Administration</td>
</tr>
<tr>
<td>IME</td>
<td>Indirect Medical Education</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
</tr>
<tr>
<td>LIS</td>
<td>Low Income Subsidy</td>
</tr>
<tr>
<td>MA</td>
<td>Medicare Advantage</td>
</tr>
<tr>
<td>MEDPAC</td>
<td>Medicare Payment Advisory Commission</td>
</tr>
<tr>
<td>MEI</td>
<td>Medicare Economic Index</td>
</tr>
<tr>
<td>MIPPA</td>
<td>Medicare Improvement for Patients and Providers Act of 2008</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>MSA</td>
<td>Medical Savings Account</td>
</tr>
<tr>
<td>OIG</td>
<td>Office of the Inspector General for the Department of Health and Human Services</td>
</tr>
<tr>
<td>PD</td>
<td>Part D</td>
</tr>
<tr>
<td>PFFS</td>
<td>Private Fee-for-Service</td>
</tr>
<tr>
<td>PPO</td>
<td>Participating Provider Organization</td>
</tr>
<tr>
<td>QI</td>
<td>Qualifying Individual</td>
</tr>
<tr>
<td>Secretary</td>
<td>Secretary of Health and Human Services</td>
</tr>
<tr>
<td>SCHIP</td>
<td>State Children’s Health Insurance Program</td>
</tr>
<tr>
<td>SNPs</td>
<td>Special Needs Plans</td>
</tr>
<tr>
<td>SSA</td>
<td>Social Security Administration</td>
</tr>
<tr>
<td>TMA</td>
<td>Transitional Medical Assistance</td>
</tr>
</tbody>
</table>
On July 15, 2008, Congress overrode President Bush’s veto and enacted the Medicare Improvement for Patients and Providers Act of 2008 (“MIPPA”), Pub. L. 110-275. Most conspicuously, MIPPA replaces a 10.6% payment cut for physicians with a 1.1% increase. MIPPA, however, did far more and affects virtually all provider types, Medicare Advantage (“MA”) plans, and Part D (“PD”) plans. The more significant MIPPA provisions are summarized below.

Title I – Medicare
Subtitle A – Beneficiary Improvements

Sec. 101. Improvements to Coverage of Preventive Services

Section 101 expands Medicare coverage for preventive services furnished on or after January 1, 2009. Such services will be covered by Medicare if the Secretary of Health and Human Services (“the Secretary”) finds that they meet several criteria, including being reasonable and necessary for the prevention or early detection of an illness or disability. Also, payment for clinical diagnostic laboratory tests will be the same amount as determined under 42 U.S.C. §1395l(a)(1)(D). This Section includes “end-of-life planning” as part of the definition of the “initial preventive physical examination” covered under Medicare. “End-of-life planning” refers to an individual’s ability to create an advance directive in the event injury or illness renders the individual unable to make health care decisions. This Section also extends the eligibility period for coverage of an initial physical examination from 6 months after the individual’s first coverage date to one year after that date.

Sec. 102. Elimination of Discriminatory Copayment Rates for Medicare Outpatient Psychiatric Services

Medicare has historically paid only 50% of the allowed amount for outpatient mental health services, while paying 80% of the allowed amount for outpatient physical health services. Section 102 phases-in an increase to Medicare’s payment responsibility for outpatient mental health services to 80% by 2014. When this Section is fully implemented in federal fiscal year (“FFY”) 2014, Medicare will pay outpatient mental health services at the same level as other Part B services.
Sec. 103. Prohibitions and Limitations on Certain Sales and Marketing Activities under Medicare Advantage Plans and Prescription Drug Plans

Effective for the 2009 plan year, MA and PD plans are prohibited from engaging in several marketing activities, including: (a) unsolicited direct contact, such as door-to-door sales and cold calling; (b) the sale of non-health related products (i.e., annuities and life insurance) during sales and marketing activities; (c) the provision of meals, regardless of the value; and (d) any sales or marketing in health care settings and educational events.

In addition, the Centers for Medicare and Medicaid Services (“CMS”) must establish limitations, effective by November 15, 2008, with respect to at least the following: (a) the scope of marketing appointments between sales representatives and prospective enrollees; (b) the use of the name and logo of a co-branded network provider on membership and marketing materials; (c) the offering of gifts and promotional items, other than those of nominal value, at promotional activities; (d) the creation of guidelines for the compensation of sales representatives, which creates incentives for agents and brokers to enroll prospective enrollees in the plan that best meets their health care needs; and (e) requirement for initial and annual retraining and a testing program for agents and brokers.

MA organizations and PD sponsors may only use state licensed agents and brokers and must comply with any state appointment laws. In addition, the MA organization and PD sponsor must, to the extent required by law, report agent and broker terminations to the state. They must also comply with state requests for information regarding the performance of a broker or agent.

