Title I – Medicare (GOEO8409)

Subtitle A – Beneficiary Improvements

Part I – Prevention, Mental Health, and Marketing

Section 101. Improvements to Coverage of Preventive Services

Current Law

Medicare Part B provides coverage for a range of preventive services including certain vaccines, mammograms, colorectal cancer screening tests, prostate cancer screening tests, and pap smears and pelvic exams. The program also covers a one-time "Welcome to Medicare" exam within the first six months of enrollment in Part B; coverage is provided for a physical exam and referral for preventive and other screening services covered under Part B. Regular Part B and deductible cost-sharing apply for preventive services, except as otherwise specified.

Explanation of Provision

The provision would add "additional preventive services" to the list of covered services. The term "additional preventive services" would mean services not otherwise described in Title XVIII that identify medical conditions or risk factors and that the Secretary determined were: (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 would be required to use the process for making national coverage determinations. As part of the use of such process, the Secretary could conduct an assessment of the relation between predicted outcomes and the expenditures for such services and could take into the account the results of such assessment in making such determination.

The provision would specify that that payment for "additional preventive services" would be equal to 80% of the lesser of the actual charge or the amount determined under a fee schedule established by the Secretary. Clinical diagnostic laboratory services would be paid according to the payment rules currently in effect for such services.

The provision would specify that nothing in this section could be construed to provide coverage under Medicare of items and services for the treatment of a medical condition not otherwise covered under Medicare.

The provision would modify the list of services covered under the initial preventive physical exam to include measurement of body mass index. It would also add end-of-life planning upon agreement with the individual. End of life planning would be defined as verbal or written information regarding an individual's ability to prepare an advance directive in the case that an injury or illness causes 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.

The provision would waive the deductible for the initial preventive screening exam. It would also extend the eligibility period from the first six months to the first year of Part B enrollment.

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

Current Law

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.

Explanation of Provision

The provision would raise 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 was fully phased-in in 2014, outpatient psychiatric services would be paid on the same basis as other Part B services.

The provision would also clarify that the term treatment does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

Section 103. Prohibitions and Limitations on Certain Sales and Marketing Activities under Medicare Advantage Plans and Prescription Drug Plans

Current Law

Marketing materials and application forms from MA plans cannot be distributed to eligible enrollees unless two conditions are met: (1) they have been submitted for the Secretary's review at least 45 days prior to distribution, and (2) the Secretary has not

disapproved their distribution. If an MA plan uses model marketing materials developed by the Secretary, the review period is reduced from 45 to 10 days.

Each MA plan is required to conform to fair marketing standards. The standards are required to include a prohibition against providing cash or other monetary rebates to induce enrollment, and may include a prohibition against an MA plan or agent completing an election form on behalf of any individual. When applying the standards, the Secretary can disapprove materials that are inaccurate or misleading.

PDP plans are statutorily required to comply with the same marketing requirements as MA plans.

Explanation of Provision

This provision would expand the current prohibition against providing cash or other monetary rebates to induce enrollment. MA and PDP plans would be prohibited from providing cash, gifts, prizes, or other monetary rebates to induce enrollment. The provision would also establish new prohibitions on marketing-related activities. For plan years beginning January 1, 2009, MA and PDP plans would be prohibited from engaging in the following four activities: (1) contacting prospective enrollees directly, either through door-to-door solicitation or outbound telemarketing, without the enrollee previously initiating contact; (2) selling non-health related products, such as annuities and life insurance (i.e. cross-selling), during any sales or marketing activity; (3) providing meals to prospective enrollees at promotional and sales activities; and (4) marketing or selling MA or PDP plans at educational events or in areas where health care is delivered (i.e. physician offices or pharmacies). Plans could, however, continue to conduct marketing or sales activities in health care common areas. These prohibitions would apply to MA and PDP plans as well as their agents, brokers, and other third parties representing the plan.

The provision would require the Secretary establish limitations on other marketing activities conducted by MA and PDP plans, including the scope of marketing appointments with beneficiaries, co-branding, gifts to prospective enrollees, agent compensation, and agent training. Plans would be required to document in advance agreements with prospective enrollees on the scope of marketing appointments. Documentation for in-person appointments would be required to be in writing. The Secretary would be required to establish limitations on co-branding and the offering of gifts and other promotional items greater than a nominal value. Co-branding is defined as the use of a network provider's name or logo on plan membership and marketing materials. The Secretary would be required to establish limitations on compensation, other than as provided under guidelines. Guidelines would be required to ensure that agent and broker compensation creates incentives to enroll individuals in health care plans best suited to their needs. Finally, the Secretary would be required to establish limitations regarding an MA or PDP plan's use of an agent or broker that has not completed an initial or annual training or testing program. The Secretary would have the

authority to establish the effective date for these limitations provided it is no later than November 15, 2008.

For plan years beginning January 1, 2009, the provision would establish new requirements related to plan agents and brokers. Plans would be required to use only State licensed agents and brokers and abide by state appointment laws (in states with appointment laws). Plans would also be required to report to the State any agent or broker terminations and reasons for their termination (as required under State law). Further, each plan would be required to comply in a timely manner to State requests for information regarding the performance of a licensed agent, broker, or other third party.

Finally, the provision would add an additional requirement related to the names of MA plans. For plan years beginning on or after January 1, 2010, MA and PDP plans would be required to include the type of plan in its name using standard terminology developed by the Secretary.

Section 104. Improvements to the Medigap Program

Current Law

Many Medicare beneficiaries have individually purchased health insurance policies, commonly referred to as "Medigap" policies. Beneficiaries with Medigap insurance typically have coverage for Medicare's deductibles and coinsurance; they may also have coverage for some items and services not covered by Medicare. Individuals generally select from one of 10 standardized plans (Plan "A" through Plan "J," though not all 10 plans are offered in all states). 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. MMA added two new standardized plan types, Plan "K" and Plan "L" which, unlike the other standardized plans, eliminated first-dollar coverage for most Medicare cost-sharing and included an annual out-of-pocket limit on such charges.

Explanation of Provision

The provision would require the Secretary to provide for the implementation of the changes in the NAIC model law and regulation approved by the NAIC in its Model #651 (“Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act”) on March 11, 2007, as modified to reflect the changes in this Act and the Genetic Information Nondiscrimination Act of 2008 (P.L.110-233). The modifications would have to be completed by the Commissioners by October 31, 2008. Each state would have one year from the date the NAIC adopted the revised NAIC model law and regulation to conform to the regulatory program established by the State to such revised NAIC model law and regulation. Extension of the effective date would be permitted in the case where a state required legislation. In this case, a state would not be regarded as failing to comply solely on the basis of its failure to meet the requirement before the first day of the first calendar quarter beginning after the close of the first

regular session of the state legislature that begins after the date of enactment. In the case of a state with a 2-year legislative session, each year would be considered to be a separate regular session.

The provision would prohibit a carrier from issuing a new or revised Medigap policy that met the requirements of the revised NAIC model law and regulations for coverage effective before June 1, 2010. A carrier could continue to offer or issue a Medigap policy meeting the requirements of the NAIC model law and regulations and state law (as in effect prior to revisions) prior to June 1, 2010. Nothing would prohibit carriers from marketing new or revised Medigap policies meeting the requirements of the revised NAIC model law and regulations on or after the date the state conformed its regulatory program to the revisions.

Policy issuers would be required to offer at least policies with benefit packages "C" and "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

Current Law

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. Further, they are not otherwise eligible for Medicaid. The QI-1 program is currently slated to terminate June 2008.

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 percent 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 would 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.

Explanation of Provision

The provision would extend authorization for the QI-1 program through December 2009. It would also extend 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 increase the allocation amount for this period to $300 million. The provision would also allocate $100 million for the period that begins October 1, 2008 and ends December 31, 2008; would allocate $350 million for the period that begins January 1, 2009 and ends September 30, 2009; and would allocate $150 million for the period that begins October 1, 2009 and ends on December 31, 2009.

Section 112. Application of Full LIS Subsidy Assets Test under Medicare Savings Program

Current Law

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.

Qualified Medicare Beneficiaries (QMBs) are among these eligible groups. QMBs have incomes no greater than 100% of the federal poverty level (FPL) and generally have assets that are no greater than $4,000 for an individual and $6,000 for a couple.

Explanation of Provision

Beginning January 1, 2010, this provision would allow individuals to qualify as QMBs with assets levels of $6,000 for an individual and $9,000 for a couple as of 2006. These amounts would be updated annually by increases in the Consumer Price Index (CPI) and rounded to the nearest multiple of $10.

Section 113. Eliminating Barriers to Enrollment

Current Law

State Medicaid programs make eligibility determinations for persons applying for coverage under a Medicare Savings Program (MSP). States may also make eligibility determinations for persons applying for the low-income subsidy (LIS) under the Medicare Part D drug program. The Commissioner of the Social Security Administration (SSA) is required to make such LIS determinations for persons applying at SSA offices.

Current law requires the Commissioner of Social Security to conduct outreach efforts to identify persons potentially eligible for assistance under the MSP program and to notify such persons of the availability of assistance. Outreach efforts are to be coordinated with the States.

Explanation of Provision

The provision would extend the outreach requirements currently applicable for the Commissioner of Social Security. The Commissioner would be required, for each individual submitting an applications 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 MSP program; (2) provide an application for enrollment under the LIS program (if not already received by the Commissioner); (3) transmit data from such application to the state for purposes of initiating an application for MSP; (4) provide information on how the individual could obtain assistance in completing the application and an application under the MSP program, including information on how they could contact the appropriate State health insurance assistance program; and (5) make such application and information available in local social security offices. The Commissioner would be required to provide training to SSA employees who were involved in receiving LIS applications; the training would be to promote beneficiary understanding of the LIS and MSP programs in order to increase participation in these programs. The employees would be required to assist applicants, upon request, in completing an LIS application.

Beginning January 1, 2010, the Commissioner would be required, with the applicants consent, to transmit data from the LIS application to the appropriate state Medicaid agency. The transmittal would initiate an application of the individual for MSP benefits. The Commissioner would be required to consult with the Secretary (after the Secretary consulted with the states) regarding the content, form, frequency, and manner of data transmittals (on a uniform basis for all states). The required consultation would be intended to ensure that the data transmittal provided effective assistance for state adjudication of MSP benefit applications.

The provision would provide for reimbursement of SSA costs. It would appropriate $21.1 million dollars to the Commissioner to be available October 1, 2008 and to remain available until expended. It would appropriate $24.8 million for FY 2009 to carry out LIS activities to remain available until expended. The FY 2009 funds would be in addition to SSA's Limitation on Administrative Expenditure appropriations. Effective for fiscal years beginning with FY2011, the Commissioner and the Secretary would enter into an agreement which would provide funding for administration of activities of the Commissioner under this section. The agreement would (1) provide funds to the Commissioner for SSA's required MSP-related activities under this section; (2) provide advance quarterly funding based on agreed estimating methodology; and (3) require an annual accounting and reconciliation of actual costs. The provision would appropriate to the Secretary solely for the purpose of providing payments to the Commissioner under an agreement not more than $3 million for each fiscal year beginning with 2011. In no case could funds from SSA's Limitation of Administrative Expenses be used to carry out activities under this section. Beginning with FY 2011, no activities could be undertaken by SSA unless the agreement was in effect and full funding provided to the Commissioner.

GAO would be required to conduct a study of the impact of this section on increasing participation in MSP and on states and the SSA. GAO would be required to submit a report by January 1, 2012 to Congress, the Commissioner, and the Secretary.

States would be required to accept data transmitted under this section and to act on the data in the same manner and in accordance with the same deadlines as if the data constituted an initiation of an MSP application submitted directly by the individual. The date of the individual's application for LIS from which the summary data was derived would constitute the application date for MSP.

Except as otherwise provided, the provision would be effective January 1, 2010.

Section 114. Elimination of Medicare Part D Late Enrollment Penalties Paid by Subsidy Eligible Individuals

Current Law

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 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.

Explanation of Provision

The provision would waive 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

Current Law

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.

There are two instances in which states are required to seek recovery of payments for Medicaid assistance: (1) when an individual of any age is an inpatient in a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR) and is not reasonably expected to be discharged from the institution and return home; and (2) when

an individual age 55 years and older receives Medicaid assistance for nursing facility services, home and community-based services and related hospital and prescription drug services. Included in these groups are dual eligibles who are entitled to Medicare Part A and/or Part B and are eligible for full Medicaid benefits.

Explanation of Provision

The provision would 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 would take effect as of January 1, 2010.

Section 116. Exemptions from Income and Resources for Determination of Eligibility for Low-Income Subsidy

Current Law

The definitions of income and assets used for making eligibility determinations for low-income subsidies generally follow that used for determining eligibility under the QMB, SLIMB, and QI-1 programs (which in turn link back to the definitions used for purposes of the SSI program). There are, however, some differences. For purposes of low-income subsidy determinations, only liquid resources (or those that could be converted to cash within 20 days) and real estate that is not the applicant's primary residence is considered. Liquid resources include such things as checking and savings accounts, stocks, and bonds. Vehicles are excluded because they are not considered liquid assets. The first $1,500 of burial expenses is also excluded.

Explanation of Provision

For purposes of the low income subsidy program, the provision would exclude from the definition of income support and maintenance furnished in kind. It would also exclude from the definition of resources any part of the value of any life insurance policy. The provision would be effective January 1, 2010 and apply to eligibility determinations for months beginning January 2010.

Section 117. Judicial Review of Decisions of the Commissioner of Social Security under the Medicare Part D Low-Income Subsidy Program

Current Law

The processes for redetermining eligibility and for appealing findings of ineligibility for low income subsidy assistance are dependent upon the entity originally making the determination. For eligibility determinations made by a state Medicaid agency, redeterminations and appeals are made in accordance with the state agency=s processes. For eligibility determinations made by the Commissioner of Social Security,

redeterminations may be made at such time or times as provided by the Commissioner. With respect to appeals, the Commissioner is required to have in place an appeals process similar to the process described in Title XVI of the Social Security Act for those requesting hearings following unfavorable determinations for Supplemental Security Income payments.

Explanation of Provision

With respect to eligibility determinations made by the Commissioner of Social Security, a right to a judicial review would be added for those found ineligible for low-income subsidies. This opportunity would be provided following the final determination by the Commissioner. The judicial review process would be as provided under the Social Security Act for individuals appealing Social Security payment decisions as described in Section 205 of the Social Security Act. The provision would take effect as if included in the enactment of Section 101 of the MMA.

Section 118. Translation of Model Form

Current Law

Medicaid law requires the Secretary to develop and distribute to the states a simplified application form for use by individuals (including both qualified Medicare beneficiaries and specified low income beneficiaries) in applying for Medicare cost-sharing assistance in states which elect to use the model form.

