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MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND MODERNIZATION ACT OF 2003

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(This summary is a detailed, but not complete summary of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). This information in this document comes from many sources. The primary sources are: P.L. 108-173 and its conference report and the CMS Legislative Summary, *Summary of H.R. 1- Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108-173.*)

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
OVERVIEW	
General Approach	<ul style="list-style-type: none"> ▪ Effective January 1, 2006, a new “Voluntary Prescription Drug Benefit Program,” under a new Medicare Part D, would be established. ▪ It is a voluntary program, but beneficiaries who fail to enroll in the first year will pay a penalty for late enrollment. Dual eligibles that fail to enroll will be randomly enrolled in a plan. These enrollees may disenroll or change plans. ▪ The bill would rely on private plans to provide coverage and to bear a portion of the financial risk for drug costs. Federal subsidies would be provided to encourage participation. ▪ Plans must be licensed as risk-bearing entities eligible to offer health insurance or health benefits by the state or states in which they plan to offer Medicare Part D benefits on a full risk or limited risk basis. <ul style="list-style-type: none"> ▪ The HHS Secretary may authorize the use of limited risk plans only if needed to ensure that at least two plans will be available in each region. In awarding bids in a region, the Secretary must give priority to plans that would bear the highest level of risk, taking into account the level of bids submitted in the region. The Secretary is prohibited from reducing a plan’s risk to zero, unless it is a fallback plan. [For detail see “Fallback Plan” below.] ▪ Everyone eligible for Medicare Part D must have a choice of at least two plans and one plan must be a freestanding prescription drug plan (PDP). If these conditions cannot be met, the individuals must be given the opportunity to enroll in a “fallback” plan. [See “Fallback Plan” below.]
Fallback Plan	<p>Sec. 101 – New Sec. 1860D-11</p> <ul style="list-style-type: none"> ▪ If no risk plans or fall back plans bid in a region, the fallback plan would provide coverage in that area. Fallback plans must offer the standard benefit, accept performance risk, and Medicare would set its premiums. <ul style="list-style-type: none"> ▪ A plan that submits a bid to be a fallback plan in a region, for the first year of the fallback plan contract period, cannot have bid to be a full or reduced risk plan in any region of the country. ▪ A plan served as a fallback plan in a region cannot submit a bid to be a full or reduced risk plan in that region the following year. ▪ The fallback plan contract period is up to three years, but may be terminated sooner if the Secretary approves two or more plans to provide Part D benefits in the region. ▪ Entities services as fallback plans will be subject to performance risk, but not insurance risk. ▪ Fallback plans are prohibited from marketing or branding the plan.
Pharmacy Network Access Requirements	<ul style="list-style-type: none"> ▪ A plan must accept any willing pharmacy provider that meets the terms and conditions of the plan’s pharmacy contract. ▪ A plan may use lower-than-standard coinsurance/copayment requirements for members who use in-network pharmacies. ▪ A plan’s pharmacy access standards must be at least as favorable as the access rues used in the TRICARE Retail Pharmacy Program RFP issued in May 2003.¹
Formulary Requirements	<ul style="list-style-type: none"> ▪ The plan’s pharmaceutical and therapeutic (P&T) committee must include at least one physician and one pharmacist who has expertise in the care of elderly and disabled people and the majority of the committee must be comprised of practicing physicians and/or pharmacists. ▪ Requires the formulary to include two or more drugs within each therapeutic category and class of covered Medicare Part D drugs.

¹ The TRICARE RFP requires that the pharmacy must be available within two miles of 90 percent of the beneficiaries residing in an urban area, within five miles of 90 percent of the beneficiaries residing in a suburban area; and within 15 miles of 70 percent of the beneficiaries residing in a rural area.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Directs the HHS Secretary to ask U.S. Pharmacopeia (USP) to develop, in consultation with pharmacy benefit managers and other interested parties, a list of categories and classes of drugs that may be used by plans.²
Medicare Prescription Drug Account in the Federal Supplemental Insurance Trust Fund	<p>Sec. 101 – New Sec. 1860D-16</p> <ul style="list-style-type: none"> ▪ Establishes a Medicare Prescription Drug Account in the Part B Trust Fund. Funds in the account will be kept separate from other fins within the Trust Fund. Payments will be made from the account for: (1) low-income subsidies; (2) subsidy payments; (3) payments to qualified retiree prescription drug plans; and (4) administrative expenses.
Cost Containment	<p>Title VIII – Cost Containment [See Title VIII, Sec. 801 for additional detail]</p> <ul style="list-style-type: none"> ▪ Limits the portion of Medicare spending that comes from the federal Treasury to 45%.
DRUG BENEFIT – TITLE I	
Overview	<p>Sec. 101 – New Sec. 1860D-2</p> <ul style="list-style-type: none"> ▪ Beginning in 2006, Medicare beneficiaries may purchase prescription drug coverage from a private health plan that offers prescription drug coverage or from an insurance carrier offering a stand-alone prescription drug plan. ▪ All full dual eligibles with incomes below 135% FPL are eligible for subsidies available to Medicare beneficiaries, regardless of the asset test. ▪ Dual eligibles are not eligible to receive prescription drug coverage through Medicaid. ▪ States, in conjunction with the Social Security Administration (SSA) are responsible for determining eligibility for the low-income subsidies.³ ▪ SSI guidelines, without regard to the application of income disregards, will be used for eligibility determination. ▪ Authorized the Secretary to permit states to use the same asset or resource methodologies that are used for determining eligibility for a Qualifying Medicare Beneficiary (QMB), provided that methodology does not result in any significant differences in the number of individuals determined to be eligible for Part D subsidies. ▪ Directs the Secretary to periodically and on a timely basis to reimburse the PDP sponsor or MA organization for the amount of the reduced premiums and cost-sharing.
Access	<p>Sec. 101 – New Sec. 1860D-3</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to assure that each beneficiary has a choice of at least two qualifying plans in the area in which they reside. At least one of the qualifying plans must be a prescription drug plan (PDP). The second plan can be either a PDP or a Medicare Advantage (MA) plan that offers basic coverage or supplemental coverage, provided no additional premium is charged. The two plans cannot be offered by the same sponsor. ▪ If there is an insufficient number of qualifying plans, beneficiaries will have the option of enrolling in a “fallback plan.”

² Plans are not required to use the guidelines established by USP, but since the HHS Secretary is required to find that the formulary design of a plan is not likely to “substantially discourage enrollment by certain Part D eligible individuals under the plan,” a plan may opt to use the USP classification plan because they Secretary cannot make a finding of a violation of this requirement if the plan is using the USP classification plan.

³ The Secretary is directed to develop a model simplified application form and process for determining and verifying eligibility. The Social Security Commissioner may only require the submission of statements from financial institutions for an application for low-income subsidies to be considered complete. No other documentary evidence may be required with the submission of the application. The HHS Secretary is permitted to verify information submitted on the application. The Secretary must develop a process to notify the PDP sponsor or Medicare Advantage organization that an individual is eligible for a subsidy and the amount of the subsidy. The sponsor or entity would then reduce the individual’s premium or cost sharing accordingly.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Authorizes the Secretary to approve “limited risk plans” to avoid approving a “fallback” plan. ▪ Prohibits the Secretary from approving a “fallback” plans unless efforts to approve limited risk plans to meet the two-plan minimum fail.
<p>Standard Benefit – Medicare Beneficiaries with Incomes at or above 150 % of the federal poverty level (FPL)</p>	<p>Sec. 101 – New Sec. 1860D-2</p> <ul style="list-style-type: none"> ▪ Beneficiaries with incomes above 150% of the federal poverty level (FPL) enrolled in a prescription drug plan (PDP) or a Medicare Advantage (MA) plan will be responsible for: <ul style="list-style-type: none"> ▪ an estimated average premium cost of \$35 per month (\$420 annual);⁴ ▪ A \$250 deductible; ▪ 25% coinsurance after the deductible is met, up to the initial coverage limit of \$2,250 in expenditures; ▪ 100% coinsurance expenditures between the initial coverage limit of \$2,250 and \$3,600 of True Out-of-Pocket (TrOOP),⁵ which is equal to \$5,100 in total prescription drug expenditures.⁶ ▪ After the beneficiary has crossed the \$3,600 TrOOP threshold, he will pay the greater of a \$2 co-payment for generic drugs and preferred multi-source drugs and a \$5 co-payment for brand name or non-preferred drugs or 5% coinsurance. ▪ Beginning in 2007, the deductible and cost-sharing amounts will be increased by the annual percentage increase in the per capita beneficiary expenditures for Medicare Part D covered drugs.
<p>Alternative Coverage</p>	<p>Sec. 101 – New Sec. 1860D-2</p> <ul style="list-style-type: none"> ▪ Prescription drug coverage offered by a Prescription Drug Plan (PDP) or Medicare Advantage (MA) may differ from the standard benefit provided the benefit: (1) is at least actuarially equivalent to the standard benefit; (2) includes a deductible that is no greater than the deductible applicable to the standard benefit; and (3) includes the same protection against high out-of-pocket expenditures as is provided in the standard benefit.
<p>Definition of Covered Part D Drug</p>	<p>Sec. 101 – New Sec. 1860D-2</p> <ul style="list-style-type: none"> ▪ Defines Part D covered drugs as those covered under Medicaid, plus insulin, insulin-related supplies, certain vaccines and smoking cessation agents. Drugs currently covered under Medicare Part A and Part B will continue to be covered in that way.
<p>Premiums</p>	<p>Sec. 101 – New Sec. 1860D-13</p> <ul style="list-style-type: none"> ▪ A national weighted average drug bid will be constructed using all bids from drug plans and the drug portion of bids from Medicare Advantage (MA) plans. The weights will be average plan enrollment in the prior year. The HHS Secretary will establish a mechanism for determining the weights in the first year. ▪ Bids from Medical Savings Account (MSA) plans, private fee-for-service plans (PFFS), specialized plans for special needs individuals, PACE plans, and cost contract plans are not included in the national weighted average bid. ▪ Part D premiums will vary by plan. The plan’s premium for basic coverage will be set at approximately 25.5 percent of the national weighted average plan bid plus or minus the difference between the average (geographically adjusted) and the plan’s bid. The plan

⁴ The premium amount is not legislated in the statute. The \$35 monthly premium is an estimate.

⁵ Out-of-pocket expenditures will be determined using the True Out-of-Pocket (TROOP) definition of stop/loss. Under this approach only contributions by the beneficiary, the beneficiary’s family, and **state pharmacy assistance programs (SPAP)** will count toward the stop/loss. Out-of-pocket expenditures for drugs not covered by the individual’s drug plan will not count towards TROOP. The HHS Secretary is authorized to establish procedures for determining whether insurance or other third party payers were reimbursing costs. Misrepresentation regarding reimbursement by insurance or other third party payers will constitute grounds for termination of Part D enrollment.

⁶ The period of time between the end of the 75% government coverage and the triggering of the catastrophic coverage is called the “coverage gap” or the “donut.”

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>premium will be uniform for all enrollees in a region, except that the premium will be increased by any late enrollment penalty that applies or decreased if the enrollee is eligible for low-income assistance. The plan may charge an additional premium for any supplemental coverage it offers.</p> <ul style="list-style-type: none"> ▪ Part D enrollees may pay plan premiums directly to the plan or through a Social Security check deduction. The HHS Secretary will develop a mechanism to apportion any late enrollment penalties between the government and the plan.
<p>Late Enrollment Penalties</p>	<ul style="list-style-type: none"> ▪ The late enrollment penalty applies to eligible individuals who either do not enroll in Part D by the last day of the initial enrollment period (5/15/06) in 2006 and the last day of the enrollment period in subsequent years. The late enrollment penalty also applies if an eligible individual fails to maintain other creditable coverage⁷ for more than a continuous period of 63 days. ▪ The penalty will be calculated as the greater of an actuarially sound amount for the uncovered period, or for each uncovered month, 1 percent of the average basic enrollee premium.
<p>Low Income Subsidy – Dual Eligibles with Incomes at or below 100% of the Federal Poverty Level (FPL)</p>	<p>Sec. 101 – New Sec. 1860D-14</p> <ul style="list-style-type: none"> ▪ Dually-eligible beneficiaries enrolled in a prescription drug plan (PDP) or a Medicare Advantage (MA) plan will be responsible for: <ul style="list-style-type: none"> ▪ \$0 premium ▪ \$0 deductible ▪ 100% federal funding through the “coverage gap” except for \$1 co-payments for generic drugs and preferred multi-source drugs and \$3 for brand name drugs for prescription drug benefits up to the catastrophic level, \$3,600 in True Out-of-Pocket (TrOOP) expenditures which represents \$5,100 in total expenditures. ▪ The premium subsidy is equal to 100 percent of the low-income benchmark premium amount. The low-income benchmark premium amount for a region equals either: (1) the weighted average of the basic premiums, if all prescription drug plans are offered by the same PDP sponsor; or (2) the weighted average of premiums for prescription drug plans and MA-PD plans, if plans in the region are offered by more than one sponsor. The low-income benchmark premium cannot exceed the actual premium amount for basic coverage under the plan. ▪ Beginning in 2007 the co-payment amount will be increased by the percentage increase in the consumer price index (CPI-U).⁸ ▪ These low-income beneficiaries are also eligible for a premium subsidy for late enrollment penalties equal to 80 percent for the first 60 months and 100 percent thereafter.
<p>Low Income Subsidy – Dual Eligibles Residing in Nursing Facilities with Incomes up to 135% of FPL</p>	<p>Sec. 101 – New Sec. 1860D-14</p> <ul style="list-style-type: none"> ▪ Dually-Eligible Medicare beneficiaries residing in nursing facilities and enrolled in a prescription drug plan (PDP) or a Medicare Advantage (MA) plan will be responsible for: <ul style="list-style-type: none"> ▪ \$0 premium ▪ \$0 deductible ▪ \$0 copayments or other cost-sharing

⁷ Creditable coverage is defined as coverage provided through a group health plan and other specified coverage that meets or exceeds the actuarial value of standard Medicare Part D coverage. Entities that offer drug coverage are required to notify eligible individuals whether their coverage qualifies as creditable.

⁸ The Consumer Price Index for All Urban Consumers or the CPI or CPI-U An index of prices of goods and services typically purchased by urban consumers, is compiled and published monthly by the Bureau of Labor Statistics (BLS), using price data obtained from an elaborate survey of 25,000 retail outlets and quantity data generated by the Consumer Expenditures Survey.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The premium subsidy is equal to 100 percent of the low-income benchmark premium amount. The low-income benchmark premium amount for a region equals either: (1) the weighted average of the basic premiums, if all prescription drug plans are offered by the same PDP sponsor; or (2) the weighted average of premiums for prescription drug plans and MA-PD plans, if plans in the region are offered by more than one sponsor. The low-income benchmark premium cannot exceed the actual premium amount for basic coverage under the plan. ▪ These low-income beneficiaries are also eligible for a premium subsidy for late enrollment penalties equal to 80 percent for the first 60 months and 100 percent thereafter.
<p>Low Income Subsidy – Full Dual Eligibles with Incomes Above 100% of the Federal Poverty Level (FPL) and Below 135% FPL; Supplemental Security Income (SSI) Beneficiaries</p>	<p>Sec. 101 – New Sec. 1860D-14</p> <ul style="list-style-type: none"> ▪ Low-income beneficiaries with incomes at or below 135% of FPL enrolled in a prescription drug plan (PDP) or a Medicare Advantage (MA) plan will be responsible for: <ul style="list-style-type: none"> ▪ \$0 premium ▪ \$0 deductible ▪ \$2 copayment for generic drugs and \$5 copayment for brand name or non-preferred drugs, through the “donut”⁹ and up to the stop-loss of \$3,600 in True Out-of-Pocket (TrOOP) expenditures which represents \$5,100 in total expenditures. ▪ No cost sharing above the catastrophic level. ▪ The premium subsidy is equal to 100 percent of the low-income benchmark premium amount. The low-income benchmark premium amount for a region equals either: (1) the weighted average of the basic premiums, if all prescription drug plans are offered by the same PDP sponsor; or (2) the weighted average of premiums for prescription drug plans and MA-PD plans, if plans in the region are offered by more than one sponsor. The low-income benchmark premium cannot exceed the actual premium amount for basic coverage under the plan. ▪ Beginning in 2007, cost-sharing amounts will be increased by the annual percentage increase in the per capita beneficiary expenditures for Medicare Part D covered drugs. ▪ These low-income beneficiaries are also eligible for a premium subsidy for late enrollment penalties equal to 80 percent for the first 60 months and 100 percent thereafter. ▪ Authorizes the Secretary to deem Qualified Medicare Beneficiaries (QMBs); Specified Low-Income Medicare Beneficiaries (SLMBs); and Qualifying Individuals (QI-1s) as eligible for subsidies under this category. <i>[For additional detail on QMBs, SLMBs and QI-1s, see Appendix A – Dual Eligibles]</i>
<p>Low Income Subsidy – Beneficiaries with Incomes at or below 135% of the Federal Poverty Level (FPL)</p>	<p>Sec. 101 – New Sec. 1860D-14</p> <ul style="list-style-type: none"> ▪ Low-income beneficiaries with incomes at or below 135% of FPL enrolled in a prescription drug plan (PDP) or a Medicare Advantage (MA) plan will be responsible for: <ul style="list-style-type: none"> ▪ \$0 premium ▪ \$0 deductible ▪ \$2 copayment for generic drugs and \$5 copayment for brand name or non-preferred drugs, through the “donut” and up to the

9 The “donut” is the coverage gap between the deductible and the stop-loss limit of \$3,600 or \$5,100 in true out-of-pocket (TrOOP) expenditures.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p style="text-align: center;">stop-loss of \$3,600 in True Out-of-Pocket (TrOOP) expenditures which represents \$5,100 in total expenditures.</p> <ul style="list-style-type: none"> ▪ No cost sharing above the catastrophic level. ▪ The premium subsidy is equal to 100 percent of the low-income benchmark premium amount. The low-income benchmark premium amount for a region equals either: (1) the weighted average of the basic premiums, if all prescription drug plans are offered by the same PDP sponsor; or (2) the weighted average of premiums for prescription drug plans and MA-PD plans, if plans in the region are offered by more than one sponsor. The low-income benchmark premium cannot exceed the actual premium amount for basic coverage under the plan. ▪ Beginning in 2007, cost-sharing amounts will be increased by the annual percentage increase in the per capita beneficiary expenditures for Medicare Part D covered drugs. ▪ An asset test will be applied (\$6,000 for singles/\$9,000 for couples). It will be indexed annually by the percentage increase in the consumer price index (CPI-U). ▪ These low-income beneficiaries are also eligible for a premium subsidy for late enrollment penalties equal to 80 percent for the first 60 months and 100 percent thereafter.
<p>Low Income Subsidy – Beneficiaries with Incomes between 135% - 150% of FPL</p>	<p>Sec. 101 – New Sec. 1860D-14</p> <ul style="list-style-type: none"> ▪ Low-income beneficiaries with incomes between 135% - 150% of FPL enrolled in a prescription drug plan (PDP) or a Medicare Advantage (MA) plan will be responsible for: <ul style="list-style-type: none"> ▪ Premium subsidies on a sliding fee scale based on income (full premium paid at 135% of FPL, phased down to no subsidy at 150% FPL); ▪ \$50 deductible ▪ 15% coinsurance up to the catastrophic limit (for expenditures between the \$50 deductible and the \$3,600 in True Out-of-Pocket (TrOOP) expenditures which represents \$5,100 in total expenditures. ▪ \$2 copayment for generic drugs and preferred multi-source drugs and \$5 copayment for brand name or non-preferred drugs, after the catastrophic limit is reached. ▪ Beginning in 2007, the deductible and cost-sharing amounts will be increased by the annual percentage increase in the per capita beneficiary expenditures for Medicare Part D covered drugs. ▪ An asset test will apply (\$10,000 for singles/\$20,000 for couples). It will be indexed annually by the percentage increase in the consumer price index (CPI-U).
<p>Treatment of Territories</p>	<p>Sec. 101 – New Sec. 1860D-14</p> <ul style="list-style-type: none"> ▪ Residents of territories are not eligible for low-income subsidies. [See “Treatment of Territories” under section, “Medicaid – Treatment of Dual Eligibles.”]
<p>Subsidies for Part D Eligible Individuals for Qualified Prescription Drug Coverage</p>	<p>Sec. 101 – New Sec. 1860D-15</p> <ul style="list-style-type: none"> ▪ The government subsidy for Part D will total 74.5 percent of the cost of the benefit on average. It will be delivered through two mechanisms: a direct subsidy and reinsurance. <ul style="list-style-type: none"> ▪ The direct subsidy for each plan will be calculated as the difference between the plan's bid (individually risk adjusted) and the plans' enrollee premium for basic coverage.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The reinsurance payments will cover the plan's allowable costs that are associated with 80 percent of drug costs in the catastrophic coverage range for each enrollee. Allowable costs do not include administrative costs and are net of any discounts or rebates the plan may receive for the drugs provided in the catastrophic range. The Secretary determines the method of payment to plans and may make interim payments based on projected costs. Plans must provide any information on claims experience and costs that the Secretary determines are necessary to administer the reinsurance payments. ▪ The Secretary will establish a risk-adjustment mechanism for the drug bids. Drug plans and Medicare Advantage plans are required to submit claims data to the Secretary to aid in the development and improvement of the risk adjuster. ▪ The Secretary will establish a geographic-adjustment mechanism for the drug plan bids, taking into account variations in drug prices by region. If the price variation is determined to be de minimis, the adjuster will not be used. ▪ A system of risk corridors will also partially protect plans from unexpected losses and allow the government to share in any unexpected gains. <ul style="list-style-type: none"> ▪ For benefit years 2006 and 2007, the corridors will be specified as follows: the plan is fully at risk for expenses that fall within 2.5 percent of the plan's target amount; for amounts between 2.5 percent and 5 percent, the government pays (recoups) 75 percent of the amount above (below) 2.5 percent; finally, for amounts above (below) 5 percent, the government pays (recoups) 80 percent. After 2007, the risk corridor thresholds rise from 2.5 percent to 5 percent in the first case and from 5 percent to 10 percent in the second case. Also after 2007, the risk sharing in the first threshold declines from 75 to 50 percent. ▪ A further protection mechanism retroactively makes the risk corridors more protective of plans in 2006 or 2007 if most plans have significant losses. Specifically, if more than 60 percent of plans, covering more than 60 percent of eligible individuals have costs that exceed the first threshold, the government will pick up 90 percent of those costs.
APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND RELATED MANAGED CARE PROGRAMS	
Application to Medicare Advantage Program and Related Managed Care Programs	Subpart 3 – New Sec. 1860D-21 <ul style="list-style-type: none"> ▪ Beginning January 1, 2006, Medicare Advantage organizations must offer a plan with either basic prescription drug coverage or qualified prescription drug coverage that provides supplemental coverage for no premium. They may offer a plan without drug coverage in an area, but only if they also offer a plan with drug coverage in the same area. ▪ Enrollees in a Medicare Advantage plan on December 31, 2005 who fail to make a plan election for 2006 are deemed to continue in their Medicare Advantage plan as long as the plan had at least some drug coverage in 2005. If the Medicare Advantage Plan had no drug coverage in 2005 and the enrollee fails to make an election, then the enrollee is returned to the traditional fee-for-service program. ▪ An enrollee who exercises his or her option for a one-time switch out of a Medicare Advantage plan when first becoming eligible for Medicare will be allowed to then enroll in a prescription drug plan. ▪ If a Medicare Advantage plan that does not offer prescription drug coverage leaves the service area, then that plan's enrollees are deemed to return to traditional fee-for-service Medicare (unless he or she makes an election to another plan) and is guaranteed issue of a Medigap plan. ▪ All requirements for prescription drug plans apply to the drug benefit in Medicare Advantage plans. The Secretary may waive these requirements to the extent they duplicate or conflict with requirements already applicable for Medicare Advantage plans or to improve coordination of benefits provided under those plans. ▪ Private fee-for-service plans that offer prescription drug coverage are not required to negotiate prices, set up exclusive pharmacy networks, perform drug utilization management or medication therapy management. These plans receive the average reinsurance

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>payments paid to other drug plans, rather than claim-by-claim reinsurance. They also do not receive risk corridors. The Secretary may not negotiate the terms and conditions of the plans' bids.</p> <ul style="list-style-type: none"> ▪ Plans with cost contracts that offer prescription drug coverage must meet the requirements for Medicare Advantage plans. Only participants in such a plan may enroll in its Part D plan. The bids of such plans will not be taken into account in computing average benchmark bids and low-income benchmark premium amounts. ▪ If a PACE program chooses to provide Part D drug coverage to a Medicare beneficiary who participates in its program, the coverage will be treated as though the PACE program were an MA-PD local plan. Only participants in such a plan may enroll in its Part D plan. The bids of such plans will not be taken into account in computing average benchmark bids and low-income benchmark premium amounts.
TREATMENT OF MEDICARE PART B DEDUCTIBLES AND PREMIUMS	
Indexing Part B Deductible to Inflation	<p>Sec. 629</p> <ul style="list-style-type: none"> ▪ Increases the Part B deductible from \$100 in 2004 to \$110 in 2005, to be updated annually by the same percentage increase as the Part B premium increase.
Income-Relate Part B Premium	<p>Title VIII-Subpart B, Sec. 811</p> <ul style="list-style-type: none"> ▪ Income thresholds: <ul style="list-style-type: none"> ▪ All beneficiaries under \$80,000 (single) \$160,000 couple continue to receive the existing 75% subsidy. ▪ 65% premium subsidy for beneficiaries between \$80,000 and \$100,000 ▪ 50% premium subsidy for beneficiaries between \$100,000 and \$150,000 ▪ 35% premium subsidy for beneficiaries between \$150,000 and \$200,000 ▪ 20% premium subsidy for beneficiaries over \$200,000 ▪ Five year phase-in of new premiums beginning in 2007. ▪ Income levels doubled for married couples. ▪ Permits beneficiaries to appeal if their family situation has changed (e.g., death of spouse, divorce). ▪ Permits the Internal Revenue Service (IRS) to release certain information to employees and contractors of the Social Security Administration to facilitate the income-related reduction in the Part B premium subsidy. <p><i>Note: In September the Centers for Medicare and Medicaid Services announced the largest increase in the Medicare Part B premium in history. On January 1, 2005, the monthly premium will increase from \$66.60 to \$78.20.</i></p>
MEDICAID – TREATMENT OF DUAL-ELIGIBLES (TITLE I)	
Overview	<ul style="list-style-type: none"> ▪ Phases down the state financial contribution for the cost of providing prescription drug coverage to dual eligibles to 75% over a 10-year period. [See Medicaid “Claw-Back” below for more detail] ▪ Full dual eligible individuals are to be treated as subsidy eligible persons. The HHS Secretary may provide that other Medicaid beneficiaries are treated as subsidy eligible. ▪ Directs the Secretary to develop a model simplified application form and process for determining and verifying eligibility.
Eligibility Determination	Sec. 101, New Sec. 1860D-14

