

Major Differences Between H.R. 1 and S. 1

Proposal	H.R. 1	S. 1
Vote	216-215	76-21
Eligibility	Individuals entitled to Part A or enrolled in Part B. Enrollment in Part D is voluntary.	Individuals entitled to Part A and enrolled in Part B, except for dual eligibles. Enrollment in Part D is voluntary.
Plan Delivery Structure	<p>All beneficiaries have choice of two plans, at least one of which must be a prescription drug only plan</p> <p>Allows Secretary to buy down risk (not to equal 100%) if 2 plans do not enter an area</p>	<p>Secretary is required to approve 2 competing stand-alone Prescription Drug Plans (“PDPs”) in each area.</p> <p>Allows Secretary to buy down risk (not to equal 100%) if 2 PDPs do not enter an area.</p> <p>If two plans are unavailable after reduction of risk, the Secretary may enter into a contract with one plan, which provides standard coverage for one year, and the bidding cycle for competing PDPs then begins for the following year. The contract is for performance risk only.</p>
Risk Sharing	<p>Reinsurance payments as follows:</p> <ul style="list-style-type: none"> • 20% of drug costs for individuals whose out-of-pocket expenditures are \$1001-\$2000 • 80% of drug costs for individuals whose out-of-pocket expenditures are in excess of \$3500. <p>Reinsurance payments are adjusted so they are no more than 30% of total plan payments made for standard coverage.</p>	<p>PDPs and Medicare Advantage plans are eligible for risk sharing for prescription drug expenditures through risk corridors. Risk corridors provide reduced risk during 2006 and 2007 and then provide for increased risk in future years.</p> <p>Reinsurance payments to plans equal to 80% of drug costs for individuals whose out-of-pocket expenditures are in excess of \$3700.</p>
Benefit Package	<ul style="list-style-type: none"> • \$250 deductible • 80% coverage up to \$2,000 • After \$3,500 out-of-pocket, 100% costs covered • Or an actuarially equivalent plan 	<ul style="list-style-type: none"> • \$275 deductible • 50% coverage up to \$4,500 • After \$3,700 in out-of-pocket expenses, 90% of costs covered • Same

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Income Related Catastrophic	<p>Higher stop loss for enrollees with incomes above:</p> <ul style="list-style-type: none"> • \$60,000/individuals, • \$120,000/married <p>equal to 5.8 percent of the beneficiary's income</p> <p>The stop loss phases up until income reaches \$200,000 individual or \$400,000 married</p>	No provision
Premium and premium subsidy	<p>\$35 per month</p> <p>73% subsidy in aggregate (43% direct, 30% reinsurance)</p>	<p>\$35 per month</p> <p>70% subsidy in aggregate (50% direct, 20% reinsurance)</p>
Access to Pharmacies	<p>Any willing pharmacist. Plans must assure access to pharmacies based on the TRICARE military health standards.</p>	<p>Plans must provide convenient access to pharmacies in rural and urban areas. Plans are required to offer a point-of-service option for access to non-network pharmacies with any additional costs passed on to enrollees.</p>

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Low Income Assistance – Cost Sharing	<ul style="list-style-type: none"> • Cost sharing covered up to 135% of poverty (\$2 copays for generics and \$5 copays for brand name permitted.) • Asset test applies at three times normal level (\$6,000) indexed to inflation 	<ul style="list-style-type: none"> • Qualified Medicare Beneficiaries (incomes below 100% FPL and assets below \$4,000/\$6,000 single/couple): <ul style="list-style-type: none"> • no deductible • 2.5% up to initial limit, 5% to stop-loss, 2.5% above stop-loss. • SLMBs and QI-1s (incomes between 100-135% FPL and assets below \$4,000/\$6,000 single/couple): <ul style="list-style-type: none"> • no deductible • 5% up to initial limit, 10% up to stop-loss, 2.5% above stop-loss. • All other beneficiaries with incomes below 160% FPL (except dual eligibles): <ul style="list-style-type: none"> • \$50 deductible (indexed) • 10% to initial limit, 20% to stop-loss, 10% above stop-loss <p>Asset test follows current law Medicaid until 2009 (\$2,000 in 2006) and is then increased to \$10,000 in 2009, and indexed to inflation.</p>
Low Income Assistance – Lower Premiums	Premiums covered up to 135% of poverty, phased-out to 150% of poverty	Premiums covered up to 135% of poverty, phased out to 160% or poverty
Treatment of Dual Eligibles	Dual eligibles drug costs federalized. State costs for portion of the federal drug benefit phased out over 15 years	Dual eligibles qualified to receive Medicaid drug benefits continue under Medicaid