Explanation of Provision

The provision would require the Secretary to provide for the translation of the model application form into at least 10 languages, other than English, most often used by individuals applying for Medicare Part A. The translated forms would be made available to States and to the Commissioner of Social Security. The provision would be effective January 1, 2010.

Section 119. Medicare Enrollment Assistance

Current Law

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. In April 2008, CMS announced the distribution of $36 million to SHIPs and noted that it was the first installment of more than $50 million that would be provided in FY2008.

Explanation of Provision

The provision would require the Secretary to provide for the transfer, in appropriate proportions from the Federal Hospital Insurance Trust fund and the Federal Supplementary Medical Insurance Trust fund, of a total of $7.5 million to the CMS Program Management Account for FY 2009 for the purpose of making grants to the states for SHIPs. The funds would remain available until expended. The funds would be allocated to the states as follows. Two-thirds of the total would be allocated among the states based on the number in each state of persons 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 would be allocated among the states based on the number in each state of Part D eligible beneficiaries residing in rural areas relative to the total number of such individuals in all states. The portion of the grant based on the percentage of low-income beneficiaries would be used to provide outreach to individuals who may be subsidy eligible individuals or eligible for the Medicare Savings program.

The provision would require the Secretary, to provide for the transfer, in appropriate proportions from the Federal Hospital Insurance Trust fund and the Federal Supplementary Medical Insurance Trust fund, of a total of $7.5 million to the Administration on Aging for FY 2009 for the purpose of making grants to the states for area agencies on aging. In making the grants, the Secretary would act through the Assistant Secretary for Aging. The funds would remain available until expended. The allocation to the states would be made in the same way as the allocation is made for SHIPs. Each grant would be used to provide outreach to eligible Medicare beneficiaries regarding program benefits with the portion based on the percentage of low income beneficiaries to be used to provide outreach to persons who may be subsidy eligible individuals or eligible for the Medicare Savings program.

The provision would require the Secretary to provide for the transfer, in appropriate proportions from the Federal Hospital Insurance Trust fund and the Federal Supplementary Medical Insurance Trust fund, of a total of $5.0 million to the Administration on Aging for FY 2009 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 Center grant program. The funds would remain available until expended. Each grant would be used to provide outreach to individuals regarding benefits under Part D and the Medicare Savings Program.

The provision would require the Secretary, acting through the Assistant Secretary for Aging, in cooperation with related Federal agency partners, to make a grant to, or enter a contract with, a qualified experienced entity. The entity would maintain and update web-based decision support tools and integrated person-centered systems designed to inform older individuals about the full range of benefits for which the individuals may be eligible under Federal and state programs. The entity would utilize cost-effective strategies to find older individuals with the greatest economic need and inform them of the programs. The entity would develop and maintain an information clearinghouse on best practices and the most cost effective methods for finding such individuals. The entity would also provide, in collaboration with related federal partners administering the Federal programs, training and technical assistance on the most

effective outreach, screening and follow-up strategies for Federal and state programs. The Secretary would be required to provide for the transfer, in appropriate proportions from the Federal Hospital Insurance Trust fund and the Federal Supplementary Medical Insurance Trust fund, of $5.0 million to the Administration on Aging for FY 2009 for the purpose of making a grant or entering into a contract with an entity.

Subtitle B – Provisions Relating to Part A

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

Current Law

The 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). Grants may be awarded to States to implement the rural hospital flexibility program and to improve the provision of rural emergency medical services. Grants of up to $50,000 may be awarded to small rural hospitals to upgrade their data systems and meet the requirements imposed by the BBA (known as Small Hospital Improvement Program or SHIP grants). 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.

Explanation of Provision

The purpose of the grant program would be expanded. The Secretary would 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 and other residents of rural areas, including rural census tracks, as defined by HRSA. This would include the provision of crisis intervention services and the detection of post-traumatic brain injury and other signature injuries of veterans of Operation Iraqi Freedom and Operation Enduring Freedom and for the referral of such veterans to medical facilities operated by the Department of Veterans Affairs.

When awarding grants, the Secretary would be able to consider whether a state's application includes proposals to use regional approaches, networks, health information technology, telehealth or telemedicine to deliver services. A network may include federally qualified health centers, rural health clinics, home health agencies, community mental health clinics and other providers of mental health services, pharmacists, local government and other providers deemed necessary to meet the needs of veterans. The Secretary would require the State demonstrate appropriate consultation with the state hospital association, rural hospitals, mental health providers, and other stakeholders.

When awarding grants, the Secretary would be 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 would 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 would be delivered under the application.

The Secretary would consult, as appropriate, with the Director of the Office of Rural Health of the Department of Veterans Affairs in awarding grants to states. A state awarded such a grant may use the funds to reimburse providers of services. A state would not be able to expend more than 15% of the grant amount on administrative expenses. The Secretary would provide for an independent evaluation of the mental and other health grants. No later than one year after the date on which the last grant is awarded, the Secretary would submit a report to Congress which would 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 would be authorized to spend up to 5% of the total amount appropriated for FLEX and SHIP grants for each of the fiscal years from 2005 through 2008 on administering the grants. Beginning FY2009, HRSA would be authorized to spend up to 5% of the total amount appropriated for FLEX grants, SHIP grants and the newly established grants for rural mental and other health services.

The FLEX grant program would be authorized at $55 million for each fiscal year from 2009 and 2010 and the new rural mental health and other services grants would be authorized at $50 million for each of fiscal years 2009 and 2010 to be available until expended. **{What about the SHIP grants which are established in (g)(3)?}**

The FLEX grant program would be available to provide support for CAHs for quality improvement, quality reporting, performance improvements and benchmarking.

An additional grant program would be established where eligible CAHs would be able to 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. An eligible CAH would submit a grant application as required by the Secretary. The Secretary would not be able to award a grant unless local organizations or the State in which the eligible CAH is located provides matching funds and the CAH provides assurances that it will surrender its CAH status within 180 days of receiving the grant. These grants would not be able to exceed $1 million. There would be $5 million appropriated from the Federal Insurance Trust Fund for making these grants.

Section 122. Rebasing for Sole Community Hospitals

Current Law

Medicare payments to sole community hospitals 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 would result in the largest payment.

Explanation of Provision

For cost reporting periods beginning on or after January 1, 2009, an SCH would be able to elect payment based on its FY2006 hospital-specific payment amount per discharge. This amount would 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

Current Law

No provision.

Explanation of Provision

A demonstration project would be established that would 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. To be eligible to participate, an entity must be a Rural Hospital Flexibility Program grantee and be located in a state where at least 65% of the counties have 6 or few residents per square mile. An eligible entity would apply to participate in the 3-year demonstration as required by the Secretary. The Secretary would select eligible entities in no more than 4 states. These participants would select no more than 6 counties in the state for the project. An eligible county has 6 or fewer residents per square mile and must have a facility designated as a CAH on the date of enactment located in the county that meets certain criteria. Specifically, on the date of enactment, the CAH must have furnished home health services, or hospice care or rural health services and had an average daily inpatient census of 5 or less. At enactment skilled nursing facility services were available in county in a CAH using swing beds or in a local nursing home.

Health care providers participating in the demonstration would be paid at a rate that covers at least the reasonable costs of furnishing acute and extended care as well as other essential health care services. Methods to coordinate the survey and certification process would be tested to assure quality and safety while reducing administrative burden. Participating health care providers and the Secretary would work with the state to revise Medicaid payments to improve access to health care services in frontier counties. The Secretary would identify regulations that may be revised to improve access to care.

The demonstration would be administered jointly by the Office of Rural Health Policy of the Health Resources and Services Administration (HRSA) and the Centers for Medicare and Medicaid Services. HRSA duties would include awarding grants to the eligible entities participating in the demonstration and provide technical assistance to the participants. CMS duties would include the determination of which Medicare and Medicaid provisions that are relevant to the development of alternative payment methods that should be waived. This may include covering at least the reasonable costs of the provider in furnishing acute care, extended care and other essential health services as well as streamlining the survey and certification process across all service categories included in the demonstration project. The Secretary would be able to waive Medicare and Medicaid requirements as may be necessary and appropriate for carrying out the demonstration project. The 3-year project would begin October 1, 2009. The project would be considered to have begun in a state on the date when the eligible counties have begun operations in accordance with the project's requirement. The Secretary would provide for the transfer of necessary funds from the Medicare trust funds. The Secretary would ensure that the aggregate Medicare expenditures do not exceed the amount that would have been expended if the demonstration project would not have been implemented. There would be $800,000 authorized to be appropriated to the Office of Rural Health Policy (ORHP) of HRSA for each of the fiscal years 2010, 2011, and 2112, which would remain available for the project's duration.

No later than 2 years after the demonstration's implementation date, ORHP in coordination with CMS would submit a report to Congress on the project's status and would include initial recommendations on ways to improve access and availability of health care in these counties. No later than one year after the project's completion, the ORHP in coordination with CMS would submit a report to Congress that would include recommendations for legislation and for administrative action.

Section 124. Extension of the Reclassification of Certain Hospitals

Current Law

Section 508 of the MMA provided $900 million for a one-time, 3 year geographic reclassification of certain hospital who were otherwise unable to qualify for administrative reclassification to areas with higher wage index values. These reclassifications were extended from March 31, 2006 to September 30, 2007 by the TRCHA. The MMSEA act extended the reclassifications to September 30, 2008. The extensions were exempt from any budget neutrality requirements.

MMSEA also extended the reclassifications for hospitals that were reclassified through the Secretary's authority to make exceptions and adjustments during the FY2005 rulemaking process until September 30, 2008.

Explanation of Provision

The Section 508 reclassifications would be extended until September 30, 2009. The reclassifications made under the Secretary's authority to make adjustments in the FY2005 rulemaking process were extended to September 30, 2009.

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

Current Law

In order to receive Medicare payments, providers, and most suppliers must meet certain requirements specified in statute and regulation established by the Secretary. Generally, state agencies, under contract with CMS as specified by Section 1864 of the Social Security Act, survey providers and certain suppliers to determine compliance with the conditions or standards set forth in the statute and regulations. Alternatively, a provider can be deemed to meet these requirements if it has been accredited by an approved national accreditation body which has demonstrated that its inspection program ensures that all applicable conditions are met or exceeded.

Under Section 1865(a), a hospital that is accredited by the Joint Commission of Healthcare Organizations (JCAHO) is deemed to meet conditions of participation, except those for utilization review, discharge planning, or other requirements imposed on hospitals under Section 1861(e)(9) that are higher than JCAHO requirements. For JCAHO to be able to deem compliance in these areas, the Secretary is required to determine that JCAHO's process is at least equivalent to the standards promulgated by CMS.

Under Section 1865(b), the Secretary has the authority to grant deeming authority to approved national organizations that accredit other provider entities if these national accrediting organizations demonstrate that Medicare's conditions and requirements are met. The Secretary must consider an organization's accreditation requirements, its survey procedures, the adequacy of available resources for survey activities and the provision of information for enforcement activities, monitoring procedures, and ability to provide necessary validation data when evaluating its application as a deeming entity. Provider entities in this case are defined as providers of services, suppliers, facilities, clinics, agencies or laboratories excluding end-stage renal disease facilities or durable medical equipment suppliers (DME). Under this provision, the Secretary must grant deemed status to any provider entity, except skilled nursing facilities (SNFs), if private accreditation demonstrates compliance with program requirements; with respect to SNFs, the Secretary may grant such deemed status but is not mandated to do so.

Explanation of Provision

This provision would revoke the unique authority granted the Joint Commission of Healthcare Organizations (JCAHO) to accredit hospitals for participation in Medicare. Hospitals, like other Medicare provider entities, would be accredited by national accrediting organizations approved by the Secretary. The Secretary would have the

authority to recognize JCAHO as a national accreditation body. This provision would not take effect until 24 months after the legislation were enacted and would 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

Current Law

Medicare pays for services of physicians and certain nonphysician practitioners on the basis of a fee schedule. With a few exceptions, most physicians' services are considered together in the calculation of the fee schedules, related expenditure targets and annual updates. In some instances, special rules apply to the calculation of Medicare fees for some services including anesthesia, radiology, and nuclear medicine.

The Medicare physician fee schedule assigns relative values to services that reflect physician work (i.e., the time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variations in costs. The adjusted relative values are then converted into a dollar payment amount by a conversion factor.

The physician fee schedule places a limit on payment per service but not on overall volume of services. The formula for calculating the annual update to the conversion factor responds to changes in volume. If the overall volume of services increases, the update is lower; if the overall volume is reduced, the update is higher. The intent of the formula is to place a restraint on overall increases in Medicare spending for physicians' services.

Several factors enter into the current calculation of the annual update (and increase or decrease) of Medicare physician fees. These include (1) the Medicare economic index (MEI), which measures inflation in the inputs needed to produce physicians' services; (2) the sustainable growth rate (SGR), which is essentially a target for Medicare spending growth for physicians' services; and (3) an adjustment that modifies the update, which would otherwise be allowed by the MEI, to bring spending in line with the SGR target. The SGR target is not a limit on expenditures. Rather, the fee schedule update reflects the success or failure in meeting the target. If expenditures exceed the target, the update for a future year is reduced. This is what occurred for 2002. Fee reductions were also slated to occur in subsequent years; however, legislation has prevented this from occurring through June 30, 2008. Under the current update formula, a reduction in the conversion

factor will occur for the next several years. In the absence of legislation, payment rates will be reduced by about 10.6% beginning July 1, 2008 and annually for at least several years thereafter.

MedPAC has recommended that CMS measure physicians' resource use over time and share results with physicians. It states 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. It notes that in the private sector use of feedback has had a small downward trend on resource use. It states that its use by Medicare has the potential to be more successful since it is the single largest purchaser of health care and therefore its reports should command more attention. MedPAC states that using the results for physician education would provide CMS and physicians with experience with the measurement tool and allow for refinements. Once experience and confidence were gained, it could be use the results for payment or to create other incentives.

In an April 2007 report (Focus on Physician Practice Patterns Can Lead to Greater Program Efficiency), GAO explored linking physician compensation to efficiency - defined as providing and ordering a level of services sufficient to meet a patient's needs but not excessive given a patient's health status. The analysis focused on generalists, namely physicians who defined their specialty as general practice, internal medicine, or family practice. The report categorized physicians who treated a disproportionate share of overly expensive patients as outlier generalists. The report found outlier generalist physicians in all twelve metropolitan areas studied. GAO found that Medicare patients who saw outlier generalists were more likely to have been hospitalized, more likely to have been hospitalized multiple times, and more likely to have used home health services. They were however, less likely to have been admitted to a skilled nursing home.