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Eligibility determinations will be conducted by the state Medicaid program or by the Commissioner of the Social Security Administration through local offices. The Social Security offices may only require the submission of statements from financial institutions for an application for low-income subsidies. No other documentary evidence may be required at the time of application. The HHS Secretary is authorized to verify information submitted on the application. ▪ Provides that low-income subsidy information be available at all Medicaid and Social Security offices and directs these offices to engage in outreach activities. ▪ Eligibility determinations will remain effective for a period to be determined by the HHS Secretary, but cannot exceed one year. Redeterminations or appeals are to be conducted in the same manner as they are conducted by state Medicaid offices or by the Social Security Commissioner for the Supplemental Security Income (SSI) program.
Default Election Process for Dual Eligibles	Sec. 101 – New Sec. 1860D-1(b)(1)(C) <ul style="list-style-type: none"> ▪ Establishes a default election process for full-benefit dual eligible beneficiaries by directing the HHS Secretary to enroll dual eligibles who are not enrolled in a prescription drug plan or MA-PD plan, in a plan that has a premium equal to or below the premium subsidy amount available to Medicare beneficiaries with incomes below 135% of FPL. ▪ If more than one plan is available, the Secretary must enroll the beneficiary on a random basis among all plans in the PDP region. A beneficiary may decline enrollment or change enrollment.
State Program Administration	Sec. 103 (a) <ul style="list-style-type: none"> ▪ Requires states, as a condition of receiving federal matching payments under Medicaid, to: (1) determine eligibility for premium and cost-sharing subsidies; (2) inform the Secretary regarding the eligibility determinations and provide other information as may be required by the Secretary; and (3) screen applicants for eligibility for other Medicare cost-sharing programs and offer to enroll them if they are eligible. ▪ Provides no additional federal assistance for Medicaid program administration. These activities would be matched at the regular 50 percent rate for program administration.
Medicaid “Claw-Back” Provision	Sec. 103 (b) The “Claw-Back” Concept (also called the Phased-Down State Contribution) <ul style="list-style-type: none"> ▪ States will be required to continue to pay a portion of prescription drug costs for dual eligibles that enroll in Medicare Part D. Beginning at 90 percent in 2006, states will pay a decreasing percentage of the costs over a 10-year period that will end at 75 percent in 2014. The state “claw-back” or maintenance of effort percentage will remain at 75 percent in 2015 and thereafter. ▪ The “claw-back” provision is a maintenance of effort (MOE) requirement based on state expenditures for Medicaid prescription drug coverage for full dual eligibles in calendar year 2003. In 2006, the federal government will assume 10% of the “costs” which means that states will pay to the federal government the product of 90% x 2003 per capita expenditures for prescription drug coverage for dual eligibles, trended forward to accommodate inflation x the number of dual eligibles enrolled in full Medicaid coverage. ▪ The Secretary is required to notify each state of its “state contribution” amount by October 15, 2005. This amount is net of rebates. ▪ If a state fails to pay the “claw-back” the law authorizes the Secretary to deduct the amount owed plus interest from the state’s federal Medicaid payment as provided for under the Federal Claims Collection Act of 1996. The “Claw-Back” Details

PROVISION	MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Beginning in 2006, each month a state is required to provide a payment to the HHS Secretary equal to the product of: <ul style="list-style-type: none"> ▪ 1/12 (“base year”¹⁰ state Medicaid per capita expenditures for full benefit dual eligibles x state FMAP), updated to the year involved by the “applicable growth factor;”¹¹ ▪ the total number of dual eligibles for the state for the month; and ▪ the “phase-down” or “claw-back” factor¹² for the month. ▪ Requires the HHS Secretary when determining gross expenditures for 2003 to: (1) use data from the Medicaid Statistical Information System (MSIS) and other available data; (2) exclude expenditures attributable to covered outpatient prescription drugs that are not covered by Medicare Part D; and (3) reduce the portion of expenditures not attributable to dispensing fees by an adjustment factor applied to that portion. <ul style="list-style-type: none"> ▪ The adjustment factor is the ratio for the state for 2003 of: (1) aggregate payments under Medicaid rebate agreements; to (2) the gross state expenditures for covered outpatient drugs for full benefit dual eligible individuals who are not receiving medical assistance for prescription drugs through a Medicaid managed care plan.
Medicaid Coordination with the Medicare Prescription Drug Benefit	<p>Sec. 103 (c)</p> <ul style="list-style-type: none"> ▪ Establishes Medicare as the primary payer for covered drugs for dual eligibles.¹³ As such, Medicaid coverage is not available for covered drugs or the cost sharing for covered drugs. Dual eligibles are not eligible for prescription drug coverage under Medicaid. ▪ Prohibits Medicaid from “wrapping around” the Medicare Part D drug benefit, except for prescribed over-the-counter (OTC) drugs and drugs not covered under Medicare Part D.¹⁴
Treatment of Territories	<p>Sec. 103(d)</p> <ul style="list-style-type: none"> ▪ Provides additional Medicaid funds for the territories. Makes \$28.125 million available in the last three quarters of 2006; \$37.5 million in 2007 and in subsequent years the amount would be increased by the annual percentage increase in prescription drug costs for Medicare beneficiaries. ▪ To qualify for the additional funding, territories must provide assurances that the additional funds would be used to cover the cost of drugs and program administration. ▪ Limits the amount that can be spent on program administration to 10% of the total. ▪ Directs the Secretary to submit a report to Congress on these provisions.
Medicaid “Best Price”	<p>Sec. 103 (e)</p> <ul style="list-style-type: none"> ▪ Exempts from the calculation of the Medicaid “best price”¹⁵, prices negotiated from: (1) manufacturers for discount card drugs under the discount card program; (2) Medicare Part D, Medicare Advantage prescription drug plan (MA-PD); or a qualified retiree health plans

10 The base year is defined as the weighted average of: (1) the gross Medicaid expenditures, excluding dispensing fees, for prescription drugs in 2003; and (2) the estimated actuarial value of prescription drug benefits provided under a capitated care plan for full benefit dual eligibles in that year.

11 In 2004, 2005 and 2006, the applicable growth factor will equal the average annual percentage change in the per capita expenditures as determined based on the most recent National Health Expenditures projections. In subsequent years, the growth factor will be equal to the annual percentage increase in average per capita expenditures under Medicare Part D.

12 The phase-down factor is 90% in 2006 and phases down to 75% in 2015. The phase-down schedule is as follows: 90% in 2006; 88.33% in 2007; 86.66% in 2008; 85% in 2009; 83.33% in 2010; 81.66% in 2011; 80% in 2012; 78.33% in 2013; 76.66% in 2014 and 75% in 2015 and subsequent years.

13 For more detail on dual eligibles, see Appendix A.

14 States may wrap-around the Medicare drug benefit provided that only state funds are used.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	and State Pharmaceutical Assistance Plans (SPAPs). ¹⁶
Extension of Medicare Cost Sharing for Part B Premiums for Qualifying Individuals (QI-1 Program)	<p>Sec. 103 (f)</p> <ul style="list-style-type: none"> ▪ Extends the authority for the QI-1 program¹⁷ through 9/30/04 and makes \$300 million available, effective 4/1/04. ▪ [Note: Currently pending signature by President Bush is S. 2618, legislation that would extend authority for the program through September 31, 2005.]
SSA Outreach	<p>Sec. 103 (g)</p> <ul style="list-style-type: none"> ▪ Directs the SSA Administrator to provide awareness not only of Medicare cost sharing but of subsidies for low income individuals under Medicare Part D and for the transitional drug card program through SSA outreach efforts.
MEDICAID AND MISCELLANEOUS PROVISIONS¹⁸ – TITLE X	
SUBTITLE A - MEDICAID PROVISIONS	
Temporary Increase In Medicaid DSH Allotments For Fiscal Years 2004 And 2005	<p>Sec. 1001(a)</p> <ul style="list-style-type: none"> ▪ Increases state DSH allotments in FY 2004 by 16 percent. Thereafter, allotments remain at the FY 2004 allotment level subject to the 12 percent limit established in BBA 1997 until the year in which current law “catches up” with the new proposal’s allotments. When that occurs, allotment levels will be the previous year’s allotment increased by the CPI-U, subject to the 12 percent limit. ▪ Effective upon enactment
Increase in floor for treatment as an extremely low DSH State under the Medicaid program for fiscal years 2004 and 2005	<p>Sec. 1001(b)</p> <ul style="list-style-type: none"> ▪ Low DSH states will receive a 16% increase annually for five years.
Allotment Adjustment	<p>Sec. 1001 (c)</p> <ul style="list-style-type: none"> ▪ For FY 2004 and FY 2005, if a statewide waiver under section 1115 is revoked or terminated before the end of either fiscal year and there is no DSH allotment for the state, the HHS Secretary will: <ul style="list-style-type: none"> ▪ permit the state to submit an amendment to its state plan that would describe the methodology to be used by the state to identify and to make payments to disproportionate share hospitals; and ▪ provide for computation of an appropriate DSH allotment for the state for FY 2004 or FY 2005 (or both) that would not exceed amounts provided for in the Act and that does not result in greater expenditures than would have been made if the waiver had not been revoked or terminated. ▪ Directs the HHS Secretary, in determining the appropriate DSH allotment, to take into account the level of state DSH expenditures for

15 The Medicaid drug rebate program was established in the Omnibus Budget Reconciliation Act of 1990 (OBRA). Under the provisions of the rebate program, drug manufacturers are required to provide state Medicaid programs a rebate on outpatient prescription drugs as a condition of the drugs being covered by the program. For all brand-name products, the rebate is the greater of either 15.1 percent of the average manufacturer price (AMP) or 100 percent of the difference between the AMP and the manufacturers best price. The best price is the lowest price offered to any domestic purchaser other than the Medicaid program. Prior to the enactment of DIMA, the following prices were excluded from the “best price” calculation: (1) federal supply schedule (FFS) prices; (2) prices charged to entities under the Veteran’s Health Care Act (outpatient 340B prices); (3) prices under state pharmaceutical assistance programs; (4) prices that are nominal in amount; and (5) single-award contract prices charged to any federal agency.

16 Medicaid drug rebates are calculated based on the difference between the average manufacturer’s price (AMP) and the manufacturer’s “best price.” In determining the “best price” certain discounted prices and fee schedules are disregarded.

17 See Appendix A for description of QI-1 program.

18 Miscellaneous reports, studies, commissions and working groups can be found in a separate section of this report, “Studies, Reports, Working Groups and Commissions.”

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	the fiscal year preceding the fiscal year in which the waiver program was initiated.
Increased Reporting and Other Requirements to Ensure the Appropriate Use of Medicaid DSH Payment Adjustments	Sec. 1001 (d) <ul style="list-style-type: none"> ▪ Requires states, as a condition of receive federal Medicaid payments, to submit to the HHS Secretary an annual report identifying: <ul style="list-style-type: none"> ▪ each disproportion share hospital that received a payment; ▪ the amount the hospital received; and ▪ any other information deemed appropriate by the HHS Secretary to ensure that the payments were used properly.
Clarification Regarding Non-Regulation of Transfers	Sec. 1001(e) <ul style="list-style-type: none"> ▪ Permits the HHS Secretary to allow a publicly-owned regional medical center to use the disproportionate share hospital allotment of another state. ▪ Effective through 12/31/05.
Clarification Of Inclusion Of Inpatient Drug Prices Charged To Certain Public Hospitals In The Best Price Exemptions For The Medicaid Drug Rebate Program.	Sec. 1002 <ul style="list-style-type: none"> ▪ Exempts 340B public hospital purchases of inpatient drugs from the Medicaid “best price” calculations.¹⁹ ▪ Establishes an anti-diversion provision that subjects any drug for inpatient use covered under the 340B program to the auditing and record keeping requirements of the 340B program.
Extension of Moratorium on the Determination of the Saginaw Community Hospital as an IMD²⁰	Sec. 1003 <ul style="list-style-type: none"> ▪ Extends for two years the moratorium on the determination of Saginaw Community Hospital as an IMD. Effective as if included in the Balanced Budget Act of 1997.
National and State Background Checks on Direct Access Employees of Long Term Care Facilities or Providers – Pilot Program	Sec. 307 <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to establish pilot programs in up to 10 states. ▪ Provides \$25 million in mandatory funding for background checks. The HHS Secretary is authorized to reserve 2% of the program’s funds for program evaluation. ▪ States that agree to participate in the pilot program will be responsible for monitoring provider compliance and must establish procedures for workers to appeal or dispute the findings of the background checks. ▪ Long term care providers in participating states are required to: (1) give notice to new workers about background checks; (2) obtain a written statement disclosing any conviction for a relevant crime or finding of patient or resident abuse from the worker; (3) receive written permission from workers authorizing a criminal background check; (4) obtain a rolled set of finger prints of workers; (5) obtain

19 The 340B Drug Pricing Program was established in the Veterans Health Care Act of 1992 (P.L. 102-585) and was codified as section 340B of the Public Health Service Act. The program limits the costs of drugs of to federal purchasers and to certain grantees of federal agencies. Outpatient prescription drugs for public hospitals, Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) were already excluded from the Medicaid “best price” calculation.

20 Medicaid payment for services provided by an institution for mental disease (IMD) may be made only for beneficiaries who are under age 21 or over age 65. An IMD is a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases. For two facilities in Michigan, Kent Community Hospital Complex and Saginaw Community Hospital, previous legislation imposed a moratorium on determination of the facilities as IMDs through 12/31/02.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>any other information specified by the state; and (6) initiate a check of available registries that document findings of resident or patient neglect, abuse , or misappropriation of property. Providers must also obtain information on the workers from the state through a 10-fingerprint background check to be conducted using state criminal records and the Integrated Automated Fingerprint Identification System of the Federal Bureau of Investigation (FBI). At least one state should test if providers could contract with employment agencies, subject to conditions specified by the state, to conduct background checks.</p> <ul style="list-style-type: none"> ▪ Pending completion of the national and state criminal history background checks, states may permit providers to provisionally employ workers provided they comply with supervisory requirements established by the state. These requirements would take into account the cost or other burdens associated with small rural providers and the nature of care delivered by home health and hospice providers. ▪ Information obtained from the background check may only be used to determine the suitability of the applicant for employment. Providers are also protected from liability for denying employment based on reasonable reliance on information from background checks.
SUBTITLE B – FEDERAL REIMBURSEMENT OF EMERGENCY HEALTH SERVICES PROVIDED TO UNDOCUMENTED IMMIGRANTS	
Federal Reimbursement Of Emergency Health Services Furnished To Undocumented Immigrants²¹	Sec. 1011 <ul style="list-style-type: none"> ▪ Permits reimbursement to providers for the uncompensated provision of emergency health services to immigrants who have been allowed to enter the United States for the sole purpose of receiving such services. ▪ Appropriates \$250 million annually for fiscal years 2005-2008, \$167 million of which would be allotted to the 50 states in proportion to each state’s proportionate share of undocumented immigrants residing in the United States. The remaining \$83 million would be allotted to the 6 states with the highest number of apprehensions of undocumented immigrants. ▪ From the \$250 million in state allotments, the HHS Secretary is directed to make payments directly to eligible providers located in the state for unreimbursed costs incurred by providing emergency health care services to: (1) undocumented immigrants; (2) immigrants who have been paroled in the United States at a port of entry for the purpose of receiving eligible services; (3) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a specified identification card. ▪ If the amount of funds allotted to a state is insufficient to ensure that each eligible provider receives appropriate funding, the HHS Secretary is required to reduce the payments to all providers to ensure that each eligible provider receives payment. ▪ Program becomes effective upon enactment. For preliminary information on state allocations, go to Appendix B – Section 1011 Preliminary State Allocations – Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens.²²
DIRECT SUBSIDY PAYMENTS FOR SPONSORS OF QUALIFIED RETIREE PRESCRIPTION DRUG PLANS (TITLE I)	
Direct Subsidy for Sponsors of Qualified Retiree Prescription Drug Plans for Plan Enrollees Eligible for, but Not Enrolled in	Title I, Subpart 3, Sec. 1860D-22 <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to make special subsidy payments to sponsors of qualified retiree prescription drug plans²³ and clarifies that state and local governments are eligible to receive the subsidy. The employer subsidy for retiree prescription drug coverage is excludable from taxation.²⁴

21 The Balanced Budget Act of 1997 provided \$25 million in funding for state emergency health services furnished to undocumented immigrants for each of FY 1998 – FY 2001. Funds were distributed among the 12 states with the highest number of undocumented immigrants.

22 The Centers for Medicare and Medicaid Services published guidance on this program on 11/16/04 a summary and a link to the CSM guidance can be found on the NCSL Health Policy website at <http://www.ncsl.org/statefed/health/Sec1011StAlloc.htm>. A chart providing preliminary state-by-state funding allocations for FY 2005 are in Appendix B – Section 1011 Preliminary State Allocations – Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens.

23 Qualified retiree prescription drug plans must be employment-based group health plans. Group health plans include: welfare plans defined under the Employee Retirement Income Security Act (ERISA), federal and state governmental plans, including plans such as the Federal Employee Health Benefits Program (FEHBP) and CalPERS, collectively bargained plans and church plans.

24 State and local governments cannot take advantage of the tax exclusion. For this reason, the benefit to for-profit entities is greater than the 28% subsidy available to state and local governments and non-profit entities.

PROVISION	MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
a Medicare Prescription Drug Plan	<ul style="list-style-type: none"> ▪ The subsidy payments would be made on behalf of an individual covered under the retiree prescription drug plan, who is entitled to enroll in a Medicare prescription drug plan, but opts not to do so. ▪ Subsidy payments would equal 28% of allowable costs over the \$250 deductible and up to \$5,000. (The dollar amounts would be adjusted annually by the percentage increase in Medicare per capita prescription drug costs). Allowable costs exclude administrative costs and any discounts or rebates an employer receives. <ul style="list-style-type: none"> ▪ The sponsor must provide the HHS Secretary with an attestation that the actuarial value of its prescription drug plan is at least equivalent to the actuarial value of the standard prescription drug coverage under Medicare Part D. ▪ Individuals covered under an employer-based plan may enroll in a PDP or MA-PD plan and may have their employer pay the premium. ▪ Qualified retiree health plans have maximum flexibility on plan design, formularies and networks.²⁵ ▪ Employers may also provide premium subsidies and cost-sharing assistance for retirees that enroll in a Medicare prescription drug plan or an integrated plan. Plan payments towards a retiree’s deductible and/or coinsurance does not count towards the retiree’s out-of-pocket expenditure requirement. ▪ Employers may negotiate preferential treatment from integrated plans.
DIRECT SUBSIDY PAYMENTS FOR QUALIFIED STATES OFFERING A STATE PHARMACEUTICAL ASSISTANCE PROGRAM (TITLE I)	
Direct Subsidy for Qualified States Offering a State Pharmaceutical Assistance Program (SPAPs) for Program Enrollees Eligible for, but not Enrolled in a Medicare Prescription Drug Plan	Title I, Subpart 3, Sec. 1860D-23 <ul style="list-style-type: none"> ▪ Requires coordination of benefits with “qualified” state pharmacy assistance programs.²⁶ Medicare Part D is the primary payer. <ul style="list-style-type: none"> ▪ The coordination requirements relate to payment of premiums and coverage and payment for supplemental drug benefits, and assistance with cost-sharing. <u>When a state pays cost-sharing on behalf of a Part D beneficiary, the costs incurred by the state counts toward the beneficiary’s out-of-pocket expenditure requirement.</u> ▪ Requirements must be included for enrollment file-sharing, claims processing, claims reconciliation reports, application of the catastrophic out-of-pocket protection, and other administrative procedures as determined by the HHS Secretary. ▪ A card used under Part D may also be used for benefits under the state program. ▪ SPAPs may act as administrative intermediaries for the purpose of facilitating enrollment of SPAP members in Medicare prescription drug plans and into a discount drug card program. ▪ Authorizes \$62.5 million in each of FY 2005 and FY 2006 for payments to states with approved applications, to provide: (1) education programs for beneficiaries about Medicare Part D coverage; (2) technical assistance to facilitate selection and enrollment in plans, and (3) other activities to promote effective coordination.
State Pharmaceutical Assistance	Sec. 106

25 The provision in the Senate bill (S.1) would have amended the Age Discrimination in Employment Act of 1967 (ADEA) to allow an employee benefit plan that provides medical benefits to be offered to retirees who are not eligible for Medicare benefits or benefits provided under a state plan without offering medical benefits, or the same medical benefits to Medicare-eligible retirees or retirees eligible for benefits under a state plan. The bill as enacted did not include the Senate provision, but language in the conference report states that the “conferees reviewed the ADEA and its legislative history and believe the legislative history clearly articulates the intent of Congress that employers should not be prevented from providing voluntary benefits to retirees only until they become eligible to participate in the Medicare program.” This will continue to be a controversial issue.

26 A qualified SPAP is one that: (1) provides financial assistance for the purchase or provision of supplemental prescription drug coverage on behalf of eligible individuals; and (2) in determining program eligibility and amount of payment, provides assistance to beneficiaries in all Part D plans and does not discriminate based on the Part D plan in which an individual is enrolled.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Transition Commission (SPATC)	<ul style="list-style-type: none"> ▪ Establishes a State Pharmaceutical Assistance Transition Commission²⁷ to address transition and implementation issues regarding State Pharmaceutical Assistance Programs (SPAPs) and the new Medicare Part D. The Commission is expected to play an integral role in identifying potential problems and proposing solutions to ensure a seamless transition for states and beneficiaries in coordinating and interacting with the new Medicare plans. ▪ The Commission has held two meetings (7/7/04 and 10/14/04). For a list of the Commissioners and the agendas and minutes of its meetings, go to http://www.cms.hhs.gov/faca/spatc/details.asp. ▪ The Commission is to report to the President and Congress by 1/1/05. The Commission is scheduled to sunset 1/31/03.
COORDINATION REQUIREMENTS FOR PLANS PROVIDING PRESCRIPTION DRUG COVERAGE	
Coordination Requirements for Plans Providing Prescription Drug Coverage	<p>New Sec. 1860D-24</p> <ul style="list-style-type: none"> ▪ Plans, including Medicaid, group health plans, the Federal Employees Health Benefit Plan (FEHBP), military coverage and other plans are expected to use the coordination mechanisms established for state pharmaceutical assistance programs (SPAPs) and Part D to exchange drug claims and to track out-of-pocket expenditures. ▪ Prohibits the Secretary from imposing user fees on SPAPs unless the program fails to meet the requirements established by the Secretary. ▪ Provides that the coordination mechanisms cannot interfere with a Part D plan's cost management tools.
MEDIGAP AMENDMENTS	
Medigap Amendments²⁸	<p>Sec. 104 (a)</p> <ul style="list-style-type: none"> ▪ All of the provisions related to Medigap policies with drug coverage apply to the standardized policies (H, I, and J, including J with high deductible), as well as the pre-standardized Medigap policies with drug coverage and the Medigap policies with drug coverage in the waiver states.
Sales of New Medigap Policies with Drug Coverage	<ul style="list-style-type: none"> ▪ No <u>new</u> Medigap policies with drug coverage can be sold or issued on or after January 1, 2006. Issuers can offer new H, I, and J policies with benefit packages modified to exclude drug coverage after January 1, 2006. Issuers offering Medigap policies with drug coverage in the three waiver states can offer these policies with the benefit package modified to exclude drug coverage. Failing to meet the requirements of this provision could result in a criminal penalty (e.g., a fine, or imprisonment of not more than 5 years, or both) and/or a civil money penalty not to exceed \$25,000 (or \$15,000 in the case of a person other than the issuer of the policy) for each such failure.
Renewal of Existing Policies with Drug Coverage	<ul style="list-style-type: none"> ▪ No existing Medigap policies with drug coverage can be renewed on or after January 1, 2006 for individuals who are part D enrollees. However, an existing Medigap policy with drug coverage that was issued before January 1, 2006 can be renewed for a non-part D enrollee.
Elimination of Duplicative Coverage for Part D Enrollees	<ul style="list-style-type: none"> ▪ Individuals who enroll in a Part D plan who are covered under an existing Medigap policy with drug coverage will have the following options for eliminating the duplicative drug coverage:

27 The membership must include: (1) a representative of each governor from each state with a program that the HHS Secretary identifies as having a benefit package comparable to or more generous than those provided by Medicare Part D; (2) representatives from other states that had pharmaceutical assistance programs, as appointed by the Secretary; (3) representatives of organizations that represented interests of participants, as appointed by the Secretary, but not to exceed the number of state representatives; (4) representatives of Medicare Advantage (MA) organizations, Pharmacy Benefit Managers and other private insurance plans; and (5) the Secretary or the Secretary's designee and other members specified by the Secretary.