Sec. 104. Improvements to the Medigap Program

Section 104 addresses the time for implementation by the states of the changes to the Medigap program resulting from the addition of Medicare PD.

Sec. 111. Extension of Qualifying Individual (“QI”) Program

Section 111 extends the Medicare QI subsidy program, which pays Part B premiums for low-income individuals, and increases the total amount available for such subsidies in FFY 2009.

Sec. 112. Application of Full Low Income Subsidy (“LIS”) Assets Test Under Medicare Savings Program

Section 112 alters the asset test for determination of qualification for the Medicare Savings Program to equal the assets level applicable under the PD LIS program. Effective January 1, 2010, the maximum assets test for such qualification will allow an exclusion for the value of life insurance policies previously included in this calculation.
Sec. 113. Eliminating Barriers to Enrollment

Section 113 requires the Social Security Administration (“SSA”) to provide enrollment information to, and collect enrollment data from, individuals identified as being potentially eligible for the LIS program. SSA is required to transmit this information electronically to the States for use in their state health insurance assistance programs and Medicaid eligibility determinations. The states in turn are required to treat this information as if an individual had filed for a LIS.

Sec. 114. Elimination of Medicare PD Late Enrollment Penalties Paid by Subsidy Eligible Individuals

Effective January 1, 2009, Section 114 eliminates the late enrollment penalty for LIS beneficiaries.

Sec. 115. Eliminating Application of Estate Recovery

Effective January 1, 2010, Section 115 limits the ability of states to recover certain Medicare cost sharing expenses from the estate of any dually-eligible person who was over age 55 when that person incurred the expense.

Sec. 117. Judicial Review of Decisions of the Commissioner of Social Security Under the Medicare PD LIS Program

Section 117 provides judicial review rights to individuals appealing SSA determinations of eligibility for the Medicare LIS on the same basis as appeals of other SSA determinations.

Sec. 118. Translation of Model Form

Effective January 1, 2010, Section 118 requires the translation of the Medicare Savings Program application form into at least the ten most often used languages (other than English) of individuals applying for these subsidies.

Sec. 119. Medicare Enrollment Assistance

Section 119 creates funding for CMS to make grants to state health insurance assistance programs to help in outreach to individuals who may be eligible for the LIS program. Special funds are identified for use for PD outreach, special rural population assistance, and state agencies regarding the aging and the disabled. This Section also mandates the creation of a program to improve the system for disseminating information about Medicare subsidies to older Americans, including the creation of a web-based decision support tool.
Subtitle B – Provisions Relating to Part A

Sec. 121. Expansion and Extension of the Medicare Rural Hospital Flexibility Program

FLEX grants, administered by Health Resources and Services Administration (“HRSA”), are provided to rural health care providers to improve the quality of care and strengthen health care networks. In the past, certain limitations have been imposed on the use of the grant funds for administrative expenses, both at the state and federal level. Section 121 expands the grant program to allow the Secretary to award amounts to states to increase delivery of mental health services or other health services for veterans of Operation Iraqi Freedom and Operation Enduring Freedom and other residents of rural areas. It also extends the FLEX program through 2010.

Sec. 122. Rebasing for Sole Community Hospitals

For cost reporting periods beginning on or after January 1, 2009, Section 122 permits sole community hospitals to elect payment based on their FY 2006 rebased target amount, with annual updating.

Sec. 123. Demonstration Project on Community Health Integration Models in Certain Rural Counties

Section 123 requires the Secretary to establish a demonstration, beginning October 1, 2009, allowing eligible retirees in rural areas to develop and test new models for the delivery of health care services in eligible counties in order to improve access and better integrate the delivery of health care services to Medicare beneficiaries.

Sec. 125. Revocation of Unique Deeming Authority of the Joint Commission

Section 125 strikes from the Social Security Act the explicit deeming authority granted to the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”) to accredit hospitals. Under this Section, hospitals will be accredited by national accrediting organizations approved by the Secretary, which can include the JCAHO. This Section will take effect 24 months after the legislation is enacted and, during that stub period, will not affect hospitals currently accredited by the JCAHO.

Subtitle C – Provisions Relating to Part B

Sec. 131. Physician Payment, Efficiency and Quality Improvements

Section 131 establishes the “single conversion factor,” or the increase in the Physician Fee Schedule for the remainder of 2008 and 2009 at 0.5% and 1.1% respectively. This slight increase in the fee schedule came after intense debate, and avoids the planned
reduction in the payment rates which would have gone into effect on July 1, 2008. The fee schedule remains at risk for significant reductions in 2010.

This section also revises the Physician Assistance and Quality Reporting System by extending the incentive payment system through 2010 and increasing the maximum payment a physician may earn based on quality performance from 1.5% to 2.0% in 2009 and 2010.