The GAO report noted that certain public and private health care purchasers routinely evaluate physicians in their networks using measures of efficiency and other factors. It noted that the purchasers it studied linked their evaluation results to a range of incentives, from steering patients toward the most efficient providers to excluding physicians from the provider's network because of inefficient practice patterns. GAO noted that while CMS has the tools available to evaluate physician practices it may not have the flexibility that other purchasers have to link physician profiling results to a range of incentives to encourage efficiency.

TRHCA authorized $1.35 billion for 2008 for a Physician Assistance and Quality Initiative Fund, which is to be available to the Secretary for physician payment and quality improvement initiatives. The initiatives may include adjustments to the conversion factor. The Medicare, Medicaid, and SCHIP Extension Act of 2007 (Public Law 110–173) modified the PAQI fund so that $150.5 million would be available for expenditures during 2008, $24.5 million for 2009, and $4.96 billion for 2013.

Explanation of provision

The provision would extend the 0.5% increase in the Medicare physician payment update to the conversion factor from section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Public Law 110–173) through the end of 2008. For 2009, the update to the conversion factor would be 1.1 percent. The conversion factor for 2010 and subsequent years would be computed as if this modification had never applied.

The estimate of Medicare Part B beneficiary premiums for 2009 would be modified by this provision by excluding $1.2 billion of benefits and administrative costs from the calculation.

The amount available in the physician assistance and quality initiative (PAQI) fund would be modified. Specifically, the statute would be modified so that funds for expenditures during 2013, an amount equal to $4.96 billion in current statute, would be eliminated.

The physician quality reporting system, which currently runs only through 2009, would be extended through 2010. The quality measures in 2010 and each subsequent year, including electronic prescribing quality measures, would be those selected by the Secretary from measures that have been endorsed by the consensus-based quality measurement entity with a contract with the Secretary (see section 183). In the case of a specified area or medical topic where no feasible and practical measure has been endorsed by the consensus-based quality measurement entity, the Secretary could specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary, such as the AQA alliance. Providers would have opportunities for input on how the measures would change for 2010. For each quality measure (including an electronic prescribing quality measures) adopted by the Secretary, the Secretary would ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.

The provision would make incentive payments available to physicians under the reporting system for quality measures for the years 2007 through 2010. Eligible professionals who provide covered professional services would 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, would also be paid an incentive payment equal to 1.5 percent for 2007 and 2008 and 2.0 percent for 2009 and 2010 of the allowed charges under this part for all such covered professional services furnished by the eligible professional from the Part B Trust Fund. For years after 2008, electronic prescribing quality measures would not be included among the quality measures for purposes of this incentive program.

The provision would define satisfactory reporting of measures for group practices. By January 1, 2010, the Secretary would establish and have in place a process under

which eligible professionals in a group practice (as defined by the Secretary) would be treated as satisfactorily submitting data on quality measures for the above incentive program if the group practice reports measures determined appropriate by the Secretary, such as measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time, specified by the Secretary. This reporting process would provide for the use of a statistical sampling model to submit data on measures, such as the model used under the Physician Group Practice demonstration project. For years after 2009, the Secretary, in consultation with stakeholders and experts, could revise the criteria for satisfactorily submitting data on quality measures and the criteria for submitting data on electronic prescribing quality measures. The Secretary would post a list of the names of the eligible professionals or the group practices who satisfactorily submitted data on quality measures and the eligible professionals or group practices who are successful electronic prescribers on the CMS website. Nothing in the amendments made by this subsection would affect the incentive payments for 2007 or 2008.

The provision would include qualified audiologists as eligible professionals for purposes of Medicare payment, beginning in 2009. This modification would do nothing to change the way in which billing for audiology services occurs under the Medicare program as of July 1, 2008.

The provision would establish a physician feedback program with the intent to improve efficiency and to control costs. The Secretary would establish a Physician Feedback Program ('Program') under which the Secretary would use Medicare claims data (and could use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to Medicare beneficiaries. If determined appropriate by the Secretary, information on the quality of care furnished to individuals under this title by the physician (or group of physicians) could be used in such reports. 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 Secretary would implement the Program no later than January 1, 2009. To the extent practicable, reports under the Program would be based on the most recent data available. The Secretary could focus the application of the Program as appropriate, such as focusing the Program on (a) physician specialties that account for a certain percentage of all spending for Medicare physicians' services; (b) physicians who treat conditions that have a high cost or a high volume, or both, under Medicare; (c) physicians who use a high amount of resources compared to other physicians; (d) physicians practicing in certain geographic areas; or (e) physicians who treat a minimum number of Medicare beneficiaries.

The Secretary would have the authority to exclude certain information regarding a service from a report under the Program with respect to a physician (or group of physicians) if the Secretary were to determine that there is insufficient information relating to that service to provide a valid report on that service. To the extent practicable, the Secretary would make appropriate adjustments to the data used in preparing reports

under the Program, such as adjustments to take into account variations in health status and other patient characteristics. The Secretary would provide for education and outreach activities to physicians on the operation of, and methodologies employed under, the Program. Reports under the Program would be exempt from disclosure under the Freedom of Information Act.

The Comptroller General of the United States would conduct a study of the Physician Feedback Program as described above, including the implementation of the Program, and would 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.

The provision would require 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 would 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

Current Law

No provision.

Explanation of Provision

The provision would establish 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 would receive an incentive payment from the Federal Supplementary Medical Insurance (Part B) Trust Fund. The amount of the payment would equal a percentage of the allowed charges for all covered professional services furnished by the eligible professional (or by the group practice) during the reporting period. The 'applicable electronic prescribing percent' would decrease over time, from 2.0 percent for 2009 and 2010, to 1.0 percent for 2011 and 2012, and 0.5% for 2013. The Secretary would establish the applicable electronic prescribing percentage based on claims submitted not later than 2 months after the end of the reporting period, as described below.

The electronic prescribing incentive bonus would not apply to an eligible professional (or the group practice) if, for the reporting period (i) the allowed Medicare charges furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing quality measure applies are less than 10 percent of the total of the allowed charges; or (ii) if, as determined by the Secretary, the eligible professional does not submit a sufficient number of prescriptions under part D, both electronically and nonelectronically.

To be eligible for the electronic prescribing incentive payment, an eligible professional would be treated as a successful electronic prescriber for a reporting period (1) if the eligible professional reported each of the measures in at least 50 percent of the cases in which there are any electronic prescribing quality measures that have been established under the physician reporting system, or (2) if the Secretary determines that the eligible professional electronically submitted a sufficient number of prescriptions under part D during the reporting period. Notwithstanding other sections in the Social Security Act, the Secretary could use data submitted for purposes of part D for purposes as described above. To the extent practicable, in determining whether eligible professionals meet the requirements for the electronic prescribing bonus, the Secretary would ensure that eligible professionals use electronic prescribing systems in compliance with standards established pursuant to the Part D Electronic Prescribing Program.

There would be an incentive for Medicare professionals to participate in electronic prescribing; if an eligible professional is not a successful electronic prescriber for the reporting period for the year, the fee schedule amount for their services would be reduced. For 2012, the applicable fee schedule amount would be equal to 99 percent of the fee schedule amount that would otherwise apply; for 2013, the percentage would fall to 98.5 percent; and for 2014 and each subsequent year, 98 percent.

The Secretary could exempt an eligible professional from the application of the electronic prescribing payment adjustment if the Secretary were to determine that compliance with the requirement for being a successful electronic prescriber 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 would submit to Congress a report on the implementation of the incentives for electronic prescribing established by this section. The report would include information regarding the following:

(1) the percentage of eligible professionals that are using electronic prescribing systems, including a determination of whether less than 50 percent of eligible professionals are using electronic prescribing systems;
(2) if less than 50 percent of eligible professionals are using electronic prescribing systems, recommendations for increasing the use of electronic prescribing systems by eligible professionals, such as changes to the incentive payment adjustments established above;
(3) the estimated savings to the Medicare program resulting from the use of electronic prescribing systems;
(4) reductions in avoidable medical errors resulting from the use of electronic prescribing systems;
(5) the extent to which the privacy and security of the personal health information of Medicare beneficiaries is protected when such beneficiaries' prescription drug data and usage information is used for purposes other than their direct clinical care, including (a) whether information identifying the beneficiary is, and remains,

removed from data regarding the beneficiary's prescription drug utilization, and (b) the extent to which current law requires sufficient and appropriate oversight and audit capabilities to monitor the practice of prescription drug data mining; and

(6) such other recommendations and administrative action as the Comptroller General determines to be appropriate.

Section 133. Expanding Access to Primary Care Services

Current Law

For physicians' services furnished on or after January 1, 2005, and before July 1, 2008, Medicare pays a 5% bonus to primary care physicians in identified primary care scarcity counties as well as to non-primary care physicians in a specialist care scarcity county. The Secretary designates scarcity counties based on the county's ranking of the ratio of the number of physicians to the number of Medicare beneficiaries in the area. The lowest ranked counties where 20% of the Medicare beneficiaries reside are designated scarcity areas. The Secretary periodically revises the list of designated scarcity areas, not less often than once every three years.

Explanation of Provision

The provision would expand the incentive payment program for primary care services furnished in physician scarcity areas. For primary care services furnished by a primary care physician in a primary care scarcity county on or after January 1, 2011, a 5% percent incentive payment amount would be paid in addition to the amount that would otherwise be paid under Medicare. The term 'primary care services' would mean procedure codes for services in the category of the Healthcare Common Procedure Coding System, consisting of evaluation and management services, but limited to the procedure codes in the category of office or other outpatient services, and consisting of subcategories of the procedure codes for services for both new and established patients. There would be no administrative or judicial review respecting the identification of primary care physicians, primary care specialty areas, or primary care services under this subsection.

The provision would revise the Medical Home Demonstration Project in Section 204(b) of division B of the TRCHA (42 U.S.C. 1395b–1 note). The Secretary would be given the authority to expand the duration and the scope of the project as appropriate if the Secretary determines that the expansion would meet either of the following conditions: (a) the expansion of the project is expected to improve the quality of patient care without increasing spending under the Medicare; or (b) 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 would be made available from the Federal Supplementary Medical Insurance Trust Fund.

The provision would change the application of the budget-neutrality adjustor from the relative value units to the conversion factor. For fee schedules established beginning with 2009, with respect to the 5-year review of work relative value units used in fee schedules for 2007 and 2008, in lieu of continuing to apply budget-neutrality adjustments for 2007 and 2008 to work relative value units, the Secretary would apply the budget-neutrality adjustments to the conversion factor otherwise determined for years beginning with 2009.

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

Current Law

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. The law specifies that the practice expense and malpractice indices reflect the full relative differences. However, the work index must reflect only one-quarter of the difference. Using only one-quarter of the difference generally means that rural and small urban areas receive higher payments and large urban areas lower payments than if the full difference were used. A value of 1.00 represents an average across all areas. MMA placed a floor of 1.00 on the work adjustment for the 2004-2006 period; TRHCA extended the provision through 2007; and MMSEA extended it through June 30, 2008.

Explanation of Provision

The provision would extend, through December 31, 2009, the period that the floor on the geographic adjustment for work is set at 1.00. Beginning January 1, 2009, it would raise the work geographic adjustment to 1.5 in Alaska if the index would otherwise be less than 1.5.

Section 135. Imaging Provisions

Current Law

MedPAC and other observers have expressed concerns that sizeable volume increases, particularly for imaging services, needed to be addressed. DRA modified the payment rules for certain imaging services. Specifically, the law capped the technical component of the payment for services performed in a doctor's office at the level paid to hospital outpatient departments for such services. The limitation does not apply to the professional component (i.e., the physician's interpretation). Services subject to the cap are defined in Section 1848(b)(4)(B) of the Social Security Act (SSA). They are imaging and computer assisted imaging services including X-rays, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography),

magnetic resonance imaging, computed tomography, and fluoroscopy. Diagnostic and screening mammographies are excluded. The provision was effective January 1, 2007.

MedPAC has noted that providers vary in their ability to perform quality imaging services. It therefore recommended that the Congress direct the Secretary to set standards for all providers who bill Medicare for performing and interpreting diagnostic imaging services.

MedPAC has also noted that the current calculation of practice expenses for imaging providers assumes that the equipment is used half the time the practice is open for business. It suggests that this assumption is an underestimate, thereby yielding a per unit price which is too high.

Explanation of Provision

The provision would specify 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 nuclear medicine (including positron emission tomography). The term also includes such other imaging and computer-assisted imaging services as defined in Section 1848(b)(4)(B) of the SSA (excluding X-ray, ultrasound, and fluoroscopy) as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

The accreditation organization would have to be designated by the Secretary. The Secretary would be required to consider the following factors both in designating an accreditation organization and in reviewing and modifying the list of designated organizations: (1) the ability of the organization to conduct timely review of accreditation applications; (2) whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into its accreditation program; (3) whether the organization uses random site visits, audits, and other strategies for ensuring accredited suppliers maintain adherence to the required accreditation criteria established by the Secretary; (4) the ability of the organization to take into account the capacities of suppliers in rural areas; (5) whether it has established reasonable fees to be charged to suppliers for accreditation; and (6) such other factors as the Secretary determined appropriate.

The Secretary would designate, by January 1, 2010, organizations designated to accredit suppliers furnishing the technical component of advanced diagnostic imaging services.

The Secretary would be required to review the list of designated accreditation organizations, taking into account the specified factors. The Secretary could modify the list taking into account the results of the review. The provision would specify that if the Secretary removed an organization from the designated list, any supplier designated as an

accredited organization from the date of designation to the date it was removed from the list would be considered a designated organization for the remaining period the designation was in effect.

The Secretary would 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 criteria would include: (1) standards for qualifications of nonphysician medical personnel furnishing the technical component; (2) standards for qualifications of medical directors and supervising physicians; (3) procedures to ensure the equipment meets performance specifications; (4) standards that require the supplier to have procedures in place to ensure the safety of individuals who are furnished the technical component; (5) standards that require the establishment of a quality assurance and quality control program; and (6) any other standards or procedures deemed appropriate by the Secretary. The standards relating to evaluation of medical directors and supervisory physicians would be required to recognize whether a medical director or supervisory physician: (1) in a particular specialty receives training in advanced diagnostic imaging in a residency program; (2) has attained, through experience, the necessary expertise; (3) has completed any related continuing medical education courses; or (4) has met such other standards the Secretary determines appropriate.

The provision would specify that a supplier accredited before January 1, 2010, by an accreditation organization designated by the Secretary as of such date, would be considered to be accredited for the remainder of the period the accreditation was in effect.

The provision would require the Secretary to establish a demonstration project using specified models to collect data regarding physician compliance with appropriateness criteria for advanced diagnostic imaging services. The Secretary could 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 exists.