28 Medicare beneficiaries with Medigap insurance usually have coverage for Medicare deductibles and coinsurance. They may also have coverage for items and services not covered by Medicare. Individuals must select from ten standardized plans (Plan A through Plan J) although all plans are not offered in every state. Plan A covers a basic benefit package. Each of the remaining plans include the basic benefit plus some combination of additional benefits. Plans H, I and J provide prescription drug coverage. Plan J is the most comprehensive.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ <u>If they enroll in Part D before the end of the initial Part D enrollment period</u>, they can either: <ul style="list-style-type: none"> ▪ continue with a modified version of their existing Medigap policy that excludes coverage for prescription drug expenses incurred after the effective date of the individual’s coverage under a Part D plan and adjusts their Medigap premiums to reflect the elimination of drug coverage (as with previous coverage, the modified policy would be guaranteed renewable); or ▪ enroll on a guarantee issue basis in a Medigap policy with a different benefit package (A, B, C, or F, including F with high deductible, the two proposed new benefit packages (described below), or comparable benefit packages in the three waiver states) through their current insurer if they seek to do so not later than 63 days after the effective date of their coverage under a Part D plan and if that benefit package is offered and available for issuance to new enrollees by such insurer. Any issuer that fails to meet the requirements related to guaranteed renewability and guaranteed issue of a substitute policy will be subject to a civil money penalty not to exceed \$5,000 for each such failure. ▪ <u>If they enroll in Part D after the initial Part D enrollment period</u>, they can only continue with a modified version of their existing Medigap policy that excludes coverage for prescription drug expenses incurred after the effective date of the individual’s coverage under a Part D plan and adjusts their Medigap premiums to reflect the elimination of drug coverage (as with previous coverage, the modified policy would be guaranteed renewable).
<p>Notification of Current Policyholders with Drug Coverage</p>	<ul style="list-style-type: none"> ▪ Requires issuers to provide written notice to each individual who holds a Medigap policy with drug coverage during the 60-day period immediately preceding the initial Part D enrollment period. The written notice must be in accordance with standards that the Secretary establishes in consultation with the National Association of Insurance Commissioners, and must: <ul style="list-style-type: none"> ▪ Notify individual policyholders of their Medigap options if they do or do not enroll in a Part D plan during the initial enrollment period. ▪ Notify policyholders whose current Medigap plan does not provide creditable prescription drug coverage of that fact, and that if they do not enroll in Part D during the initial enrollment period, there will be limitations on when they can enroll in Part D during a given year, and that any such enrollment will be subject to a late enrollment penalty. ▪ Provide other information that the Secretary may specify, including information about the potential impact of their decision on their Medigap premiums.
<p>Guaranteed Issue for Eligible Individuals Who Try Medicare Advantage</p>	<ul style="list-style-type: none"> ▪ The current law provision providing certain return rights for individuals who leave Medigap coverage to try M+C is modified to address the situation where the Medigap coverage included drug coverage. These individuals would have guaranteed issue rights to their previous Medigap policy, modified to exclude drug coverage.
<p>Development of New Standards for Medigap Policies</p>	<p>Sec. 104 (b)</p> <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to request the National Association of Insurance Commissioners (NAIC) to review and revise standards for Medigap policies to conform to the provisions of the Act. Urges that the review and revisions be completed by 1/1/06. ▪ Provides that the revision include two new benefit packages: (1) the first package would provide 50% coverage of the otherwise applicable cost sharing, no coverage of the Part B deductible, coverage of all hospital coinsurance for long stays and 365 extra lifetime days of coverage and limit annual out-of-pocket costs to \$4,000 in 2006; and (2) the first package would provide 75% coverage of the otherwise applicable cost sharing, no coverage of the Part B deductible, coverage of all hospital coinsurance for long stays and 365 extra lifetime days of coverage and limit annual out-of-pocket costs to \$2,000 in 2006.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Medigap issuers can not be red to participate as a Medicare prescription drug plan (PDP) sponsor.
Preemption of State Law	<ul style="list-style-type: none"> ▪ States are prohibited from requiring Medigap insures to participate as a Medicare prescription drug plan (PDP) sponsor as a condition for issuing policies in the state.
MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM	
Card Availability and Program Design	<p>Title I, Subpart 4, New Sec. 1860D-31</p> <ul style="list-style-type: none"> ▪ Establishes a voluntary Medicare-endorsed drug discount card program that will be available no later than 6 months after enactment, and would end when the prescription drug benefit becomes available to the beneficiary in 2006. A transition provision would ensure an appropriate transition for ending the discount card and beginning the drug benefit. ▪ Beneficiaries will have a choice of at least two Medicare endorsed cards. ▪ Cards will be available on at least a statewide basis, except for Medicare+Choice sponsors who could offer cards in their service area. ▪ There would be a continuous open enrollment for beneficiaries, and a standard enrollment form. ▪ The Secretary will disseminate card information, enrollment information and availability of transitional assistance to beneficiaries. ▪ Card sponsors may charge an annual enrollment fee of up to \$30, which may be paid by a state. ▪ Card sponsors must offer beneficiaries access to negotiated prices.
Eligibility	<p>Title I, Subpart 4, New Sec. 1860D-31(f)</p> <ul style="list-style-type: none"> ▪ All Medicare beneficiaries would be eligible for the card, except those enrolled in Medicaid and entitled to Medicaid drug coverage, including individuals participating in Section 1115 Medicaid waiver programs. Individuals could only enroll in one Medicare-endorsed card at a time. The HHS Secretary will determine eligibility rules for individuals who qualify for Medicaid under the state’s “medically needy” program. ▪ Medicare beneficiaries with incomes below 135% of FPL, who enroll in an endorsed discount card program, are eligible to receive \$600 in 2004 and 2005 to purchase prescription drugs (See “Transitional Low Income Assistance” in this section for more detail). ▪ In 2004, individuals may change their designated drug card for 2005.
Drug Card Sponsors	<p>Title I, Subpart 4, New Sec. 1860D-31(h)</p> <ul style="list-style-type: none"> ▪ Medicare-endorsed discount card sponsors must be non-governmental entities approved by the HHS Secretary. ▪ Pharmacy Benefit Managers (PBMs), wholesalers, retail pharmacies, insurers, or Medicare+Choice plans could be sponsors of a Medicare-endorsed drug card. ▪ Sponsors must: <ul style="list-style-type: none"> ▪ obtain approval from the Secretary in order to offer the Medicare endorsed card; ▪ provide information on enrollment fees and negotiated prices for drugs; ▪ provide convenient access to pharmacies (using the TRICARE access standard) <i>[See footnote #1 for more information];</i> ▪ administer a system to reduce medication errors and prevent adverse drug interactions; and ▪ maintain a grievance process to resolve disputes.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Sponsors are precluded from marketing non-drug products to Medicare beneficiaries.
<p>Transitional Low-Income Assistance/Special Transitional Low-Income Assistance</p>	<p>Title I, Subpart 4, New Sec. 1860D-31(g) Transitional Low Income Assistance/Special Transitional Low-Income Assistance</p> <ul style="list-style-type: none"> ▪ All individuals with income under 135 percent of the federal poverty level will be eligible for transitional assistance unless they have third party coverage from an employer, the Department of Defense, Medicaid or the Federal Employees' Health Benefit Program (FEHBP). ▪ Individuals receiving Transitional Low Income Assistance will be entitled to have their discount card enrollment fee paid by the federal government. ▪ Provides that individuals will self-certify income, but HHS, subject to strict confidentiality constraints will verify eligibility. There will be no asset test. ▪ Up to \$600 in both 2004 and 2005 will be provided in conjunction with the discount card to purchase prescription drugs, but the amount may be prorated for beneficiaries who enroll for part of a year.²⁹ ▪ Eligible beneficiaries between 101%- 135% of FPL will pay a 10% coinsurance on each discounted drug. Under the Special Transitional Low-Income Assistance Program, eligible beneficiaries with incomes at or below 100% FPL will pay a 5% coinsurance on each discounted drug. ▪ If a beneficiary has a balance in 2004, the funds will rollover into 2005, except no rollover is permitted if the individual voluntarily disenrolls from an endorsed plan. ▪ Pharmacies may reduce coinsurance otherwise applicable and states may pay some or all of the coinsurance for some or all transitional assistance enrollees. In the case where a state pays the fee, the state will pay the pharmacy directly. No federal matching funds for state expenditures under Medicaid is authorized. These expenditures will not be considered Medicare cost-sharing for the purposes of the Qualified Medicare Beneficiary (QMB) program. ▪ Directs the HHS Secretary to ensure that residents of long term care facilities and American Indians have access to the Transitional Assistance Program. ▪ The availability of negotiated prices or transitional assistance cannot be taken into account in determining an individual's eligibility for or benefits under any other federal program.
<p>Transition Period – Special Rules</p>	<p>Title I, Subpart 4, New Sec. 1860D-31(d)</p> <ul style="list-style-type: none"> ▪ The assistance provided through the discount card and transitional assistance will not apply to covered discount card drugs after 12/31/05, except as provided for during an individual's transition period. Any transitional assistance for low-income individuals will be available after that date to the extent the assistance is for drugs dispensed on or before the date. ▪ Special rules may apply for an individual in a transition period that is also enrolled under a card program as of 12/31/05. The transition period to the new Part D is the period beginning January 1, 2006 and ending on the effective date of the individual's coverage under Part D or at the close of the individual's enrollment period for Part D. During this period, discounts may continue to apply for drugs dispensed to the individual. No annual fee will be applicable and the individual cannot switch plans. The balance of any transitional assistance remaining on January 1, 2006 would be available during this period.

²⁹ The \$600 will be prorated in 2004 for persons who enroll after the initial implementation date. In 2005, the \$600 will be prorated for individuals who enroll after 2/1/05.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Treatment of Territories	<p>Title I, Subpart 4, New Sec. 1860D-31(j)</p> <ul style="list-style-type: none"> ▪ Provides \$35 million for territories to establish a plan to provide transitional assistance for covered discount drugs to some or all eligible people living in the jurisdiction. ▪ Individuals who are entitled to benefits under Medicare Part A or enrolled in Medicare Part B with incomes below 135% of FPL will be eligible to participate. ▪ Allotments to the territories will be based on the relative number of Medicare recipients in each jurisdiction compared to the total number of Medicare recipients in all of the jurisdictions.
Transitional Assistance Account	<p>Title I, Subpart 4, New Sec. 1860D-31(k)</p> <ul style="list-style-type: none"> ▪ Creates a Transitional Assistance Account in the Part B Trust Fund. Funds in this account will be kept separate from the other Part B funds. ▪ Costs associated with the discount card program and the transitional assistance program will be excluded from the calculation of the Part B premium.
Medicaid “Best Price”	<p>Title I, Subpart 4, New Sec. 1860D-31(e)(1)(D)</p> <ul style="list-style-type: none"> ▪ Negotiated prices for this program will not be considered for the purposes of making the “best price” calculation for the Medicaid drug rebate program.
Confidentiality	<p>Title I, Subpart 4, New Sec. 1860D-42(e)(4)</p> <ul style="list-style-type: none"> ▪ Applies the confidentiality provisions included in the Medicaid drug rebate program to similar information provided under this Act.³⁰
Medical Errors	<p>Title I, Subpart 4, New Sec. 1860D-31</p> <ul style="list-style-type: none"> ▪ Each endorsed card program will be required to implement a system to reduce medication errors and adverse drug reactions and to improve medication use.
Access to Coverage in the Territories	<p>Title I, Subpart 4, New Sec. 1860D- 42(a)</p> <ul style="list-style-type: none"> ▪ Authorizes the HHS Secretary to waive requirements established in the Act, including the requirement to provide all beneficiaries with a choice of two plans, if the Secretary determines it is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals.
Application for Demonstration Authority	<p>Title I, Subpart 4, New Sec. 1860D- 42(b)</p> <ul style="list-style-type: none"> ▪ Clarifies that the Secretary’s current demonstration authority under Medicare includes Medicare Part C and Part D. Under section 402(b), the Secretary is authorized to waive requirements under Medicare that relate to reimbursement and payment.³¹
Study on Transitioning Part B Prescription Drug Coverage	<p>Title I, Subpart 4, New Sec. 1860D-42(c)</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to submit a report to Congress making recommendations regarding ways to include prescription drug benefits provided through Medicare Part B to Medicare Part D. ▪ Report is to be submitted no later than 1/1/05.

30 Provides that information disclosed by manufacturers or wholesalers under Medicaid or through the Department of Veterans Affairs (VA) is confidential and must not be disclosed in a way that would identify a specific manufacturer or wholesaler, prices charged for drugs by these providers, except: (1) if the Secretary determines it necessary to carry out the law; (2) to permit the Comptroller General to review the information provided; and (3) to permit the Director of the Congressional Budget Office (CBO) to review the information provided.

31 According to the conference report, conferees intend that any demonstration of benefit flexibility be limited to evaluate innovations in drug benefit design and not to increase total prescription drug outlays.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Report on Progress in Implementation of Prescription Drug Benefit	<p>Title I, Subpart 4, New Sec. 1860D-42(d)</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to report to Congress no later than 3/1/05 on the progress made in implementing the Medicare Part D program.
BENEFICIARY PROTECTIONS – TITLE I	
Disclosure and Dissemination of Beneficiary Information	<p>Title I, Subpart 1, New Sec. 1860D-4(a)</p> <ul style="list-style-type: none"> ▪ Establishes beneficiary protection requirements for qualified prescription drug plans. ▪ PDP plan sponsors are required to disclose, to each enrolling beneficiary, information about the plan’s benefit structure. ▪ The plan will disclose information on: 1) access to specific covered drugs (including access through pharmacy networks); 2) how any formulary (including a tiered formulary) used by the sponsor functions, including how a beneficiary might obtain information on the formulary; 3) copayment and deductible requirements (including any applicable tiered copayment requirements; and 4) grievance and appeals procedures. ▪ In addition, beneficiaries will have the right to obtain more detailed plan information. ▪ Plans will be required to have a mechanism for providing specific information to enrollees on request. ▪ The sponsor will be required to make available, through an Internet website, information on specific changes in the formulary (including tiered or preferred status). ▪ Sponsors will be required to furnish to enrollees, a detailed explanation of benefits when drug benefits were provided, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.
Access to Covered Part D Drugs	<p>Title I, Subpart 1, New Sec. 1860D-4(b)</p> <ul style="list-style-type: none"> ▪ PDP sponsors are required to permit the participation of any pharmacy that meets the plan’s terms and conditions. ▪ A PDP could reduce copayments for its enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the Secretary to the plan. ▪ The PDP sponsor is required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to assure convenient access. ▪ The conference report adopts the House language, with the clarification that the minimum in-network pharmacy for each plan offered by a PDP or MA plan in a geographic area must provide access to pharmacies that is not less restrictive than the TRICARE access standards. ▪ These standards require that 90 percent of plan enrollees in urban areas will have access to a retail pharmacy within 2 miles; that 90 percent of suburban plan enrollees will have access to a retail pharmacy within 5 miles; and that 70 percent of rural plan enrollees will have access to a pharmacy within 15 miles. ▪ PDP sponsors or MA sponsors can offer broader networks than those meeting the TRICARE access standards. ▪ Plan sponsors cannot create any pharmacy networks that are more restrictive than the TRICARE access standards. ▪ PDP plan sponsors or MA sponsors cannot include mail order only pharmacies. ▪ The rules would include adequate emergency assess for enrolled beneficiaries.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The rules may include standards with respect to access for enrollees in long-term care facilities. ▪ Sponsors will permit enrollees to receive benefits (which may include a 90-day supply) through a community pharmacy, rather than through mail-order, with any differential in charge paid by enrollees. ▪ In addition, the conference report clarifies that pharmacies could not accept insurance risk.
Cards or Other Technology	<p>Title I, Subpart 1, New Sec. 1860D-4</p> <ul style="list-style-type: none"> ▪ PDP sponsors are required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for drugs. ▪ The Secretary will provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology. ▪ These standards are to be compatible with the administrative simplification requirements of Title XI of the Social Security Act. ▪ The standards will be implemented by such date the Secretary determines to be sufficient to ensure PDP sponsors utilize such standards beginning January 1, 2006, and developed in consultation with the National Counsel for Prescription Drug Programs (NCPDP) and other standard setting organizations.
Formularies	<p>Title I, Subpart 4, New Sec. 1860D-4(b)(3)</p> <ul style="list-style-type: none"> ▪ The provision would specify that if a PDP sponsor used a formulary, it would have to meet certain requirements. ▪ A pharmaceutical and therapeutic committee would develop and review the formulary. ▪ The committee would include at least one practicing physician and one practicing pharmacist, independent and free of conflict with respect to the committee, both with expertise in the care of elderly or disabled persons. ▪ The majority of members would be physicians or pharmacists. ▪ The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. ▪ The committee would also take into account whether including a particular covered drug in the formulary (or in a particular tier in a formulary) had therapeutic advantages in terms of safety and efficacy. ▪ The formulary would have to include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories or classes. ▪ The Secretary is required to request the United States Pharmacopeia to develop a list of categories and classes that may be used by plans. ▪ The Secretary’s request would also include the revision of such classification from time to time to reflect changes in therapeutic uses of covered drugs and the addition of new covered drugs. ▪ The plan sponsor cannot change therapeutic categories and classes in a formulary other than at the beginning of a plan year, except as the Secretary may permit to take into account new therapeutic uses and newly approved covered drugs. ▪ Each sponsor is required to establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Any removal of a drug from the formulary, and any change in the preferred or tier cost-sharing status of a drug, could not occur until appropriate notice had been provided to the Secretary, beneficiaries, and physicians, pharmacies, and pharmacists. ▪ The plan must provide for periodic evaluation and analysis of treatment protocols and procedures. ▪ The PDP sponsor would be required to have (directly, or indirectly through arrangements) a cost-effective drug utilization management program; quality assurance measures, a medication therapy management program; and a program to control fraud, waste, and abuse.
Medication Therapy Management Program	<p>Title I, Subpart 4, New Sec. 1860D-4(c)(2)</p> <ul style="list-style-type: none"> ▪ A medication therapy management program is a program of drug therapy management and medication administration, that may be furnished by a pharmacist and that is designed to assure with respect to targeted beneficiaries that drugs under the plan are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. ▪ Targeted individuals are those with multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure) or are taking multiple drugs or are likely to incur annual costs that exceed a specified level. ▪ The program would be developed in cooperation with licensed practicing pharmacists and physicians. ▪ Such plans would be coordinated with disease management programs to the extent beneficiaries are enrolled in such programs. ▪ The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. ▪ The sponsor or entity would disclose the amount of such fees to the Administrator upon request; the fees would be confidential.
Consumer Satisfaction Survey	<p>Title I, Subpart 1, New Sec. 1860D-(d)</p> <ul style="list-style-type: none"> ▪ The Secretary will be required to conduct consumer satisfaction surveys in order to provide comparative information during the enrollment period.
Standards for Electronic Prescribing	<p>Title I, Subpart 4, New Sec. 1860D-4(e)</p> <p>Application of Standards</p> <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to develop final electronic prescription standards by April 1, 2008. The standards apply to prescriptions for covered part D drugs and required information that is transmitted electronically under an electronic prescription drug program conducted by a PDP or MA plan. The standards must be consistent with the objectives of improving patient safety and the quality and efficiency of patient care. <p>Program Requirements</p> <ul style="list-style-type: none"> ▪ The program must provide for the electronic transmittal of information on eligibility and benefits (including formulary drugs, any tiered formulary structure, and prior authorization requirements), information on the drug being prescribed and other drugs listed in the patient's medication history (including drug-drug interactions), and information on the availability of lower-cost, therapeutically appropriate alternative drugs. ▪ Disclosure of information must meet the requirements of the HIPAA privacy rule and, to the extent feasible, be on an interactive, real-time basis. ▪ To the extent practicable, the standards must be designed so that they do not impose an undue administrative burden on prescribing physicians and pharmacists.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The standards must also be compatible with the HIPAA Administrative Simplification standards and other health information technology standards, and must permit the electronic exchange of drug labeling and drug listing information maintained by the FDA and the National Library of Medicine. ▪ Finally, the standards must accommodate the messaging of information about appropriate prescribing of drugs and allow a beneficiary (consistent with their prescription drug plan) to designate a particular pharmacy to dispense a prescribed drug. <p>Initial Standards</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to promulgate initial standards by September 1, 2005, taking into account recommendations from the National Committee on Vital and Health Statistics (NCVHS). The NCVHS is required to develop recommendations in consultation with standard setting organizations, practicing physicians, hospitals, pharmacies, practicing pharmacists, pharmacy benefit managers, state boards of pharmacy and medicine, and appropriate federal agencies. <p>Pilot Projects</p> <ul style="list-style-type: none"> ▪ Prior to the promulgation of final standards, the Secretary must enter into voluntary agreements with physicians, pharmacies, hospitals, and PDP sponsors and MA plans to conduct a pilot project to test the initial standards. The pilot project must be conducted during the 1-year period that begins on January 1, 2006, except that pilot testing is not required where there is adequate industry experience. ▪ The Secretary must then evaluate the pilot project and report to Congress not later than April 1, 2007. Based on the evaluation and not later than April 1, 2008, the Secretary must promulgate final standards to take effect within one year. <p>Relation to State Laws</p> <ul style="list-style-type: none"> ▪ The electronic prescriptions standards shall supercede any contrary state laws. <p>Safe Harbor</p> <ul style="list-style-type: none"> ▪ Requires the Secretary, in consultation with the Attorney General, to provide a safe harbor from both criminal sanctions and 2) of the Act and the self-referral prohibition with respect to the provision of nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information in accordance with Part D standards. ▪ Nonmonetary remuneration includes hardware, software, or information technology and training services. ▪ This safe harbor is to apply in the case of: <ul style="list-style-type: none"> ▪ a hospital by the hospital to members of its medical staff; ▪ a medical group practice by the practice to prescribing health care professionals who are members of the practice; and ▪ a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in its network and to prescribing health professionals.
<p>Grievance Mechanism, Coverage Determinations, Independent Reviews and Appeals</p>	<p>Title I, Subpart 1, New Sec. 1860D-(f)</p> <ul style="list-style-type: none"> ▪ Each PDP sponsor is required to have meaningful procedures for the hearing and resolving of any grievances between the sponsor (including any entity or individual through which the sponsor provided covered benefits) and enrollees. ▪ Enrollees will be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. ▪ A beneficiary in a plan that provides for tiered cost-sharing can request coverage of a non-preferred drug on the same conditions applicable to preferred drugs, if the prescribing physician determines that that the preferred drug for the treatment of the same condition

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>is not as effective for the enrollee or has adverse effects for the enrollee.</p> <ul style="list-style-type: none"> ▪ A PDP is required to have an exceptions process consistent with guidelines established by the Secretary. ▪ In general, PDP plan sponsors will be required to meet the requirements for independent review and appeals of coverage denials and tiered cost-sharing in a similar manner that such requirements applied to MA organizations for fee-for-service benefits. ▪ An individual enrolled in a PDP plan may appeal to obtain coverage for a drug not on the formulary only if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not as effective for the individual or would have adverse effects for the individual or both.
Privacy and Confidentiality	<p>Title I, Subpart 4, New Sec. 1860D-4(i)</p> <ul style="list-style-type: none"> ▪ The PDP sponsor will be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements applied to MA organizations.
Disclosure of Price Differential Between the Price to the Enrollee and Generic Drugs	<p>Title I, Subpart 4, New Sec. 1860D-4(k)</p> <ul style="list-style-type: none"> ▪ Each PDP sponsor will provide that each pharmacy that dispenses a covered drug shall inform enrolled beneficiaries at the time of purchase (or at the time of delivery in the case of mail order drugs) of any price differential between the price to the enrollee and the price of the lowest cost generic drug covered under the plan that is therapeutically equivalent and bioequivalent and available at the pharmacy. The Secretary is permitted to waive this requirement.
Grants to Physicians to Implement Electronic Prescribing Program	<p>Sec. 108</p> <ul style="list-style-type: none"> ▪ Authorizes \$50 million in FY 2007 and such sums as may be necessary in FY 2008 and FY 2009 for the HHS Secretary to make grants to physicians to assist them in implementing the electronic prescription programs that comply with the standards established under the Act. Grant funds may be used to: (1) purchase, lease, and install hardware and software; (2) make upgrades and other improvements; and (3) provide education and training to eligible physician staff on the use of the technology. ▪ Directs the Secretary, in the awarding of the grants, to give special consideration to physicians who serve a disproportionate number of Medicare patients and to give preference to physicians who serve a rural or underserved area. ▪ Each applicant must agree to make non-federal contributions equal to least 50 percent of the cost.
MEDICARE ADVANTAGE – TITLE II	
SUBTITLE A – IMPLEMENTATION OF THE MEDICARE ADVANTAGE PROGRAM	
Implementation of the Medicare Advantage Program	<p>Sec. 201</p> <ul style="list-style-type: none"> ▪ Establishes the Medicare Advantage (MA) program and indicates that references to the Medicare+Choice program are deemed to be references to MA. ▪ Authorizes transition in use of terms in beneficiary educational materials. The transition is to be completed by 1/1/06.
SUBTITLE B – IMMEDIATE IMPROVEMENTS	
Equalizing Payments with Fee-For-Service	<p>Sec. 211(a)</p> <ul style="list-style-type: none"> ▪ For 2004, adds to the current 3 amounts in the "largest of" methodology a fourth amount of 100% of projected fee-for-service Medicare costs (excluding direct medical education and including a VA/DOD adjustment). ▪ For years after 2004, the Secretary is required to recalculate 100% of fee-for-service Medicare costs at least every 3 years.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ For 2004 and succeeding years, modifies the minimum increase rate to be the larger of 102% of the previous year's rate or the prior year's rate increased by the Medicare growth percentage, with no adjustment to this rate for over- or under-projection for years before 2004.
Change in Budget Neutrality	Sec. 211(b) <ul style="list-style-type: none"> ▪ For 2004, eliminates the budget neutrality requirement for the blend capitation rate.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Blend	
Increasing Minimum Percentage Increase to National Growth Rate	<p>Sec. 211(c)</p> <ul style="list-style-type: none"> ▪ The Secretary is to announce new rates for 2004 within 6 weeks of enactment. [Rates for 2004 that were announced in May 2003 apply for January-February 2004, but the Secretary will ensure that total 2004 payments are what plans would have been paid if the revised rates had been in effect all year.] ▪ Applies the provisions of section 604 of BIPA of 2001 related to submission of revised Adjusted Community Rate (ACR) proposals, return to the program, and use of additional payment amounts. Under these provisions: <ul style="list-style-type: none"> ▪ Existing organizations that experience rate increases because of the 2004 revised rates are required to submit a revised ACR proposal for 2004 within 2 weeks of the announcement of revised rates. When submitting an ACR proposal, an organization may use additional payment amounts only to reduce premiums, reduce cost sharing, enhance benefits, utilize benefit stabilization funds, or stabilize and enhance access to providers. Organizations choosing to use additional payment amounts to stabilize and enhance access to providers may do so only if it does not result in increased premiums, increased cost-sharing, or reduced benefits. Any regulations that limit the amounts withheld in a benefit stabilization fund are waived, with respect to ACR proposals for March to December 2004. ▪ Organizations that previously had provided notice of termination or service area reductions may return to the program or their service area if they provide an ACR proposal within 2 weeks after the Secretary announces the revised 2004 rates. ▪ Notwithstanding the issuance of revised rates, organizations will continue to be paid on a fee-for-service basis for 2004 for costs associated with certain new national coverage determinations and legislative changes in benefits that are made mid-year. ▪ Organizations that are required to submit revised ACR proposals must provide written notice to enrollees of changes in eligible individual premiums, eligible individual cost-sharing, or benefits under the plan not more than 3 weeks after the Secretary approves their revised ACR proposals. ▪ Provides that private FFS plans with sufficient providers or professionals under contract (for a category of provider or health care professional) can charge eligible individuals higher co-payments when they obtain care from non-contract providers or professionals. <p>Studies/Reports</p> <ul style="list-style-type: none"> ▪ The Secretary is required to study the impact of additional funding for Medicare Advantage plans on the availability of such plans and on the benefits and premiums of such plans. The report is due by July 1, 2006. ▪ The Medicare Payment Advisory Commission (MedPAC)³² is required to study the method for calculating 100% of fee-for-service costs, including the bases for variation in costs between different geographic areas and the accuracy of risk adjustment methods, within 18 months of enactment. ▪ MedPAC is required to study the extent to which Medicare Advantage plan cost-sharing structures affect access to services or influence the health status of individuals who enroll in such plans. The report is due by December 31, 2004.
SUBTITLE C – OFFERING OF MEDICARE ADVANTAGE (MA) REGIONAL PLANS; MEDICARE ADVANTAGE COMPETITION	
Establishment of MA Regional	Sec. 221

32 The Medicare Payment Advisory Commission (MedPAC) is an independent federal body established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program. The Commission's statutory mandate is quite broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
<p>Plans</p>	<ul style="list-style-type: none"> ▪ A new regional plan offering is established for Medicare Advantage based on a preferred provider organization (PPO) model. A regional PPO is defined as a plan that has a network of providers who contractually agree on reimbursement for covered services, but that also pays some reimbursement if the enrollee sees a provider outside the network. ▪ The Secretary cannot approve local MA PPOs in 2006 and 2007 unless they were already operating in an area in 2005. ▪ Following a market survey, the Secretary will establish 10 to 50 Medicare Advantage regions, designed to maximize plan participation. A regional PPO plan must serve the entire region. Plans may offer a PPO in more than one region or in all regions. ▪ If a regional MA plans feature a deductible, it must have a unified deductible (unlike the separate Part A and Part B deductibles in traditional Medicare). Plans may waive the deductible for preventive services or other services. Regional MA plans must also feature a catastrophic limit on out-of-pocket expenditures for in-network services and a limit for all covered services. ▪ A set of risk corridors will protect plans from unexpected losses in 2006 and 2007. <ul style="list-style-type: none"> ▪ The plan’s target spending amount for the year includes total payments to plans from the government and enrollee premiums, minus the plan’s administrative costs assumed in its bid. ▪ The risk corridors are symmetrical in that the government pays plans if costs are above the target and recoups its share of the savings when costs are below the target. ▪ The plan is fully at risk for the first 3 percent of costs above or below a target amount. ▪ The plan and the government share 50 percent of costs/savings that are 3 to 8 percent off the target. ▪ The government pays/keeps 80 percent of the costs/savings when costs are more than 8 percent off the target. ▪ Plans’ costs are subject to audit by the Secretary, and the Secretary must hold the plans’ financial information confidential. ▪ MA regional plans must be licensed in at least one state in the MA region and must file applications to be licensed in the remaining states. The Secretary may temporarily waive the licensure requirement for any states in which the application has not yet been approved. In the case of a waiver, the MA plan will select one state’s licensure rules, and the Secretary will require the plan to meet that state’s standards throughout the service area. ▪ A stabilization fund will be established to provide plans with incentives to enter and remain in MA regions. <ul style="list-style-type: none"> ▪ The fund will have an initial capitalization of \$10 billion on January 1, 2007 and the money will be available until December 31, 2013. ▪ The stabilization fund will also receive one half of the government’s 25 percent share of any rebates that result when regional MA plans bid below the regional MA benchmarks. ▪ Subject to the budget constraint, the stabilization fund can be used in several ways: <ul style="list-style-type: none"> ▪ NATIONAL BONUS -- For organizations that offer a national plan by bidding on all regions, CMS increases the benchmark payment by 3 percent for each of the organization’s regional plans. ▪ REGIONAL PLAN ENTRY BONUS -- If a region had no MA regional plans offered in the prior year, the Secretary may increase the benchmark amount for the region. The amount and duration of the increase are at the Secretary’s discretion, and the increase will be available to all plans that enter. ▪ REGIONAL PLAN RETENTION BONUS -- If plans notify the Secretary that they intend to exit, and