In addition, this section requires the Secretary to establish a “Physician Feedback Program” by January 1, 2009. Through confidential reports to high volume users, certain physician specialties, specific geographic areas, etc., the Secretary is now required to provide physicians with feedback on their performance – presumably with the intent that such confidential feedback will lead to corrective actions by out-of-conformance performers.

Sec. 132. Incentives for Electronic Prescribing

Section 132 establishes incentives for physicians and other prescribing professionals to use e-prescribing for Medicare PD enrollees. Prescribers who qualify would receive a bonus percentage on top of their regular Medicare Part B payments of 2.0% for 2009, 1.0% for 2011 and 2012, and 0.5% for 2013.

To qualify, prescribers would need to report on electronic prescribing quality measures established by the Secretary for at least 50% of the cases in which such measures are reportable, or, if the Secretary so determines, the prescriber has submitted a sufficient number of prescriptions under PD. However, prescribers would be ineligible for a bonus if allowed charges for covered Medicare professional services they provide for which the Secretary has established an electronic prescribing quality measure are not at least 10% of the allowed charges for covered Medicare professional services. If the Secretary elects not to impose that restriction, prescribers would then still need to write enough PD prescriptions to meet a floor to be established by the Secretary.

The new incentives include penalties as well. Starting in 2012, if a prescriber is eligible for a bonus, but does not qualify because the prescriber does not satisfy the 50% test for reporting on electronic prescribing quality measures, then the amounts otherwise payable for covered Medicare professional services will be reduced by 1.0% in 2012, by 1.5% in 2013 and 2.0% in 2014 and thereafter. Hardship exceptions may be made, such as for an eligible professional who practices in a rural area without sufficient Internet access.

Sec. 133. Expanding Access to Primary Care Services

Section 133 conditionally authorizes the Secretary to expand the duration and scope of the Medical Home Demonstration Project beginning in 2009 to improve the quality of patient care and funds and potential expansion with $100,000,000 from the Federal Supplementary Medical Insurance Trust.
Sec. 134. Extension of Floor on Medicare Work Geographic Adjustment Under the Medicare Physician Fee Schedule

Medicare payments for physician services are made under a fee schedule that includes an adjustment to take into account cost differences among geographic areas as compared to the national average in a “market basket” of goods, that is set at 1.00. Section 134 extends through December 31, 2009 the 1.00 floor on the geographic adjustment that had been in place from January 2004 through June 2008 for rural and other areas. This section also provides that the geographic adjustment floor that applies in Alaska after January 1, 2009 will be 1.50.

Sec. 135. Imaging Provisions

Section 135 reflects the most recent attempt by Congress to address the cost, quality, and utilization of imaging services provided by outpatient suppliers of these services. While Section 135 contains a number of new initiatives related to the provision of imaging services, it is this Section’s new accreditation requirements that will have the most direct impact on diagnostic imaging suppliers.

Beginning January 1, 2012, payment may only be made for the technical component of “advanced diagnostic imaging services” if the supplier of such services is accredited by an accreditation organization designated by the Secretary. The term “advanced diagnostic imaging services” is defined to include “diagnostic magnetic resonance imaging, computer tomography, nuclear medicine (including positron emission tomography)” and any other imaging services designated by the Secretary, with the exception of x-ray, ultrasound, and fluoroscopy.

The Secretary is required to designate accreditation organizations no later than January 1, 2010. The factors to be considered in making such designations include the ability of the organization to conduct timely reviews of applications, whether the organization has established procedures for integrating new technologies into its accreditation program, the nature of the strategies used (e.g., random site visits, site audits) to ensure adherence to established criteria, the ability of the organization to reach rural suppliers, and the reasonableness of the organization’s fees.

The criteria to be used by these designated organizations when accrediting imaging suppliers must be specific to each imaging modality. The criteria are required to include: (a) standards for the qualifications and responsibilities of technicians, medical directors and supervising physicians; (b) procedures to ensure that imaging equipment meets performance requirements; (c) standards and procedures to ensure the safety of both the persons performing and receiving technical component imaging services; and (d) quality assurance standards to ensure the “reliability, clarity, and accuracy of the technical quality of diagnostic images produced” by the supplier.

This Section allows for imaging suppliers already accredited by a Secretary-designated organization prior to January 1, 2010, to be deemed accredited as of January 1, 2012,
for the remaining period such accreditation is in effect. Similarly, if a supplier is accredited by a Secretary-designated organization as of January 1, 2012, and the accrediting organization is subsequently removed from the Secretary's list, the suppliers accreditation remains in effect for the duration of the accreditation period.