The Secretary would implement the 2-year project beginning no later than January 1, 2010. Each physician desiring to participate in the project would submit an application to the Secretary. The Secretary would make the selection and would ensure that selected physicians represent a wide range of geographic areas and practice settings and would have the capability to submit data to the Secretary (or an entity under contract with the Secretary) in electronic format in accordance with established standards. The Secretary would reimburse physicians for reasonable administrative costs and provide reasonable incentives to encourage physicians to participate.

The Secretary, in consultation with medical specialty societies and other stakeholders, would select criteria with respect to the clinical appropriateness of advanced diagnostic imaging for use in the demonstration. The criteria would have to be developed or endorsed by a medical specialty society and be developed in adherence to appropriateness principles developed by a consensus organization, such as the AQA

alliance. The Secretary would use the following models for collecting data: point-of-service model, point-of-order model, or any other model the Secretary determined to be useful. However, in no case could the Secretary use prior authorization as a model for collecting data regarding physician compliance with appropriateness criteria or under any model used for collecting such data under the demonstration project.

The Secretary would enter into contracts to carry out the model. The Secretary would also be required to establish and enforce performance standards for entities under the contracts including performance standards relating to beneficiary satisfaction, physician satisfaction, timelines (if applicable) for the provision of feedback reports, and any other areas deemed appropriate by the Secretary.

The Secretary would be required to consult with medical specialty societies and other stakeholders to develop mechanisms for comparing utilization of advanced diagnostic imaging services by physicians participating in the project against the established appropriateness criteria and, to the extent feasible, against the utilization of such services by physicians not participating in the project.

The Secretary would develop mechanisms to provide feedback reports to physicians participating in the project. The reports would include: (1) a profile of the rate of compliance by the physician with selected appropriateness criteria, including the physician's own compliance rate and the compliance by the physician's peers; and (2) to the extent feasible, a comparison of the rate of utilization of services by the physician compared with utilization by peers not participating in the demonstration project.

The Secretary would be required to evaluate the demonstration project to assess its timeliness and efficacy and assess the performance of contracted entities. The Secretary would be required to analyze data on: (1) the rates of appropriate, uncertain, and inappropriate advanced diagnostic imaging by physicians participating in the project; (2) patterns and trends in the appropriateness and inappropriateness of such services; (3) patterns and trends in national and regional variations of care with respect to the furnishing of such services; and (4) the correlation between the appropriateness of services and imaging results. The Secretary would also be required to evaluate the project to address: (1) the thresholds used under the demonstration project to identify acceptable and outlier levels of performance; (2) whether the prospective use of appropriateness criteria could have an effect on the volume of such services furnished; (3) whether expansion of such criteria to a broader Medicare population would be advisable; (4) whether under such expansion to physicians who demonstrate consistent compliance with the criteria should be exempted from certain requirements; (5) the use of incident-specific versus practice-specific outlier information in formulating future recommendations for appropriateness criteria; and (6) the potential for using methods, including financial incentives, in addition to the demonstration models, to ensure compliance with criteria.

The Secretary would be required to submit, within 1 year of completion of the demonstration project, a report to Congress containing the results of the evaluation together with recommendations for legislative and administrative action as the Secretary

determined appropriate. The Secretary would provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund of $10 million to carry out the demonstration. The funds would be used for administrating the project, reimbursing physicians for administrative costs, providing incentives to encourage participation, entering into contracts, and evaluating the project.

The GAO would be required to conduct a study by imaging modality of the new accreditation requirement added by this section and any other relevant questions involving access to and the value of advanced diagnostic imaging services for beneficiaries. The study would examine: (1) the impact of such accreditation requirement on the number, type, and quality of imaging services furnished to Medicare beneficiaries; (2) the cost of such accreditation requirement, including costs to facilities of compliance with such requirement and the costs to the Secretary of administering the requirement; (3) access to imaging services by beneficiaries, especially in rural areas, before and after implementation of the requirement; and (4) such other issues as the **Secretary (shouldn't this be GAO??)** determines appropriate. GAO would be required to submit a preliminary report to Congress by March 1, 2013 and a final report, together with recommendations, by March 1, 2014.

The GAO would be required to conduct a study on the assumptions used for interest rate and equipment utilization in the methodology used for determination of practice expense relative value units for imaging services. GAO would be required to collect data for the study for different modalities of imaging equipment used in different types of practices and different geographic areas. GAO would submit a report to Congress on the study together with legislative and administrative recommendation, by June 1, 2010.

Section 136. Extension of Treatment of Certain Physician Pathology Services under Medicare

Current Law

BBA 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. MMSEA extended the provision through June 30, 2008.

Explanation of Provision

The provision would be extended through December 31, 2009.

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

Current Law

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. P.L. 110-54 (enacted August 3, 2007) permitted, for services provided prior to January 1, 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. MMSEA extended this accommodation through June 30, 2008.

Explanation of Provision

The provision would make the accommodation permanent.

Section 138. Adjustment for Medicare Mental Health Services

Current Law

Medicare pays for mental health services under the physician fee schedule.

Explanation of Provision

The provision would increase the fee schedule amount otherwise applicable for specified services by [5%]. The increase would apply for the period beginning July1, 2008 and ending on December 31, 2009. The specified services would be defined as HCCPS procedure codes as of July 1, 2007 (and as subsequently modified by the Secretary) consisting of psychiatric therapeutic procedures furnished in office or other outpatient facility settings or in inpatient hospital, partial hospital, or residential care facility settings. The increase would be limited to such services in such categories that were subcategories of services which are: (1) insight oriented, behavior modifying, or supportive psychotherapy; or (2) interactive psychotherapy.

The Secretary could implement the provision by program instruction or otherwise. The budget neutrality requirement would not apply to these adjustments.

Section 139. Improvements for Medicare Anesthesia Teaching Programs

Current Law

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.

Under the teaching physician policy for complex surgery, the full fee schedule payment can be made for the service of the teaching physician as long as the teaching

physician is present with the resident for the critical or key portions of the service. In order to bill for two overlapping surgeries, the teaching surgeon must be present during the key or critical portions of both surgeries. The teaching physician payment policy has been applied to the teaching anesthesiologist only when the teaching anesthesiologist is involved in one case with a resident.

Non-medically directed teaching certified registered nurse anesthetists (CRNAs) may be paid for involvement with two concurrent cases with student nurse anesthetists but not at the full fee level.

Explanation of Provision

The provision would establish 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 would be 100% of the fee schedule amount otherwise applicable if the anesthesia services were personally performed by the teaching anesthesiologist alone. This payment provision would 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.

The provision would require the Secretary to make appropriate payment adjustments for items and services furnished by teaching CRNAs. These adjustments would be to implement a policy for these individuals that was consistent with the adjustments made by the special rule for teaching anesthesiologists and maintained the existing payment differences between teaching anesthesiologists and teaching CRNAs. The provision would apply to items or services furnished on or after January 1, 2010.

Part II – Other Payment and Coverage Improvements

Section 141. Extension of Exceptions Process for Medicare Therapy Caps

Current Law

The BBA established annual per beneficiary payment limits for all outpatient therapy services provided by non-hospital providers. The limits applied to services provided by independent therapists as well as to those provided by comprehensive outpatient rehabilitation facilities (CORFs) and other rehabilitation agencies. The limits did not apply to outpatient services provided by hospitals.

Beginning in 1999, there were two beneficiary limits. The first was a $1,500 per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second was a $1,500 per beneficiary annual cap for all

outpatient occupational therapy services. Beginning in 2002, the amount was to increase each year by the Medicare economic index (MEI). Subsequent legislation delayed implementation of the cap from 2000 - 2005 (except for a brief period in 2003). The caps went into effect again beginning January 1, 2006. The 2008 caps are each $1,810.

The DRA required the Secretary to implement an exceptions process for 2006 for cases in which the provision of additional therapy services was determined to be medically necessary. TRHCA extended the exception process through 2007. MMSEA extended the process through June 30, 2008.

Explanation of Provision

The provision would extend the exceptions process through 2009.

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

Current Law

The MMA required Medicare's outpatient prospective payment system to make separate payments for specified brachytherapy sources. As mandated by the TRCHA, this separate payment will be made using hospitals' charges adjusted to their costs until January 1, 2008. MMSEA extended cost reimbursement for brachytherapy services until July 1, 2008. MMSEA also specified that therapeutic radiopharmaceuticals will be paid using this methodology for services provided on or after January 1, 2008, and before July 1, 2008.

Explanation of Provision

This provision would extend cost reimbursement for brachytherapy and therapeutic radiopharmaceuticals until January 1, 2010.

Section 143. Speech-Language Pathology Services

Current Law

Medicare Part B covers outpatient services of physical therapists, occupational therapists, and speech-language pathologists. The coverage and payment rules are essentially the same, except that speech therapy performed in independent practice can not be paid for under the program. In the law, outpatient speech-language pathology is included within the definition of outpatient physical therapy.

Explanation of Provision

The provision would establish a separate definition for outpatient speech-language pathology services. It would permit 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 would apply to services furnished on or after January 1, 2009.

The provision would specify that nothing in the section shall be construed to affect existing regulations and policies of the Centers for Medicare and Medicaid Services that require physician oversight of care as a condition of payment for speech-language pathology services under Part B.

Section 144. Payment and Coverage Improvements for Patients with Chronic Obstructive Pulmonary Disease and Other Conditions

A. Coverage of Pulmonary and Cardiac Rehabilitation

Current Law

CMS policy covers cardiac rehabilitation services for a patient with: (1) documented diagnosis of acute myocardial infarction (MI) within the preceding 12 months; (2) coronary artery bypass surgery; (3) stable angina pectoris; (4) heart valve repair/replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or (6) heart or heart-lung transplant. The policy allows up to 18 weeks for a beneficiary to receive the maximum of 36 cardiac rehabilitation services, with additional services covered through local coverage determinations subject to certain limits. Required components of cardiac rehabilitation programs are a medical evaluation, a program to modify risk factors, prescribed exercise, education, and counseling. Services are covered as incident to a physician's professional services and must be under the direct supervision of a physician.

In September 2007, CMS announced that no national coverage determination for pulmonary rehabilitation services was appropriate at the time. Coverage decisions would continue to be made by local contractors. Services that make up the individual components of pulmonary rehabilitation may be covered under various Medicare benefit categories. Respiratory therapy services are identified as covered services under the CORF benefit.

Explanation of Provision

The provision would 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.

The provision would define a cardiac rehabilitation program or a pulmonary rehabilitation program as a physician-supervised program furnishing specified items and services. Items and services would have to be delivered in a physician's office, in a hospital on an outpatient basis, or in other settings determined appropriate by the

Secretary. The physician would have to be immediately available and accessible at all times, except that when services were furnished in a hospital the availability would be presumed. The provision would require individualized treatment furnished under a written plan established, reviewed and signed by the physician at least every 30 days. The plan would describe the patient's diagnosis; the type, amount, frequency, and duration of items and services furnished; and the patient goals.

The provision would define covered items and services under a cardiac rehabilitation program as: physician-prescribed exercise; cardiac risk factor modification and behavioral intervention; psychosocial assessment; and outcomes assessment. The term would also include other items and services as determined by the Secretary, but only if they were reasonable and necessary for the diagnosis or active treatment of the individual's condition; reasonably expected to improve or maintain the individual's condition and functional level; and furnished under frequency guidelines established by the Secretary.

The provision would require the Secretary to establish standards to ensure that a physician with expertise in the management of patients with cardiac pathophysiology (and licensed in the state) was responsible for the cardiac rehabilitation program and involved (in consultation with appropriate staff) in substantially directing its progress.

The provision would define covered items and services under a pulmonary rehabilitation program as: physician-prescribed exercise; education or training; psychosocial assessment; and outcomes assessment. The term would also include other items and services as determined by the Secretary, but only if they were reasonable and necessary for the diagnosis or active treatment of the individual's condition; reasonably expected to improve or maintain the individual's condition and functional level; and furnished under frequency guidelines established by the Secretary.

The provision would require the Secretary to establish standards to ensure that a physician with expertise in the management of patients with respiratory pathophysiology (and licensed in the state) was responsible for the pulmonary rehabilitation program and involved (in consultation with appropriate staff) in substantially directing its progress.

The provision would be effective January 1, 2010.

B. Oxygen Equipment

Current Law

The Deficit Reduction Act (DRA P.L. 109-171) changed how long Medicare would make rental payments for oxygen equipment. It changed from the entire period of medical need, to a rental period of 36-months. After 36 months of rental payments, the supplier is required to transfer the title of the equipment to the beneficiary. Payments for maintenance and servicing (for parts and labor not covered by the supplier's or manufacturer's warranty) are made if the Secretary determines them to be reasonable and

necessary. In the case of an individual receiving oxygen equipment on December 31, 2005, the 36-month period began January 1, 2006.

Medicare Part B pays for certain items of durable medical equipment including oxygen and oxygen equipment. In areas other than competitive acquisition areas described below, payments for oxygen equipment is made on a monthly basis for the entire period of medical need not to exceed 36 months. (Payments for oxygen contents are made for the entire period of medical need). Payments are based on a fee schedule. As of January 1, 2007, as specified in the final rule published November 9, 2006, a fee schedule amount is calculated separately for five categories of oxygen and oxygen equipment: (a) stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable); (b) portable oxygen equipment only (gaseous or liquid tanks); (c) oxygen generating portable equipment only (portable concentrators or transfilling systems); (d) stationary oxygen contents only; and (e) portable oxygen contents only. For 2007 the following represents the calculation of the fee schedule amount for the five categories of oxygen equipment and contents. For stationary equipment and contents, the national limited monthly fee schedule amount is equal to the weighted average fee schedule amount for 2005 and 2006 reduced by $1.44. For portable equipment only, the national limited monthly fee schedule amount is equal to the weighted average of the fee schedule amount for 2005 and 2006. For oxygen generating portable equipment, the national limited monthly payment rate is equal to the national limited monthly payment rate for 2005 and 2006 multiplied by 24 and divided by 36. The national limited monthly payment rate for stationary oxygen contents and portable oxygen contents is equal to half of the weighted fee schedule amount for the oxygen content for 1991 through 2006. Beginning in 2008, CMS makes an annual adjustment to the national limited monthly payment rates for each class of items to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

The Secretary is required to establish a competitive acquisition program for specified durable medical equipment; the competitive acquisition program would replace the Medicare fee schedule payments. The program is to be phased-in, starting in 10 of the largest metropolitan statistical areas (MSAs) in 2008; expanding to 80 of the largest MSAs in 2009 and remaining areas after 2009. The Secretary is permitted to phase-in first items and services with the highest cost and highest volume, or those items and services that the Secretary determines to have the largest savings potential first, which includes oxygen and oxygen equipment.

Explanation of Provision

Effective January 1, 2009, this provision would repeal the requirement that DME suppliers transfer the title for oxygen equipment to the beneficiary after 36 months of continuous use; suppliers would retain ownership of the equipment but would continue to furnish the equipment to the beneficiary during the period of medical need.