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p style="text-align: center;">the Secretary determines that fewer than two MA regional plans would be available, and the enrollment in regional MA plans in that region is below the national average, then the Secretary may increase the benchmark payment for plans in that region. The maximum increase is the greater of either 3 percent of the regular benchmark or an amount that would bring the region's benchmark up to the average benchmark relative to average adjusted per capita costs in traditional Medicare. This plan retention funding cannot be used in more than two consecutive years in a region. It also cannot be used in a region that received a plan entry bonus payment in the prior year.</p> <ul style="list-style-type: none"> ▪ Increases in the benchmark apply to that year only; the following year's benchmarks are calculated without regard to any prior increases due to use of the stabilization fund. ▪ The Secretary and the CMS Actuary must determine in advance of a year that the use of the stabilization fund will not exceed the funds available. The Secretary may impose enrollment limits on plans receiving increases in order to keep from exceeding the fund limit. ▪ Starting in 2008, the Secretary must report annually to Congress and to the Comptroller General on the use of the stabilization fund, the amounts available, and cost containment steps taken. ▪ The General Accounting Office will report every two years, starting in 2009 about the use of the stabilization fund, costs to the program, and any effects on enrollee satisfaction and the quality of care in MA regional plans. ▪ For their non-drug benefits, MA regional plan bids will be compared to an MA regional benchmark (described further in Sec. 222). The regional MA benchmark will be a blend consisting of a statutory component and component based on plan bids. <ul style="list-style-type: none"> ▪ The statutory component of the MA regional benchmark will consist of a weighted average of the county Medicare Advantage rates for all counties in the region. The weights will be the number of Medicare beneficiaries in each county. ▪ The bid-based component will consist of a weighted average of plan bids in the region. The weights will be each plan's enrollment in the region during the prior year. The Secretary has two options for determining the weight in the first year. Plans are either weighted equally or by the projected enrollment estimates included in their bids, as verified and/or adjusted by the Chief Actuary. ▪ The MA regional benchmark will consist of a weighted average of the two components. The weight on the statutory component will be the share of Medicare beneficiaries nationally who are enrolled in traditional Medicare during the prior year. The weight on the plan-bid component will be one minus the statutory component weight. ▪ MA regional plans may choose to apply a single local coverage determination throughout the region. ▪ Regional MA plans must meet network adequacy standards throughout the region. The Secretary is authorized to spend up to \$25 million per year (in 2006 -- indexed by hospital market basket increases for later years) for bonus payments to hospitals in areas where regional PPO plans are unable to agree to contracts with those hospitals. The payment is the difference between what the plan pays and what the hospital would have been paid if the patient were in traditional Medicare and the hospital were a critical access hospital. In these cases, the MA regional plan must pay hospitals at least the Medicare fee schedule, and hospitals must demonstrate that the cost of providing the service exceeds the Medicare fee rate. ▪ Effective Dates: In general 1/1/06. PPO regions to be established by January 1, 2005. The stabilization fund will be capitalized on January 1, 2007

PROVISION	MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
<p>Competition Program Beginning in 2006</p>	<p>Sec. 222</p> <ul style="list-style-type: none"> ▪ In general, this section sets forth a structure that applies to most MA plans (but not to MSAs or ESRD enrollees in MA plans). The essentials of this structure are: <ul style="list-style-type: none"> ▪ benchmark amounts for Part A and B benefits, determined by the Secretary, ▪ bids submitted by MA organizations, for Part A and B and other benefits, and ▪ a comparison of bids and benchmarks for Part A and B benefits for purposes of determining (1) eligible individual rebates (if bid is lower) or premiums for those benefits (if bid is higher) and (2) plan payment amounts for those benefits. ▪ For local plans, the Secretary determines benchmark amounts for benefits covered by Parts A and B for geographic areas. These are based on the capitation rates determined under current law as amended by Section 211, summarized above. Per section 221, calculation of benchmark amounts for regional plans is based on a blend of capitation rates and plan bids. ▪ The Secretary announces benchmark amounts and risk adjustment factors and related information by the first Monday in April. ▪ Plans submit a 3-part bid by the first Monday in June addressing (1) Medicare Part A and B benefits (with cost sharing required for Part A and B services or an actuarially equivalent amount), (2) Part D (basic prescription drug) benefits, and (3) supplemental benefits (i.e., reduction in cost sharing for Part A and B benefits, enhancement to the basic drug package, and additional health care benefits). Bids must also include information on the actuarial bases for bids. ▪ With respect to bids, the Secretary may accept only bid amounts that are supported by the actuarial bases provided by the MA organization. The Secretary has negotiating authority similar to the authority of the Director of the Office of Personnel Management under the Federal Employees Health Benefits Program (this authority does not apply to bids from private FFS plans). ▪ In order to determine beneficiary rebate amounts (if any), the Secretary compares the plan's bid for Part A and B benefits to the benchmark (which is for Part A and B). If the risk-adjusted bid is lower than the risk-adjusted benchmark, a rebate of 75% of the difference is available to the plan to provide supplemental benefits (described above) or a reduction in the prescription drug, supplemental, or Part B premium. ▪ The determination of a plan's basic premium (if any) also involves a comparison of the bid to the benchmark. If the plan's unadjusted bid for Part A and B benefits is higher than the unadjusted benchmark, the plan's basic premium is the difference between the unadjusted bid and the unadjusted benchmark. ▪ Eligible individuals may choose to have plan premiums withheld from their Social Security check, through an electronic funds transfer mechanism, or other means the Secretary may specify including payment by an employer. ▪ With respect to payments to the plan, <ul style="list-style-type: none"> ▪ If the bid is lower than the benchmark, the payment amount for Part A and B benefits is the portion of the 3-part bid for Medicare Part A and B benefits (subject to risk adjustment for individual enrollee demographic and health status factors) plus the rebate amount (except rebates related to the Part B premium). ▪ If the bid is equal to or higher than the benchmark, the payment is the benchmark amount, also subject to risk adjustment. If the bid is higher than the benchmark, the plan must charge a basic premium (described above). If it charges a basic premium, the plan also receives an additional payment related to the plan's risk profile. ▪ Payments to plans are also adjusted based on the variation in capitation rates among the different local areas included in the region or service area.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The competitive bidding provisions do not apply to MSAs. MSAs will be paid under the methodology in effect before enactment of this statute, with payments based on MA benchmark amounts. ▪ The Secretary can decide when to implement bid-based payment for ESRD enrollees. Until that time, plans will be paid for their ESRD enrollees under the methodology in effect before enactment of this Act. ESRD enrollees will pay the same premium and receive the same rebates provided to other plan enrollees. ▪ The Secretary may not require an MA organization to contract with any specific entity or individual nor can he or she require any particular price structure for payment by plans to entities or individuals. ▪ There will be a separate payment for MA-PD plans consisting of subsidies under 1860D-15. Also under 1860D-15 there is a provision for risk corridors for prescription drug payment. Finally, payment will also be made for premium and cost-sharing reductions for low-income individuals. (See discussion of Title I drug benefit, “Subsidies for Part D Eligible Individuals for Qualified Prescription Drug Coverage” for additional detail.) ▪ Premiums for Part A and B benefits (if any), prescription drug benefits, and supplemental benefits must be the same for all enrollees in a plan, except if an employer/union negotiates a different benefit package, in which case premiums for those retirees would be uniform. ▪ Repeals the ACR process for years after the 2005 contract year. ▪ Allows the Secretary to waive or modify provisions that hinder the design of, offering of, or enrollment in MA plans offered by employers, labor organizations or the trustees of funds established by employers or labor organizations. ▪ The Secretary may not approve a plan if he or she determines that the plan’s design is likely to substantially discourage enrollment by certain eligible individuals. ▪ Revises funding for eligible individual education and information activities, authorizing \$200 million beginning with fiscal year 2006.
Effective Date	<p>Sec. 223</p> <ul style="list-style-type: none"> ▪ Provisions of subtitle C (sections 221 and 222) are effective for plan years beginning on or after January 1, 2006. ▪ The Secretary is to revise regulations for Part C to carry out the provisions of this statute (no date specified).
SUBTITLE D – ADDITIONAL REFORMS	
Specialized MA Plans for Special Needs Individuals	<p>Sec. 231</p> <ul style="list-style-type: none"> ▪ Establishes a Medicare Advantage (MA) option for private plans that exclusively or disproportionately enroll “special needs” individuals. Two groups of special needs Medicare individuals are specified, the institutionalized and those who also have Medicaid coverage. ▪ The Secretary can also establish standards for other “special needs” groups, i.e., those with severe or disabling chronic conditions that would benefit from enrollment in a specialized MA plan. The Secretary may include End Stage Renal Disease (ESRD) eligible individuals as special needs individuals. (ESRD eligible individuals are otherwise prohibited from enrolling in an MA plan, but they may remain in a plan in which they were enrolled if they develop ESRD after enrollment). ▪ These Specialized MA plans will be paid on the same basis as other MA plans. ▪ This option is available for periods before January 1, 2009. ▪ Requires a report to Congress due December 31, 2007 on the quality of services and costs and savings under this option.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Effective Dates: <ul style="list-style-type: none"> ▪ In general, upon enactment (i.e., for the institutionalized and those with Medicaid coverage). ▪ A final regulation establishing requirements for special needs eligible individuals with severe or disabling chronic conditions is to be issued no later than 1 year after enactment. ▪ Establishes a MA option for private plans that enroll exclusively or disproportionately “special needs” individuals.³³
Preemption of State Laws	<p>Sec. 232</p> <ul style="list-style-type: none"> ▪ Provides that the federal standards established in the Act regarding Medicare Advantage (MA) plans supercede any state law or regulation, other than state licensing laws or state laws relating to plan solvency. This provision applies prospectively. ▪ Prohibits states from imposing a premium tax or similar tax on premiums paid to MA organizations established under the provisions of this Act.
Medicare Medical Savings Accounts (MSAs)	<p>Sec. 233</p> <ul style="list-style-type: none"> ▪ The MSA program becomes a permanent option, the capacity limit is removed, and the deadline for enrollment is eliminated. Non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of MA coordinated care plans. ▪ Effective upon enactment.
Extension of Reasonable Cost Contracts	<p>Sec. 234</p> <ul style="list-style-type: none"> ▪ Under previous law, reasonable cost contracts could not be extended or renewed after December 31, 2004, the MMA: <ul style="list-style-type: none"> ▪ Extends current law through December 31, 2007. ▪ Beginning January 2008, cost contracts cannot continue in any area that has at least 2 MA regional plans or at least 2 MA local plans that meet minimum enrollment requirements of at least 5,000 enrollees in most urban areas and at least 1,500 enrollees in other areas. ▪ Effective upon enactment
Two-year Extension of Municipal Health Service Demonstration Projects	<p>Sec. 235</p> <ul style="list-style-type: none"> ▪ Extends demonstration through 12/31/06.³⁴
Payment by PACE Providers for Medicare and Medicaid Services Furnished by	<p>Sec. 236</p> <ul style="list-style-type: none"> ▪ Extends Medicare Advantage limits on balance billing to cover PACE programs.³⁵ ▪ Medicare-participating providers, physicians, and other entities must accept these limits when they furnish Medicare-covered services to

33 Two groups of special needs individuals are specified in the law: institutionalized individuals and those that have Medicaid coverage. The law directs the Secretary to establish by rule, standards for other special needs groups.

34 This demonstration has operated since 1978 in Baltimore, San Jose, Milwaukee, and Cincinnati. Participating clinics provide Medicare-covered primary and preventive care as well as non-covered services including prescription drugs, dental and vision care, and transportation. The demonstration was originally scheduled to end in 1984 but has been extended six times by Congress. Under the most recent extension (in BIPA 2000), the demonstration will end December 31, 2004. In BBA 1997, Congress limited participation in the demonstration to eligible individuals who were already enrolled and had received at least one project service between Jan. 1, 1996, and enactment of the BBA (August 5, 1997). The BBA also required the four sites to develop transition plans (which began in 2000) to phase-in cost-sharing for non-covered services, and provide counseling on managed care options available in the area.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Noncontract Providers	<p>a participant of a PACE program with which they do not have a contract or other agreement establishing payment amounts.</p> <ul style="list-style-type: none"> ▪ Providers participating under a State Medicaid program must accept payments of no more than those they would receive under the State plan when they furnish services covered under Medicaid but not under Medicare to a participant of a PACE program with which they do not have a contract or other agreement establishing payment amounts. ▪ Effective for services furnished on or after January 1, 2004.
Reimbursement for Federally Qualified Health Centers (FQHCs) Providing Services to MA Plans	<p>Sec. 237</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to make a wrap-around payment for FQHCs in Medicare, to make up the shortfall between what a MA plan pays an FQHC and the reasonable cost-based payments the FQHC other would receive under Medicare fee-for-service. ▪ Requires a contract between an MA organization and the Secretary to provide that any written agreement the organization has with an FQHC will provide that payments for services provided by the FQHC will not be less than payments the organization would make for services if they had not been provided by the FQHC. Applies to services provided on or after 1/1/06 and contract years beginning on or after 1/1/06.
Institute of Medicine (IOM) Evaluation and Report on Health Care Performance Measures	<p>Sec. 238</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to enter into an arrangement under which the Institute of Medicine (IOM) and the National Academy of Sciences will conduct an evaluation of leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the Medicare program. ▪ IOM shall consult with MedPAC in conducting this evaluation and submit a report on the evaluation describing the findings and recommendations for an overall strategy and approach for aligning payment with performance, including options for updating performance measures in the original Medicare fee-for-service, Medicare Advantage, and any other programs under Title XVIII. ▪ Effective not later than 18 months after enactment.
SUBTITLE E – COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM	
Comparative Cost Adjustment Program	<p>Sec. 241</p> <ul style="list-style-type: none"> ▪ Beginning in 2010, the comparative cost adjustment (CCA) program will be implemented in up to 6 Metropolitan Statistical Areas (MSAs) for 6 years. Eligible MSAs will have at least 2 local Medicare Advantage plans with at least 25% of area Medicare eligible individuals enrolled in such plans. (Eligible individuals in counties within a targeted MSA that lack at least 2 private plans would not be affected). ▪ Criteria for designating sites include requirements that at least one site will be from the largest 4 eligible MSAs (defined by total MA eligibles) and at least one site from the 4 eligible sites with the lowest population density. Preference is to be given to areas that are not in a PPO demonstration. ▪ The benchmark in CCA areas will be calculated using a formula that weights a fee-for-service (FFS) portion (based on the greater of the national or local enrollment percentage) and a local plan portion (based on 1.0 minus the FFS percentage). The portion for FFS beneficiaries is based on a projected fee-for-service amount for the area (with adjustments, including an adjustment for the demographics and health status of the FFS beneficiaries to reflect the average costs for a typical beneficiary in the CCA area). The local plan portion is

35 Programs of all-inclusive care for the elderly (PACE) provide to frail elderly eligible individuals of Medicare and/or Medicaid a comprehensive package of community-based services covered by both programs under a capitated payment system. PACE programs enter into contracts (specifying payments and other conditions) with various types of providers, physicians, and other entities to furnish this care. Sometimes, a PACE participant needs to use a non-contract provider, physician, or other entity, which can then charge the PACE program high amounts for that care. Such high charges make it more difficult for a PACE program to operate within its capitation payments.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>based on the weighted average of bids for plans in the area (with adjustments for plan service area and CCA area differences and the distribution of plan enrollees).</p> <ul style="list-style-type: none"> ▪ Part B premiums for eligible individuals in CCA areas with incomes and assets above a specified level who remain in the FFS program would be adjusted, based on whether the FFS amount is more or less than the CCA benchmark amount. <ul style="list-style-type: none"> ▪ If the FFS amount is more than the benchmark, the Part B premium would be increased by 100% of the difference, subject to the 5% limit described below. ▪ If the FFS amount is less than the benchmark, the Part B premium would be reduced by 75% of the difference, also subject to the 5% limit described below. ▪ Any reduction or increase in the Part B premium (that results from the CCA program) for eligible individuals in the FFS Medicare program could not exceed 5% of the national Part B premium. ▪ Eligible individuals with incomes below 150% of poverty, and assets as under Title I, would not be subject to any Part B premium change as a result of the benchmark. ▪ For the MA local plans in the CCA program area, the CCA benchmark will be used rather than the benchmark established under Section 222. It is phased-in over a 4-year period. ▪ The program does not change the entitlement to defined benefits for all eligible individuals. ▪ Upon completion of the program, the Secretary will report to the Congress on the financial impact of the CCA program, beneficiary satisfaction, changes in access to physicians and other health care providers, and recommendations regarding extension or expansion of the CCA program.: ▪ Effective for plan years beginning in 2010.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
COMBATTING FRAUD AND ABUSE – TITLE III	
Medicare Secondary Payor (MSP) Provisions³⁶	<p>Sec. 301</p> <ul style="list-style-type: none"> ▪ Under previous law, Medicare was prohibited from making payment for a health care claim if payment is expected to be made promptly under workmen’s compensation or other insurance plans. Medicare is permitted to make a conditional payment in certain circumstances, including if Medicare could reasonably expect payment under another insurance plan, but determines that the payment will not be made promptly. The amendments in the MMA clarify: <ul style="list-style-type: none"> ▪ that conditional payments can be recovered because primary responsibility does not turn on whether a plan can pay “promptly.” The amendment eliminates the word “promptly” from the operative section of the statute and adds language which makes it clear that any payment made by the Secretary when a plan is not expected to make payment promptly is conditioned upon reimbursement to the appropriate Trust fund. ▪ that a business, trade or professional entity is deemed to have a “self-insured plan” if it carries its own risk, whether by failing to obtain insurance or otherwise. ▪ that the United States may bring an action against “all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise)” ▪ All amendments are effective as of 1984 and last two amendments are effective as of 1980.
Payment for Durable Medical Equipment³⁷	<p>Sec. 302</p> <ul style="list-style-type: none"> ▪ This provision establishes a competitive bidding process for durable medical equipment (DME), enteral nutrition, and off-the-shelf orthotics (those requiring minimal adjustment) as a nationwide permanent part of Medicare by phasing-in the program as follows: in 10 of the largest metropolitan statistical areas in 2007; 80 of the largest metropolitan statistical areas in 2009; and additional areas after 2009. In areas where competitive acquisition is not conducted after 2009, the Secretary may either apply competitive bidding payment amounts (from areas where competitive bidding is conducted) or may set payment amounts through inherent reasonableness (IR) authority. Class III devices, as defined in the Food, Drug, and Cosmetic Act, that are categorized as DME, would be exempt from this provision. Inhalation drugs are <i>not</i> included under this provision. ▪ Clinical laboratory tests are included as a demonstration project but only for tests furnished without a face-to-face encounter between the patient and the entity furnishing the test (i.e., reference labs). The Secretary must submit an initial report to Congress on the demonstration project by December 31, 2005 and progress and final reports to Congress as appropriate. There is no initial start date for the demonstration. ▪ Establishes a freeze on payments for all durable medical equipment (DME), excluding Class III devices, from 2004 to 2008; however the freeze may end prior to 2008 as the freeze shall not apply in competitive acquisition areas after competitive bidding has been implemented in those areas. Payments for prosthetic devices, prosthetics, and orthotics are frozen from 2004 to 2006. GAO is required to report by March 1, 2006, (and the Secretary is required to take GAO’s recommendations into account) on the appropriate payment update for Class III devices for 2007 and 2008. ▪ For 2005 and subsequent years, or until competitive bidding is implemented for each of these items, the Secretary will establish a

36 Under previous law, Medicare was prohibited from making payment for a health care claim if payment is expected to be made promptly under workmen’s compensation or other insurance plans. Medicare is permitted to make a conditional payment in certain circumstances, including if Medicare could reasonably expect payment under another insurance plan, but determines that the payment will not be made promptly.

37 Suppliers of the following items and services are included: durable medical equipment, prosthetic devices, orthotics and prosthetics, medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products and transfusion machines.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>payment amount for oxygen, oxygen equipment, standard wheelchairs including standard power wheelchairs, nebulizers, diabetic supplies including lancets and test strips, hospital beds, and air mattresses by applying an update factor that is based on findings of the OIG on differences between Medicare and FEHP regarding payments.</p> <ul style="list-style-type: none"> ▪ This section also requires the Secretary to establish and implement quality standards that independent accreditation organizations will apply to certain DME; prosthetic devices; orthotics; prosthetics; parenteral and enteral nutrients, equipment and supplies; medical supplies, home dialysis supplies and equipment; therapeutic shoes; electromyogram devices; salivation devices; blood products; and transfusion medicine, as the Secretary deems appropriate. Quality standards shall include consumer service standards. ▪ This section requires that an eligible individual receive a face-to-face examination and a written prescription from a physician or certain practitioners other than a physician before Medicare pays for a power wheelchair. In addition, this section requires the Secretary to establish standards for clinical conditions for payment for all DME. The standards shall specify the types of equipment that require a face-to-face examination as a condition for payment. In addition, the Secretary is directed to first establish standards for those DME items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation for payment. ▪ Effective upon enactment.
<p>Payment Reform for Covered Outpatient Drugs and Biologicals</p>	<p>Sec. 303(b) – 303(d) Section 303(b).</p> <ul style="list-style-type: none"> ▪ Physicians who opt out of the competitive acquisition program (which is described subsequently) would be paid under a new, separate payment method. Subject to the beneficiary cost-sharing, non-generic drugs would be paid 112% of the applicable price in 2005 and 2006 and 100% of the price subsequently. ▪ The multiple source drug applicable price would be the reported volume-weighted average of the average sales price; the applicable price for a single source drug would be the lesser of the <i>manufacturer's average sales price (ASP)</i> for the NDC code or the reported <i>wholesale acquisition cost (WAC)</i>. ▪ Payments would not account for special packaging, labeling or identifiers on the dosage form or product or package. ▪ By April 1, 2004, the <i>ASP</i> would be calculated by NDC each calendar quarter by dividing a manufacturer's total sales by the units sold in that quarter with certain adjustments to account for volume discounts and other rebates. Certain sales would be exempt from the calculation. ▪ The <i>WAC</i> would be the manufacturer's list price to wholesalers or direct purchasers for the most recent available month, not including discounts or other price reductions, as reported in wholesale price guides or other pricing publications. Payment rates would be updated on a quarterly basis. ▪ There would be no administrative or judicial review of the ASP. <p>New drugs.</p> <ul style="list-style-type: none"> ▪ The Secretary would be able to disregard the average sales price during the first quarter of a new drug's sales if the price data is not sufficient to determine an average amount payable. <p>Competitive Pricing</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to establish a competitive acquisition program to acquire and pay for covered outpatient drugs. Under this program, at least two contractors would be established in each competitive acquisition area (which would be defined as an appropriate geographic region) throughout the United States. ▪ Each year, a physician would be able to select a contractor who would deliver covered drugs and biologicals to the physician; as

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>discussed above, a physician would be able to elect payment under the ASP payment methodology.</p> <ul style="list-style-type: none"> ▪ Blood clotting factors, drugs and biologicals furnished as treatment for end-stage renal disease (ESRD), radiopharmaceuticals, and vaccines would not be considered covered drugs under the competitive acquisition program. <p>Contracting Requirements for Competitive Acquisition Program</p> <ul style="list-style-type: none"> ▪ Program would have two drug categories: the oncology drugs which will be implemented by 2005 and the nononcology drugs which will be implemented by 2006. ▪ Certain contractor selection and contracting requirements for the program would be established. Specifically, the Secretary will establish an annual selection process for a contractor in each area for each of the two categories of drugs. The Secretary may not award the 2-year contract to any entity that does not meet capacity, quality, service, financial performance, solvency standards, conduct standards or disclosure requirements. ▪ The number of qualified entities selected in each category and area may be limited but cannot be less than two. As part of the awarded contract, the selected contractor will be required to disclose the reasonable, net acquisition costs regularly (but not more often than once a quarter) as specified by the Secretary. ▪ Contract offers could be rejected if the aggregate average bid price exceeds the ASP. The bid price would be required to be the same for all portions of the area. ▪ The appropriate contractor, as selected by the physician, would supply covered drugs directly to the physician, except under the circumstances when a beneficiary is presently able to receive a drug at home or at other specified non-physician office settings. ▪ Adequate safeguards against fraud and abuse and consistent with safe drug practices, in order for a physician to maintain a supply of drugs that may be needed in emergency situations, would be established.
<p>Payment Reform for Covered Outpatient Drugs and Biologicals</p>	<p>Sec. 303(b) – 303(d) Section 303(b).</p> <ul style="list-style-type: none"> ▪ Most drugs and biologicals furnished during 2004 would be paid 85 percent of the April 1, 2003, AWP, except for specified drugs for which an alternative percent of not less than 80 percent is substituted for 85 percent. The drugs for which an alternative percent would be substituted are those identified in table 3 of the NPRM (68 Fed. Reg. 50,445 (Aug. 20, 2003)) and are based on an average of the percent of the AWP at which the drugs and biologicals are widely available in the market based on IG and GAO studies. The percent would also be different where manufacturers had submitted data to the Secretary by the close of the comment period on the NPRM (i.e., by October 15, 2003) that an alternative percent reflect the market price. ▪ The following drugs and biologicals would be paid 95 percent of AWP during 2004 and in some cases after 2004: vaccines furnished on or after January 1, 2004; blood clotting factors furnished during 2004; new drugs furnished during 2004 which were not available for payment as of April 1, 2003; drugs and biologicals furnished in connection with the furnishing of renal dialysis service if separately billed by renal dialysis facilities during 2004 and 2005. ▪ Infusion drugs furnished through an item of covered durable medical equipment would be paid at 95 percent of the October 1, 2003 AWP until such drugs were under the competitive bidding system for durable medical equipment. Blood and blood products would continue to be paid in the same manner as such payment amount was determined on October 1, 2003. ▪ Beginning with 2005, payment would be based on 106 percent of the average sales price for drugs and biologicals. In order to have payment made under both Medicare and Medicaid, a manufacturer would have to submit quarterly information on the manufacturer's average sales price (MASP) and the total number of units, wholesale acquisition cost, if required to make payment, and nominal sales price. Such data are subject to audit by the HHS Inspector General. The Secretary takes the MASPs and determines the average sales