Congress has also provided for a two-year demonstration project to be conducted by the Secretary, the purpose of which is to collect data regarding physician compliance with appropriateness criteria “developed and endorsed by a medical specialty society”, in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries. Physicians are to be selected for the demonstration project based on geography, demographics, practice setting, and the ability to submit data in an electronic format.

The study will be conducted utilizing two models for data collection, one a “point of service” model (using information collected at the time the imaging service is provided), and the other a “point of order” model (requiring transmittal of information at the time the service is ordered). Prior authorization is explicitly excluded from use as a data collection model. The demonstration project must include a mechanism for providing feedback to participating physicians, and ultimately, the Secretary must submit a report of its findings to the General Accountability Office (“GAO”) within one year of completion of the project.

Sec. 136. Extension of Treatment of Certain Physician Pathology Services Under Medicare

Legislation enacted in 1997 permitted independent labs that had agreements with hospitals as of July 22, 1999 to bill Medicare directly, for a certain period of time, for the technical component of pathology services provided to the hospitals’ patients. Section 126 permits independent labs to continue to do so through December 31, 2009.

Sec. 137. Accommodation of Physicians Ordered to Active Duty in the Armed Services

Generally, Medicare prohibits payment for services to anyone other than the patient who received the covered services or the physician who performed them. An exception to this rule allows a patient’s regular physician to submit bills for work performed by a locum tenens physician for a continuous period of 60 days if the regular physician is unavailable. Other Medicare amendments made the 60-day maximum for such billing arrangements inapplicable to physicians called to active duty in the armed forces. Although this exception expired on July 1, 2008, Section 137 strikes that date from the Medicare, Medicaid, and State Children’s Health Insurance Program (“SCHIP”) Extension Act of 2007, which has the effect of indefinitely extending the exemption for physicians ordered to active duty in the armed services.
Sec. 138. Adjustment for Medicare Mental Health Services

Medicare pays for mental health services under the physician fee schedule. Section 138 increases by 5.0% the fee schedule amount otherwise applicable for certain specified mental health services from July 1, 2008 through December 31, 2009.

Sec. 139. Improvements for Medicare Anesthesia Teaching Programs

Medicare has historically paid only 50% of the fee schedule amount for the medical direction of two, three, or four concurrent anesthesia cases. Section 139 establishes that beginning January 1, 2010, the fee schedule applied to teaching anesthesiologists for training physician residents in a single anesthesia case or two concurrent cases will be 100% of the fee schedule amount otherwise applicable, provided the teacher personally performs the anesthesia services alone. The 50% limitation will also not apply if the teaching anesthesiologist is present during all critical portions of the anesthesia service and if the teaching anesthesiologist or a proxy is immediately available to furnish anesthesia services during the entire procedure. This Section also requires the Secretary to make similar adjustments to payments for certified registered nurse anesthesiologists while maintaining the existing payment differences between the two groups.

Sec. 141. Extension of Exceptions Process for Medicare Therapy Caps

Section 141 extends through December 31, 2009 the exception process established by the Secretary from the annual limitation for medically necessary physical, speech and occupational therapy service expenses.

Sec. 142. Extension of Payment Rule for Brachytherapy and Therapeutic Radiopharmaceuticals

Section 142 extends cost-based payments for brachytherapy and therapeutic radiopharmaceuticals devices through December 31, 2009.

Sec. 143. Speech-Language Pathology Services

Effective July 1, 2009, Section 143 redefines “outpatient speech-language pathology services” and permits speech-language pathologists in independent practice to bill Medicare Part B under the same conditions and physical and occupational therapists in independent practice.

Sec. 144. Payment and Coverage Improvements for Patients with Chronic Obstructive Pulmonary Disease (“COPD”) and Other Conditions

Effective January 1, 2010, Section 144 expands payment and coverage of COPD and other conditions by adding two new programs: the Cardiac Rehabilitation Program and
the Pulmonary Rehabilitation Program. This Section also establishes and sets forth standards, coverage and payment terms for these two new programs. Section 144 also mandates that effective January 1, 2009, medical equipment suppliers will retain title and ownership of oxygen equipment, but will continue to furnish the equipment to the beneficiary during the period of medical need.

Sec. 145. Clinical Laboratory Tests

Section 145 repeals the mandate for a Medicare competitive bidding demonstration project for clinical laboratory services. It also specifies that the clinical laboratory fee schedule update will be reduced from 2009 through 2013 by 0.5 percentage points. In the Medicare Prescription Drug, Improvements and Modernization Act passed in 2003, Congress called on CMS to undertake a clinical laboratory competitive bidding demonstration project to test means of more prudently paying for clinical laboratory services under Medicare Part B. The demonstration would have excluded pap smears and colorectal cancer screening and other tests furnished by providers having “face to face encounters” with patients.