The provision would revise payment rates for oxygen and various types of oxygen equipment starting January 1, 2009. For oxygen equipment (other than portable oxygen and oxygen equipment), the provision would establish the monthly rental payment to be equal to: (a) the sum of the monthly payment amount otherwise made for oxygen equipment *and oxygen contents*, less (b) 71% of the monthly payment amount for oxygen contents. The payment for oxygen contents for stationary oxygen equipment would be increased by the amount established by the Secretary (or 71% of that amount paid during the 36-month rental period for the stationary oxygen equipment). The add-on amount for portable oxygen equipment would be equal to the payment amount for portable oxygen equipment and contents after the 36 month rental period. The Secretary would be required to add an additional payment for oxygen generating portable equipment during the 36 month rental period. The add-on payment would be equal to the sum of an amount equal to the monthly payment for portable oxygen and an amount otherwise established by the Secretary for oxygen generating portable equipment.

Starting in 2010, the new payment amounts for oxygen equipment (other than portable oxygen and oxygen equipment) would be updated by the increase in the consumer price index. The payment update would not apply to oxygen equipment furnished in competitive bidding areas.

The total monthly payment amount for liquid or gaseous stationary and portable equipment systems (including add-on payments) would not be allowed to exceed the total monthly payment amounts otherwise recognized if the provisions of the Medicare Improvements for Patients and Providers Act of 2008 had not been enacted. Payment changes and payment updates to oxygen equipment would not apply to equipment furnished in competitive bidding areas.

Not later than 3 months after enactment, the Secretary would be required to enter into a contract with the Institute of Medicine of the National Academies (IOM) to conduct a study on the furnishing of, and payments for, oxygen and oxygen equipment under the Medicare program. The study would be required to include the following: (a) the costs and activities associated with furnishing different types of oxygen equipment, including the acquisition cost, delivery and refilling of contents, delivery of equipment and provision of supplies, training and education, intake of patient information, related documentation, and the servicing of different types of equipment, and other considerations; (b) whether the items and services described above are medically necessary and affect patient outcomes; (c) the adequacy of Medicare payments for oxygen equipment and necessary servicing, and how payment rates compare with the competitive bidding program; (d) whether payments under Medicare should vary by equipment type; (e) the adequacy of add-on payments under Medicare for contents for stationary equipment, contents for portable equipment, and oxygen-generating portable equipment; (f) whether, during the rental period, payments for equipment and servicing should be bundled or separated; and (g) options that could be considered for suppliers to document or report detailed information about furnishing oxygen and oxygen equipment to beneficiaries. As part of the study, the IOM would be required to conduct a survey of oxygen suppliers. Not later than 18 months after enactment, the IOM would be required

to submit a report to the Secretary containing the results of the study. The Secretary would be required to transfer $5 million from the Federal Supplementary Medical Insurance Trust Fund to the Program Management Account to pay for the study.

Section 145. Revision of Payment for Power-Driven Wheelchairs

Current Law

Wheelchairs, including power-driven wheelchairs, are covered by Medicare under the capped-rental category of the durable medical equipment (DME) benefit. Medicare pays for power-driven wheelchairs in one of two ways: either Medicare will pay the supplier a monthly rental amount during the beneficiary's period of medical need (though payments are not to exceed 13 continuous months), or, payment is made on a lump-sum basis at the time the supplier furnishes the chair, if the beneficiary chooses the lump-sum payment option. If the reasonable lifetime of a power-driven wheelchair is reached, or the wheelchair is lost or irreparably damaged, Medicare will pay for a replacement. The beneficiary may elect to have the replacement purchased through (1) monthly rental payments not to exceed 13 months, or (2) a lump-sum payment.

Rental payments for wheelchairs are statutorily determined as 10% of the purchase price of the chair for each of the first 3 months of rental and 7.5% of the purchase price for each of the remaining 10 months of the rental period.

The Secretary is required to establish a competitive acquisition program for specified durable medical equipment; the competitive acquisition program would replace the Medicare fee schedule payments. The program is to be phased-in, starting in 10 of the largest metropolitan statistical areas (MSAs) some time in 2008; expanding to 80 of the largest MSAs in 2009 and remaining areas after 2009. The Secretary is permitted to phase-in first items and services with the highest cost and highest volume, or those items and services that the Secretary determines to have the largest savings potential first, which includes power-driven wheelchairs.

Explanation of Provision

Starting January 1, 2009, the provision would limit the option to purchase a power-driven wheelchair with a lump-sum payment only to complex, rehabilitative power wheelchairs. The lump-sum payment option would be eliminated for all other wheelchairs. The provision would also eliminate the lump-sum purchase option for replacing a wheelchair for all chairs except complex, rehabilitative power wheelchairs. The calculation of rental payments for complex, rehabilitative power wheelchairs would be increased to 15% of the purchase price for the first three months, and 6% of the purchase price for the remaining 10 months. This provision would not apply to contracts entered into under the Durable Medical Equipment Competitive Acquisition Program prior to October 1, 2009.

Section 146. Clinical Laboratory Tests

Current Law

MMA required the Secretary to conduct a demonstration project on the application of competitive bidding for clinical laboratory tests that would otherwise be paid under the physician fee schedule and for which no face to face encounter took place. CMS has developed the specifics for the project. San Diego was named as the first competitive bidding area. However, in April 2008, a federal court issued a preliminary injunction which temporarily halted the project.

Medicare pays for clinical laboratory services on the basis of a fee schedule. By law, the fee schedules are to be updated annually to account for inflation. However, BBA eliminated the updates for 1998-2002. The update for 2003 was 1.1%. MMA froze the updates for 2004-2008.

Explanation of Provision

The provision would repeal the competitive bidding requirement effective upon enactment.

The provision would specify that the fee schedule update otherwise slated to occur each year would be reduced each year from 2009 through 2013 by 0.5 percentage points.

Section 147. Improved Access to Ambulance Services

Current Law

Ambulance services are paid on the basis of a national fee schedule, which is being phased in. The fee schedule establishes seven categories of ground ambulance services and two categories of air ambulance services. The national fee schedule is fully phased in for air ambulance services. For ground ambulance services, payments through 2009 are equal to the greater of the national fee schedule or a blend of the national and regional fee schedule amounts. The portion of the blend based on national rates is 80% for 2007-2009. In 2010 and subsequently, the payments in all areas will be based on the national fee schedule amount.

The fee schedule payment for an ambulance service equals a base rate for the level of service plus payment for mileage. Geographic adjustments are made to a portion of the base rate. For the period July 2004 – December 2009, mileage payments are increased for ground ambulance services originating in rural low population density areas. For the period July 1, 2004 – December 31, 2008, there is a 25% bonus on the mileage rate for trips of 51 miles and more.

The fee schedule amount is updated each year by the CPI-U. The update for 2008 is 2.7%.

For the period July 1, 2004 – December 31, 2006, payments for ground transports originating in rural areas were increased by 2% and those originating in other areas were increased by 1%.

Explanation of Provision

The provision would increase payments for ground transports originating in rural areas or rural census tracts by 3% for the period July 1, 2008 – December 31, 2009. It would increase the payments for ground transports originating in other areas by 2% for the period July 1, 2008 – December 31, 2009.

The provision would specify that any area designated as rural for the purposes of making payments for air ambulance services on December 31, 2006, would be treated as rural for the purpose of making air ambulance payments during the period July 1, 2008 – December 31, 2009. This section would apply notwithstanding any other provision of law.

The provision would further clarify that the satisfaction of the requirement of medical necessity for air ambulance services is met when the physician or other qualified medical personnel "certifies or reasonably determines" such need rather than "reasonably determines or certifies" the need. This clarification would be effective on the date of enactment.

Section 148. Extension and Expansion of the Medicare Hold Harmless Provision under the Prospective Payment System for Hospital Outpatient (HOPD) Services for Certain Hospitals

Current Law

Small rural hospitals (with no more than 100 beds) that are not sole community hospitals (SCHs) can receive additional Medicare payments if their outpatient payments under the prospective payment system are less than under the prior reimbursement system. For calendar year (CY) 2006, these hospitals will receive 95% of the difference between payments under the prospective payment system and those that would have been made under the prior reimbursement system. The hospitals will receive 90% of the difference in CY2007 and 85% of the difference in CY2008. MMA had extended outpatient hold harmless protection to rural sole community hospitals for services furnished on or after January 1, 2004 until January 1, 2006.

Explanation of Provision

The provision would establish that small rural hospitals would receive 85% of the payment difference in CY2009. SCHs with not more than 100 beds would receive 85% of the payment difference for covered OPD services furnished on or after January 1, 2009 and before January 1, 2010

Section 149. Clarification of Payment for Clinical Laboratory Tests Furnished by Critical Access Hospitals

Current Law

Medicare outpatient covered clinical laboratory services are generally paid based on a fee schedule. Clinical diagnostic laboratory services provided to patients who receive services directly from 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 SNF inpatients (who Medicare beneficiaries that are covered under Medicare Part A) are paid under consolidated billing as part of the SNF-PPS.

Explanation of Provision

Under this provision, starting for services furnished on July 1, 2009, clinical diagnostic laboratory services furnished by a CAH would be reimbursed as outpatient hospital services at 101% of costs without regard to whether individual to whom such services are furnished 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 150. Adding Certain Entities as Originating Sites for Payment of Telehealth Services

Current Law

Section 1895(m) of the Social Security Act defines payment rules for 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 or practitioner; (2) a critical access hospital; (3) a rural health clinic; (4) a federally qualified health center, and (5) a hospital. ESRD dialysis centers are not currently defined as originating sites, and therefore Medicare providers are not eligible to be reimbursed for telehealth services that they provide to patients at those centers.

Explanation of Provision

The proposal would add: (1) a hospital-based or critical access hospital based renal dialysis centers (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 151. MedPAC Study and Report on Improving Chronic Care Demonstration Programs

Current Law

No provision.

Explanation of Provision

The Medicare Payment Advisory Commission (MedPAC) would 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 would also be required to make recommendations for appropriate legislative and administrative action.

Section 152. Increase of FQHC Payment Limits

Current Law

Medicare covers services furnished by a federally qualified health center (FQHC). Payments for FQHC services are based on an all inclusive rate for each beneficiary visit for covered services. An interim payment is made to the entity based on estimates of allowable costs and number of visits; reconciliation is made at the end of the year based on actual costs and visits. Per visit payment limits are established for FHQCs. They are updated on January 1 of each year by the Medicare economic index (MEI) which measures inflation for certain medical services. For 2008, the urban FQHC limit is $117.41 and the rural FQHC limit is $100.96.

Explanation of Provision

The provision would increase the FQHC payment limits otherwise applicable in 2010 by $5. In subsequent years the previous year's amount would be increased by the increase in the MEI.

The provision would require the GAO to study whether the structure for FQHC payments adequately reimburses FQHCs for care furnished to Medicare beneficiaries. The GAO, in conducting the study, would be required to: (1) use the most current cost report data available; (2) examine the effects of the established Part B payment limits on the ability of FQHCs to furnish services to Medicare beneficiaries; and (3) examine the cost of furnishing covered Medicare services which were not included within the list of covered services when the Secretary determined the FQHC payment rates in 1991. The GAO would be required to submit a report to Congress on the study within 15 months of enactment, together with any legislative or administrative recommendations. In making

the recommendations, the GAO would take into consideration the structure and adequacy of the prospective payment methodology for FQHCs under Medicaid.

Section 153. Kidney Disease Education and Awareness Provisions

Current Law

No provision.

Explanation of Provision

The Public Health Service Act is amended by adding a new section on chronic kidney disease initiatives. The Secretary may establish pilot projects to: (1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regarding chronic kidney disease, focusing on prevention; (2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and (3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease. The Secretary would select at least 3 states in which to conduct pilot projects, for a period that is no longer than 5 years, beginning on January 1, 2009. GAO would be required to 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 would be expanded to include coverage for kidney disease education services, defined as education services: (1) furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary would require 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 ensure that individuals have the opportunity to actively participate in the choice of therapy and tailored to meet the needs of individuals. Qualified person would mean a physician, physician assistant, nurse practitioner or clinical nurse specialist, but would not include a provider of services (except for those in rural areas) or a renal dialysis facility. The Secretary would be required to set standards for the educational services, after consulting with physicians, dialysis facilities and others as required by statute. To the extent possible, the Secretary would consult with those (other than a dialysis facility) who had not received industry funding from a drug or biological manufacturer or dialysis facility. Individuals would be eligible for no more than 6 sessions of kidney disease education services. These amendments would be effective for services furnished on or after January 1, 2010.

Section 154. Renal Dialysis Provisions

Current Law

Medicare reimbursement for dialysis services is paid based on a basic case-mix adjusted prospective payment system for dialysis services, furnished at a hospital-based facility, an independent facility or in a patient's home. The basic case-mix adjusted system has two components: (1) the composite rate, which covers services, including dialysis; and (2) a drug add-on adjustment for the difference between the payment amounts for separately billable drugs and biologicals and their acquisition costs, as determined by Inspector General Reports. Additionally, certain drugs, biologicals and laboratory tests are billed separately.

The composite rate is derived from audited cost data and adjusted for the national proportion of patients dialyzing at home versus in a facility, and for area wage differences. Adjustments are made to the composite rate for hospital-based dialysis facilities to reflect higher overhead costs.

The Secretary is required to update the basic case-mix adjusted payment amounts annually beginning with 2006, but only for that portion of the case-mix adjusted system that is represented by the add-on adjustment and not for the portion represented by the composite rate.

Beneficiaries electing home dialysis may choose not to be associated with a facility and may make independent arrangements with a supplier for equipment, supplies, and support services. Payment to these suppliers, known as Method II, is made on the basis of reasonable charges, limited to 100% of the median hospital composite rate, except for patients on continuous cycling peritoneal dialysis, when the limit is 130% of the median hospital composite rate.

Explanation of Provision

For services furnished on or after January 1, 2009, and before January 1, 2010, the composite rate would be increased by 1 percent above the amount for such services furnished on December 31, 2008. For services furnished on or after January 1, 2010, the composite rate would be increased by **[1]** percent above the amount for such services furnished on December 31, 2009.

Beginning January 1, 2009, the payment rate for dialysis services furnished by providers of service would be the same as the rate for such services furnished by renal dialysis facilities, and in applying the geographic index to providers of services, the labor share would be based on the labor share otherwise applied for renal dialysis facilities.

Beginning January 1, 2011, the Secretary would implement a bundled payment system under which a single payment would be made for Medicare renal dialysis services, in lieu of any other payment, ensuring that the estimated total payment for 2011 for Medicare renal dialysis services would equal 98% of payments that would have been made if the bundled payment system had not been implemented. The Secretary would use 2007, 2008, or 2009 utilization data (whichever is lower) in making this estimation.