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>price (ASP) using a method specified in statute for single and multiple source drugs. The manufacturer’s average sales price includes sales to all purchasers other than sales exempt from best price (as such term is used by Medicaid) and sales at nominal charges. Such price is net of volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under section 1927).</p> <ul style="list-style-type: none"> ▪ Requires the IG to conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals. Requires the IG to compare the ASP to the widely available market price and to the average manufacturer’s price (AMP). If the ASP exceeds 105 percent of the widely available market price or the AMP (in 2005 and a percent specified by the Secretary in 2006 and thereafter) , the IG is required to inform the Secretary and the Secretary is required to substitute for the ASP, the lesser of the widely available market price or 103 percent of the AMP. The Secretary may apply civil money penalties if the manufacturer made a misrepresentation in the reporting of the average sales price. Several elements of the ASP payment system are exempt from judicial and administrative review. The Secretary is required to conduct a study on sales of drugs and biologicals to large volume purchasers such as pharmacy benefit managers and health maintenance organizations for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to physicians. A report to Congress on such study is required by January 1, 2006. ▪ Requires the Secretary to establish and implement a competitive acquisition program where physicians are given the opportunity annually to make a choice to have drugs and biologicals furnished to them by competitively selected contractors upon submission of a prescription for a particular eligible individual. The program begins on January 1, 2006. The competitively selected contractors would collect applicable deductibles and coinsurance. Medicare payment would only be made for drugs and biologicals actually administered to an eligible individual, not to those dispensed to a physician. The Secretary could not award a contract to a competitive contractor unless the contractor had sufficient arrangements to acquire and deliver the drugs and biologicals and meet certain quality, service, financial performance and solvency standards. Multiple contractors would be selected for an area. Contracts would apply for 3 years. The Secretary would be required to conduct the competition for a single drug within a multiple source HCPCS code. ▪ In order to maintain the integrity of the drug and biological distribution system, contractors would be required to acquire all drug and biological products they distribute directly from the manufacturer or from a distributor that has acquired the products directly from a manufacturer and comply with any product integrity safeguards determined to be appropriate by the Secretary. Contractors would be required to comply with a code of conduct specified by the Secretary that includes standards relating to conflicts of interest and comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the HHS IG. Contractors would be required to furnish drugs and biologicals only to physicians and not to eligible individuals. The Secretary is required to establish rules whereby drugs and biologicals acquired through a contractor may be used to resupply inventories of such drugs and biologicals if they are required immediately, the physician could not have obtained them from the contractor and they were administered in an emergency situation. ▪ Contractors are required to disclose to the Secretary not more often than quarterly their net acquisition costs. The Secretary is required to make appropriate price adjustments to reflect significant increases or decreases in a contractor’s reasonable net acquisition costs. ▪ Several elements of the bidding process are specified. Costs of delivery and dispensing are to be included in the bid but costs related to administration, wastage, spillage and spoilage are not to be included. The Secretary is required to determine a single payment amount for each drugs and biologicals based on the bids submitted. The contractor would collect applicable coinsurance and deductibles. Several features of the competitive contractor system are exempt from judicial and administrative review. The Secretary is required to submit a report to Congress by July 1, 2008 on the competitive contractor program. ▪ The Secretary is required, beginning with January 1, 2005, to establish a separate payment amount for furnishing blood clotting factors. In establishing such fee, the Secretary is authorized to take into account the mixing (if appropriate) and delivery of clotting factors to an eligible individual, including special inventory management and storage requirements, and ancillary supplies and patient training

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>necessary for the self-administration of clotting factors. The Secretary is required to establish a pharmacy supplying fee in the case of oral immunosuppressive drugs, oral cancer and oral anti-emetic drugs furnished by a retail pharmacy. The current payment methodology for radiopharmaceuticals is continued.</p> <ul style="list-style-type: none"> ▪ Requires changes in the data and methodology used to determine practice expense Relative Value Units (RVUs) for drug administration services beginning with 2004. Requires use of survey data on practice expenses to the Secretary by oncologists. Requires use of data on compensation of clinical nurses from the oncologist survey in the methodology for determining practice expense RVUs for drug administration services. Requires adding to drug administration services work relative value units equal to the work RVUs for the lowest level office visit. Also requires the Secretary to review and modify policy regarding payment for each administration of multiple chemotherapeutic agents in a single day to a single patient. All these changes are exempt from the normal budget-neutrality requirement that applies for adjustments to relative value units under the Medicare physician fee schedule. ▪ As a transition, requires payments for drug administration services to be increased by an additional 32 percent in 2004 and 3 percent in 2005. ▪ Requires the Secretary to further adjust RVUs for 2005 and 2006, without application of the budget-neutrality requirement, based on timely submission of surveys by other specialties as long as 40 percent of the specialty's Medicare revenues are from drug administration services. Any changes would be exempt from the budget-neutrality requirement. ▪ Requires the Secretary to promptly evaluate existing drug administration codes to ensure accurate reporting and billing for such services taking into account levels of complexity of the administration and resource consumption. Requires the Secretary to use existing processes for consideration of coding changes and changes in RVUs. Requires consultation with relevant physician specialties. Any resulting changes in RVUs would be exempt from the budget-neutrality requirement. ▪ Requires the Secretary to make adjustments of the non-physician work pool methodology so that services whose practice expense RVUs are determined by such methodology are not affected relative to services whose practice expense RVUs are determined by the basic practice expense RVU method. ▪ Requires MedPAC to review the changes made under this section with respect to drug administration and submit reports on the changes to payment for items and services furnished by oncologists and those furnished by other specialties. The former is due by January 1, 2006 and the latter by January 1, 2007. The Secretary may use the reports= conclusions as a basis for adjustments in payment rates for items and services furnished by oncologists. ▪ For drugs and biologicals and drug administration services furnished by physicians, the provisions apply to physicians in the specialties of medical oncology, hematology and hematology/oncology.: ▪ Drugs and biologicals furnished beginning January 1, 2004.
<p>Items and Services Related to Blood Clotting</p>	<p>Sec. 303(e)(1)</p> <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to review the GAO report on payment for blood clotting factors and to provide a separate payment for the administration of these factors. ▪ Provides that the total amount of payments for blood clotting factors furnished in calendar year 2005 cannot exceed the amount that would have otherwise been expended. ▪ In calendar year 2006 and in subsequent years, the separate payment amount will be updated by the change in the medical CPI for the previous year ending in June.
<p>Pharmacy Supplying Fee for</p>	<p>Sec. 303(e)(2)</p>

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Certain Drugs and Biologicals	<ul style="list-style-type: none"> ▪ Requires the Secretary to pay a supply fee (less applicable deductibles and coinsurance) to licensed approved pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs, and oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. ▪ This fee is not to be considered a dispensing fee. This fee does not include payment for cognitive services.
Linkage of Revised Drug Payments and Increases for Drug Administration	<p>Sec. 303(f)</p> <ul style="list-style-type: none"> ▪ Provides that the Secretary cannot implement the revision in payment amount for categories of drug or biological administered by physicians unless the Secretary concurrently makes the practice expense payment adjustment on the basis of survey data as specified in the law.
Prohibition of Administrative and Judicial Review	<p>Sec. 303(g)</p> <ul style="list-style-type: none"> ▪ Most of the provisions in this section will not be subject to administrative or judicial review. ▪ Effective upon enactment.
Continuation of Payment Methodology for Radiopharmaceuticals	<p>Sec. 303(h)</p> <ul style="list-style-type: none"> ▪ The law does not change the Part B payment methodology for radiopharmaceuticals, including the use by carriers of the invoice pricing method.
Extension of Application of Payment Reform for Covered Outpatient Drugs and Biologicals to Other Physician Specialties	<p>Sec. 304</p> <ul style="list-style-type: none"> ▪ Applies the AWP reform to physicians of all specialties. Effective 1/1/04.
Payment for Inhalation Therapy	<p>Sec. 305</p> <ul style="list-style-type: none"> ▪ Requires payment for inhalation drugs furnished during 2004 at 80 percent of the April 1, 2003 AWP. Beginning with 2005, sets payment for inhalation drugs at ASP plus 6 percent. Effective for drugs and biologicals furnished beginning with 2004. ▪ Requires GAO to conduct a study to examine the adequacy of current reimbursements for inhalation therapy. The report is due one year from enactment.
Demonstration Project for Use of Recovery Audit Contractors	<p>Sec. 306</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to conduct a demonstration project where recovery audit contractors would be paid on a contingency basis to identify underpayments and overpayments and recoup overpayments for both Part A and Part B services. The provision would also permit the money collected by the recovery audit contractors (less their contingency fee) to be made available to the CMS program management account. ▪ The demonstration project is required to cover two states that are among the states with the highest per capita utilization rates of Medicare services and must have at least three recovery audit contractors. ▪ Within six months of completion, the Secretary is required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program. ▪ Effective upon enactment.
National and State Background Checks on Direct Access	<p>Sec. 307</p> <ul style="list-style-type: none"> ▪ This provision would authorize \$25 million in funds from the Treasury for a 3-year pilot program for national and state background

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
<p>Employees of Long Term Care Facilities or Providers – Pilot Program</p>	<p>checks on employees of long-term care facilities or providers. No more than 10 states would be selected for the pilot. The Secretary of the Department of Health & Human Services, in consultation with the Attorney General, would evaluate the pilot.</p> <ul style="list-style-type: none"> ▪ The pilot program would identify efficient, effective and economical processes for long term care facilities or providers to conduct background checks on employees with direct access to residents and patients. The pilot would only apply to long-term care facilities and providers that participate in the Medicare and/or Medicaid programs. The facilities and providers included in the pilot are: nursing homes; home health agencies, providers of hospice care, providers of personal care services, residential long-term care providers; and intermediate care facilities for the mentally retarded. Pilot states may expand the program, during the first year of the pilot, to other long-term care providers, as they deem appropriate. Self-directed care arrangements are excluded from the pilot. ▪ States would develop procedures for conducting the background checks. These procedures should include certain elements. Facilities and providers would notify potential employees of the requirement to conduct a background check, obtain their authorization to conduct the check, and collect information such as a statement disclosing any disqualifying information and a rolled set of fingerprints. Then, facilities and providers would start the background check process by checking available registries such as the Federal Healthcare Integrity Practitioner Data Bank (HIPDB) and the state Nurse Aide Registry. If no disqualifying information were found through these checks, then the facility or provider would request the state to conduct state and national level checks (FBI records). ▪ Disqualifying information would be information about a conviction for a relevant crime or a finding of abuse, neglect or misappropriation of resident or patient property. A conviction for a relevant crime includes crimes that would be reported to the HIPDB (i.e., health care fraud, felony relating to controlled substances), and other offenses as defined by the pilot states. At any point in the background check process, if disqualifying information were found, the process would stop, and the employee would be discharged. A long-term care facility or provider may not knowingly employ any direct patient access employee who has any disqualifying information. ▪ Participating states may permit long-term care facilities or providers to provide for a period of provisional employment while a new employee is undergoing a background check. During that period, the facility or provider would provide supervision of the provisional employee. In determining the appropriate level of supervision, participating states must take into account costs or burdens that would be imposed on small rural long-term care facilities or providers, as well as the nature of care delivered by such providers that are home health agencies or providers of hospice care. ▪ The provision outlines certain selection criteria for the pilot states, such as: geographic diversity; the inclusion of a variety of long-term care facilities or providers; evaluation of a variety of payment mechanisms for covering the costs of the background checks; and the evaluation of a variety of penalties used by participating states to enforce the requirements. In addition, the Secretary shall, to the greatest extent practicable, select at least: one state that provides for a period of provisional employment and one state that does not; one state that establishes procedures under which employment agencies may contact the state directly to conduct background checks on prospective direct patient access employees; and one state that includes patient abuse prevention training for managers and employees of long-term care facilities and providers as part of its pilot. ▪ The evaluation would cover a number of topics, including: the procedures implemented by pilot states to conduct the checks; the costs and how they should be allocated across Medicare, Medicaid, providers and workers; the effectiveness of checks conducted by employment agencies; and the extent to which the checks lead to any unintended consequences such as a reduction in the available workforce. ▪ Effective October 1, 2003. Interested states were required to submit a letter of interest in participating in this pilot by 8/30/04. For additional information on this pilot program, go to: http://www.cms.hhs.gov/medicaid/survey-cert/bcp.asp.
<p>RURAL EQUITY PROVISIONS – TITLE IV</p>	
<p>SUBTITLE A – PROVISIONS RELATING TO PART A ONLY</p>	

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Equalizing Urban And Rural Standardized Payment Amounts Under The Medicare Inpatient Hospital Prospective Payment System.	Sec. 401 <ul style="list-style-type: none"> ▪ Medicare will pay hospitals in rural and small urban areas using the standardized amount used to pay hospitals in large urban areas starting for discharges in FY 2004. ▪ Directs the Secretary to compute one local standardized amount for all hospitals in Puerto Rico equal to that for hospitals in large urban areas in Puerto Rico starting with discharges in FY 2004. Hospitals in Puerto Rico will receive the legislated payment increase starting on 4/1/04.
Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds.	Sec. 402 <ul style="list-style-type: none"> ▪ Increases the cap on payments for small rural and urban hospitals from 5.25% to 12%. Effective 4/1/04. ▪ Pickle hospitals receiving a DSH adjustment under the alternative formula will not be affected by this provision.³⁸
Adjustment To The Medicare Inpatient Hospital PPS Wage Index To Revise The Labor-Related Share Of Such Index.	Sec. 403 <ul style="list-style-type: none"> ▪ Beginning in FY 2005 decreases the labor-related share from 71% to 62% in low wage areas, unless the change would result in lower payments to a hospital.³⁹
More Frequent Update In Weights Used In Hospital Market Basket	Sec. 404 <ul style="list-style-type: none"> ▪ Directs the Secretary to update the weights for the hospital market basket more frequently than once every 5 years. ▪ Requires the Secretary to submit a report to Congress by 10/1/04 regarding reasons for and options considered in establishing a new schedule.
Critical Access Hospital (CAH)⁴⁰ Improvements.	Sec. 405 (a-h) <ul style="list-style-type: none"> ▪ <u>Payment Increase</u> – Increases reimbursement for inpatient, outpatient, and covered skilled nursing facility services provided by a CAH to 101% of reasonable costs. Effective 1/1/04. ▪ <u>Emergency Services</u> – Authorizes payment of physician assistants, nurse practitioners, and clinical nurse specialists as emergency room on-call providers (in addition to physicians). Effective 1/1/05. ▪ <u>Periodic Interim Payments</u>⁴¹ – Authorizes periodic interim payments (PIPs) for CAHs for inpatient services, effective 7/1/04. Requires the Secretary to develop alternative methods for PIPs based on expenditures by CAHs. ▪ <u>Condition for Application of Special Professional Service Payment Adjustment</u> – Prohibits HHS from requiring that all physicians and other practitioners providing services in a CAH assign their billing rights to the CAH as a condition for electing the all-inclusive

38 Pickle hospitals receive DSH payments under an alternative formula that considers the proportion of a hospital’s patient care revenues that are received from state and local indigent care funds.

39 Under current law, approximately 71 percent of the standardized amount for each hospital discharge is adjusted by the area wage index. Decreasing this proportion or labor-related share increases Medicare payments to hospitals in areas with wage indices below one and decreases Medicare payments to hospitals with wage indices above one.

40 A Critical Access Hospital (CAH) is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH cannot operate more than 15 acute care beds at one time, but can have an additional 10 swing beds that are set up for skilled nursing facility (SNF) level care. SNF beds in a unit of the facility that is licensed as a distinct part SNF at the time of the facility’s application for CAH designation are not counted toward the bed limits.

41 Under current law, eligible hospitals, skilled nursing facilities, and hospices which meet certain requirements receive Medicare periodic interim payments (PIP) every 2 weeks. These payments are based on estimated annual costs without regard to the submission of individual claims. At the end of the year, a settlement is made to account for any difference between the estimated PIP and the actual amount owed. A CAH is not eligible for PIP.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>payment option. For CAHs that made an election before 11/1/03, the provision becomes effective beginning on or after 7/1/03. For others the effective date is 7/1/04.</p> <ul style="list-style-type: none"> ▪ <u>Flexibility in Bed Limit</u> –Allows up to 25 beds to be used for acute care (under the new limit), provided that no more than 10 beds are swing beds. Applies to CAH designations made before, on or after 1/1/04, but any election made as a result of regulations promulgated to implement this provision will apply prospectively. ▪ <u>Rural Flexibility Grants</u> – Authorizes \$35 million annually for FY 2005 – FY 2008 for rural hospital flexibility grants. Starting with funds appropriated for FY 2005, and in subsequent years, states will be required to consult with the hospital association and rural hospitals in the state to determine the most appropriate use of the funds. Prohibits states from using more the 15 percent of the grant or the state’s federally negotiated indirect rate for program administration. Beginning in FY 2005, 95 percent of the funds would be available for grants. ▪ <u>Authority to Establish Psychiatric and Rehabilitation Distinct Part Units</u> – Permits a CAH to establish a distinct part psychiatric or rehabilitation unit that meets the applicable requirements for the beds established for a short term, general hospital. The total number in these distinct parts cannot exceed 10. Applies to cost reporting periods starting 10/1/04. ▪ <u>Waiver Authority</u>⁴² – Limits the state waiver of the 35-mile rule, but grandfathers in facilities designated as CAHs prior to 1/1/06. Effective upon enactment.
<p>Medicare Inpatient Hospital Payment Adjustment For Low-Volume Hospitals.⁴³</p>	<p>Sec. 406</p> <ul style="list-style-type: none"> ▪ Establishes a graduated adjustment/add-on payment to inpatient hospital PPS rates for low-volume hospitals to account for the higher unit costs associated with the facilities, effective FY 2005. ▪ The maximum total adjustment is 25% of the otherwise applicable PPS rate and the payment adjustment will be based on the empirical relationship between discharges and costs.
<p>Treatment of Missing Cost Reporting Periods For Sole Community Hospitals⁴⁴</p>	<p>Sec. 407</p> <ul style="list-style-type: none"> ▪ Prohibits CMS from denying a Sole Community Hospital (SCH) application based on unavailable cost report data due to changes in ownership, fiscal intermediaries or other extraordinary circumstances, as long as data are available for at least one base cost reporting period. Applies to cost reporting periods beginning on or after 1/1/04.
<p>Recognition of Attending Nurse Practitioners As Attending Physicians To Serve Hospice Patients</p>	<p>Sec. 408</p> <ul style="list-style-type: none"> ▪ Expands the definition of “attending physician” in hospice to include nurse practitioners, effective upon enactment. ▪ Nurse practitioners would not be authorized to certify a beneficiary as terminally ill for the purposes of receiving the hospice benefit.
<p>Rural Hospital Demonstration Project</p>	<p>Sec. 409</p> <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to establish a demonstration project in three hospice programs to deliver hospice care to Medicare beneficiaries in rural areas. Each project can last no longer than five years. ▪ Waives the limit on the aggregate number of inpatient days provided to Medicare beneficiaries who elect hospice care.

42 Currently to qualify as a CAH, the rural, for-profit, non-profit or public hospital must be located more than 35 miles from another hospital or 15 miles in areas with mountainous terrain or those where only secondary roads are available. These mileage standards may be waived if the hospital has been designated by the state as a necessary provider of health care. This authority sunsets two years after enactment.

43 A low-volume hospital is a short-term general hospital that is located more than 25 road miles from another similar hospital and than has less than 800 discharges during the fiscal year.

44 A sole community hospital, is a hospital that, because of factors such as isolated location, weather conditions, travel conditions, or the absence of other hospitals, is the sole source of inpatient services reasonable available in a geographic area, or is located more than 34 road miles from another hospital.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Regular hospice reimbursement rates would apply. ▪ Directs the Secretary to submit report to Congress at the end of the demonstration period to make recommendations regarding the extension of the project to hospice programs serving rural areas. ▪ Effective upon enactment.
Exclusion of Certain Rural Health Clinic and FQHC Center Services from the Prospective Payment System for Skilled Nursing Facilities	Sec. 410 <ul style="list-style-type: none"> ▪ Provides that services provided by a RHC or FQHC after 1/1/05 will be excluded from SNF-PPS if the services would have been excluded if furnished by a physician or practitioner who was not affiliated with a RHC or FQHC. Applies to services furnished on or after 1/1/05.
Rural Community Hospital Demonstration Program	Sec. 410A <ul style="list-style-type: none"> ▪ Directs the HHS Secretary to establish a demonstration program in rural areas to test different payment methods for rural hospitals with less than 51 beds. The hospitals will be paid their costs for inpatient and extended care (swing-bed) services for 5 years, subject to a cap. The hospitals cannot be eligible for the CAH program. ▪ Directs the Secretary to report to Congress no later than 6 months after the completion of the demonstration program. ▪ Effective 10/1/04 (demonstrations must begin no later than 1/1/05).
SUBTITLE B – PROVISIONS RELATING TO PART B ONLY	
Extension of Hold Harmless Provisions For Small Rural Hospitals And Treatment of Certain Sole Community Hospitals To Limit Decline In Payment Under The OPD PPS	Sec. 411 <ul style="list-style-type: none"> ▪ Extends the hold harmless for hospital outpatient department (OPD) services performed in small rural hospitals for two years.⁴⁵ ▪ Extends the hold harmless provisions to sole community hospitals located in rural areas for services furnished on or after 1/1/04, until 1/1/06. ▪ Directs the HHS Secretary to conduct a study to determine if the costs, by ambulatory payment classification (APC) groups incurred by rural providers exceed the costs incurred by urban providers. If appropriate, the Secretary must provide for a payment adjustment to reflect the higher costs of rural providers by 1/1/06.
Establishment Of Floor On Geographic Adjustments of Payments For Physicians' Services	Sec. 412 <ul style="list-style-type: none"> ▪ Sets floor on work geographic adjuster at one for services furnished on or after 1/1/04 and before 1/1/07.
Additional Incentive Payment for Certain Physician Scarcity Areas	Sec. 413 (a) <ul style="list-style-type: none"> ▪ Establishes a new 5% incentive payment program designed to reward primary care and specialist care physicians for furnishing services in areas that have fewest physicians available to serve Medicare beneficiaries. ▪ Provides a bonus payment for physicians in physician scarcity areas for 2005-2007.
Improvement to Medicare	Sec. 413 (b)

⁴⁵ Under current law, the prospective payment system (PPS) for services provided by outpatient departments (OPD) was implemented in 2000 for most acute care hospitals. Rural hospitals with no more than 100 beds are paid no less under the PPS system than they would have received under the prior reimbursement system (hold harmless). The hold harmless provisions apply to services provided before 1/1/04.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Incentive Payment Program	<ul style="list-style-type: none"> ▪ Directs the Secretary to pay the current law 10 percent Health Professional Shortage Area (HPSA) incentive payment for services furnished in full county primary care geographic areas HPSAs automatically rather than having the physician identify that the services were furnished in the area. This shifts the responsibility for identifying eligibility for the 10 percent bonus from physicians to the Secretary.
GAO Study of Geographic Differences in Payments for Physicians	<p>Sec. 413(c)</p> <ul style="list-style-type: none"> ▪ Directs GAO to study payment differences under the physician fee schedule for different geographic areas. The study, including recommendations concerning the use of more current data, is due to Congress within one year of enactment.
Phase-In Providing Floor Using Blend of National and Regional Fee Schedules for Ambulance Services	<p>Sec. 414 (a)</p> <ul style="list-style-type: none"> ▪ Provides that payments for ambulance services will be based on the ambulance specific amount blended with the national fee schedule amount or a combined rate of the national fee schedule and a regional fee schedule, whichever results in the larger payment. Effective 7/1/04. The national fee schedule will be fully implemented in 2010.
Adjustment for Certain Long Ambulance Trips	<p>Sec. 414(b)</p> <ul style="list-style-type: none"> ▪ Increases Medicare’s payments for ground ambulance services by one quarter of the payment per mile rate otherwise established for trips longer than 50 miles occurring on or after 1/1/04 and before 1/1/09. The payment increase applies regardless of where the transportation originate. Effective 7/1/04.
Improvement in Payments to Retain Emergency Capacity for Ambulance Services in Rural Areas	<p>Sec. 414(c)</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to provide a percentage increase in the base rate of the fee schedule for ground ambulance service originating in qualified rural areas. Effective 7/1/04. Applies to services provided before 1/1/2010.
Temporary Increase For Ground Ambulance Services	<p>Sec. 414 (d)</p> <ul style="list-style-type: none"> ▪ Increases payments for ground ambulance services originating in a rural area by 2%. Increases the fee schedule in other areas by 1%. Applies to services provided after 7/1/04 and before 1/1/08.
GAO Report on Cost of and Access to Ambulance Services	<p>Sec. 414(f)</p> <ul style="list-style-type: none"> ▪ Directs the GAO to conduct a study on the cost differences between the various types of ambulance services and the impact the difference may have on access to care. The report is to be submitted to Congress by 12/31/05.
Rural Air Ambulance Services	<p>Sec. 415</p> <ul style="list-style-type: none"> ▪ Establishes a presumption of medical necessity for certain air ambulance services. Effective 1/1/05.
Treatment of Certain Clinical Laboratory Tests Furnished to Hospital Outpatients	<p>Sec. 416</p> <ul style="list-style-type: none"> ▪ Provides that hospitals with under 50 beds in qualified rural areas will receive 100 percent reasonable cost reimbursement for clinical diagnostic laboratory tests covered under Medicare Part B provided on an outpatient basis. Applies to services furnished during a cost reporting period beginning during the two-year period starting 7/1/04.
Extension of Telemedicine Demonstration Project	<p>Sec. 417</p> <ul style="list-style-type: none"> ▪ Extends the existing demonstration project for four years and increases total funding from \$30 million to \$60 million, effective upon enactment.
Report on Demonstration Project Permitting Skilled	<p>Sec. 418</p> <ul style="list-style-type: none"> ▪ Directs the HHS Secretary to evaluate a demonstration project under which a skilled nursing facility is treated as an originating site for

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Nursing Facilities to be Originating Telehealth Sites; Authority to Implement	<p>telehealth services. Effective upon enactment.</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to report to Congress no later than 1/1/05. ▪ Authorizes the Secretary to expand originating telehealth sites to include skilled nursing facilities beginning 1/1/06, provided the evaluation concludes that such an expansion is advisable.
SUBTITLE C – PROVISIONS RELATING TO PARTS A AND B	
One-Year Increase for Home Health Services Furnished in Rural Areas	<p>Sec. 421(a)</p> <ul style="list-style-type: none"> ▪ Provides a one-year, 5 percent additional payment for home health care services furnished in a rural area. The temporary additional payments begin with episodes and visits ending on or after 4/1/04 and before 4/1/05, and are not to be used in calculating future home health payment amounts.
Redistribution of Unused Resident Positions	<p>Sec. 422</p> <ul style="list-style-type: none"> ▪ A teaching hospital's total number of Medicare-reimbursed resident positions will be reduced for cost reporting periods starting July 1, 2005 if its reference resident level is less than its applicable resident limit. Rural hospitals with less than 250 acute care inpatient beds would be exempt from such reductions. ▪ For other such hospitals, the reduction will equal 75% of the difference between the hospital's limit and its reference resident level.⁴⁶ ▪ Authorizes the Secretary to increase the applicable resident limits for hospitals for portions of cost reporting periods occurring on or after 7/1/05 by an aggregate number that does not exceed the overall reduction in the limits. Requires the Secretary to take into account the demonstrated likelihood of the hospital filling the positions within the first three cost reporting periods beginning on or after 7/1/05 when determining which hospitals would receive an increase in their resident levels. ▪ Directs the Secretary to establish a priority order to distribute the increased resident count first to programs in hospitals located in rural areas, then to hospitals that are not in large urban areas and finally to other hospitals in a state where there is no other training program for a particular specialty. ▪ The Secretary must consider giving special consideration to hospitals that train a large share of graduates from historically large medical colleges. ▪ The Secretary will determine increases to limits with the same priority category. Not more than 25 additional FTEs will be given to any hospital. These hospitals will be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. ▪ These provisions will not apply to reductions in residency programs that occurred as part of the voluntary reduction program or will not affect the ability of certain hospitals to establish new medical residency training programs. ▪ Requires the Secretary to submit a report to Congress no later than 7/1/05 on whether to extend the application deadline for increases in resident limits.
SUBTITLE D – OTHER PROVISIONS	

⁴⁶ The resident reference level is the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. This reference level is the either (1) the resident level of the most recent cost reporting period of the hospital for which a cost report has been settled (or submitted, subject to audit) on or before September 30, 2002 or (2) the resident level for the cost reporting period that includes July 1, 2003, if requested on a timely basis by the hospital subject to audit. Upon this timely request at the discretion of the Secretary, a hospital's reference level will be adjusted to include the number of medical residents for the cost reporting period that includes July 1, 2003. Upon timely request of the hospital, the Secretary will adjust the reference resident level to include the number of medical residents that were approved in an application to the appropriate accrediting organization before January 1, 2002 if the program was not in operation by the cost reporting period in question (either September 30, 2002 or July 1, 2003 depending upon the hospital's circumstances and the Secretary's approval). The reduction will apply to hospitals that are members of the same affiliated group as of July 1, 2003.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Providing Safe Harbor For Certain Collaborative Efforts That Benefit Medically Underserved Populations	<p>Sec. 431</p> <ul style="list-style-type: none"> ▪ Provides that remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute, if the agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to underserved populations. ▪ Directs the Secretary to promulgate final rules establishing standards related to the safe harbor no later than one year from the date of enactment.
Office of Rural Health Policy Improvements	<p>Sec. 432</p> <ul style="list-style-type: none"> ▪ Expands the functions of the Office of Rural Health by authorizing it to administer grants, cooperative agreements, and contracts to provide technical assistance and other activities to improve rural health care. Effective upon enactment.
MedPAC Study on Rural Hospital Payment Adjustments	<p>Sec. 433</p> <ul style="list-style-type: none"> ▪ Directs MedPAC to study the effect of certain rural health provisions including total payments, growth in costs, capital spending and other payment factors. An interim report on changes to critical access hospitals is due to Congress no later than 18 months after enactment. The final MedPAC report is due to Congress no later than three years after enactment.
Frontier Extended Stay Clinic Demonstration Project	<p>Sec. 434</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to conduct a demonstration project that would treat frontier extended stay clinics as a Medicare provider, effective upon enactment.⁴⁷ ▪ Directs the Secretary to develop life safety code standards for the facilities.
TITLE VI – PROVISIONS RELATING TO PART A (HOSPITAL PAYMENTS)	
SUBTITLE A – INPATIENT HOSPITAL SERVICES	
Revision Of Acute Care Hospital Payment Updates	<p>Sec. 501</p> <ul style="list-style-type: none"> ▪ The hospital update would be set at market basket (current law) for FY 2004. An acute care hospital will receive an operating update of the market basket from FY 2005 – FY 2007 if it submits data on the 10 quality indicators established by the Secretary on November 1, 2003. ▪ For FY 2005, the Secretary will provide a 30-day grace period for the submission of the required data. A hospital that fails to submit the data will receive an update of the market basket minus .4 percentage points for the fiscal year. The Secretary will not take into account this reduction when computing the applicable percentage increases in subsequent years. ▪ The conferees expressed concern about changes to the 75 percent rule⁴⁸ proposed by CMS on September 2, 2003 that would limit the kinds of patients that would be eligible for rehabilitation services and urged the Secretary to delay implementation pending the completion of a GAO report on the issue. Congress put a moratorium on enforcement of the 75 Percent Rule for inpatient rehabilitation services until 60 days after the Government Accountability Office (GAO) completes its formal assessment of the rule’s impact on access to the services. HHS would

⁴⁷ A frontier extended stay clinic is one that is located in a community where the closest acute care hospital or critical access hospital is at least 75 miles away or is inaccessible by public road and is designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers or patients who need monitoring and observation for a limited period of time.