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Retiree Health Coverage	Retiree plans with equivalent drug coverage could: <ul style="list-style-type: none"> • receive subsidies of 28% of costs for coverage above \$250 and up to \$5,000. • Not be subject to mandates in drug bill related to plan design CBO assumes 32% of retirees will lose their retiree coverage.	<ul style="list-style-type: none"> • Retiree plans with equivalent drug coverage would be eligible for same subsidy per enrollee for standard or equivalent drug coverage. • Employers maintain flexibility in plan design and may offer retirees drug benefits more generous than the Medicare drug benefit. • Reverses 3d circuit decision in Erie County and allows employers to offer differential benefits among active and retiree populations without violating Age Discrimination in Employment Act. • CBO assumes 37% of retirees will lose their retiree coverage.
State Pharmacy Assistance Plans	Medicare is primary payer, but spending on behalf of beneficiaries by states counts against the catastrophic stop loss.	Medicare is primary payer, but spending on behalf of beneficiaries by states counts against the catastrophic stop loss. State plans can remain primary and receive Medicare subsidies
Drug Discount Card and Interim Low-Income Benefit	Establishes a drug discount card program and interim drug benefit in 2004 and 2005. Permits individuals without drug coverage to obtain money on a drug card during that period. Individuals up to 135% of FPL will receive \$800 per annum, individuals up to 150% of FPL will receive \$500 per annum and individuals over 150% of FPL will receive \$100 per annum. All individuals will be charged \$30 for the card annually. Employers, individuals and states may contribute up to \$5,000 annually on this card though their contributions will not be tax preferred.	Establishes a drug discount card program and interim drug benefit for 2004 and 2005 with a maximum \$25 enrollment fee. Targets assistance to low-income individuals (Qualified Medicare Beneficiaries, Special Low-Income Medicare Beneficiaries and Qualified Individuals), who would receive federal subsidy amount of \$600 per annum and pay no enrollment fee.
Medicare Reform and Coordinated Care		

Proposal	H.R. 1	S. 1
Definitions	Medicare Advantage refers only to local based plans, which are current law Medicare+Choice plans. Enhanced Fee-for-Service (“EFS”) refers to the new regional preferred provider organizations (PPOs) or fee-for-service (FFS) plans.	Medicare Advantage refers to both local based plans, which are current law Medicare+Choice plans and the new regional PPOs.
Medicare Advantage Stabilization 2004-2005 (Local Plans)	<ul style="list-style-type: none"> • In 2004, adds payment option equal to the FFS rate, including costs of VA and DoD provided benefits. • Payment rates grow at same rate as FFS growth in 2004 and beyond. 	<ul style="list-style-type: none"> • For 2004, no provision. • For 2005, minimum percentage increase set at 3% (not built into base).
Local and Regional Plan Benefits	<ul style="list-style-type: none"> • EFS plans are required to offer A and B benefits, a unified deductible, and a stop-loss benefit. Each Medicare Advantage organization (except for private FFS plans) and each EFS organization in a region is required to offer a plan with Part D coverage, and may offer an additional plan without Part D coverage. 	<ul style="list-style-type: none"> • Plans are required to offer A and B benefits, a unified deductible, a stop-loss benefit, and Part D benefits.
Medicare Advantage – Local Plans	<ul style="list-style-type: none"> • In 2006, the non-drug benchmark is equal to the Medicare Advantage rate, as modified above (includes the FFS rate and growth in FFS Medicare, costs of VA and DoD care beginning in 2004.) • If plan bid is below benchmark, beneficiary gets 75% of savings and government gets 25%. • If plan bid is greater than benchmark, beneficiary pays all of excess (same as Senate). 	<ul style="list-style-type: none"> • The non-drug Medicare Advantage benchmark for a payment area would be the <i>higher of</i> floor payment rates or 100% of local FFS costs, excluding GME and including VA/DOD costs. • Beginning in 2014, growth in floor county rates updated by CPI. • If plan bid is below benchmark, beneficiary gets 100% of savings in cash rebates, credit for drug premium, or additional benefits. • If plan bid is greater than benchmark, beneficiary pays all of excess (same as House).