The term "renal dialysis services" would 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 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 furnished to individuals for the treatment of ESRD. The term "renal dialysis services" would not include vaccines. Payments could be made on the basis of services furnished during a week, month, or another unit. The payment system would include adjustments for: (1) case mix that could take into account patient weight, body mass index, co-morbidities, length of time on dialysis, age, race, ethnicity and other appropriate factors; (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 incurred in furnishing renal dialysis services in rural, low-volume facilities (as defined by the Secretary) exceed the costs incurred by other facilities in furnishing such services, with a minimum payment adjustment of 10% for such services furnished between January 1, 2011 and January 1, 2014; and (4) other appropriate payment adjustments as determined by the Secretary, such as pediatric services, geographic index and rural locations,. The Secretary would be required to consider the unique treatment needs of children and young adults.

The bundled payments system would be phased in equally over 4 years, to be fully implemented for services furnished on or after January 1, 2014. A provider of dialysis services or facility would 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. Such an election would be final and would be required to be made prior to January 1, 2011 in a form and manner specified by the Secretary. The Secretary would be required to make an adjustment to the payment rates for the years for which the phase-in occurs, so that the estimated total payments during the phase-in would equal the estimated total payments that would otherwise occur.

Beginning in 2012, the Secretary would 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. The following rules would apply to the portion of the payment that is based on the old composite rate system: (1) the update for the new bundled payment would not apply; and (2) the composite rate would be updated by the ESRD market basket increase factor (as determined by the Secretary) minus 1 percentage point.

There would be no administrative or judicial review of the determination of payment amounts, the establishment of an appropriate unit of payment, the identification of renal dialysis services included in the bundled payment and the adjustments, the application of the phase-in, or the establishment of updates. ESAs and other drugs and biologicals would be treated a prescribed and dispensed or administered and available under Part B of Medicare if they were furnished to an individual for the treatment of ESRD and

included in the bundled payment. Items and services included in the bundled payments for dialysis services would not be allowed to be unbundled.

The provision would repeal the demonstration established in the MMA for bundled case-mix adjusted payment system for ESRD services.

This provision could not be construed as authorizing or requiring the Secretary to make payments for any un-recovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix composite rate that was in effect before the date of the enactment of this Act.

Providers of renal dialysis services and renal dialysis facilities would be subject to quality incentive requirements, beginning in January 1, 2012. If a provider or facility did not meet the requirements (they are expected to meet or exceed the requirements), then the payments for the provider or facility would be reduced by up to 2%. This reduction in payments would only occur with respect to the year involved, and not be taken into account in subsequent years. The measures would include: (1) measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy; (2) to the extent feasible, such measures of patient satisfaction as specified by the Secretary; and (3) other measures including to the extent feasible, measures on iron management, bone mineral metabolism, and vascular access, including for maximizing the placement of arterial venous fistula. Any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) **[what is this referring to?]**, except in the case of a specified area determined by the Secretary for which no measure has been endorsed, the Secretary may specify a measure as long as due consideration is given to measures that have been endorsed by a consensus-based organization. The Secretary shall establish a process of updating measures. In specifying measures, the Secretary shall consider the availability of measures that address the unique treatment needs of children and young adults with kidney failure.

The Secretary shall develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the above identified measures, referred to as the "total performance score". For those that do not meet or exceed the total performance score, the Secretary would ensure that an appropriate distribution of reduction in payments was made among providers and facilities achieving different levels of scores, with those achieving the lowest scores receiving the largest reduction. In calculating the total performance score, the Secretary would weight the scores with respect to individual measures, to reflect priorities for quality improvement, such as weighting scores to ensure that providers of services and facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary. The Secretary shall also calculate separate scores for each measure, including dialysis adequacy and anemia management. The Secretary would establish performance standards with respect to the measures for a period with respect to a year, which include levels of achievement and improvement, as determined by the Secretary. These standard would be

establish prior to the beginning of the period for the year involved, which would occur prior to the beginning of the year. The Secretary would initially use as the performance standard for a provider or services or renal dialysis facility the lesser of: (1) the performance of the provider or facility for such measure in the year selected by the Secretary, or (2) a performance standard based on the national performance rates for such measures in a period determined by the Secretary.

No administrative or judicial review would be allowed for the determination of the payment reduction, the establishment of the performance standards and period, the measures or the methodology developed to calculate individual and total performance scores. The Secretary shall establish procedures for making information regarding performance available to the public, including the total performance scores and appropriate comparison of providers or facilities to the national average of such scores, and the performance score with respect to individual measures. A provider or facility must have the opportunity to review the information, prior to it being made public. The Secretary must provide certificates to facilities and providers which must be displayed prominently in patient areas, which indicates the total performance score. The Secretary must establish a web-based list that indicates both the total and individual measures performance scores.

No later than March 1, 2013, GAO must submit a report to Congress on the implementation of the payment system and the quality initiatives, which includes: (1) changes in utilization rates for ESAs; (2) the mode of administering such agents, including information on the proportion of individuals receiving such agents intravenously, as compared to subcutaneously; (3) an analysis of the payment adjustment, including an examination of the extent to which costs incurred by rural, low-volume providers and facilities exceed the costs incurred by other providers and facilities in furnishing such services, along with recommendations regarding the appropriateness of such adjustment; (4) changes, if any, in utilization rates of drugs and biologicals that the Secretary identifies, and any oral equivalent or oral substitutable forms of such drugs and biologicals or of other drugs and biologicals, that occurred after implementation of the bundled payment system; and (5) any other information or recommendations for legislative and administrate actions determined appropriate by the GAO.

Subtitle D – Provisions Relating to Part C

Section 161. Phase-Out of Indirect Medical Education (IME)

Current Law

Beginning in 2006, the Secretary annually determines Medicare Advantage (MA) payment rates by comparing plan bids to a benchmark. Plans submit bids representing their estimated revenue requirements for providing required Parts A and B benefits. The benchmark is the maximum amount Medicare is willing to pay a plan for providing Part A and B benefits. If a plan's bid is less than the benchmark, its payment equals its bid

plus a rebate of 75% of the difference and the remaining 25% of the difference is retained by the federal government. If a plan's bid is equal to or above the benchmark, its payment is the benchmark.

The benchmark is calculated, according to statute, by updating the previous year's payment in a local area by the minimum percentage increase or in years when rebasing occurs, by 100% of Fee-For-Service (FFS), with certain adjustments. Beginning in 2004 and at a minimum every third year, CMS is required to rebase FFS payment rates. Rebasing means CMS updates the FFS rates to reflect more recent county growth trends in original Medicare. The rebased amounts are statutorily required to exclude the direct cost of medical education while retaining the *indirect* costs of medical education (IME). Medicare also pays teaching hospitals directly for the cost of IME when an MA enrollee is treated in the hospital.

Medicare pays PACE (Programs of All-Inclusive Care for the Elderly) providers for each eligible enrollee on a capitated basis. Payments are made in the same manner and from the same sources as capitated payments to other MA plans. Such payments are adjusted to take into account the comparative frailty of PACE enrollees and other factors the Secretary determines appropriate. The total payment level for all PACE program eligible individuals must be less than the projected payment level for a comparable population not enrolled in a PACE program.

Explanation of Provision

Beginning in 2010, the Secretary would be required to adjust the local MA monthly benchmarks to phase-out the value of indirect medical education (IME). In 2010, the proportion of IME to be phased-out would be equal to the ratio of 0.60 percent (the maximum cumulative adjustment percentage) to the percentage of per capita FFS spending attributed to IME payments for that year (standardized IME cost percentage). FFS spending would be equal to 100% of per capita FFS spending as determined in a rebasing year. After 2010, the maximum cumulative adjustment percentage would be equal to the maximum cumulative adjustment percentage from the previous year increased by 0.60 percentage points. At no point would the percentage of IME phased-out of the benchmark be greater than 100%. All adjustments would be made prior to any adjustment for budget neutrality. This provision would not apply to capitation rates for PACE program providers.

Section 162. Revisions to Requirements for Medicare Advantage Private Fee-for-Service Plans

Current Law

MA coordinated care plans are required to form networks with providers to meet certain access requirements. Among these are ensuring that benefits are available to plan enrollees with reasonable promptness and in a manner which assures the continuity of benefits; providing medically necessary services 24 hours a day 7 days a week; arranging

for payment for Medicare covered services provided by out-of-network providers (under certain circumstances); ensuring access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and covering emergency services without regard to prior authorization or the provider's contractual relationship with the plan.

MA PFFS plans are not required to form networks of providers and may provide services through "deemed" contracting providers". A "deemed" provider is a provider who, before delivering a service, knows that a beneficiary is enrolled in the PFFS plan, and has been given, or has reasonable access to, the PFFS plan's terms and conditions for participation. To meet access requirements, MA PFFS plans must demonstrate to the Secretary that the plan has a sufficient number and range of health care professionals and providers willing to provide services under the terms of the plan. These requirements are considered met if the plan meets one of the following two requirements: (1) the plan establishes payment rates for Part A and B services that are equal to or greater than payment rates in original Medicare; or (2) the plan has contracts or arrangements with a sufficient number and range of providers to deliver services under the terms of the plan. MA PFFS plans are also required to reimburse hospitals, physicians, and providers, at a rate determined by the plan, on a fee-for-service basis. PFFS plans cannot vary provider reimbursement rates based on utilization, place a provider at financial risk, or restrict the selection of providers among those that are lawfully authorized to provide services and agree to the plan's terms and conditions for payment.

Employer-sponsored MA plans are defined as plans offered by employers, labor organizations, or the trustees of a fund established by employers or labor organizations to provide benefits to the entity's employees or former employees, or the organization's members or former members. To facilitate the offering of employer-sponsored MA plans, the Secretary may waive or modify requirements that hinder the design, offering, or enrollment in these plans.

Explanation of Provision

Beginning in year 2011, non-employer sponsored MA PFFS plans operating in a network area would be required to meet Medicare access requirements in that area by establishing written contracts with providers. (Non-employer sponsored MA PFFS plans would remain able to meet Medicare access requirements by establishing payment rates that are equal to or greater than those under traditional Medicare in the non-network areas of the plan's service area). A network area is defined as an area which the Secretary identifies as having at least 2 network-based plans, such as a coordinated care plan (i.e. HMO, PSO or local PPO), a network-based MSA plan, or a cost plan. The Secretary would be required to announce these areas in its annual announcement of proposed payment rates. Non-network Regional PPO plans would not be considered network-based plans.

The provision would establish new access requirements for employer-sponsored MA PFFS plans. Beginning in year 2011, employer-sponsored MA PFFS plans would be

required to establish written contracts with providers. Employer-sponsored MA PFFS plans would no longer be able to meet access requirements, in whole or in part, by establishing payment rates that are equal to or greater than those under traditional Medicare.

For plan years beginning in 2010, MA PFFS plans that are meeting Medicare access requirements by establishing written contracts with providers would be required to meet the same access requirements that apply to MA coordinated care plans. The provision would not prevent a MA PFFS plan from varying rates among providers based on specialty, location, or other factors unrelated to utilization, or prevent a PFFS plan from increasing rates based on increased utilization of specific preventive or screening services.

Section 163. Revisions to Quality Improvement Programs

Current Law

MA plans, except Private Fee for Service (PFFS) and Medical Savings Account (MSA) plans, are required to have a quality improvement program for the purpose of improving the quality of care provided to enrollees. As part of the quality improvement program, each MA organization is required to have a chronic care improvement program to monitor and identify enrollees with multiple or sufficiently severe chronic conditions. The MA organization is required to establish criteria for participation in its chronic care improvement program. Further, the MA organization is required to collect, analyze, and report data that allows for the measurement of health outcomes and other quality indicators. Preferred Provider Organizations (PPOs) are only required to comply with these requirements for in-network providers. The Secretary is required to establish separate data collection and reporting requirements for MA regional plans. Requirements for regional PPO plans are not to exceed the comparable requirements for local PPOs. The law also sets the following limitations on the Secretary's data collection requirements: (1) the Secretary is prohibited from collecting new types of data that had not been collected as of November 1, 2003; and (2) the Secretary may not change the types of data collected from MA organizations without consulting MA organizations and private accrediting organizations and submitting a report to Congress on the reasons for the changes.

Explanation of Provision

This provision would remove the exemption granted PFFS plans and MSA plans from having a quality improvement program. The provision would also require that the data collection and reporting requirements that apply to PFFS and MSA plans not exceed those pertaining to local PPO plans. However, unlike local PPOs, PFFS and MSA plans would be required to collect data from both in-network and out-of-network providers. The provision would also remove the requirement that the Secretary establish separate data collection requirements for MA regional plans. Instead MA regional plans would be

subject to the same requirements as local PPOs. All requirements would apply to MA plans for plan years beginning January 1, 2010.

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

Current Law

Special Needs Plans (SNPs) are Medicare Advantage (MA) plans that serve special needs beneficiaries. Special needs beneficiaries are defined as eligible enrollees who are institutionalized (as defined by the Secretary), are entitled to Medicaid, or would benefit from enrollment in a SNP, such as a specialized MA plan that serves individuals with severe or disabling chronic conditions. SNP plans may restrict enrollment to special needs beneficiaries until January 1, 2010. The Secretary is statutorily prohibited from designating any new SNP plan until January 1, 2010. Enrollment in SNPs is prohibited until January 1, 2010 unless the SNP was available for enrollment on January 1, 2008.

The Secretary is required to conduct annual audits of the financial records of at least one-third of the MA participating organizations (including data relating to utilization, costs, and computation of the plan's bid). The Secretary, or any person or organization designated by the Secretary, also has the right to inspect and audit the quality, appropriateness, and timeliness of the services provided to enrollees as well as any records pertaining to the organization's ability to bear risk.

MA plans, except Private Fee for Service (PFFS) or Medical Savings Account (MSA) plans, are required to have a quality improvement program for the purpose of improving the quality of care provided to enrollees. As part of the quality improvement program, each MA organization is required to have a chronic care improvement program to monitor and identify enrollees with multiple or sufficiently severe chronic conditions. The MA organization is required to establish criteria for participation in its chronic care improvement program. Further, the MA organization is required to collect, analyze, and report data that allows for the measurement of health outcomes and other quality indicators. Preferred Provider Organizations (PPOs) are only required to comply with these requirements for in-network providers. The Secretary is required to establish separate data collection and reporting requirements for MA regional plans. The law also sets the following limitations on the Secretary's data collection requirements: (1) the Secretary is prohibited from collecting new types of data that had not been collected as of November 1, 2003; and (2) the Secretary may not change the types of data collected from MA organizations without consulting MA organizations and private accrediting organizations and submitting a report to Congress on the reasons for the changes.