The demonstration project faced industry opposition that it was overly complex and unworkable, could lessen competitive opportunities for smaller laboratories, and raised concerns about quality of care. Industry groups obtained a preliminary injunction against implementation of the San Diego site for the demonstration project and had sought legislative repeal.

Sec. 146. Improved Access to Ambulance Services

Section 146 increases payment for ground ambulance services through 2009 and clarifies how locations should be classified as “rural areas” for the purpose of air ambulance payments during this period.

Sec. 147. Extension and Expansion of the Medicare Hold Harmless Provision under the Prospective Payment System for Hospital Outpatient Department (“HOPD”) Services for Certain Hospitals

Section 147 extends until December 31, 2009 the right of small rural hospitals (less than 100 beds) and sole community hospitals to receive payment for outpatient services based on 85% of their adjusted costs to the extent such payment exceeds outpatient prospective payment system payments.

Sec. 148. Clarification of Payment for Clinical Laboratory Tests Furnished by Critical Access Hospitals

Section 148 clarifies certain statutory confusion, and permits critical access hospitals to receive 101% of their “reasonable costs” for clinical laboratory tests performed on
or after July 1, 2009, whether or not the patient is present at the hospital or at an off-site program of the hospital when the specimen is collected.

**Sec. 149. Adding Certain Entities as Originating Sites for Payment of Telehealth Services**

Effective January 1, 2009, Section 149 expands reimbursement for “telehealth services” provided to include services provided to eligible individuals at the following “originating” sites: (a) a hospital based or critical access hospital based renal dialysis center (including satellites); (b) a skilled nursing facility; or (c) a community mental health center.

**Sec. 150. Medicare Payment Advisory Commission (“MEDPAC”) Study and Report on Improving Chronic Care Demonstration Programs**

Section 150 directs the MEDPAC to study the feasibility and advisability of establishing a Medicare Chronic Care Practice Research Network that would serve as a standing network of providers testing new models of coordinating care for chronically ill beneficiaries, and, if appropriate, expanding such models to the broader Medicare patient population. The MEDPAC report is due to Congress by June 15, 2009.

**Sec. 151. Increase of Federally Qualified Health Center (“FQHC”) Payment Limits**

Section 151 increases the payment limit applicable to services provided by FQHCs by $5 for each patient visit in 2010. In subsequent years, the limits established for the previous year will be increased by the percentage increase in the Medicare Economic Index (“MEI”).

**Sec. 152: Kidney Disease Education and Awareness Provisions**

Section 152 establishes a comprehensive initiative to address the prevention and treatment of chronic kidney disease. The initiative includes two principal features:

- **Pilot Program.** A pilot program to increase public and medical community awareness of chronic kidney disease, with a focus on diabetes and hypertension, including increased patient screening. The program will begin on January 1, 2009, last no longer than five years, and include no fewer than three States. The Comptroller General shall be responsible for evaluating the results of the pilot program and submitting a report to Congress.

- **Medicare Patient Education Services.** Medicare will now pay for certain patient education services relating to kidney disease for covered individuals when the education services are provided by certain types of providers and meet certain
content requirements. Such sessions are limited to six per beneficiary, beginning on January 1, 2010.

Sec. 153. Renal Dialysis Provisions

Section 153 makes several changes to the composite reimbursement rate for dialysis services, based on such factors as patient weight, body mass index, and comorbidities, as well as the unique needs of children and young adults, among other factors. Under certain circumstances, providers will have a limited right to elect whether and when to participate in the new payment system. Further, the Secretary shall establish “quality incentives” for renal dialysis services and providers beginning in 2012, under certain “performance measures” established by the Secretary. The results will be made publicly available, including mandatory “prominent” display in “patient areas” of a CMS-issued certificate reflecting the provider’s performance score, and similar postings on the CMS web-site.

Sec. 154. Delay In and Reform of Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (“DMEPOS”) Competitive Acquisition Program

Generally, Medicare pays for most DMEPOS on the basis of a fee schedule. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required the Secretary to develop and phase in a DMEPOS Competitive Acquisition Program for specified medical equipment in specialized areas that would replace the Medicare fee schedule. Section 154 delays until 2011 the requirement for the Secretary to implement the second phase of that Competitive Acquisition Program for the furnishing of competitively priced durable medical equipment, medical supplies, off-the-shelf orthotics, as well as home dialysis supplies and equipment, electromyogram devices, salivation devices, blood products and transfusion medicine. Under previous legislation, the competitive acquisition programs were to be phased in among competitive acquisition areas so that competition occurred in ten of the largest metropolitan areas in the year 2007 (Phase 1) and in 80 of these areas in 2009 (Phase 2). Amendments made by this section were effective as of June 30, 2008. Contracts awarded during the first phase of the competitive acquisition program rollout and before June 30, 2008 are automatically terminated, and no payment may be made under them on or after June 30, 2008.