⁴⁸ Inpatient rehabilitation facilities (IRF) provide Medicare patients with rehabilitation services. They are distinguished from acute care settings by a number of criteria, including that 75 percent of their cases must be in ten categories (stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of a femur, brain injury, and polyarthritis). This criterion is commonly referred to as the “75 percent rule.”

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p style="text-align: center;">reissue the rule after taking into account GAO’s recommendations.</p> <p><i>[Note: The FY 2005 Omnibus Appropriations legislation includes a provision that would delay the implementation of the “75 percent rule” until 60 days after the GAO completes its assessment of the rule’s impact on access to services. After GAO makes its report, CMS would then reissue the rule, taking into account GAO’s findings.]</i></p>
Revision of The Indirect Medical Education (IME) Adjustment Percentage	<p>Sec. 502</p> <ul style="list-style-type: none"> ▪ Increases IME from 5.5% to 6.0% for the last half of FY 2004; 5.8% in 2005; 5.55% in FY 2006; and 5.35% in FY 2007. ▪ Effective 4/1/04.
Recognition of New Medical Technologies under inpatient Hospital Prospective Payment System	<p>Sec. 503</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to add new diagnosis and procedure codes on April 1st of each year, but is not required to affect Medicare’s payment or DRG classification until the fiscal year that begins after April 1st. ▪ Requires the Secretary to implement these provisions to new technology determinations beginning in FY 2005.
Revision of Federal Rate For Hospitals In Puerto Rico	<p>Sec. 504</p> <ul style="list-style-type: none"> ▪ Permanently increases the PPS rate for hospitals in Puerto Rico to 75% of the national rate over a 2-year transition period, starting 4/1/04. <ul style="list-style-type: none"> ▪ Phase-in is as follows: FY 2004 – 59% national/41% local; FY 2005 – 67% national/33% local; and in FY 2006 and thereafter – 75% national/25% local.
Wage Index Adjustment Reclassification Reform	<p>Sec. 505</p> <ul style="list-style-type: none"> ▪ Establishes a new process, similar to the current wage index reclassification process, based on commuting data, which would enable hospitals to receive a blended wage index amount based on the percent of employees, which commute from adjacent MSAs. Effective FY 2005.
Limitation on Charges for inpatient Hospital Contract Health Services Provided to Indians by Medicare Participating Hospitals	<p>Sec. 506</p> <ul style="list-style-type: none"> ▪ Hospitals that participate in Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Service (HIS), an Indian tribe or tribal organization, or an urban Indian organization, will be paid in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodologies, and rates of payments. This will include the requirement to accept these rates as payment in full. This will apply to Medicare participation agreements in effect or entered into by a date specified by the Secretary. In no case will the date be later than one year after the date of enactment.
Treatment Of Specialty Hospitals - Clarifications To Certain Exceptions To Medicare Limits On Physician Referrals ⁴⁹	<p>Sec. 507</p> <ul style="list-style-type: none"> ▪ For a period of 18-months from the date of enactment, amends the “whole hospital” exception to exclude those circumstances where a physician’s ownership interest is in a subsection of the hospital devoted primarily or exclusively to cardiac, orthopedic surgical, or other specialties designated by the Secretary. Specialty hospitals in operation or under development as of November 18, 2003 would be exempt from this provision.⁵⁰ ▪ Directs MedPAC, in consultation with GAO and HHS, to study the effects of the whole-hospital exception for physician-ownership in

49 Physicians are generally prohibited from referring Medicare patients to facilities where they or an immediate family member have financial interests. Physicians are not prohibited from referring patients to whole hospitals (and some other entities) where they have ownership or investment interests.

50 To maintain the exemption, a specialty hospital may not increase the number of physician investors as of 11/18/03; change or expand the field of specializations it treats; expand beyond the main campus; or increase the total number of beds by more than the greater of five beds or 50 percent of the number of beds in the hospital as of 11/18/03.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>specialty hospitals. The study is to be conducted within 15 months of enactment.</p> <ul style="list-style-type: none"> ▪ Directs the HHS Secretary to examine referral patterns and quality of care issues. ▪ Effective upon enactment.
One-time Appeals Process for Hospital Wage Index Reclassification	<p>Sec. 508</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to establish by instruction no later than 1/1/04 a one-time process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the state. ▪ A qualifying hospital is not eligible for a wage index classification on the basis of distance and/or commuting. ▪ The reclassification will be effective for three years, beginning with 4/1/04. Hospitals can waive reclassification under this provision during the three-year period. ▪ The Secretary is prohibited from spending more than \$900 million to implement this provision.
SUBTITLE B – OTHER PROVISIONS	
Payment for Covered Skilled Nursing Facility Services	<p>Sec. 511</p> <ul style="list-style-type: none"> ▪ Medicare payments to skilled nursing facilities will be refined to reflect the high cost of treating patients with AIDS, effective for services on or after 10/1/04.
Coverage of Hospice Consultation Services	<p>Sec. 512</p> <ul style="list-style-type: none"> ▪ Provides reimbursement for hospice physicians for educating patients about the program. Applies to consultation services provided by a hospice program on or after 1/1/05.
Study on Portable Diagnostic Ultrasound Services for Beneficiaries in Nursing Facilities	<p>Sec. 513</p> <ul style="list-style-type: none"> ▪ Directs GAO to report no later than two years after enactment. Effective upon enactment.
TITLE VI – PROVISIONS RELATING TO PART B	
SUBTITLE A – PROVISIONS RELATING TO PHYSICIAN SERVICES	
Revision of Updates for Physician Services	<p>Sec. 601</p> <ul style="list-style-type: none"> ▪ The update to the conversion factor for 2004 and 2005 will be not less than 1.5 percent and will be exempt from the budget neutrality adjustment, instead of –4.5 percent in 2004 and a smaller reduction in 2005. Effective 1/1/04. ▪ This modification will not be treated as a change in law and regulation in determining the sustainable growth rate (SGR).
Treatment of Physicians Services Furnished in Alaska	<p>Sec. 602</p> <ul style="list-style-type: none"> ▪ Requires the HHS Secretary in calendar years 2004 and 2005 to increase geographic practice cost indices to a level of 1.67 for each of the work, practice expense and malpractice cost indices, for physician services provided in Alaska. Effective 1/1/04.
Inclusion of Podiatrists, Dentists, and Optometrists	<p>Sec. 603</p> <ul style="list-style-type: none"> ▪ Extends to podiatrists, dentists, and optometrists the current law authority to utilize private contracts. Effective upon enactment.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Under Private Contracting Authority⁵¹	
GAO Study on Access to Physicians' Services	Sec. 604 <ul style="list-style-type: none"> ▪ Requires GAO to conduct a study on access of Medicare beneficiaries to physicians' services under Medicare. The study will make an assessment of beneficiaries' use of physician services through an analysis of claims data. GAO must report within 18 months after enactment.
Collaborative Demonstration-Based Review of Physician Practice Expense Geographic Adjustment Data	Sec. 605 <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to review and consider alternative data sources than those currently used to establish the geographic index for the practice expense component under Medicare's physician fee schedule no later than 1/1/05. ▪ Requires the Secretary to collaborate with state and other appropriate organizations representing physicians and other appropriate people.
MedPAC Report on Payment for Physicians' Services	Sec. 606 <ul style="list-style-type: none"> ▪ Directs MedPAC to report to Congress on the effects of refinements to the practice expense component of payments for physicians' services after full implementation of the resource-based payment in 2002. The report is due within one year of enactment.
SUBTITLE B – PREVENTIVE SERVICES	
Coverage of an Initial Preventive Physical Examination	Sec. 611 <ul style="list-style-type: none"> ▪ Authorizes coverage for an initial preventive physical examination upon becoming eligible for Medicare. Medicare cost sharing requirements (deductible, beneficiary cost sharing) apply. Applies to services furnished on or after 1/1/05, but only for individuals whose Medicare coverage begins on or after that date.
Coverage Of Cardiovascular Screening Tests	Sec. 612 <ul style="list-style-type: none"> ▪ Authorizes coverage for screening for cardiovascular screening blood tests. Applies to services furnished on or after 1/1/05.
Coverage Of Diabetes Screening Tests	Sec. 613 <ul style="list-style-type: none"> ▪ Includes diabetes screening tests furnished to an individual at risk for diabetes for the purpose of early detection of diabetes. Applies to tests furnished starting 1/1/05.
Improved Payment For Certain Mammography Services	Sec. 614 <ul style="list-style-type: none"> ▪ Excludes screening mammography and diagnostic mammography from the outpatient prospective payment system (OPPS). This provision will apply to screening mammography services furnished on or after the date of enactment and will apply to diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after 1/1/05.
SUBTITLE C – OTHER PROVISIONS	
Hospital Outpatient Department (HOPD) Payment Reform	Sec. 621 <ul style="list-style-type: none"> ▪ Starting for services furnished beginning January 1, 2004, certain covered HOPD drugs would be paid no more than 95% of AWP or less than the transition percentage of the AWP from CY 2004 through CY 2006. ▪ In subsequent years, payment would be equal to average price for the drug in the area and year established by the competitive acquisition program.

51 Private contracting allows a physician and Medicare beneficiary to not submit a claim for a service, which would otherwise be covered and paid by Medicare. Under private contracting, physicians can bill patients at their discretion without being subject to upper payment limits specified by Medicare.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The covered HOPD drugs affected by this provision are radiopharmaceuticals and outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which pass-through payments were first made beginning January 1, 2003 or those drugs for which a temporary HCPCS code has not been assigned. ▪ Drugs for which a temporary HCPCS code has not been assigned would be reimbursed at 95% of the AWP. The transition percentage to AWP for sole-source drugs manufactured by one entity is 83% in CY 2004, 77% in CY 2005, and 71% in CY 2006. ▪ The transition percentage to AWP for innovator multiple source drugs is 81.5% in CY 2004, 75% in CY 2005, and 68% in CY 2006. The transition percentage to AWP for multiple source drugs with generic drug competitors is 46% in CY 2004 through CY 2006. ▪ The additional expenditures resulting from these provisions would not be subject to the budget neutrality requirement. ▪ Starting in CY 2004, the Secretary would be required to lower the threshold for establishing a separate APC group for higher cost drugs from \$150 to \$50 per administration. These separate drug APC groups would not be eligible for outlier payments. ▪ Starting in CY 2004, Medicare’s transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract would reflect the amount paid under that contract, not 95% of AWP.
Special Payment for Brachytherapy	Sec. 621 (b) <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to make payment for each brachytherapy⁵² device furnished under the hospital outpatient prospective payment system equal to the hospital’s charges for the brachytherapy device adjusted to cost for all brachytherapy devices furnished on or after 1/1/04 and before 1/1/07.
Limitation Of Application Of Functional Equivalence Standard⁵³	Sec. 622 <ul style="list-style-type: none"> ▪ Prohibits the HHS Secretary from publishing regulations, program memorandum, local medical review policies or any other guidance that may apply a functional equivalence or similar standard to a drug or biological for transitional passthrough payments under OPPS. ▪ This prohibition applies to the application of the functional equivalence standard on or after the date of enactment, unless the application was made prior to enactment and the Secretary applies the standard to the drug only for the purposes of transitional pass-through payments. ▪ This provision does not preclude the Secretary from deeming a particular drug to be identical to another drug if the two products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of the Food and Drug Administration. ▪ Effective upon enactment.
Payment for Renal Dialysis Services	Sec. 623(a) <ul style="list-style-type: none"> ▪ Increases the composite rate for renal dialysis by 1.6 percent for CY 2005.
Two-year Moratorium on Therapy Caps	Sec. 624 <ul style="list-style-type: none"> ▪ Suspends the application of the therapy caps from the date of enactment through calendar year 2005. ▪ The implementation of this provision will not have any retroactive impact on beneficiaries who exceeded their caps prior to the date of enactment.

52 Brachytherapy is an advanced cancer treatment. Radioactive seeds or sources are placed in or near the tumor itself, giving a high radiation dose to the tumor while reducing the radiation exposure in the surrounding healthy tissues.

53 In the November 1, 2002 Federal Register, CMS established a new concept of functional equivalence for drugs to an existing treatment. The transitional pass-through rate for a drug was reduced to zero starting for services in 2003.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Directs the GAO to identify conditions and diseases that may justify waiving the application of the therapy caps and to report to Congress by 10/1/04.
Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period⁵⁴	Sec. 625 <ul style="list-style-type: none"> ▪ Waives the late enrollment penalty for military retirees who did not enroll in Medicare Part B upon becoming eligible for Medicare. The waiver applies to the late enrollment penalty for military retirees, age 65 and older, who enroll in the TRICARE for Life program from 2001 to 2004. ▪ Directs the Secretary to provide a special Part B enrollment period for these military retirees beginning as soon as possible after enactment and ending 12/31/04. ▪ The provision applies to premiums for months beginning January 2004. ▪ The Secretary is required to rebate premium penalties paid for months on or after January 2004 for which a penalty does not apply as a result of this provision, but for which a penalty was collected.
Payment for Services Furnished in Ambulatory Surgical Centers (ASC)	Sec. 626 <ul style="list-style-type: none"> ▪ In FY 2004, starting 4/1/04, the ASC update will be the CPI-U (estimated March 31, 2003 CPU-I was minus three percent). In FY 2005, the last quarter of calendar year 2005, and each of the calendar years 2006 – 2009, there will be no update. ▪ After the new ASC payment system has been implemented, the Secretary will no longer be required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every five years.
Freeze In Payments For Certain Items of Durable Medical Equipment And Certain Orthotics; Establishment of Quality Standards And Accreditation Requirements For DME Providers	Sec. 627 <ul style="list-style-type: none"> ▪ Freezes reimbursement for durable medical equipment or orthotics (excluding custom-fabricated) from 2004 – 2006. The rates for the top five services will be adjusted to reflect prices paid under the Federal Employees Health Benefit Program (FEHBP) plans. Applies to items and services provided after 1/1/05. ▪ Competitive bidding for the largest MSAs begins in 2007, phasing up to 80 MSAs in 2009. Competitive bidding prices will be applied nationwide for those selected services
Payment for Clinical Laboratory Diagnostic Tests	Sec. 628 <ul style="list-style-type: none"> ▪ Provides for no updates in the fee schedule for clinical diagnostic laboratory tests for 2004 – 2008. Effective 1/1/04.
Indexing Part B Deductible to Inflation⁵⁵	Sec. 629 <ul style="list-style-type: none"> ▪ Increase the Part B deductible to \$110 in 2005, updated annually by the growth rate in the Medicare prescription drug program. ▪ Effective 1/1/05. <p><i>[Note: States pay the Part B deductible for certain low-income Medicare beneficiaries.]</i></p>
Five-Year Authorization of Reimbursement for All	Sec. 630 <ul style="list-style-type: none"> ▪ Provides a five-year expansion of the items and services covered under Medicare Part B when furnished in Indian hospitals and

54 Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound coverage to Medicare for military retirees age 65 and older. To take advantage of the program, military retirees must enroll in Medicare Part B.

55 Under Medicare Part B, Medicare generally pays 80 percent of the approved amount for covered services after the beneficiary pays an annual deductible of \$100. The Part B deductible has been set at \$100 since 1991.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Medicare Part B Services Furnished to Certain Indian Hospitals and Clinics	ambulatory care clinics. The provision applies to items and services furnished on or after 1/1/05.
SUBTITLE D – ADDITIONAL DEMONSTRATIONS, STUDIES AND OTHER PROVISIONS	
Demonstration Project For Coverage Of Certain Prescription Drugs And Biologicals.	<p>Sec. 641</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to conduct a two-year demonstration project in six states covering more than 50,000 patients under Medicare Part B that pays for drugs and biologics that are prescribed as replacements for existing covered drugs that are furnished incident to a physician’s professional service which are not usually self-administered, including oral anticancer chemotherapeutic agents. ▪ The project is required to provide for cost-sharing comparable to the cost sharing in Medicare Part D. ▪ The project cannot cost more than \$500 million. ▪ No less than 40 percent of the funds must be for oral cancer. ▪ The demonstration project is to begin 90 days following enactment and end no later than 12/31/05. ▪ [Note: The conferees intend that this demonstration will provide immediate Part B coverage for all immunomodulating drugs and biologicals used when treating multiple sclerosis. Coverage will be extended without regard to whether there is medical or other supervision with respect to the administration of the drug or biological.]
Extension Of Coverage Of Intravenous Immune Globulin (IVIG) For The Treatment Of Primary Immune Deficiency Diseases In The Home	<p>Sec. 642</p> <ul style="list-style-type: none"> ▪ Includes intravenous immune globulin for the treatment in the home of primary immune deficiency diseases as a covered medical service under Medicare. Applies to items furnished on or after 1/1/04.
MedPAC Study of Coverage of Surgical First Assisting Services of Certified Registered nurse First Assistants.	<p>Sec. 643</p> <ul style="list-style-type: none"> ▪ Requires MedPAC to study the feasibility and advisability of Medicare Part B payment for surgical first assisting services furnished to Medicare beneficiaries by a certified registered nurse first assistant. The report is to be submitted to Congress by 1/1/05 and is to include recommendations for legislative and administrative action.
MedPAC Study of Payment for Cardio-Thoracic Surgeons	<p>Sec. 644</p> <ul style="list-style-type: none"> ▪ Requires the MedPAC to study the practice expense relative values in the Medicare physician fee schedule for thoracic surgery to determine whether the values adequately account for the attendant costs of nurse assistants at surgery. The study is to be submitted to Congress by 1/1/05 and is to include recommendations for legislative or administrative action.
Studies Relating to Vision Impairments	<p>Sec. 645</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to study the feasibility and advisability of: 1) providing for payment for vision rehabilitation services furnished by vision rehabilitation professionals, and 2) implementing a demonstration project for vision care PPO networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with the insertion of intra ocular lens. ▪ The Secretary is urged to examine any licensure or certification difficulties faced by vision rehabilitation professionals. ▪ The report is due to Congress by 1/1/05 and is to include recommendations for legislation or administrative action. In reviewing reimbursement for vision rehabilitation professionals, the report shall examine payments through qualified physicians to vision

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	rehabilitation professionals for either directly supervised services or services delivered under generalized supervision.
Medicare Health Care Quality Demonstration Programs	<p>Sec. 646</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to establish a 5-year demonstration program that examines the health delivery factors which encourage the delivery of improved patient care quality including: (1) incentives to improve the safety of care provided to beneficiaries; (2) appropriate use of best practice guidelines; (3) reduction of scientific uncertainty through examination of service variation and outcomes measurement; (4) encouragement of shared decision making between providers and patients; (5) the provision of incentives to improve safety, quality, and efficiency; (6) appropriate use of culturally and ethnically sensitive care; and (7) related financial effects associated with these changes. ▪ Health care groups that may participate are physician groups, integrated health care delivery systems, and regional coalitions. ▪ These health care groups may implement alternative payment systems that encourage the delivery of high quality care and streamline documentation and reporting requirements. They may also offer benefit packages distinct from those that are currently available under Medicare Parts A and B and under the Part C Medicare Advantage plan. <ul style="list-style-type: none"> ▪ To qualify for this demonstration, health care groups must meet Secretary-established quality standards; implement quality improvement mechanisms that integrate community-based support, primary care, and referral care; encourage patient participation in decisions; among other requirements. ▪ Effective upon enactment.
MedPAC Study on Direct Access to Physical Therapy Services⁵⁶	<p>Sec. 647</p> <ul style="list-style-type: none"> ▪ Requires MedPAC to study the feasibility and advisability of allowing Medicare beneficiaries in fee-for-service direct access to outpatient physical therapy services and those physical therapy services that are furnished as comprehensive rehabilitation facility services. The study is to be submitted to Congress by 1/1/05.
Demonstration Project for Consumer-Directed Chronic Outpatient Services	<p>Sec. 648</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to establish no fewer than 3 demonstration projects that evaluate methods to improve the quality of care provided to Medicare beneficiaries with chronic conditions and that reduce expenditures that would otherwise be made on their behalf by Medicare. ▪ The methods are required to include permitting beneficiaries to direct their own health care needs and services. ▪ In designing the demonstrations, the Secretary is required to evaluate practices used by group health plans and practices under State Medicaid programs that permit patients to self-direct the provision of personal care services and to determine the appropriate scope of personal care services that apply under the demonstration projects. ▪ The Secretary is required to establish the demonstrations within 2 years of enactment. Demonstrations are required to be located in an urban area, a rural area, and an area that has a Medicare population with a diabetes rate that significantly exceeds the national average rate. ▪ The Secretary is required to evaluate the clinical and cost effectiveness of the demonstrations. Reports to Congress are required biannually beginning 2 years after the demonstrations begin.
Medicare Care Management	<p>Sec. 649</p>

⁵⁶ For the purposes of the study, direct access is defined as access to physical therapy services without the requirement that beneficiaries be under the care of, or referred by, a physician. Further, the services provided are not required to be under the supervision of a physician. Finally, either a physician or a qualified physical therapist could satisfy any requirement for certification, recertification and establishment and review of a plan of care.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Performance Demonstration	<ul style="list-style-type: none"> ▪ Directs the Secretary to establish a 3-year demonstration program to promote continuity of care, help stabilize medical conditions, prevent or minimize acute exacerbation of chronic conditions, and reduce adverse health outcomes. Effective upon enactment. ▪ Four sites would be designated for the demonstration: with at least two in urban areas and one in a rural area. One of the demonstration sites would be in a state with a medical school with a geriatrics department that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia. ▪ Any Medicare beneficiary enrolled in part A and B who has one or more chronic medical conditions specified by the Secretary (one of which may be a cognitive impairment) and is unable to manage their own care or has a functional limitation and resides in a demonstration area may participate in the program if the beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the beneficiary under the demonstration.
GAO Study and Report on the Propagation of Concierge Care⁵⁷	<p>Sec. 650</p> <ul style="list-style-type: none"> ▪ GAO would be required to conduct a study on concierge care provided to Medicare beneficiaries and their affects on their access to Medicare covered services and submit a report to Congress, including recommendations, no later than 12 months after enactment. ▪ The provision would be effective upon enactment.
Demonstration of Coverage of Chiropractic Services under Medicare	<p>Sec. 651</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to establish a 2-year demonstration program at 4 sites to evaluate the feasibility and desirability of covering additional chiropractic services under Medicare. These projects may not be implemented before October 1, 2004. ▪ The chiropractic services included in the demonstration shall include, at a minimum, care for neuromusculoskeletal conditions typical among eligible beneficiaries as well as diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction where treatment occurs. ▪ An eligible beneficiary participating in the demonstration project, including those enrolled in Medicare +Choice or Medicare Advantage plans, would not be required to receive approval by physician or other practitioner in order to receive chiropractic services under the demonstration project.
TITLE VII – PROVISIONS RELATING TO PARTS A AND B	
SUBTITLE A – HOME HEALTH	
Update In Home Health Services	<p>Sec. 701</p> <ul style="list-style-type: none"> ▪ Changes the time frame for the home health update from the federal fiscal year to a calendar year basis beginning with 4/1/04. ▪ Home health agency payments are increased by the full market basket percentage for the last quarter of 2003 (October, November, and December) and for the first quarter of 2004 (January, February, and March). ▪ The update for the remainder of 2004 and for 2005 and 2006 is the home health market basket percentage increase minus 0.8 percentage points. The size of the outlier pool for home health prospective payment may not exceed 3 percent of the total payment projected under they payment system beginning January 1, 2004, total payments are not increased to account for the difference.
Demonstration Project to Clarify the Definition of Homebound	<p>Sec. 702</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to conduct a 2-year demonstration project where beneficiaries enrolled in Medicare Part B with specified chronic conditions would be deemed to be homebound in order to receive home health services under Medicare.