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Regional Plans	<ul style="list-style-type: none"> • EFFE includes private FFS and PPO plans. • The Administrator would select up to three EFFE organizations to offer plans in each region. (An organization may offer more than 1 EFFE plan.) • The non-drug benchmark would be equal to the average of Medicare Advantage rates in the region. • If plan bid is below the benchmark, the beneficiary gets 75% of savings and government gets 25%. • If plan bid is equal to or above the benchmark, the beneficiary pays the entire amount (same as Senate). 	<ul style="list-style-type: none"> • Includes PPOs only. • The Administrator would select up to three PPO plans to participate in each region. • The non-drug Medicare Advantage benchmark for a region would be the greater of weighted average of local FFS costs (excluding GME) or the weighted average local-based plan benchmark. • If plan bid is below the benchmark, the beneficiary gets 100% of savings in lower premiums or increased benefits. • If plan bid is equal to or above the benchmark (same as House).
Non-Drug Risk Corridors	No provision.	In 2006 and 2007, risk corridors would apply to medical (non-drug) costs in Medicare Advantage regional PPOs. Medicare would share 50% of the risk incurred between 105% and 110% of plan premiums 90% of the risk above 110% of premium revenue. Administrative costs are not included in the accounting of plan costs for purposes of the risk corridor.

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FEHBP-Style Competition in 2010	<ul style="list-style-type: none"> • Defines competitive areas as areas with at least two private plans offered by different organizations, and private plan enrollment at least as great as private plan enrollment nationwide. Competitive Medicare Advantage areas would be limited to metropolitan statistical areas or areas with substantial numbers of Medicare Advantage enrollees. • The competitive benchmark would be set at the weighted average of all plan bids and the traditional FFS amount in the competitive area. • For private plans, this competitive benchmark would be blended with the older, pre-2010 benchmark for the area over a 5-year period to provide a transition to a more competitive system. • Beneficiaries enrolling in plans with bids below the benchmark would receive 75% of the savings, and the government would get 25%. Beneficiaries enrolling in plans with bids above the benchmark would pay the excess. • Local FFS rates would be compared to the benchmark and premiums for FFS beneficiaries would be adjusted. • Changes for FFS beneficiary premiums would be phased-in over a 5-year period. 	

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<p>Demonstration and Evaluation of Alternative Payment and Delivery Systems</p>	<p>Care coordination and disease management in fee-for-service, Medicare Advantage and enhanced FFS. Budget cap of \$100 million.</p>	<ol style="list-style-type: none"> 1. Alternative Payment System for PPOs in highly competitive regions costing \$6 billion from 2009-2013: <ul style="list-style-type: none"> • Beginning in 2009, the Secretary would designate a limited number of regions, but not less than one, as “highly competitive regions” in which the benchmark is based on the plan bids. • Special consideration would be given to regions without bids from PPOs in the previous year. • Benchmarks would be equal to the second lowest plan bid in region with three plans and the lowest bid in regions with fewer than three plans. • In 2014 and beyond, the authority to designate highly competitive regions continues and funding is budget neutral. 2. \$6 billion in projects for FFS with enhanced benefits or services, from 2009 – 2013. <ul style="list-style-type: none"> • Cover additional preventive services, chronic care coordination services, disease management services, or other related services identified by the Secretary. • Budget neutral for fiscal year 2014 and beyond.

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Fraud and Abuse		
AWP Reform	<p>Physician has choice of competitive bidding contractor model or reimbursement for drugs at Average Sales Price (ASP) plus 12% in 2005 and 2006. ASP plus 0% thereafter</p> <p>Physician practice expenses increased by 83% for drug administration.</p>	<p>Payment for drugs available on or after January 1, 2004 is the lesser of:</p> <ul style="list-style-type: none"> • Average Wholesale Price (“AWP”) or • A proxy of market price defined as 85% of AWP, as of April 1, 2003, increased annually by CPI-medical care. <p>Using market survey data, Secretary can substitute the “widely available market price” for a drug if found to be different than above amount.</p> <p>Physician practice expenses increased by 83% for drug administration. Also includes increased payments to physicians for multiple pushes and discarded drugs. Revises payment for ESRD drugs and returns savings through higher composite rates.</p>
Durable Medical Equipment	<p>Competitive bidding for durable medical equipment and orthotics, excluding custom items. The bids include the attendant services, where applicable. Inhalation and infusion drugs and equipment are included in competitive bidding</p>	<p>Freeze for durable medical equipment, prosthetics and orthotics (excluding custom-fabricated) from 2004- 2010.</p> <p>Inhalation and infusion drugs are included in AWP reform and the Secretary is given authority to increase the equipment price for inhalation drugs up to a level that retains 10% of the AWP savings.</p>
Rural Provisions		
Standardized Amount	<p>Equalizes base payment amount for rural and small urban providers, starting in FY 2004</p>	<p>Same provision</p>
Medicare DSH	<p>Increases cap on payments for small rural and urban hospitals from 5% to 10%, starting in FY 2004</p>	<p>Eliminates cap on payments, starting in FY 2005</p>