In 2011, during the newly-scheduled Phase 2 of the program, an additional 70 of the largest metropolitan statistical areas must be phased in among the competitive acquisition areas. The metropolitan statistical areas to be included in Round 2 will be those areas selected by the Secretary for such round as of June 1, 2008. Additional areas must be phased in after 2011 (or, in the case of national mail order, after 2010). The Secretary may subdivide metropolitan statistical areas with populations of at least 8,000,000 into separate areas for competitive acquisition purposes.
The Secretary maintains the ability to first phase into the competitive acquisition program the highest cost and highest volume items and services or those items and services the Secretary determines to have the largest savings potential. Notwithstanding, this Section exempts from the competitive acquisition requirements durable medical equipment and certain off-the-shelf orthotics where they are furnished by a physician or other practitioner as part of his or her professional services or where they are furnished by a hospital to its patients during an admission or on the date of discharge.

After CMS implements Round 2 of the competitive acquisition program and for competitions occurring before 2015, certain areas will be exempt from inclusion in the program. These areas include rural areas, metropolitan statistical areas with a population of less than 250,000 that were not selected under Round 1 or Round 2, as well as areas with a low population density within a metropolitan statistical area that is otherwise selected.

This Section further revises requirements related to the Secretary’s duty to establish and implement quality standards for DMEPOS suppliers. Specifically, the Secretary must designate one or more independent accreditation organizations for DMEPOS suppliers. On or after October 1, 2009, the Secretary must require DMEPOS suppliers, whether they are direct suppliers or subcontractors for another entity, to submit evidence that the supplier meets applicable quality standards. These quality standards and accreditation requirements will not apply to individual professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to the professional or person. The Secretary also may exempt professionals and persons from the quality standards if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply.

This Section leaves intact the Secretary’s ability to waive such provisions of the Federal Acquisition Regulations as are necessary for the efficient implementation of the competitive acquisition program. However, the Secretary also must provide for a competitive acquisition ombudsman who will respond to complaints and inquiries made by suppliers and individuals relating to the competitive acquisition program.

This Section also increases reporting requirements for DMEPOS suppliers under the competitive acquisition program. Not later than ten days after a supplier enters into a contract with the Secretary, the supplier must disclose each subcontracting relationship it has in furnishing items and services under the contract and whether each such subcontractor meets applicable accreditation requirements. The same reporting time limits and requirements apply when a supplier enters into a subcontracting relationship at some time after entering into a contract with the Secretary.

This Section also implements special rules of competition for diabetic testing strips. After Round 1 of the competitive acquisition program, the Secretary must reject the bid of any diabetic testing strip supplier if the entity does not demonstrate that its bid
Subtitle D – Provisions Relating to Part C

Sec. 161. Phase-Out of Indirect Medical Education (“IME”)

Section 161 phases out the payments made to MA plans for the indirect medical education costs incurred by teaching hospitals. This cost-saving measure begins in 2010. This Section does not affect the IME payments teaching hospitals receive directly under Fee-For-Service Medicare for these costs.

Sec. 162. Revisions to Requirements for Medicare Advantage Private Fee-for-Service (“PFFS”) Plans

Under Section 162, effective for the 2011 plan year, PFFS plans may no longer rely on deeming for network adequacy, except in limited circumstances when there are not at least two network-based plans in the service area. This exception is intended to permit for deeming in rural areas. Employer-based PFFS plans are not subject to this exception and must rely on provider contracts.

In addition, effective for the 2010 plan year, PFFS plans must implement a quality improvement plan and must collect, analyze and report data that permits for the measurement of health outcomes and other indices of quality.

The Congressional Budget Office estimates that these restrictions will have a significant impact on PFFS plan participation and will lead to reduced beneficiary enrollment.

Sec. 163. Revisions to Quality Improvement Programs

Section 163, as of January 1, 2010, extends to MA PFFS plans and medical savings account (“MSA”) plans the requirement to have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees. With regard to a plan’s duty to collect, analyze and report data permitting measurement of health outcomes and other indices of quality, this Section provides that data collection requirements for PFFS plans and MSA plans may not exceed the requirements applicable to MA local preferred provider organization plans.

Sec. 164. Revisions Relating to Specialized Medicare Advantage Plans for Special Needs Individuals

There are several important provisions that affect Special Needs Plans (“SNPs”). Most importantly, Section 164 extends the authority for SNPs for an additional year, until
December 2010 and sustains the existing moratorium on disproportionate SNPs. In addition, there are several provisions that are intended to address the concern that SNPs are not “special.”