⁵⁷ Concierge care is an arrangement where a physician or practitioner charges an individual seeking care a membership fee or other fee or requires the purchase of an item or service as a prerequisite for providing the care.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ A beneficiary is eligible to be deemed to be homebound if the beneficiary: (1) has been certified by a physician to have a permanent and severe condition that is not expected to improve; (2) permanently needs assistance with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing, and dressing); (3) permanently requires skilled nursing services (not including medication management); (4) needs either an attendant during each day to monitor and treat the beneficiary’s medical condition or to assist the beneficiary with activities of daily living; (5) requires technological assistance or the assistance of another person to leave the home; and (6) does not regularly work in a paid position full-time or part-time outside the home. ▪ The Secretary is required to select 3 states in the northeast, midwest and western regions of the United States in which to conduct the demonstration. ▪ Up to 15,000 beneficiaries can participate. ▪ Data must be collected regarding the quality of care, patient outcomes, and additional costs, if any to Medicare. ▪ The demonstration is required to begin within 6 months of enactment. ▪ Within 1 year of completing the demonstration, the Secretary is required to report to Congress on: whether the subject of the demonstration adversely effected the provision of home health services under Medicare or has directly caused an unreasonable increase of expenditures under Medicare.
<p>Demonstration Project for Medical Adult Day Care Services</p>	<p>Sec. 703</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility⁵⁸, provides medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary’s home. Such services would be provided as part of a plan for an episode of care for home health services established for a beneficiary. ▪ Payment for the episode will equal 95% of the amount that would otherwise apply subject to budget neutrality provisions. ▪ The agency or facility is prohibited from charging the beneficiary separately for the medical adult day care services. ▪ Requires the Secretary to reduce payments made to medical adult day care facilities under the demonstration to offset excess spending. ▪ The 3-year demonstration project is to be conducted in not more than 5 sites in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries is on a voluntary basis. ▪ Effective upon enactment.
<p>Temporary Suspension of OASIS Requirement for Collection of Data on Non-Medicare and Non-Medicaid Patients⁵⁹</p>	<p>Sec. 704</p> <ul style="list-style-type: none"> ▪ Suspends the requirement that home health agencies must collect OASIS data on private pay (non-Medicare, non-Medicaid) until the Secretary (1) reports to Congress on the benefits of these data, the value of the data compared to the administrative burden of data collection in small agencies, and the use of the OASIS information by both large and small agencies, and then (2) publishes final regulations regarding the collection and use of OASIS.

58 A medical adult day care facility is one that: (1) has been licensed or certified by a State to furnish medical adult day care services for a continuous 2-year period; (2) has been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary.

59 Medicare is required to monitor the quality of home health care and services for all patients as part of the survey process with a standardized, reproducible assessment instrument. The purpose of the monitoring is to determine whether the agency is helping all patients achieve and maintain the highest functional capacity that is possible as is reflected in the care plan the home health agency has developed for the patient. Medicare has implemented this requirement using the Outcomes and Assessment Information Set (OASIS). The OASIS data are used for Medicare payment (under home health prospective payment) and for quality improvement purposes for all patients.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The provision does not prohibit home health agencies from collecting OASIS data on private pay patients for the agencies' own use. ▪ The suspension is effective upon enactment. The report is due 18 months after enactment.
MedPAC Study on Medicare Margins of Home Health Agencies	<p>Sec. 705</p> <ul style="list-style-type: none"> ▪ Requires MedPAC to study payment margins of home health agencies paid under the Medicare home health prospective payment system, using cost reports filed by agencies. ▪ The study is required to examine whether systematic differences in payment margins are related to differences in case mix, as measured by home health resource groups (HHRGs), among agencies. ▪ MedPAC is required to submit a report to Congress on the study within 2 years of enactment.
Coverage of Religious Non-medical Health Care Institution (RNHCI) Services Furnished in the Home	<p>Sec. 706</p> <ul style="list-style-type: none"> ▪ Expands coverage under Medicare to include RNHCI services when furnished in the home, but only with respect to items and services ordinarily furnished by home health agencies and that are comparable to items and services furnished by home health agencies that are not RNHCI. ▪ Caps payments at \$700,000 in a year. ▪ Effective upon enactment and expires 12/31/06.
SUBTITLE B – GRADUATE MEDICAL EDUCATION	
Extension of Update Limitation on High Cost Programs	<p>Sec. 711</p> <ul style="list-style-type: none"> ▪ Hospitals with per resident amounts about 140% of the geographically adjusted national average amount would not get an update from FY 2004 through FY 20013. ▪ Effective 10/1/04.
Clarification of Congressional Intent Regarding the Counting of Residents in a Non-provider Setting and a Technical Amendment Regarding the 3-year Rolling Ratio and the IME Ratio	<p>Sec. 712(a)</p> <ul style="list-style-type: none"> ▪ For 12 months as of January 1, teaching hospitals can count residents in non-hospital locations regardless of the financial arrangement between the hospital and the teaching physician at the nonhospital clinic site participating in a family practice program. ▪ Provisions regarding the payment of IME and DME for training in non-hospital sites that were included in the Balanced Budget Act of 1997 Congress were intended to encourage placement of residents in rural and other underserved areas and in ambulatory sites that are more in alignment with the types of practice they would have upon practice. ▪ The purpose was two-fold: to increase access to care by increasing the numbers of residents training in those settings, and to increase the likelihood of physicians placing themselves in practice in rural and underserved areas. For programs established after January 1, 2002, the Secretary shall clarify in future regulation its definition of reasonableness of payment for supervisory physicians.
Exception to Initial Residency Period for Geriatric Residency of Fellowship Programs	<p>Sec. 712(b)</p> <ul style="list-style-type: none"> ▪ The conference agreement clarifies that Congress intended to provide an exception to the initial residency period for geriatric fellowship programs to accommodate programs that require 2 years of training to initially become board eligible in the geriatric specialty. ▪ Directs the Secretary to promulgate interim final regulations after notice and comment consistent with this intent after notice and subject to public comment.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ The regulations will be effective for cost reporting periods on or after October 1, 2003.
Treatment of Volunteer Supervision	<p>Sec. 713</p> <ul style="list-style-type: none"> ▪ Creates a one-year moratorium on HHS regulations regarding financial arrangements between hospitals and teaching physicians in osteopathic and allopathic family practice programs training at non-hospital sites. Directs the HHS Office of the Inspector General to conduct a study and to report within one year after enactment. ▪ Directs the Secretary to initiate a study on the training of residents in non-hospital settings, and the use of volunteer faculty in those settings. The study is due within six months of enactment. The study shall include the following: <ul style="list-style-type: none"> ▪ Examination of the effect of the change in the BBA that allowed payment by Medicare for graduate medical education in non-hospital settings, to include whether access and numbers of physicians placing in rural and underserved areas has increased. ▪ Examination of programs on a national level regarding evidence of possible misuse of federal money with respect to volunteering supervisory physicians. ▪ A determination whether supervisory physicians are freely volunteering their time. ▪ Descriptions of what incentives are available in each state that is offered to physicians who volunteer their time as supervisory physicians (eg. CME credit hours, hospital privileges).
SUBTITLE C - CHRONIC CARE IMPROVEMENT	
Voluntary Chronic Care Improvement under Traditional Fee-for-Service	<p>Sec. 721</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to establish and implement chronic care improvement programs. Phase one must begin no later than one year after enactment. ▪ If the programs are established, they are required to improve clinical quality and beneficiary satisfaction and achieve spending targets for Medicare for beneficiaries with certain chronic health conditions. ▪ Requires the Secretary to submit an interim report on later than 3 ½ years after the completion of phase one.
Medicare Advantage Quality Improvement Program	<p>Sec. 722</p> <ul style="list-style-type: none"> ▪ Each Medicare Advantage organization is required to have an on-going quality improvement program for improving the quality of care provided to enrollees (except for private fee-for-service plans or MSA plans) effective for contract years beginning January 1, 2006. ▪ As part of the quality improvement program, each MA organization is required to have a chronic care improvement program. Each chronic care improvement program is required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.
Chronically Ill Medicare Beneficiary Research, Data, Demonstration Strategy	<p>Sec. 723</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to develop a plan to improve quality of care and to reduce the cost of care for chronically ill Medicare beneficiaries within 6 months after enactment. ▪ The plan is required to use existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill Medicare beneficiaries. ▪ The plan is required to: (1) integrate existing datasets including the Medicare Current Beneficiary Survey, the Minimum Data Set, the Outcome and Assessment Information Set, data from the Quality Improvement Organizations, and claims data; (2) identify any new data needs and a methodology to address new data needs; (3) plan for the collection of such data in a data warehouse; and (4) develop a research agenda using the data

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ In developing the plan, the Secretary is required to consult with experts in the fields of care for the chronically ill (including clinicians) and is required to enter into contracts with appropriate entities for the development of the plan ▪ The Secretary is required to implement the plan no later than 2 years after enactment. Appropriations are authorized from amounts in the Treasury not otherwise appropriated, such sums as may be necessary in fiscal years 2004 and 2005 to carry out this provision.
SUBTITLE D - OTHER PROVISIONS	
Improvements in National and Local Coverage Determination Process to Respond to Changes in Technology	<p>Sec. 731</p> <ul style="list-style-type: none"> ▪ Establishes processes and timeframes for national coverage determinations to promote consistency in local coverage determinations. ▪ The Secretary is required to develop guidance documents similar to those required by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371(h)). The provision establishes a timeframe for decisions regarding national coverage determinations of 6 months after a request when a technology assessment is not required and 9 months when a technology assessment is required and in which a clinical trial is not requested. <p>Coverage</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. ▪ Following the 6- or 9-month period, the Secretary is required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; make the clinical evidence and data used in making the decision available to the public when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coding change. ▪ In instances where a request for a national coverage determination is not reviewed by the Medicare Coverage Advisory Committee, the Secretary is required to consult with appropriate outside clinical experts. ▪ The Secretary is also required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort. ▪ The provision is effective for national determinations as of January 1, 2004 and for local coverage determinations made on or after July 1, 2004. <p>Clinical Trials</p> <ul style="list-style-type: none"> ▪ The conference agreement prohibits the Secretary from excluding from Medicare coverage the routine costs of care incurred by a Medicare beneficiary participating in a category A clinical trial, beginning with routine costs incurred on and after January 1, 2005. The conference agreement makes clear that this provision does not apply to, or affect, Medicare coverage or payment for a non-experimental/investigational (category B) device. <p>Coding</p> <ul style="list-style-type: none"> ▪ The conference agreement requires the Secretary to implement revised procedures for issuing temporary national HCPCS codes under Medicare Part B no later than July 1, 2004.

PROVISION	MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Extension of Treatment of Certain Pathology Services under Medicare⁶⁰	Sec. 732 <ul style="list-style-type: none"> ▪ Direct payments for the technical component for these pathology services will be made for services furnished during 2005 and 2006. ▪ Effective 1/1/05.
Payment of Pancreatic Islet Cell Investigation Transplants for Medicare Beneficiaries in Clinical Trials	Sec. 733 <ul style="list-style-type: none"> ▪ Requires the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, to conduct a clinical investigation of pancreatic islet cell transplantation, which includes Medicare beneficiaries. ▪ Beginning no earlier than 10/1/04, the Secretary is required to pay for the routine costs as well as transplantation and appropriate related items and services for Medicare beneficiaries who are participating in such a trial. ▪ In implementing the clinical investigation of pancreatic islet cell transplantation, CMS, in working with NIH, should ensure that a sufficient number of Medicare beneficiaries participate so that the results are applicable to the broader Medicare population with Type 1 diabetes and Medicare is able to make an informed decision regarding coverage of pancreatic islet transplantation.
Restoration of Medicare Trust Funds	Sec. 734 <ul style="list-style-type: none"> ▪ After consultation with the Secretary of HHS, the Secretary of the Treasury would be required to transfer into the HI Trust fund an amount that would have been held by that fund if the clerical error had not occurred within 120 days of enactment.⁶¹
Modifications to MedPAC	Sec. 735 <ul style="list-style-type: none"> ▪ Requires MedPAC to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service. Effective 1/1/04. ▪ MedPAC is required to submit 2 additional reports no later than 6/1/04. The first report is to study the need for current data and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. The second report is to address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals. ▪ The conference agreement requires that the Comptroller General appoint experts in the area of pharmaco-economics or prescription drug benefit programs to MedPAC. In addition, members of the Commission are required to be treated as employees of Congress for purposes of financial disclosure requirements and the Comptroller General is required to ensure compliance with this requirement.
TITLE VIII – COST CONTAINMENT	

60 In general, independent laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. BIPA permitted independent laboratories with existing arrangements with acute care hospitals to bill Medicare separately for the technical component of pathology services provided to the hospitals' inpatients and outpatients. The arrangement between the hospital and the independent laboratory had to be in effect as of July 22, 1999. The direct payments for these services apply to services furnished during a 2-year period starting on January 1, 2001 and ending December 31, 2002.

61 The Federal Hospital Insurance (HI) Trust Fund was established on July 30, 1965 as a separate account in the U.S. Treasury. All of the HI financial operations are handled through this fund. The trust fund's primary source of income consists of amounts appropriated to it, under permanent authority, on the basis of taxes paid by workers, their employers, and individuals with self-employment income. Up to 85% of an individual or a couple's Old Age and Survivors, Disability Insurance (OASDI) benefits may be subject to federal income taxation if their income exceeds certain thresholds. The income tax revenue attributable to the first 50% of the OASDI benefits is allocated to the OAS and DI trust funds. The revenue associated with the amount between 50% and 85% is allocated to the HI trust funds. An incorrect amount of income from the taxation of OASDI benefits was transferred into the HI Trust Fund in April 2001, because of clerical error. An additional amount was transferred into the HI Trust Fund in December 2001 to correct for the principal component of the error. Correction of the interest component associated with the clerical error requires legislation.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
SUBTITLE A – COST CONTAINMENT	
Cost Containment	<p>Sec. 801-804</p> <ul style="list-style-type: none"> ▪ Limits the portion of Medicare spending that comes from the federal Treasury to 45%. ▪ Beginning in 2005, each year the Medicare Trustees are directed to issue a report indicating whether projected excess general revenue funding⁶² in the current year and the next 6 years is likely to exceed the 45% cap. If they report two years consecutively that the program will exceed the cap, this would constitute a “Medicare funding warning,” and the agreement establishes a procedure for bringing the program into compliance.⁶³
SUBTITLE B – INCOME-RELATED REDUCTION IN PART B PREMIUM SUBSIDY	
Income-Relate Part B Premium	<p>Sec. 811</p> <ul style="list-style-type: none"> ▪ Income thresholds: <ul style="list-style-type: none"> ▪ All beneficiaries under \$80,000 (single) \$160,000 couple continue to receive the existing 75% subsidy. ▪ 65% premium subsidy for beneficiaries between \$80,000 and \$100,000 ▪ 50% premium subsidy for beneficiaries between \$100,000 and \$150,000 ▪ 35% premium subsidy for beneficiaries between \$150,000 and \$200,000 ▪ 20% premium subsidy for beneficiaries over \$200,000 ▪ Five year phase-in of new premiums beginning in 2007. ▪ Income levels doubled for married couples. ▪ Permits beneficiaries to appeal if their family situation has changed (e.g., death of spouse, divorce). ▪ Permits the Internal Revenue Service (IRS) to release certain information to employees and contractors of the Social Security Administration to facilitate the income-related reduction in the Part B premium subsidy.
REGULATORY REFORM – TITLE IX	
Overview of Major Provisions	<ul style="list-style-type: none"> ▪ The preliminary agreement reached by the conferees would modernize the Medicare program by simplify the payment process and make it more rational and understandable for both providers and beneficiaries by: ▪ Modernizing the contracting system to introduce competition and consolidate contracting in Medicare Parts A and B. Since 1965, only one new contractor has been added to the Medicare program. Competition will bring new technology, new ideas and better service to both providers and beneficiaries;

62 General revenue funding is total Medicare outlays minus “dedicated sources.” Dedicated sources is funding received outside the federal government and includes: (1) the Hospital Insurance (HI) payroll tax; (2) the income tax raised by the 1993 changes in taxation of OASDI benefits; (3) amounts states pay the federal government through the “claw-back provisions” related to federal assumption of Medicare prescription drug coverage for Medicaid/Medicare dual-eligibles; (4) premiums paid to Medicare; and (5) gifts to Medicare. Interest on trust fund assets is not considered a dedicated source.

63 After two consecutive reports that the program will exceed the 45% cap, the agreement calls for the President to submit legislation to Congress to reduce program expenditures to meet the cap. If the House fails to enact the proposed legislation by July 30th, the 88 members of the House may move to discharge a bill that addresses the problem. If the House votes to discharge the bill, which requires a majority, the bill moves to the House floor where it is subject to an “open rule” (up to 10 hours for amendments) that waives all points of order against germane amendments. The agreement calls for the House to consider the discharged bill within 3 legislative days after the discharge. In the Senate, the agreement provides that within three days upon receipt of the President’s legislative proposal, the Senate Majority Leader, Minority Leader or their designees will introduce the proposal and refer it to the Senate Finance Committee. If the Finance Committee failed to report the bill by June 30th, than a single motion to discharge would be in order. The motion to discharge would be subject to 2 hours of debate. If Congress enacted legislation that eliminated the excess general revenue (as certified by the Budget Committee chairman), the motion to discharge would not be available for the remainder of that session of Congress. Once legislation is placed on the Senate calendar, regular Senate rules apply, including the right to filibuster the motion to proceed or the bill.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Creating a beneficiary advocate inside Medicare to help beneficiaries navigate through the confusing morass of Medicare requirements; ▪ Protecting providers from arbitrary and capricious actions that may occur during the auditing process; ▪ Holding the government accountable for the guidance it gives to providers by prohibiting government sanctions (including interest on overpayments) if a provider follows written, erroneous guidance; ▪ Assisting providers in dealing with the complex maze of Medicare rules and regulations by improving provider education and technical assistance; ▪ Prohibiting retroactive application of new regulations; ▪ Strengthening the independence of reviewers in the appeals process; ▪ Establishing a process for beneficiaries and their doctors to find out in advance whether certain items and services are covered by Medicare; and ▪ Ensuring hospitals are paid for emergency services.
SUBTITLE A – REGULATORY REFORM	
Issuance of Regulations	Sec. 902 <ul style="list-style-type: none"> ▪ Requires HHS to establish a regular timeline for the publication of final regulations based on the publication of a proposed rule or interim final regulations. Requires that final regulations, including interim final regulations be the logical outgrowth of a notice of proposed rulemaking (NPRM). Effective upon enactment.
Compliance with Changes in Regulation and Policy	Sec. 903 <ul style="list-style-type: none"> ▪ Prohibits the Secretary from applying substantive policy changes retroactively. They may also not take affect for at least 30 day, and before the effective date, no action may be taken against a provider. Effective upon enactment.
Reports and Studies	Sec. 904 <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to report to Congress regarding areas of confusion, inconsistency and conflict within the Medicare statute. The report is to be submitted on later than two years after enactment. Updates are to be submitted every three years.
SUBTITLE B - CONTRACTING REFORM	
Increased Flexibility in Medicare Administration	Sec. 911 <ul style="list-style-type: none"> ▪ Provides the Secretary broad discretionary authority to prepare for the timely implementation of contracting reforms. Effective upon enactment.
Requirements for Information Security for Medicare Administrative Contractors	Sec. 912 <ul style="list-style-type: none"> ▪ Requires Medicare contractors to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare transactions. ▪ Effective for contracts effective after 10/1/05.
SUBTITLE C - EDUCATION AND OUTREACH	
Provider Education and Technical Assistance	Sec. 921 <ul style="list-style-type: none"> ▪ Directs the Secretary to use specific claims payment error rates or similar methodology to give contractors an incentive to implement effective provider education and outreach programs.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<ul style="list-style-type: none"> ▪ Requires the Secretary to report to Congress on how the error rates will be used to when assessing contractor performance. ▪ Requires the Secretary to coordinate educational activities provided through Medicare contractors to maximize the effectiveness of federal educational activities. Directs the Secretary to report to Congress on these efforts. ▪ Prohibits Medicare contractors from using attendance records related to educational activities to select or tract providers for audit or prepayment review.
Small Provider Technical Assistance Demonstration Program	Sec. 922 <ul style="list-style-type: none"> ▪ Requires the Secretary to establish a demonstration program and to contract with qualified entities to offer technical assistance to small providers and suppliers upon request. Effective upon enactment.
Medicare Beneficiary Ombudsman	Sec. 923. <ul style="list-style-type: none"> ▪ Directs the Secretary to appoint a Medicare Beneficiary Ombudsman. Effective one-year after enactment.
Beneficiary Outreach Demonstration Program	Sec. 924 <ul style="list-style-type: none"> ▪ Requires the Secretary to establish a tree-year demonstration program where Medicare specialist will provide advice and assistance to Medicare beneficiaries in at least 6 local Social Security offices, including two in rural areas. Effective upon enactment.
Inclusion of Additional Information in Notices to Beneficiaries about Skilled Nursing Facility Benefits	Sec. 925 <ul style="list-style-type: none"> ▪ Requires the Secretary to provide information concerning the number of remaining covered days in a SNF stay on notices to beneficiaries. Effective six months after enactment.
Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans	Sec. 926. <ul style="list-style-type: none"> ▪ Requires the Secretary to make information identifying Medicare-participating SNFs available to Medicare beneficiaries. Also requires the information to be included in hospital discharge plans. Effective no later than six months after enactment.
SUBTITLE D - APPEALS AND RECOVERY	
Transfer of Responsibility for Medicare Appeals	Sec. 931 <ul style="list-style-type: none"> ▪ Directs HHS and the Social Security Administration (SSA) to develop and implement a plan to transfer the Medicare appeals hearing function from SSA to HHS, while at the same time maintaining independence of Administrative Law Judges (ALJs) from the Centers for Medicare and Medicaid Services (CMS).
Process for Expedited Access to Review	Sec. 932 <ul style="list-style-type: none"> ▪ Requires the Secretary to establish a process to expedite access to judicial review for legal issues that cannot be resolved administratively. ▪ Requires expedited review of certain provider agreement determinations, including determinations where termination or certain other immediate remedies are being imposed, or where a facility's nurse aide training program is disapproved based on a finding of substandard quality of care. ▪ Requires the Secretary to establish a process for waiver of disapproval of nurse-aide training programs if an imposed civil monetary penalty is not related to quality of care. Effective 10/1/04.
Revisions to the Medicare	Sec. 933

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Appeals Process	<ul style="list-style-type: none"> ▪ Reforms the current Medicare appeals process regarding presentation of evidence. Effective 10/1/04. ▪ Reforms current process regarding notice requirements. Effective upon enactment.
Prepayment Review	Sec. 934 <ul style="list-style-type: none"> ▪ Establishes a format for the conduct of prepayment review. Effective one year after enactment. Requires rules to be promulgated within that time.
Recovery of Overpayments	Sec. 935 <ul style="list-style-type: none"> ▪ Requires the Secretary to establish repayment plans in hardship cases. Effective upon enactment.
Provider Enrollment Process/Right of Appeal	Sec. 936 <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to establish regulations under which there are deadlines for action on enrollment applications, including renewals, and providers whose applications to enroll (or renew) are denied are provided a mechanism to appeal the denial. ▪ Provides that the enrollment process be created within six months of enactment. The consultative process is effective 1/1/04 and the hearing rights are effective no later than one year after enactment.
Process for Correction of Minor Errors and Omissions without Pursuing the Appeal Process	Sec. 937 <ul style="list-style-type: none"> ▪ Directs the HHS Secretary to develop a process where, in the case of minor errors omissions that are detected in the submission of claims, a provider is given an opportunity to correct the error or omission without the need to initiate an appeal. ▪ Effective no later than one year after enactment.
Prior Determination Process for Certain Items and Services/Advance Beneficiary Notices	Sec. 938 <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to establish a process under which physicians and beneficiaries can receive prior determinations as to whether an item or service is eligible for coverage. ▪ Effective no later than 18 months after enactment and provision sunsets five years after the effective date.
Appeals by Providers When There is No Other Party Available	Sec. 939 <ul style="list-style-type: none"> ▪ Allows a provider or supplier to appeal a determination by the Secretary in the case where a beneficiary dies before assigning appeal rights. Effective upon enactment.
Revision to Appeals Timeframes and Amounts	Sec. 940 <ul style="list-style-type: none"> ▪ Increase the timeframes for decision-making at the lower levels of the appeals process (contractor or QIC) to 60 days (formerly 30 days). Effective upon enactment. ▪ Requires the dollar amounts in controversy to be adjusted annually by the percent increase of the Medicare component of the consumer price index for urban consumers. Effective 1/1/05
Mediation Process for Local Coverage Determinations	Sec. 940A <ul style="list-style-type: none"> ▪ Requires the Secretary to establish a mediation process for local coverage determinations through the use of a Regional Medical Officer or a physician trained in mediation. Effective upon enactment.
SUBTITLE E - MISCELLANEOUS PROVISIONS	
Policy Development Regarding Evaluation and Management	Sec. 941 <ul style="list-style-type: none"> ▪ Requires pilot testing of new evaluation and management guidelines used for physician visits prior to their implementation, and studies

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Documentation	of simpler systems of documentation for physician claims. Effective upon enactment.
Improvement in Oversight of Technology and Coverage	Sec. 942 <ul style="list-style-type: none"> ▪ Establishes a Council for Technology and Innovation within the Centers for Medicare and Medicaid Services (CMS) that is composed of senior and clinical CMS staff.
Treatment of Hospitals for Certain Services under Secondary Payer Provisions	Sec. 943 <ul style="list-style-type: none"> ▪ Requires Medicare Secondary Payor data collection criteria to be the same for hospitals and independent labs performing reference (no patient contact) lab tests. Effective upon enactment.
EMTALA Improvements⁶⁴	Sec. 944 <ul style="list-style-type: none"> ▪ Clarifies that Medicare will pay for mandated services. Effective 1/1/04. ▪ Requires notification of providers when an investigation on the delivery of emergency services is closed, establishes a system for prior review by peer review organizations in the care of termination of participation. Effective upon enactment.
EMTALA Technical Advisory Group	Sec. 945 <ul style="list-style-type: none"> ▪ Establishes a technical advisory group that will review EMTALA regulations, provide advice and recommendations to the HHS Secretary regarding the implementation of regulations, and disseminate information regarding the application of the regulations.
Authorizing Use Arrangements to Provide Core Hospice Services in Certain Circumstances	Sec. 946 <ul style="list-style-type: none"> ▪ Authorizes the use of arrangements with other hospice programs to provide core hospice services in certain exigent or extraordinary circumstances. Also allows contracting for highly specialized services. Effective upon enactment.
Application of OSHA Bloodborne Pathogens Standard to Certain Hospitals	Sec. 947 <ul style="list-style-type: none"> ▪ Requires public hospitals that are not otherwise subject to the OSHA Act of 1970 to comply with the Bloodborne Pathogens standard. Effective 7/1/04.
Conforming Authority to Waive a Program Exclusion	Sec. 949 <ul style="list-style-type: none"> ▪ Expands the waiver authority, applicable to mandatory program exclusions, permitting the granting of exclusion waivers in cases where a federal health care program believes that the subject is a sole community physician or sole source of essential specialized items or services in a community, and that the seclusion would impose a hardship on the program's beneficiaries. Effective upon enactment.
Treatment of Certain Dental Claims	Sec. 950 <ul style="list-style-type: none"> ▪ Prohibits group health plans from requiring dental providers to file claims for excluded services. Effective 60 days after enactment.
Furnishing Hospitals with Information to Compute DSH Formula	Sec. 951 <ul style="list-style-type: none"> ▪ Requires the HHS Secretary to furnish data to hospitals that are necessary for the computation of Medicare disproportionate share hospital (DSH) amounts. Effective no later than one year after enactment.
Revisions to Reassignment Provisions	Sec. 952 <ul style="list-style-type: none"> ▪ Allows physicians to reassign payment for Medicare covered services to entities with which they have an independent contractor

64 The Emergency Medical Treatment and Labor Act (EMTALA) is a statute which governs when and how a patient may be: (1) refused treatment or (2) transferred from one hospital to another when he is in an unstable medical condition. EMTALA was passed as part of the Consolidated Omnibus Budget Reconciliation Act of 1986.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	arrangement. Effective upon enactment.
Other Provisions	<p>Sec. 953</p> <ul style="list-style-type: none"> ▪ Requires the Comptroller General to submit a report on the appropriateness, stability, and predictability of the updates in the conversion factor for the physician fee schedule, including the appropriateness of the sustainable growth rate formula for 2002 and succeeding years an possible alternatives to the formula. Effective within six months of enactment. ▪ Requires the HHS Secretary to make available to the public a list of the national coverage determinations issued the previous year along with information on how to obtain more information with respect to the determinations. Effective upon enactment. ▪ Requires the Comptroller General to submit a report on the implications of allowing flexibility in the application of the Medicare conditions of participation for home health agencies with respect to patients that are not Medicare beneficiaries. Effective within six months of enactment. ▪ Requires the Inspector General to submit a report on the extent to which hospitals provide notice to Medicare beneficiaries before they use the 60 lifetime reserve days. Effective within one year of enactment. ▪ Requires the Comptroller General to submit a report on physician compensation. Effective no later than one year after enactment.
ACCESS TO AFFORDABLE PHARMACEUTICALS – TITLE XI	
ACCESS TO AFFORDABLE PHARMACEUTICALS	
30-Month Stay-of-Effectiveness Period	<p>Sec. 1101</p> <ul style="list-style-type: none"> ▪ Makes changes in the application process for FDA approval of a new drug. Applies to patent information submitted after 8/18/02.
Declaratory Judgements	<ul style="list-style-type: none"> ▪ The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the "reasonable apprehension" test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.
Forfeiture of 180-Day Exclusivity Period	<p>Sec. 1102</p> <ul style="list-style-type: none"> ▪ Defines the conditions under which a first applicant for FDA approval of a new drug would lose the 180-day exclusivity period that prevents a second applicant from applying for approval of the same drug. Applies to applications filed after enactment.
Bioavailability and Bioequivalence	<p>Sec. 1103</p> <ul style="list-style-type: none"> ▪ Defines bioavailability as the rate and extent to which the active ingredient is absorbed from a drug and gives the Secretary the authority to assess bioavailability and bioequivalence using scientifically valid measures for drugs not intended to be absorbed into the bloodstream. Effective upon enactment.
SUBTITLE B - FEDERAL TRADE COMMISSION REVIEW	
Notification of Agreements	<p>Sec. 1112</p> <ul style="list-style-type: none"> ▪ Outlines the procedure and requirements for abbreviated drug application (ANDA) agreements between a brand-name drug company and a generic drug application, or between two generic drug applicants. Effective 30 days after enactment.
Filing Deadlines	<p>Sec. 1113</p> <ul style="list-style-type: none"> ▪ States that any filing required under section 1112 must be filed no later than ten business days after the date the agreement takes place. Effective 30 days after enactment.