Explanation of Provision

This provision would extend the time SNPs may restrict enrollment to special needs beneficiaries (from January 1, 2010 to January 1, 2011.) This provision would also extend the moratorium on the Secretary's authority to designate other MA plans as new

SNP plans (from January 1, 2010 to December 31, 2010). Beginning January 1, 2010 all new enrollees to institutional SNPs would be required to be special needs beneficiaries that are institutionalized (as defined by the Secretary); new enrollees to Medicaid SNPs would be required to be special needs beneficiaries that are eligible for medical assistance under a State Medicaid plan; and new enrollees to severe or chronic care SNPs would be required to be special needs beneficiaries with severe or disabling chronic conditions. The provision would also amend the definition of a severe or chronic care SNP to include individuals with one or more comorbid and medically complex conditions that are substantially disabling, life threatening, have a high risk of hospitalization, or other significant adverse health outcomes, and require specialized delivery systems across domains of care. To help determine the conditions that meet the definition of a severe or disabling chronic condition, the Secretary would be required to convene a panel of clinical advisors, including the Director of the Agency for Healthcare Research and Quality. MA organizations would be required to comply with the revised definition of a chronic care SNP by January 1, 2010 irrespective of when they entered the MA program.

The provision introduces additional requirements for SNP plans. SNPs would be required to comply with these additional requirements for plan years beginning January 1, 2010. Institutional SNPs would be required to enroll only those individuals that have received a determination indicating that they specifically require an institutional level of care. These determinations must be made using a State assessment tool or by an entity other than the MA organization offering the SNP plan. Medicaid SNPs would be required to provide each prospective enrollee, prior to enrollment, a comprehensive written statement describing the benefits and cost-sharing protections defined in the state's Medicaid program and which of these benefits and protections would be covered by the plan. SNPs would be required to use standard content and formats established by the Secretary in preparing these statements. The provision would also require that Medicaid SNPs either have a contract with the State Medicaid agency to provide benefits or arrange for the benefits to be provided to its enrollees. However, states would not be required to enter into a contract with a SNP. Benefits may include long-term care services provided they are consistent with State policy. If the Medicaid SNP does not have a contract with a State Medicaid agency or has not arranged for these benefits to be provided, the SNP could continue to operate during 2010, but would be prohibited from expanding its service area. The provision would require the Secretary allocate staff and resources to address inquiries related to the coordination of State and Federal policies for Medicaid SNPs. A provision specifies that no provision or amendment under the bill would affect the benefits available under the State Medicaid program.

The provision would also introduce care management requirements for SNPs. First, SNPs would be required to have in place an evidence-based model of care with appropriate networks of providers and specialists. For every enrollee, SNPs would be required to perform an initial assessment and annual reassessment of the enrollees' physical, psychosocial, and functional needs. Care for the enrollee must also be managed by an interdisciplinary team. SNPs would be required to develop a plan, in consultation with the enrollee (as feasible) that identifies goals, objectives, measurable outcomes, and specific services and benefits that will be provided. To ensure compliance with these

requirements, the provision would require that the Secretary, in conjunction with its periodic financial audit of MA plans, conduct a review of how the plan is meeting these requirements. SNPs would be required to comply with these requirements for plan years beginning January 1, 2010 irrespective of when they entered the MA program.

This provision would require that SNPs comply with additional quality reporting requirements. In addition to providing for the collection, analysis, and reporting of data on health outcomes and other quality indicators, SNPs would be required to collect and report data related to new SNP requirements, including care management. SNPs would be required to report data at the plan level. The Secretary would determine the effective data for the data collection requirements provided its no later than 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

Current Law

Special Needs Plans (SNPs) are Medicare Advantage (MA) plans that serve special needs beneficiaries. Special needs beneficiaries are defined as eligible enrollees who are institutionalized (as defined by the Secretary), are entitled to Medicaid, or would benefit from enrollment in a SNP, such as a specialized MA plan that serves individuals with severe or disabling chronic conditions.

Medicare beneficiaries meeting financial requirements (income and asset levels) and categorical restrictions are eligible for full benefits under state Medicaid programs. These requirements vary by state. Medicare beneficiaries who do not qualify for full benefits under Medicaid may, however, be eligible for limited assistance. Through the Qualified Medicare Beneficiaries (QMBs) program, beneficiaries who are aged or disabled with incomes at or below the federal poverty level, and with assets below a specified level, are entitled to have their Medicare cost-sharing and Part B premiums paid by the Medicaid program.

Provision

Effective January 1, 2010, Medicaid SNPs serving beneficiaries eligible for full benefits under Medicaid, or limited benefits under the Qualified Medicare Beneficiary program, would be prohibited from charging cost-sharing in excess of what would be permitted under Medicaid.

Section 166. Adjustment to the Medicare Advantage Stabilization Fund

Current Law

The MMA created the MA Regional Program and established the MA Regional Plan Stabilization Fund to encourage plans to enter into and/or remain in the MA Regional Program. The fund was originally set at $10 billion with additional money added to the fund from savings in the bidding process. Funds were to be available from 2007 through the end of 2013. Subsequent legislation decreased the amount of funds available and delayed their availability. Currently, $1.79 billion (from the original $10 billion) is available for 2013.

Explanation of Provision

This provision would reduce the amount available in the stabilization fund from $1.79 billion to one dollar and delay the availability of the funds for one year. Funds would not be available until 2014.

Section 167. Access to Medicare Reasonable Cost Contract Plans

Current Law

Reasonable Cost plans are those that are reimbursed by Medicare for the actual cost of furnishing covered services to Medicare beneficiaries. These plans are allowed to operate indefinitely, unless two other plans of the same type (i.e., either 2 local or 2 regional plans) operate for the entire year in the cost contract's service area. After January 1, 2009, the Secretary may not extend or renew a reasonable cost contract for a service area if: (a) during the entire previous year there were either two or more MA regional plans or two or more MA local plans in the service area; and (b) these regional or local plans meet minimum enrollment requirements. Minimum enrollment requirements are: (1) 5,000 individuals if any portion of the service area, including contiguous counties, is within a Metropolitan Statistical Area (MSA) with a population of more than 250,000; or (2) 1,500 individuals with respect to any other portion of the service area.

Explanation of Provision

The provision would extend for one year – from January 1, 2009 to January 1, 2010 - the length of time reasonable cost plans could continue operating regardless of any other MA plans serving the area. The provision would modify the conditions under which a reasonable cost plan would be denied the ability operate in an area after January 1, 2010. A reasonable cost plan would be prohibited from operating in an area if, during the previous year, the area was within the service area of either 2 local or 2 regional plans meeting minimum enrollment requirements, *provided the two plans were not offered by the same MA organization*. Finally, the provision would modify the minimum enrollment requirements for local or regional plans operating within the cost plan's service area. The revised minimum enrollment requirements would be: (1) 5,000 individuals for MSAs greater than 250,000 provided any contiguous counties are not in another MSA; or (2)

1,500 individuals with respect to any other service area. In instances where the service area includes more than 1 MSA, the Secretary would be required to make the enrollment determination with respect to each MSA.

Not later than December 31, 2009, GAO would be 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.

Section 168. MEDPAC Study and Report on Quality Measures

Current Law

No provision.

Explanation of Provision

The Medicare Payment Advisory Commission (MEDPAC) would be 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. The study would be required to address technical issues, such as data requirements, in addition to issues related to appropriate quality benchmarks that: (1) compare the quality of care across MA plans; and (2) compare the quality of care in MA plans and original Medicare. Not later than March 31, 2010, MEDPAC would be 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

Current Law

No provision.

Explanation of Provision

The Medicare Payment Advisory Commission (MEDPAC) would be required to conduct a study on the correlation between MA costs in providing Medicare coverage (as reflected in plan bids) and county level, per-capita spending in the original fee-for-service (FFS) program. The study would be required to include differences in plan type and geographic area. Based on the results of this study, and other data, MEDPAC would be required to examine: (1) alternatives to county-level payment equivalents; and (2) the accuracy and completeness of county-level estimates of per capita FFS spending (including Puerto Rico), as used to determine the annual MA capitation rate. Specifically, MEDPAC would be required to investigate whether such estimates include expenditures with respect to Medicare beneficiaries at the Department of Veterans Affairs (VA) facilities and all appropriate administrative expenses, such as claims

processing. Finally, MEDPAC would be required to recommend ways to improve the accuracy and completeness of county-level estimates of per capita spending. Not later than March 31, 2010, MEDPAC would be required to submit a report to Congress containing the results of the study, together with recommendations for 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

Current Law

By design, PDP sponsors and MA-PD plans are allowed to include the terms of payment as part of the contracts negotiated with pharmacies. These terms are allowed to vary across plans, pharmacies, and contracts.

Explanation of Provision

Each contract entered into with respect to a prescription drug plan offered by a PDP sponsor or MA-PD plan would be required to provide that payment would 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 would 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, including any lack of any required substantiating documentation, or particular circumstance requiring special treatment that prevents timely payment from being made. Claims submitted electronically would be considered to have been received on the date on which the claim is transferred. Claims not submitted electronically would be considered to have been received on the 5^{th} 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" would 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 would be required to pay interest to the pharmacy that submitted the claim. The interest rate would be equal to the weighted average interest on 3-month marketable Treasury securities plus 0.1 percentage point for the period beginning the day after the required payment date up to the date on which payment is made. This interest charge would 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 would 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 would 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 would 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 would 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 would be deemed a clean claim and would be required to be paid. The date of payment of a claim would be the date on which the payment is electronically transferred or the date the payment is submitted to the United States Postal Service or common carrier for delivery.

PDP sponsors or MA-PD plans would be required to pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has requested previously. In such a case, the PDP sponsor or MA-PD plan would make remittance electronically as well.

This provision would not prohibit or limit a claim or action not covered by the section by an individual or organization against a provider or PDP sponsor or MA-PD plan, and PDP sponsor or MA-PD plans would not be allowed to retaliate against an individual or provider for exercising a right of action under this provision. A determination that a claim is a clean claim would not be construed as a positive determination regarding eligibility for payment, not an indication of government approval of, or acquiescence regarding, the claim submitted. The determination would not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim. This provision would apply to plan years beginning on or after January 1, 2010.

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

Current Law

No provision.

Explanation of Provision

This provision would establish a new set of requirements for contracts between PDP sponsors and pharmacies located in or contracting with long-term care facilities for plan years beginning on or after January 1, 2010. Each contract entered into with a PDP

sponsor or MA-PD plan would be required to provide that a pharmacy located in or having a contract with a long-term care facility would have between 30 and 90 days to submit claims for reimbursement.

Section 173. Regular Update of Prescription Drug Pricing Standard

Current Law

No provision.

Explanation of Provision

The provision would require the regular update of prescription drug pricing standards. For sponsors of a prescription drug plan that use the cost of a drug as the standard for reimbursement of pharmacies, each contract that PDP sponsors and MA-PD plans entered with pharmacies would require the sponsor to update the standard not less frequently than every 7 days, to accurately reflect the market price of acquiring the drug. This provision would apply to plan years beginning on or after January 1, 2009.

Part II – Other Provisions

Section 175. Inclusion of Barbiturates and Benzodiazepines as Covered Part D Drugs

Current Law

Prescription drug plans and MA-PD plans are not required to include barbiturates or benzodiazepines in their formularies.

Explanation of Provision

The provision would remove the exclusion of benzodiazepines from those drugs prescription drug plans are required to include in their formularies. It would also remove the exclusion for barbiturates if the barbiturate is used in the treatment of epilepsy, cancer, or chronic mental health disorder. The provision would apply to prescriptions dispensed on or after January 1, 2012.

Section 176. Formulary Requirements With Respect to Certain Categories or Classes of Drugs

Current Law

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 would 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. Under the policy, plan sponsors can not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within classes for enrollees already taking a drug.

Explanation of Provision

The provision would require the Secretary, beginning with plan year 2010, to identify categories and classes of drugs for which two criteria are met. First, restricted access to the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class. Second, 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.

PDP sponsors would be required to include all covered Part D drugs in the categories and classes identified by the Secretary. However, the Secretary could establish an exceptions process that permitted a PDP plan sponsor to exclude from its formulary (or otherwise limit access to) a particular drug otherwise required to be included in the formulary. Any process established would have to provide a formal process that ensured that any exception was based upon scientific evidence and medical standards of practice, and included a public notice and comment period.

Subtitle F – Other Provisions

Section 181. Use of Part D Data

Current Law

MMA created data that previously did not exist or were not systematically collected. With the implementation of the Medicare Part D prescription drug benefit, CMS now collects a range of information including claims data about the drug utilization patterns of the elderly and disabled, the choices the beneficiaries made among the many plans offered when they signed up for the drug benefit, the beneficiaries' providers of care, information about aggregate discounts on prescription drug prices that plans negotiated with pharmaceutical companies, and competitive bids submitted by private plans who participate in the Medicare Part D program.

In order to maintain the confidentiality of sensitive data, and to protect trade secrets, MMA placed restrictions on the Medicare Part D data and limited access only for specific purposes. Regarding payments to prescription drug plans, section 1860D-15(d)(2)(B) states that, "Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section." In the section that provides for subsidies to low income beneficiaries, section 1860D-15(f)(2) states that, "Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section." Finally, in addressing payments to Medicare Advantage (MA) plans, section 1858(c)(3)(B) contains similar language, stating that "Information disclosed or obtained pursuant to the provisions of this subsection may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subsection." In summary, the restrictions on data are consistent in restricting "officers, employees, and contractors of the Department of Health and Human Services" to using the data only to carry out the specified purposes detailed in the law.

On October 18, 2006, the CMS issued a proposed 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. The final rule was issued May 27, 2008. CMS believes that the MMA created a statutory ambiguity and that the restrictions on Medicare Part D data include limits on CMS. Specifically, CMS believes that MMA implies that data collected for calculating payments can only be used in the calculation of payments and that the agency cannot use the data for any other purpose. In the rule, CMS argues that it needs the data "for research, internal analysis, oversight, and public health purposes." In addition, CMS states that other federal and non-federal agencies would also benefit from having access to the data, including several agencies in the Department of Health and Human Services (HHS). The Food and Drug Administration (FDA) would like to conduct post-marketing surveillance studies and the Agency for Healthcare Research and Quality (AHRQ) would like to study the effectiveness of prescription drugs on outcomes using this data.

CMS argues that by collecting the same data under a different authority, Section 1860D–12(b)(3)(D), the agency is allowed to use the data for research purposes in addition to payment calculation. In the rule, CMS states that "it is in the interest of public health to share some of the information collected under that authority with entities outside CMS."

Explanation of Provision

The provision would grant 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 could 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 for conducting Congressional oversight, monitoring, and analysis of the Medicare program.

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

Current Law

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.