Effective for the 2010 plan year, all beneficiaries must qualify as having a special need (i.e., institutionalized, dual eligible or chronic condition). In addition, consistent with previous CMS guidance, all SNPs must have in place an evidence-based model of care that is periodically audited by CMS. This is intended to ensure that the SNP is focusing on the special population. For dual SNPs, the plan must provide, prior to enrollment, materials that explain the benefits and cost-sharing protections afforded under the state Medicaid program. The materials will use standard content and format established by CMS. In addition, the plan must have a contract with the State Medicaid Agency to provide or arrange Medicaid benefits as of January 1, 2010. If the plan does not have a contract, it can continue to operate but beginning January 2010, the plan cannot expand its service area.

Section 164 also clarifies the definition of severe or chronic conditions for chronic care SNPs and requires the Secretary to convene a panel of clinical advisors to determine the conditions that meet the definition of severe and disabling conditions.

Sec. 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

Section 165 provides that, effective for the 2010 plan year, SNPs may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to full-benefit dual eligible individuals and qualified Medicare beneficiaries if the individual were not enrolled in the plan.

Sec. 166. Adjustment to the Medicare Advantage Stabilization Fund

The MA Regional Stabilization Fund was created under the Medicare Modernization Act of 2003 to regional PPOs that were new entrants (as national or regional plans) or remained in underserved areas. Section 166 reduces the Fund to $1. Savings from the bidding process will continue to flow into the Fund.

Sec. 167. Access to Medicare Reasonable Cost Contract Plans

Section 167 extends the period of time for offering Cost Contract plans by one year, until December 31, 2009. In addition, the GAO shall conduct a study of the reasons why cost contractors are unable to become MA plans. The report must be submitted to Congress by December 31, 2009.
Secs. 168-169. MEDPAC Study and Report on Quality Measures and Medicare Advantage Payments

Sections 168-169 require MEDPAC to conduct a study of performance and experience under MA plans and compare the quality of care across MA plans as well as compared to original Medicare. The report will be submitted to Congress by March 31, 2010. In addition, MEDPAC shall submit a report on MA plan costs compared to original Medicare and recommend alternative approaches to payment.

Sec. 171. Prompt Payment by Prescription Drug Plans and MA-PD Plans Under PD

Beginning with the 2010 plan years, Section 171 requires PD and MA-PD plans to pay clean claims within 30 days, or within 14 days if submitted electronically. If not paid within the proscribed time frames, interest must be paid.

Sec. 172. Submission of Claims by Pharmacies Located in or Contracting with Long-Term Care Facilities

Effective January 1, 2010, Section 172 gives long term care pharmacies at least 30 days, but no more than 90 days, to submit claims to PD and MA-PD plans.

Sec. 173. Regular Update of Prescription Drug Pricing Standard

Beginning January 1, 2009, under Section 175, PD and MA-PD plans must, if the reimbursement to the pharmacy is based on the cost of the drug, update the drug pricing standards at least weekly. An initial update must be made on January 1 of each year to accurately reflect the market price of acquiring the drug.

Sec. 175. Inclusion of Barbiturates and Benzodiazepines as Covered PD Drugs

Beginning January 1, 2013, under Section 175, benzodiazepines drugs (such as Valium and Xanax) and barbiturates used for the treatment of epilepsy, cancer and chronic mental disorders, are covered PD drugs.

Sec. 176. Formulary Requirements with Respect to Certain Categories or Classes of Drugs

Beginning January 1, 2010, Section 176 requires the Secretary to identify, as appropriate, categories or classes of drugs which (i) if restricted would have a major or life threatening clinical consequence; and (ii) there is a significant clinical need for such individuals to have access to multiple drugs within a category or class. Plans must cover all drugs in the class or category unless there are exceptions based on scientific evidence and medical standards of practice.
Subtitle F – Other Provisions

Sec. 181. Use of PD Data

Section 181 provides that PD data is available for public health research purposes, including congressional support agencies.

Sec. 182. Revision of Definition of Medically Accepted Indication for Drugs

Section 182 provides that “medically accepted indication” is defined to include any FDA-approved use or, in the case of an FDA-approved drug, any other use supported by the compendia specified by law or deemed authoritative by the Secretary.

Sec. 183. Contract with a Consensus-Based Entity Regarding Performance Measurement

Section 183 requires the Secretary to identify and contract with a consensus-based entity to make recommendations on priorities and an integrated national strategy for health care performance measurement in all settings. The entity must ensure that priority is given to measures that (a) address health care provided to patients with prevalent, high-cost chronic diseases; (b) have the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and (c) may be implemented rapidly based on existing evidence, standards of care, or other reasons. The entity with which the Secretary contracts must provide for the endorsement of standardized health care performance measures. The entity also will be responsible for establishing and implementing a process to ensure that the endorsed performance measures are updated or retired as new evidence is developed.