PROVISION	▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Disclosure Exemption	Sec. 1114 <ul style="list-style-type: none"> ▪ Makes any information or material filed according to the subtitle exempt from public disclosure, but does not prevent disclosure to Congress or any duly authorized committees. Effective 30 days after enactment.
Enforcement	Sec. 1115 <ul style="list-style-type: none"> ▪ Sets the penalty for failure to comply with the provisions of this subtitle at a civil penalty of not more than \$11,000 per day for each day hat a brand-name drug company or generic drug applicant is out of compliance. Effective 30 days after enactment.
Rulemaking	Sec. 1116 <ul style="list-style-type: none"> ▪ Allows the Federal Trade Commission, with the concurrence of the Assistant Attorney General, to define terms used in this subtitle and to exempt certain applicants or agreements from the requirements. Effective 30 days after enactment.
Savings Clause	Sec. 1117 <ul style="list-style-type: none"> ▪ Prevents any action or failure to take action by the Assistant Attorney General or the FTC under this subtitle from preventing the proceeding of any existing agreements under any other provision of law between a brand-name company and a generic drug applicant or an agreement between two or more generic drug applicants. Effective 30 days after enactment.
Effective Dates	Sec. 1118 <ul style="list-style-type: none"> ▪ The subtitle is effective 30 days after enactment and will apply to agreements (described in Sec. 1112) that are entered into 30 days after the enactment date.
SUBTITLE C - IMPORTATION OF PRESCRIPTION DRUGS	
Importation of Prescription Drugs	Sec. 1121 <ul style="list-style-type: none"> ▪ Limits drug reimportation to Canada and retains current law requirement that would permit reimportation only if the HHS Secretary certifies that reimportation would pose no additional risk to the public’s health and safety.⁶⁵
Study and Report on Importation of Drugs	Sec. 1122 <ul style="list-style-type: none"> ▪ Directs the HHS Secretary to conduct a study that identifies current problems with the implementation of existing laws as well as examines a range of issues associated with the importation of drugs. <p><i>[Note: This report is due to be submitted by the Secretary December 8, 2004.]</i></p>
Study and Report on Trade in Pharmaceuticals	Sec. 1123 <ul style="list-style-type: none"> ▪ Directs the Secretary to conduct a study and report of drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development and whether those practices utilize non-tariff barriers with respect to trade in pharmaceuticals. Requires the study to include an analysis of the use of price controls, reference pricing, and other actions that affect the market access of United States pharmaceutical products.
TAX PROVISIONS - TITLE XII	

65 On October 28, 2000, the Congress enacted the Medicine Equity and Drug Safety Act (P.L. 106-387), authorizing the Food and Drug Administration (FDA) to permit the reimportation of certain prescription drug products manufactured in the United States that have been exported to a foreign country. It permitted reimportation from the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, European Union (EU) countries (Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, the United Kingdom and any new members of the EU), Iceland, Liechtenstein and Norway. The law permits the FDA to add countries to the list. The law provides that the reimportation provisions cannot become effective until the Secretary of the U.S. Department of Health and Human Services (HHS), “...demonstrates to the Congress that the implementation of this section will—(1) pose no additional risk to the public’s health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer.” To date no HHS secretary has been willing to attest to the safety of reimported prescription drugs.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
<p>Health Savings Accounts</p>	<p>Sec. 1201</p> <ul style="list-style-type: none"> ▪ Creates tax-free Health Savings Accounts (HSAs) for qualified medical expenses. ▪ Authorizes Health Savings Accounts (HSAs) to be established by any individuals who purchase a “High Deductible Health Plan (HDHP), a health plan with an annual deductible of at least \$1,000 for self-coverage and a \$5,000 cap on out-of-pocket expenses (indexed annually) or an annual deductible of at least \$2,000 for family coverage and a \$10,000 cap on out-of-pocket expenses (indexed annually). For 2005, the maximum annual out-of-pocket amount for HDHP self coverage increases to \$5,100 and to \$10,200 for family coverage. The minimum deductible amounts, \$1,000 for self coverage and \$2,000 for family coverage remain unchanged in 2005. ▪ Individuals may contribute up to 100% of the health plan deductible. ▪ For 2004 the maximum annual contribution is \$2,600 for self-only policies and \$5,150 for family policies (indexed annually). For 2005 (indexed amounts were published 11/19/04) the maximum annual contribution for self-only policies is \$2,650 and \$5,250 for family policies. For any individual, the maximum contribution is the lesser of the indexed amount or the deductible of the HDHP. ▪ Preventive care services, coverage for accidents, disability, dental care, vision care, and long-term care is not subject to the deductible. ▪ Individuals age 55-65 may make additional “catch-up” contributions of up to \$500 in 2004, increasing to \$1,000 annually in 2009 and thereafter. A married couple may make two catch-up contributions as long as both spouses are at least 55. ▪ Contributions may be made by individuals, family members and employers and are tax deductible, even if the account beneficiary does not itemize. Employer contributions are made on a pre-tax basis and are not taxable to the employee. ▪ Employers are permitted to offer HSAs through a cafeteria plan. ▪ Health Savings Account distributions are tax-free if they are used to pay for qualified medical expenses. Qualified expenses include prescription drugs, qualified long-term care services and long-term care insurance, COBRA coverage, Medicare expenses (except Medigap expenses), and retiree health expenses for individuals age 65 and older. Distributions made for any other purpose are subject to income tax and a 10 percent penalty. The 10 percent penalty is also waived for distributions made by individuals age 65 and older. <p><i>Note: The U.S. Department of Treasury has published a number of publications providing guidance on Health Savings Accounts, click here for more detail: http://www.treas.gov/offices/public-affairs/hsa/technical-guidance/. The Treasury Department published a major guidance, Notice 2004-50 on Health Savings Accounts on July 23, 2004 (revised and updated 8/9/04). This guidance was clarified on 9/9/04.</i></p>
<p>Tax Treatment of Federal Subsidy to Employers for Retiree Prescription Drug Coverage</p>	<p>Sec. 1202</p> <ul style="list-style-type: none"> ▪ Provides that the 28% employer subsidy for retiree prescription drug coverage is excludable from taxable income.⁶⁶ ▪ Provides that gross income does not include any special subsidy payment received under section 1860D-22 of the Social Security Act. The exclusion applies for purposes of both the regular tax and the alternative minimum tax (including the adjustment for adjusted current earnings). ▪ The exclusion is not taken into account in determining whether a deduction is allowable with respect to costs taken into account in determining the subsidy payment. Accordingly, a taxpayer could claim a deduction for prescription drug expenses incurred even though the taxpayer also received an excludible subsidy related to the same expenses. ▪ Effective for taxable years ending after the date of enactment.

⁶⁶ This is an additional incentive to for-profit employers to retain their existing prescription drug coverage for retirees. There is no additional incentive for state and local governments because they have no federal income

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Exception to Information Reporting Requirements Related to Certain Health Arrangements	Sec. 1203 <ul style="list-style-type: none"> ▪ Provides an exception from the generally applicable information reporting provisions for payments for medical care made under either: (1) a flexible spending arrangement, or (2) a health reimbursement arrangement that is treated as employer-provided coverage. Effective for payments made after December 31, 2002. ▪ Clarifies that employers do not have to provide 1099 Forms to service providers if services are paid for with a debit, credit, or stored-value card.
STUDIES AND REPORTS	
Regional Variations in Prescription Drug Spending	Sec. 107(a) <ul style="list-style-type: none"> ▪ Requires the Secretary to study variations in per capita spending for covered Part D drugs among PDP regions to determine the amount of such variation that is attributable to price variations and the differences in per capita utilization that is not taken into account in the health status risk adjustment made to PDP bids. ▪ The Secretary is required to submit a report to Congress on the study including information on the extent of geographic variation in per capita utilization, an analysis of the impact of direct subsidies and whether such subsidies should be adjusted to take into account such variation, and recommendations regarding the appropriateness of applying an additional geographic adjustment factor to bids
Current Standards of Practice for Pharmacy Services Provided to Patients in Nursing Facilities	Sec. 107(b) <ul style="list-style-type: none"> ▪ Requires the Secretary, within six months of enactment, to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary is to assess: 1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services; and 2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care. ▪ The report is to contain a description of the Secretary’s plans to implement this Act in a manner consistent with applicable state and federal laws designed to protect the safety and quality of care of nursing facility patients. The report must also include recommendations regarding necessary actions.
IOM Study on Drug Safety and Quality	Sec. 107(c) <ul style="list-style-type: none"> ▪ Requires the Secretary to enter into a contract with the Institute of Medicine to carry out a comprehensive study of drug safety and quality issues in order to provide a blueprint for system-wide change. ▪ The objectives of the study are to: 1) develop a full understanding of drug safety and quality issues through an evidence-based review of the literature, case studies, and analysis; 2) attempt to develop credible estimates of the incidence, severity and costs of medication errors; 3) evaluate alternative approaches to reducing medication errors; 4) provide guidance on high-priority strategies to achieve drug safety goals; 5) assess opportunities and key impediments to broad nationwide implementation of medication error reductions; and 6) develop an applied research agenda to evaluate the health and cost impacts of alternative interventions. ▪ The study is to be completed within an 18-month period. Such sums as may be necessary are authorized.
Study of Multi-Year Contracts	Sec. 107(d) <ul style="list-style-type: none"> ▪ Requires the Secretary to provide a study on the feasibility and advisability of providing multi-year contracts with PDP sponsors and MA organizations.
GAO Study Regarding the	Sec.107(e)

tax liability.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Impact of Assets Tests for Subsidy Eligible Individuals	<ul style="list-style-type: none"> ▪ Requires the GAO to conduct a study to determine the extent to which utilization and access to covered Part D drugs for low-income subsidy eligible individuals differs from that for persons who would qualify as subsidy eligible individuals except for application of the assets test. ▪ The report is due to Congress by September 30, 2007.
Making Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals	<p>Sec. 107(f)</p> <ul style="list-style-type: none"> ▪ Requires the Secretary to undertake a study of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually impaired individuals. ▪ The report is due to Congress within 18 months of enactment.
Expanding the Work of Medicare Quality Improvement Organizations	<p>Sec. 109</p> <ul style="list-style-type: none"> ▪ Expands the work of quality improvement organizations (QIOs) to include Part C and Part D. It is required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to prescription drug therapy. ▪ The secretary is to request the Institute of Medicine of the National Academy of Sciences to conduct a study of the QIO program including an evaluation of the program and the extent to which other entities could perform similar quality improvement functions as well as or better than QIOs. ▪ The Secretary will report to Congress on such study by June 1, 2006. ▪ If the Secretary finds, based on the study, that other entities could improve quality as well as or better than QIOs, the Secretary shall provide increased competition through such entities.
Conflict of Interest Study	<p>Sec. 110</p> <ul style="list-style-type: none"> ▪ The conference agreement requires the Federal Trade Commission to conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers (PBMs). The study is to include an assessment of the differences in costs incurred by such enrollees and plans for drugs dispensed by mail order pharmacies owned by PBMs compared to those not owned by PBMs, and community pharmacies. The study is to examine whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees. The report is due to Congress within 18 months of enactment. It is to include recommendations regarding any legislation to insure the fiscal integrity of the Part D program. Conferees note the Secretary has the authority to accept or reject bids, based, among other factors, costs associated with delivering drug benefits. ▪ The intent of the conferees in including this assessment by the FTC is to assess whether Medicare spending is likely to be adversely affected because of the use of mail order pharmacies that are owned and operated by a PBM under contract to a prescription drug plan or MA-PD plan. Therefore, this study should evaluate to what extent prescription drug spending is likely to be affected if a PDP or MA-PD plan approves the dispensation of covered drugs from a mail-order pharmacy owned directly or indirectly by a PBM compared to drug utilization and costs if the mail-order pharmacy were independently owned. Such assessment shall take into account the following: (1) whether mail order pharmacies that are owned by PBMs (or entities that own PBMs) dispense fewer generic drugs compared to single source drugs within the same therapeutic class when compared to mail order pharmacies that are not owned by PBMs, (2) whether mail order pharmacies that are owned by PBMs (or entities that own PBMs) routinely switch patients from lower priced drugs to higher priced drugs (in the absence of a clinical indication) when compared to mail order pharmacies that are not owned by PBMs, (3) whether mail order pharmacies owned by PBMs (or entities that own PBMs) sell a higher proportion of repackaged drugs than mail order pharmacies that are not owned by PBMs, (4) whether mail order pharmacies owned by PBMs (or entities owned by PBMs) sell repackaged drugs at prices above the manufacturer's average wholesale price, (5) Other factors deemed relevant by the FTC. In conducting this study, the FTC shall consider whether competition or drug pricing behavior by PBMs would be affected if PBMs were to

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p>bear financial risk for drug spending. The FTC shall issue a written report within 18 months of the date of enactment.</p>
<p>Study on Employer-Based Retiree Health Coverage</p>	<p>Sec. 111</p> <ul style="list-style-type: none"> ▪ Requires the Comptroller General to conduct an initial and final study to examine trends in employment-based retiree health coverage. The report on the initial study must be submitted to Congress no later than one year after enactment. The final study is to be submitted to Congress no later than 1/1/07.
<p>Commission to Study Systemic Interoperability</p>	<p>Sec. 1012</p> <ul style="list-style-type: none"> ▪ Directs the Secretary to establish a Commission on Systemic Interoperability to develop a comprehensive strategy for the adoption and implementation of health care information technology standards. The Commission will be composed of 11 members.⁶⁷ ▪ In developing its strategy, the Commission must consider the costs and benefits of the standards, the current demand on industry resources to implement these and other electronic standards (including the HIPAA administrative simplification standards), and the most cost-effective and efficient means for industry to implement the standards. ▪ Prohibits the Commission from interfering with any ongoing process of developing or adopting standards, or replicating activities related to the standards or to the HHS National Health Information Infrastructure initiative. ▪ Commission must report to the Congress and to the HHS Secretary by 10/31/05.
<p>Research on Outcomes of Health Care Items and Services</p>	<p>Sec. 1013</p> <ul style="list-style-type: none"> ▪ Authorizes and appropriates \$50 million for fiscal year 2004 for the HHS Secretary through the Agency for Healthcare Research and Quality (AHRQ) to conduct research to address the scientific information needs and priorities identified by the Medicare, Medicaid, and State Children Health Insurance Programs. ▪ The information needs and priorities will relate to the clinical effectiveness and appropriateness of specified health services and treatments, and the health outcomes associated with such services and treatments. The needs and priorities also will address strategies for improving the efficiency and effectiveness of those health care programs. ▪ Requires the Secretary to establish a process for developing research priorities. ▪ Not later than 6 months after the date of enactment, the Secretary must establish an initial list of priorities. The Secretary must complete the evaluation and synthesis of the scientific evidence related to that initial list within 18 months after development of such a list and disseminate the research findings to the public, prescription drug plans, and other plans. ▪ Not later than 18 months after the date of enactment, the Secretary is required to identify voluntary options that could be undertaken by public and private entities to improve information sharing regarding outcomes and quality of care, adopt innovative quality improvement strategies, develop management tools to improve oversight by state officials, support federal and state initiatives to improve the quality, safety, and efficiency of services, and provide a basis for estimating the fiscal and coverage impact of federal or state policy changes of the Medicare, Medicaid, and State Children’s Health Insurance Programs. ▪ The Administrator for the Center for Medicare and Medicaid Services may not use data from the research conducted to withhold coverage of a prescription drug, to mandate a national standard, or require a specific approach to quality measurement and reporting.

⁶⁷ The President will appoint three members, including a Chairperson; the Senate Majority Leader, the Senate Minority Leader, the Speaker, and the House Minority Leader will each appoint two members. Commission membership must include nationally recognized experts in health finance and economics, health plans and integrated delivery systems, health care reimbursement, health care technology and information systems, and other related fields, as well as physicians, pharmacists, and other health care providers, who provide a mix of professionals, broad geographic representation, and a balance between urban and rural representation. Each member shall be appointed for the life of the Commission.

PROVISION	<ul style="list-style-type: none"> ▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
Citizens Health Care Working Group	<p>Sec. 1014</p> <ul style="list-style-type: none"> ▪ Authorizes \$3 million for each of the fiscal years 2005 and 2006 for the Secretary of HHS, acting through the Agency for Healthcare Research and Quality, to establish a group called the "Citizens' Health Care Working Group." The working group will be composed of 15 members. ▪ One member will be the Secretary and the other 14 members will be appointed by the Comptroller General. Appointments will include certain consumers of health services, and individuals with expertise in the health care industry. Appointment will not include elected officials. The duration of appointments will be for the life of the Working Group. ▪ Not later than 15 days after which all appointments have been made, the Comptroller General will designate a chairperson from the members. The Working Group will be responsible for holding hearings and producing public reports regarding expanding coverage options, the cost of health care, innovative state and community strategies to expand coverage or reduce costs, and the role of evidence-based medicine and technology in improving quality and lowering costs. The first hearing must be held within 90 days after designation of the chairperson, and additional hearings would be permitted as long as such hearings do not delay the Working Group's other activities. ▪ Within 90 days of completing hearings, the Working Group will prepare a report that discusses numerous health care issues including health care and related services used by individuals, cost of health care services, sources of coverage and payment, and reasons for uninsurance and underinsurance. ▪ In addition to hearings, the Working Group will hold community meetings throughout the United States in sufficient number to reflect geographic differences, diverse populations, and a balance among urban and rural populations. The Working Group will prepare an interim set of recommendations on health care coverage, and ways to improve and strengthen the health care system based on the information and preferences expressed at the community meetings within 180 days after the conclusion of such meetings. There will be a 90-day public comment period on the recommendations. ▪ Not later than 120 days after the end of the public comment period, the Working Group will submit to Congress and the President a final set of recommendations. Not later than 45 days after receiving the final recommendations, the President will submit a report to Congress with additional views and comments on the recommendations, and recommendations for legislative and administrative actions. Each congressional committee of jurisdiction will hold at least one hearing on the report and the final recommendations.
Funding Start-Up Administrative Costs for Medicare Reform	<p>Sec. 1015</p> <ul style="list-style-type: none"> ▪ The MMA authorizes appropriations to fund the administrative functions necessary to carry out its provisions by transferring funds from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, not more than \$1,000,000,000 for CMS and not more than \$500,000,000 for the Social Security Administration (SSA). These amounts are available only until September 30, 2005. SSA may use its portion of these funds to reimburse the Internal Revenue Service for expenses incurred in carrying out provisions of this bill, and the President may authorize further transfers between CMS and SSA.
Health Care Infrastructure Improvement Program	<p>Sec. 1016</p> <ul style="list-style-type: none"> ▪ Provides for the establishment of a loan program to improve the cancer-related health care hospital infrastructure in the United States. Examples of potentially eligible projects would include the construction, renovation, or other capital improvement of any hospital. In order to receive assistance, the project applicant would be required to: (1) be engaged in research in the causes, prevention, and treatment of cancer; (2) be designated as a cancer center for the National Cancer Institute (NCI) or be designated by the state as the sole official comprehensive cancer effort for the state. \$200 million in budget authority would be authorized for July 1, 2004 through FY2008 to carry out the loan program, \$2 million of which may be used each year for administration of the program by the Secretary. Not later than 4 years after enactment, the Secretary would be required to submit to Congress a report summarizing the financial performance of the

PROVISION	<ul style="list-style-type: none"> <li data-bbox="533 248 1665 277">▪ MEDICARE PRESCRIPTION DRUG , IMPROVEMENT AND MODERNIZATION ACT OF 2003
	<p data-bbox="625 289 1808 339">projects that have received assistance under this program, including recommendations on the future operation of the program. The provision would be effective upon enactment.</p>

APPENDIX A – DUAL ELIGIBLES

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Medicaid is a federal-state program, which provides health insurance coverage to certain low-income individuals. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid.

Full Dual Eligibles are Medicare beneficiaries that are entitled to full Medicaid protection and who generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these “dual eligibles,” Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare.

Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low income beneficiaries (SLMBs), and certain qualified individuals. QMBs and SLMBs are not entitled to Medicaid’s prescription drug benefit unless they are also entitled to full Medicaid coverage under their state’s Medicaid program. Qualifying individuals are never entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits).

Qualified Medicare Beneficiaries (QMBs) are aged or disabled persons with incomes at or below the federal poverty level. In 2003, the monthly level is \$769 for an individual and \$1,030 for a couple. (\$9,228 per year for an individual and \$12,360 per year for a couple). The qualifying levels are higher than the HHS federal poverty guidelines because, by law, \$20 per month of unearned income, rounded to the next dollar, is disregarded in the calculation. QMBs must also have assets below \$4,000 for an individual and \$6,000 for a couple. QMBs are entitled to have their Medicare cost-sharing charges, including the Part B premium, paid by the federal-state Medicaid program. Medicaid protection is limited to payment of Medicare cost-sharing charges (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services unless the individual is otherwise entitled to Medicaid).

Specified Low-Income Medicare Beneficiaries (SLMBs) are persons who meet the QMB criteria, except that their income is over the QMB limit. The SLMB limit is 120% of the federal poverty level. In 2003, the monthly income limits are \$918 for an individual and \$1,232 for a couple (\$11,016 per year for an individual and \$14,784 for a couple). Medicaid protection is limited to payment of the Medicare Part B premium (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services unless the individual is otherwise entitled to Medicaid).

Qualifying Individuals (QI-1s) are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. The monthly income limit for QI-1 for an individual is \$1,031 and for a couple \$1,384 (\$12,372 per year for an individual and \$16,608 for a couple). Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium. In general, Medicaid payments are shared between the federal government and the states according to a matching formula. However, expenditures under the QI-1 program are paid 100% by the federal government (from the Part B trust fund) up to the state’s allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level.

Source: Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Conference Report

**APPENDIX B - SECTION 1011 PRELIMINARY STATE ALLOCATIONS - FEDERAL REIMBURSEMENT OF EMERGENCY HEALTH SERVICES
FURNISHED TO UNDOCUMENTED ALIENS**

State	Estimated Unauthorized Resident Population: January 2000	Based on the Number of Alien Apprehensions	Projected State Allocation (Total)
AL	24	--	\$572,326
AK	5	--	\$119,235
AZ	283	\$34,831,052	\$41,579,731
AR	27	--	\$643,867
CA	2,209	\$19,663,719	\$72,341,572
CO	144	--	\$3,433,957
CT	39	--	\$930,030
DE	10	--	\$238,469
DC	7	--	\$166,928
FL	337	\$807,704	\$8,844,117
GA	228	--	\$5,437,098
HI	2	--	\$47,694
ID	19	--	\$453,092
IL	432	--	\$10,301,871
IN	45	--	\$1,073,112
IA	24	--	\$572,326
KS	47	--	\$1,120,805
KY	15	--	\$357,704
LA	5	--	\$119,235
ME*	0.5	--	\$11,923
MD	56	--	\$1,335,428
MA	87	--	\$2,074,682
MI	70	--	\$1,669,285
MN	60	--	\$1,430,815
MS	8	--	\$190,775
MO	22	--	\$524,632
MT*	0.5	--	\$11,923
State	Estimated Unauthorized Resident Population: January 2000	Based on the Number of Alien Apprehensions	Projected State Allocation (Total)
NE	24	--	\$572,326

NV	101	--	\$2,408,539
NH	2	--	\$47,694
NJ	221	--	\$5,270,170
NM	39	\$4,197,426	\$5,127,456
NY	489	\$816,367	\$12,477,512
NC	206	--	\$4,912,466
ND*	0.5	--	\$11,923
OH	40	--	\$953,877
OK	46	--	\$1,096,958
OR	90	--	\$2,146,223
PA	49	--	\$1,168,499
RI	16	--	\$381,551
SC	36	--	\$858,489
SD	2	--	\$47,694
TN	46	--	\$1,096,958
TX	1,041	\$22,683,733	\$47,508,379
UT	65	--	\$1,550,050
VT*	0.5	--	\$11,923
VA	103	--	\$2,456,233
WA	136	--	\$3,243,181
WV	1	--	\$23,847
WI	41	--	\$977,724
WY	2	--	\$47,694
Total	7,003	\$83,000,000	\$250,000,000

Source: Centers for Medicare and Medicaid Service