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Labor Share	Decreases labor share from 71% to 62% in low wage areas, starting in FY 2004	Same provision but starting in FY 2005
Rural Home Health	Two year 5% increase in payments for rural home health services, starting in FY 2004	Two year 10% increase, starting in FY 2005 Two year 5% increase starting in FY 2005.
Residency Training	Redistributes unused residency slots –GME funds and training-- to hospitals in rural and small cities	Provisions relating to psychologists, geriatric and dental residents.
Rural Physicians	<ul style="list-style-type: none"> • Floor on work geographic adjuster at 1.0 for 2004 and 2005. • No provision on practice expense and malpractice adjuster. • New 5% bonus payment for physicians in physician scarcity areas. • Enhancements to Medicare Incentive Program in health shortage areas. 	<ul style="list-style-type: none"> • Floor on work geographic adjuster at .98 in 2004, 1.0 for 2005 to 2007. • Floor of 1.0 for practice expense and malpractice geographic adjusters in 2005 to 2007. • Same provision on Medicare Incentive Program.
Inpatient Hospital Services		
Inpatient Update	Updates at market basket minus 0.4% for FY 2004-2006	No provision
New Medical Technologies	Enhances new technology payments and increases the number of eligible new technologies starting in FY 2005, not budget neutral	No provision
Wage Index Reclassification	Adds an option based on commuting rather than distance, not budget neutral	Allows the Secretary to waive all reclassification rules in 2004, budget neutral
Indirect Medical Education	No provision	Increases IME from 5.5 to 5.508 in FY2004 and FY2005, and slightly above 5.5% thereafter.
Part B Services		
Indexing Part B Deductible	Indexes Part B deductible to rate of growth in Part B services.	<ul style="list-style-type: none"> • Sets deductible at \$125 in 2006, then indexes deductible by CPI
Physician Payments	<ul style="list-style-type: none"> • Update set at a minimum of 1.5% in 2004 and 2005. 	<ul style="list-style-type: none"> • No provision.

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Preventive Services	<ul style="list-style-type: none"> • Adds initial preventive physical • Adds cholesterol and blood lipid screening 	<ul style="list-style-type: none"> • Adds cholesterol and blood lipid screening
Hospital Outpatient Department Services	<p>Sole source paid at least 83% of AWP and multi-source 81.5%. Both phased down from 2004 to 2006 to CMS surveyed average hospital acquisition cost. Caps generics at 46%.</p> <p>Prohibits application of functional equivalence until the FDA establishes a standard and certifies that products are “functionally equivalent .”</p>	<p>Biologics, orphan drugs and sole source paid 94% of AWP, multi-source 91% and generics 71% in 2005 and 2006.</p> <p>Secretary may not publish regulations that apply a functional equivalence standard to a drug, unless FDA finds it “pharmaceutically equivalent.”</p>
Lab Coinsurance	No provision	Applies deductible and coinsurance to all laboratory tests.
Parts A and Part B Services		
Home Health Services	<p>Update is market basket minus 0.4%</p> <p>Establishes a 1.5% copayment</p>	<p>No provision</p> <p>No provision</p>
Specialty Hospitals	MedPAC study	Eliminates “whole hospital exemption” for physician referral for new specialty hospitals
Regulatory and Contracting Reform		
Appeals	Transfers responsibility for ALJ appeals and strengthens independence of Qualified Independent Contractors.	Lengthens the BIPA time frames and deadlines and does not give Secretary authority to transfer ALJ function. Allows the Secretary to use the QIOs (PROs) as QICs and other changes.
Regulation Length	No provision	Secretary must reduce the number of words comprising all regulations by 2/3rds as of October 1, 2004