The contracted entity must be a private nonprofit governed by a board. The members of the board must include (a) representatives of health plans and health care providers or representatives of groups representing such health plans and providers; (b) health care consumers or representatives of groups representing health care consumers; and (c) representatives of purchasers and employers or representatives of groups representing purchasers or employers. The entity’s membership also must include persons who have experience with urban health care issues, safety net health care issues, rural and frontier health care issues, and health care quality and safety issues. Furthermore, the entity must have at least four years of experience in establishing national consensus standards.

Funding for this effort is set at $10,000,000 per year for each of the 2009 through 2012 FFYS. Contracts with consensus-based entities under this Section must be competitively bid under procedures defined in the Office of Federal Procurement Policy Act, 41 U.S.C. § 403(5). Each contract must be for a period of four years.
Sec. 184. Cost-Sharing for Clinical Trials

Section 184 authorizes the Secretary to develop alternative payment methods for items and services provided under clinical trials and comparative effectiveness studies, to the extent alternative methods are necessary to preserve the scientific validity of such trials or studies. This Section also indicates that an alternative payment method would be appropriate, for example, if masking the identity of interventions from patients and investigators is necessary to comply with a trial or study design.

Sec. 185. Addressing Health Care Disparities

Section 185 requires the Secretary to evaluate existing information collection processes in order to optimize the collection of data on disparities in health care services and performance based on race, ethnicity and gender. An initial evaluation must be submitted to Congress within 18 months, and a final report (with recommendations for improvements) within four years of enactment of this provision. Recommendations in this final report would have to be implemented within an additional 24 months.

Sec. 186. Demonstration to Improve Care to Previously Uninsured

Section 186 requires the establishment of a new demonstration project to identify the most important health care needs of Medicare beneficiaries who were previously uninsured and the most effective outreach approaches to those individuals. This project must be established within one year after enactment and must involve at least ten sites, including community health centers and other existing service providers under Medicare Parts A, B and C. The project will continue for two years, and a report must be submitted to Congress within one year thereafter.


Section 187 requires that, within two years of enactment, the Office of the Inspector General for the Department of Health and Human Services (“OIG”) shall issue a report regarding (a) the extent to which Medicare providers and plans are complying with existing CLAS requirements; (b) the costs of (and/or savings related to) CLAS compliance; and (c) recommendations for improving compliance with current CLAS standards, and for improving those standards themselves.

Sec. 188. Medicare Improvement Funding

Section 188 requires the Secretary to establish the Medicare Improvement Fund, which shall be available to the Secretary to make improvements to the Medicare fee-for-service program.
Sec. 189. Inclusion of Medicare Providers and Suppliers in Federal Payment Levy and Administrative Offset Program

Section 189 requires CMS to process Medicare payments through the Federal Payment Levy Program under §6331(h) of the Internal Revenue Code of 1986, through a phase-in to be completed by September 30, 2011. As a result, the Federal government will be able to levy Medicare payments due the taxpayer to recover delinquent tax liabilities. This Section also extends the administrative offset provisions of 31 U.S.C. §3716 to Medicare payments.

Title II - Medicaid

Sec. 201. Extension of Transitional Medical Assistance ("TMA") and Abstinence Education Programs

Section 201 extends these programs from June 30, 2008 to June 30, 2009.

Sec. 203. Pharmacy Reimbursement Under Medicaid

Section 203 delays application of the new payment limit for multi-source drugs under Medicaid through September 30, 2009, and directs the Secretary not to take any action to impose the specific upper limit prior to October 1, 2009. Congress also has imposed a temporary suspension on the Secretary publishing updated “average manufacturer price” data, prior to October 1, 2009.

Sec. 204. Review of Administrative Claim Determinations

Section 204 establishes new guidelines and administrative procedures that apply to states that wish to obtain judicial review of disallowances by the Secretary relating to the amount of federal financial participation (“FFP”) for Medicaid expenses claimed by the state.

Title III - Miscellaneous

Sec. 304. IOM Reports on Best Practices for Conducting Systematic Reviews of Clinical Effectiveness Research and for Developing Clinical Protocols

Within 60 days of the enactment, Section 304 requires the Secretary to enter a contract with the Institute of Medicine (“IOM”) under which the IOM will conduct a study to identify best practices for conducting systematic reviews of clinical effectiveness research. During the same period, the Secretary must also contract with the IOM for a study on best practices in developing clinical protocols. The provision requires the
participation in both studies of stakeholders with appropriate expertise. Under each contract, the IOM is required to submit the results of each study, along with recommendations for legislation and administrative action, to the Secretary and appropriate congressional committees. The studies are to be funded through Treasury funds not otherwise appropriated, $3,000,000 for FFYS 2009 and 2010.