Explanation of Provision

In the case of a covered part D drug to be used in an anticancer chemotherapeutic regimen, PDPs and MA-PDs would 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. The Secretary also would be required to include the compendia used in the Medicaid program in the list of compendia for the Medicare outpatient prescription drug program (part D). The Secretary would not be required to do the aforementioned if the compendia used for the Medicaid outpatient drug program does not have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests on and after January 1, 2010.

The Secretary would be required to revise the list of compendia to be used for the Medicaid outpatient drug program as is appropriate for identifying medically accepted indications for drugs, in order to have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests. Any such revisions would be required to be done in a manner consistent with the process for revising compendia under the Medicare outpatient prescription drug program (part D). This provision would apply to plan years beginning on or after January 1, 2009.

The provision specifies that on and after January 1, 2010, no compendia may be included on the list of compendia for the Medicare outpatient prescription drug program (part D) unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

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

Current Law

No provision.

Explanation of Provision

This provision would enable the Secretary to contract with an organization that would develop and endorse health care quality measures. The Secretary would identify and contract with a consensus-based entity regarding performance measurement, such as the National Quality Forum, that meets the requirements described below, and the entity would perform a number of specified duties. The Secretary would enter into the first contract as soon as practicable after the date of enactment. A contract with such a consensus-based performance measurement organization would be for a period of 4 years, and may be renewed after a subsequent bidding process. The contract would be entered into following competitive procedures as defined in the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)).

The consensus-based performance measurement organization would have the following duties:

(a) The organization would synthesize evidence and convene key stakeholders to make recommendations on an integrated national strategy and establish priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity would ensure that priority is given to measures (a) that address the health care provided to patients with prevalent, high-cost, chronic diseases; (b) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and (c) that may be implemented rapidly due to existing evidence, standards of care, or other reasons. In making the recommendations, the organization would also take into account measures that (i) may assist consumers and patients in making informed health care decisions; (ii) address health disparities across groups and areas; and (iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple settings.

(b) The organization would endorse standardized health care performance measures. The endorsement process would consider whether a measure (i) is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and (ii) would be consistent across types of health care providers, including hospitals and physicians.

(c) The organization would establish and implement a process to ensure that measures endorsed are updated (or retired if obsolete) as new evidence is developed.

(d) The organization would promote the development and use of electronic health records that contain the functionality for automated collection, aggregation, and transmission of performance measurement information.

(e) The organization would prepare an annual report to Congress and the Secretary by March 1 of each year (beginning with 2009). The report would describe (i) the implementation of quality measurement initiatives under this Act and the coordination of such initiatives with quality initiatives implemented by other payers; (ii) the recommendations made; and (iii) the performance by the entity of the duties required under the contract entered into with the Secretary. Not later than 6 months after receiving such a report for a year, the Secretary would review and publish the report in the Federal Register, together with any comments of the Secretary on the report.

There are several requirements for the consensus-based performance measurement organization. The organization would be required to be a private nonprofit entity governed by a board, whose members would include (i) representatives of health plans and health care providers and practitioners or groups representing such health plans and health care providers and practitioners; (ii) health care consumers or representatives of groups representing health care consumers; and (iii) representatives of purchasers and employers or groups representing purchasers or employers. The membership of the organization would 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. The entity would have at least 4 years experience in establishing national consensus standards. If the entity were to require a membership fee for participation in the functions of the entity, such fees would be reasonable and adjusted based on the capacity of the potential member to pay the fee. In no case would membership fees pose a barrier to the participation of individuals or groups with low or nominal resources to participate in the functions of the entity.

For purposes of carrying out this subsection, the Secretary would provide for the transfer of up to $10 million from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund (in such proportion as the Secretary determined appropriate), to the CMS Program Management Account for the period of fiscal years 2009 through 2012.

With respect to matters related to the contract with the Secretary as described above, the organization would be required to conduct its business in an open and transparent manner and to provide the opportunity for public comment on its activities. The entity would operate as a voluntary consensus standards setting organization as defined for purposes of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Public Law 104– 113) and Office of Management and Budget Revised Circular A–119 (published in the Federal Register on February 10, 1998).

The provision also includes the Sense of the Senate that the selection by the Secretary of Health and Human Services of a consensus-based entity to contract with as added above, should not be construed as diminishing the significant contributions of the

Boards of Medicine, the quality alliances, and other clinical and technical experts to efforts to measure and improve the quality of health care services.

The GAO would conduct studies on the performance of the consensus-based entity and report on (a) its duties under the contract and (b) the costs incurred by the entity in performing such duties. These reports would 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 would determine appropriate.

Section 184. Cost-Sharing For Clinical Trials

Current Law

No provision.

Explanation of Provision

The Secretary could 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 payments 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

Current Law

No provision.

Explanation of Provision

The Secretary would initiate data collection and analysis efforts to address health care disparities across race, ethnicity, and gender. The Secretary would evaluate approaches for the collection of Medicare data, performed in conjunction with existing Medicare quality reporting requirements and programs, that allow for the ongoing, accurate, and timely collection and evaluation of data on disparities in health care services and performance on the basis of race, ethnicity, and gender. In conducting the evaluation, the Secretary would consider the following objectives: (1) protecting patient privacy; (2) minimizing the administrative burdens of data collection and reporting on providers and health plans participating under this title; and. (3) improving Medicare program data on race, ethnicity, and gender.

The Secretary would prepare several reports as a result of this evaluation. Not later than 18 months after the date of the enactment, the Secretary would submit to Congress a

report on the evaluation. The report would: (a) 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 under parts A and B, the Medicare Advantage program under part C, and the Medicare prescription drug program under part D; and (b) include recommendations on the most effective strategies and approaches to reporting HEDIS quality measures and other nationally recognized quality performance measures, as appropriate, on the basis of race, ethnicity, and gender.

Not later than 4 years after the date of the enactment of this section, and 4 years thereafter, the Secretary would 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 would 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

Current Law

No provision.

Explanation of Provision

Within one year after the date of the enactment, the Secretary would establish a demonstration project to determine the greatest needs and most effective methods of outreach to Medicare beneficiaries who were previously uninsured. The demonstration would be in no fewer than 10 sites, and would 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. Grantees that are plans operating under part C would document that enrollees who were previously uninsured would receive the "Welcome to Medicare" physical exam.

The Secretary would conduct the demonstration project for a period of 2 years. The Secretary would conduct an evaluation of the demonstration and would submit a report to Congress not later than 1 year after the completion of the project that would include the following: (1) an analysis of the effectiveness of outreach activities targeting beneficiaries who were previously uninsured, such as revising outreach and enrollment materials (including the potential for use of video information), providing one-on-one counseling, working with community health workers, and amending the *Medicare and You* handbook; and (2) the effect of such 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

Current Law

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 14 standards are organized by themes: Culturally Competent Care (Standards 1-3), Language Access Services (Standards 4-7), and Organizational Supports for Cultural Competence (Standards 8-14).

The CLAS standards are one means to address inequities that currently exist in the provision of health services and to make services more responsive to the individual needs of all patients/consumers. The standards are intended to be inclusive of all cultures and not limited to any particular population group or sets of groups. However, they are especially designed to address the needs of racial, ethnic, and linguistic population groups that experience unequal access to health services. Ultimately, the aim of the standards is to contribute to the elimination of racial and ethnic health disparities and to improve the health of all Americans.

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.

Explanation of Provision

Not later than two years after the date of the enactment, the Inspector General of the Department of Health and Human Services would 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 would 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 would implement changes responsive to any deficiencies identified in the report.

Section 188. Medicare Improvement Funding

Current Law

No provision.

Explanation of Provision

The Secretary would establish a Medicare Improvement Fund ('Fund'), which would be available to the Secretary to make improvements under the original fee-for-service program under parts A and B for Medicare beneficiaries. For services furnished during fiscal year 2013, $1.439 billion and during fiscal year 2014, $21.17 billion would be made available from the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds in such proportion as the Secretary would determine to be appropriate. Amounts in the Fund would be available in advance of appropriations but only if the total amount obligated from the Fund did not exceed the amount specified above. The Secretary could obligate funds from the Fund only if the Secretary determines that there are sufficient amounts available in the Fund to cover all obligations incurred consistent with the above, as certified by the Chief Actuary of CMS and the appropriate budget officer.

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 would be made available to CMS. For fiscal years 2009 through 2013, the Secretary of Health and Human Services would 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 would be in the same proportion as for Medicare managed care payments (Medicare Advantage), i.e., 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.

Title II - Medicaid

Section 201. Extension of Transitional Medical Assistance (TMA) and Abstinence Education Program

Current Law

States are required to continue Medicaid benefits for certain low-income families who would otherwise lose coverage because of changes in their income. This continuation is called transitional medical assistance (TMA). Federal law permanently requires four months of TMA for families who lose Medicaid eligibility due to increased child or spousal support collections, as well as those who lose eligibility due to an increase in earned income or hours of employment. Congress expanded work-related

TMA under Section 1925 of the Social Security Act in 1988, requiring states to provide TMA to families who lose Medicaid for work-related reasons for at least six, and up to 12, months. 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). This program is referred to as the Title V Abstinence Education block grant. Funds 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. To receive federal funds, a state must match every $4 in federal funds with $3 in state funds. This means that if maximum federal funding is provided, funding for Title V Abstinence Education must total at least $87.5 million annually. Although the Title V Abstinence Education block grant has not yet been reauthorized, the latest temporary extension continued funding through June 30, 2008.

Explanation of Provision

The provision would extend Section 1925 TMA requirements and the abstinence education block grant program through December 31, 2009, with funding at the level provided through the first quarter of FY2008.

Section 202. Medicaid DSH Extension

Current Law

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 (DSH) payments" are subject to statewide allotment caps. Allotments for Tennessee and Hawaii, however, are equal to zero. This is because the states have, in the past, operated their state Medicaid programs under the provisions of research and demonstration waivers. Granted under the authority of Section 1115 of the Social Security Act (SSA), such research and demonstration waivers allow for states to waive various provisions of Medicaid law specified in Title XIX of SSA to conduct demonstrations as long as the demonstrations are likely to assist in promoting the objectives of the Medicaid program. The requirement to make disproportionate share payments is one of the provisions that have been waived by some states under the conditions of their research and demonstration waivers.

Congress has enacted special DSH provisions for Tennessee and Hawaii in the past. Both states received a special allotment for FY 2007 and part of FY 2008. 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 additional DSH payments are required to be considered as waiver expenditures for the purpose of determining whether the states' waivers are budget neutral. Tennessee's

allotment amount was set at $30 million for FY 2007, and the same amount was prorated for the applicable portion of FY 2008. Hawaii's allotment was set at $10 million for 2007 and similarly prorated for FY 2008.

Explanation of Provision

The provision would extend the special DSH allotment arrangements for Tennessee and Hawaii through a portion of fiscal year 2010. Allotment amounts would be equal to $30 million for Tennessee for each full year -- 2008 and 2009, and one-quarter of that amount would be available for the first quarter of FY 2010. Hawaii's $10 million allotment would be extended for each full fiscal year – 2008 and 2009, and $2.5 million would be available for the first quarter of FY 2010.

Section 203. Pharmacy Reimbursement under Medicaid

Current Law

Under current law, 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 Deficit Reduction Act of 2005 (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.

Explanation of Provision

The provision would 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 would not be permitted to make AMP prices publicly available prior to such date.

Section 204. Review of Administrative Claim Determinations

Current Law

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 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 Department of Health and Human Services, Departmental Appeals Board (the Board) in accordance with specified procedures.

Explanation of Provision

The provision would 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 any item or class of items for which the state claimed FFP under Medicaid, the state would be permitted to receive a reconsideration of the disallowance (or a reconsideration of an unfavorable reconsideration of a disallowance) in whole or in part if the state files an appeal with the Board within 60 days after receiving notice.

The provision would require the Board to adhere to all applicable laws and regulations in reviewing the evidence submitted with the State's appeal and would provide that the Board's decision regarding the appeal would be the final decision of the Secretary. Such decisions would be subject to reconsideration by the Board only upon motion (of either part) filed during the 60 day period that begins on the date of the Board's decision, or of a decision to obtain judicial review.

The provision would 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 the disallowance of claims for FFP, in any United States District Court that is located within any State that is a party to the appeal. Judicial review would 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.

Title III - Miscellaneous

Section 301. Extension of TANF Supplemental Grants

Current Law

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 $319 million annual level when it extended supplemental grants for FY2002 and subsequent years. The Deficit Reduction Act of 2005 (P.L. 109-171) provided the last extension of supplemental grants, continuing their funding through FY2008. (Other TANF grants are funded through FY2010.)

Explanation of Provision

The proposal would extend supplemental grants at the $319 million level through FY2009. In FY2009, each of the 17 qualifying states would 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

Current Law

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 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%.

Explanation of Provision

This provision would 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 would make this change effective beginning with the first day, of the first quarter of FY2009.

Section 303. Extension of Special Diabetes Programs Grant Programs

Current Law

As specified in Section 330B of the Public Health Service Act, the Secretary, directly or through grants, must provide for research into the prevention and cure of Type I diabetes. Appropriations are set at $150 million per year during the period FY2004 through FY2008. As specified in Section 330C of the Public Health Service Act, the Secretary must make grants for providing services for the prevention and treatment of diabetes among American Indians and Alaskan Natives. Appropriations are set at $150 per year during the period FY2004 through FY2008. The law also requires the Secretary of HHS to conduct an evaluation of these two diabetes programs, and submit two reports to the appropriate committees of Congress. An interim report was due not later than January 1, 2000, and a final report was due not later than January 1, 2007.

Explanation of Provision

[This draft legislation has an error on page 249, lines 20 and 24. The error is the reference to "2009." Current law is "2008." I am assuming the reference should be to "2008" in this write-up of the explanation of provision.]

For each of these two grant programs, the provision would provide appropriations of $150 million per year during the period FY2009 through FY2011. It would also redesignate the final report in current law that was due in January 2007 to be a second interim report, and would add a new final report that would be due not later than January 1, 2011.

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

Current Law

No provision.

Explanation of Provision

Not later than 60 days after the date of enactment of this Act, the Secretary would be required to enter into a contract with the IOM to conduct (a) a study on the best methods used in developing clinical practice guidelines, and (b) 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 would be 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 would 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 would require that (a) stakeholders with expertise in making clinical recommendations participate on the panel responsible for conducting the study and preparing the report on

the best methods used in developing clinical practice guidelines, and (b) stakeholders with expertise in conducting clinical effectiveness research participate on the panel responsible for conducting the study and preparing the report that identifies the methodological standards for conducting systematic reviews of clinical effectiveness research on health and health care.

To carry out these studies, this provision would appropriate, out of any funds in the Treasury not otherwise appropriated, $3 million for FY 2009 and FY 2010.