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Hatch/Waxman Reforms			
Using ANDA process	If the brand sponsor files an amendment to its New Drug Application (NDA), then the generic will be able to file an amendment to its Abbreviated New Drug Application (ANDA). If the brand sponsor files a NDA for a newly listed drug, then the generic must file a new ANDA for the same drug. As a result, generics will not be able to use amendments for newly listed drugs to avoid triggering a 30-month stay.		No provision
FDA Orange Book Reform	In patent challenge situations, one 30-month stay for patents listed with FDA prior to ANDA submission. Allows counterclaim to delist improperly listed patents.		One and only one 30 month stay for patents filed prior to ANDA
Declaratory Judgments	In cases where the pioneer firm declines to bring an infringement action, a generic drug applicant may bring a declaratory judgment action if the generic drug applicant has provided the pioneer firm with a right of confidential access to the ANDA.		In cases where the pioneer firm declines to bring an infringement action, the failure of a patent owner to bring the action within 45 days shall establish an actual controversy sufficient to confer subject matter jurisdiction in federal court.
Treble Damages	No change to current treble damages standard.		Allows a court to consider the fact that a patent was not timely listed with the FDA when it determines whether to award treble damages in a patent infringement case.
DOJ/FTC Notice of Settlement Agreements	Certain settlement agreements between pioneer and generic firms (and between generic and generic firms) must be reported to the FTC. (Based on Leahy Drug Competition Act, S. (sans DOJ notice))		Certain settlement agreements between pioneer and generic firms must be reported to the FTC and DOJ. (Based on Leahy Drug Competition Act, S.926)

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180-Day Marketing Exclusivity Awards in Cases Where Pioneer Patents have been Successfully Challenged by Generic Drug Applicants	Identical to Senate.	Adopts Gregg-Schumer Amendment provisions. First-filers (not necessarily successful challengers) may qualify for 180-day exclusivity. Successful subsequent-filing invalidity or non-infringing challenger most likely must wait 180-days to go market regardless of whether first-filers may enter the market. Alters current court decision triggers. Identical to House.
<u>Reimportation</u>		
Packaging and Safety Provisions	Contains protections that ensure that any drug which is reimported into the country must be contained in packaging which is reasonably certain to be tamper-resistant and not capable of counterfeiting; must contain a statement designed to inform the end-user of the drug that such drug has been imported; must be from the first Canadian recipient of the drug; and may be imported through identified ports of entry.	No similar provision. However, both the House and Senate bills currently require a safety certification by the Secretary before reimportation may proceed.
Foreign Reference Pricing	No provision	Contains provisions that would prevent drug manufacturers from selling drugs at a price higher than they charge overseas.
Personal Importation	Permits personal importation from Canada, but only when the importation is in the possession of the individual when they enter the United States	No similar protection

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Medicaid		
Medicaid Disproportionate Share Hospital (DSH)	<p>Increase in Medicaid DSH allotments in FY 2004 equal to 120% of FY 2003.</p> <p>Next year's states get 1.9% increase until it equals the amount they would have under current law. Then payments will increase by CPI-U.</p>	<ul style="list-style-type: none"> • Increase in Medicaid DSH allotment for 2004 and 2005. Ties allotment amounts back to 2002 allotment figure with certain modifications. Effect is to push off DSH cliff. • Increases floor for extremely low DSH states for FY 2004 (to 3%) and 2005 (3% plus CPI-U) • DSH cap raised to 175%
Best Price Exemptions for the Medicaid Drug Rebate Program	<p>Exempts inpatient drug prices, charged to certain public hospitals from the calculation of Best Price for the Medicaid drug rebate program</p> <p>Anti-Diversion protections that require auditing and record keeping.</p>	<ul style="list-style-type: none"> • Same provisions
Legal Immigrants Under SCHIP and Medicaid	No provision	Between 2005-2007, States can cover legal immigrants or pregnant women under Medicaid or SCHIP
Administration of New Benefits		
Establishes New Federal Agency to Administer Drug Benefit and private plans	Establishes new federal agency to run private delivery components of Medicare program. New agency will be exempt from certain civil service requirements. Advisory Board created to advise Medicare Benefits Administrator.	Same provision, except no exemption from civil service requirements.

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Health Savings Accounts		
<p>Savings Accounts to Enhance Available Funds For Unreimbursed Expenses</p>	<p>Creates new personal savings accounts, to help pay unreimbursed medical expenses (including prescription drugs) on a tax-preferred basis</p> <ul style="list-style-type: none"> • <u>Health Savings Accounts (HSAs)</u> may be established by any individual who is covered by a health plan with an annual deductible of at least \$1,000 for self-coverage and \$2,000 for family coverage. • <u>Health Savings Security Accounts (HSSAs)</u> may be established by any individual who is either uninsured or is covered by a health plan with an annual deductible of at least \$500 for self coverage and \$1,000 for family coverage. <p>Contributions, build-up within accounts and distributions are tax-preferred</p> <p>Allows rollovers from Flexible Spending Accounts up to \$500 annually</p>	<p>No provision</p>