American Hospital Association

Summary of the
Medicare Prescription Drug, Improvement, and Modernization Act of 2003
(P.L. 108-173)
December 18, 2003

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Congressional Budget Office (CBO)
Estimated Budget Impact of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173), FY 2004-2013
(in billions of dollars)

SECTION NUMBER / PROVISION	BUDGET IMPACT
	10-year impact (in billions $)
Medicare Rural-Specific Provisions	
401 Equalize standardized amount	$7.6
402 Disproportionate share adjustment	2.7
403 Adjust wage index for labor share	5.2
404 More frequent MB weight updates	0.0
405 Critical access hospital Provisions	0.9
406 Inpatient adjustment for low-volume hospitals	0.1
407 SCH: missing cost reports	0.1
410A Rural community hospital demonstration program	*
411 HOPD PPS: Two year extension of hold harmless	0.3
416 Rural HOPD lab policy	0.2
417 Telemedicine demo extension	*
422 Redistribution of unused resident positions	0.6
Hospital Services Provisions	
501 Acute care hospital updates	-0.2
502 Indirect Medical Education	0.4
503 New technologies under PPS	0.5
504 Puerto Rico federal rates	0.4
505 Wage index adjustment	0.4
508 One-time appeals process for hospital wage index	0.9
621 HOPD PPS: Payment reform	0.7
Medicaid and Miscellaneous	
1001 Increased Medicaid DSH payments	3.0
1002 Section 340B amendment	0.0
1003 Extension of IMD moratorium	*
1011 Emergency services for undocumented aliens	1.0
HOSPITAL TOTALS	**$24.8**

***** = costs or savings of less than $50 million.
Source: CBO, November 20, 2003

SUMMARY OF HOSPITAL AND OTHER PROVIDER PROVISIONS

INPATIENT

Inpatient PPS Update	• Medicare inpatient PPS payments will maintain an inflationary increase of 3.4 percent in FY 2004, a rate equal to the full market basket index. For FYs 2005, 2006, and 2007 hospitals will receive an inpatient update equal to the full market basket rate if they submit quality data to the secretary of Health and Human Services (HHS). Those hospitals not submitting quality data will receive an increase equal to the market basket rate minus 0.4 percentage points. The update reduction is a one-year adjustment and does not affect the base amount inflated from year to year. Hospitals not submitting quality data in FY 2005 may choose to submit data in FY 2006 or 2007 and would then receive a full inflationary update. Submission of quality data will include the 10 quality measures established by the Secretary as of November 1, 2003. Specifics around data submission and reporting deadlines are left to the Secretary's discretion. • Requires GAO study by 2006 on appropriate level and distribution of payments in relation to costs across geographic areas, types of hospitals, and types of cases.
Standardized Amount	• Permanent equalization of the standardized amount for rural and other urban hospitals beginning April 1, 2004.
Wage Index/Labor Share	• Lowers the labor-related share to 62% of the standardized amount for those hospitals that would benefit beginning in FY 2005. All other hospitals held harmless. • Provides a provision to update the hospital market basket, including the labor share, more frequently than once every 5 years.
Low-Volume Adjustment	• Beginning in FY 2005, rural hospitals with less than 800 inpatient discharges would be eligible for up to a 25% increase (to be determined by the Secretary) in Medicare inpatient PPS payments if they are more than 25 miles from a similar hospital.
Indirect Medical Education (IME)	• Increases the indirect medical education (IME) adjustment to 6.0 percent in the last six months of FY 2004 (April 2004 through September 2004), to 5.8 percent in FY 2005, to 5.55 percent in FY 2006, and down to 5.35 percent in FY 2007. It reverts to current law, 5.5 percent, for FY 2008 and beyond.
Graduate Medical Education (GME)	• Allows redistribution of unused resident positions effective CY 2004 to rural hospitals and small city hospitals. • Freezes from 2004-2013 any adjustment in the rate of increase for hospitals with resident FTE amounts above 140% of the national average.
Medicare Disproportionate Share Payments (DSH)	• Raises Medicare DSH payments for rural and urban hospitals with less 100 beds by applying the Medicare DSH formula for urban hospitals with more than 100 beds capped at 12%. Urban hospitals with more than 100 beds and rural referral centers are excluded from the 12% cap. Effective April 1, 2004.

Critical Access Hospitals (CAHs)	• Provides CAHs Medicare inpatient, outpatient, and swing bed reimbursement at 101% of cost, effective with cost reporting periods beginning on or after January 1, 2004. • Expands cost-based reimbursement of on-call emergency room physicians to physician assistants, nurse practitioners and clinical nurse specialists beginning CY 2005. • Allows CAHs to receive periodic interim payments (PIP) for inpatient services for cost reports beginning on or after July 1, 2004. • Permits CAHs to operate up to 25 swing beds or acute care beds by removing the requirement that only 15 of 25 beds be used for acute care at any one time, effective on or after January 1, 2004. • Eliminates requirement that physicians providing services in CAHs must accept assignment (retroactive to cost reports beginning on or after July 1, 2001 for these electing the option prior to November 1, 2003; all others effective with cost reporting beginning on or after July 1, 2004). • Allows CAHs to operate no more than 10 psychiatric or rehabilitation distinct part beds beginning on or after October 1, 2004 with psych or rehab beds to be paid under TEFRA (Psych PPS) or Rehab PPS. • Waiver authority allowing governor to "certify" hospitals ends after January 1, 2006; hospitals designated prior to January 1, 2006 will be grandfathered. • Extends funding of FLEX Grants to states of $35 million each year from FY 2005 through FY 2008.
Rural Community Hospital Demonstration Program	• Creates a 5-year demonstration program beginning no later than January 1, 2005 for no more than 15 rural hospitals within low-density rural areas with fewer than 51 acute care beds. Designated hospitals would receive reasonable cost reimbursement for inpatient services, other than distinct-part unit services.
New Technology (Inpatient PPS)	• Provides new funding for new technologies beginning FY 2005. • Allows new diagnostic and procedure codes covering new devices to be introduced into the DRG system on a semi-annual basis (October 1 & April 1) to allow for more timely incorporation of new technology. DRG recalibration will continue only once a year. • Allows lengthy process for public input and modifies the eligibility criteria for additional new technology payment: • Relaxes the cost threshold to qualify for add-on payment from one standard deviation to the lesser of 75% of the standardized amount or 75% of one standard deviation beyond the mean charge for all cases in the DRG. • Indicates Secretary should first seek to place the new technology into an existing DRG that is similar clinically and based on cost. • Technologies denied in FY 2004 shall be reconsidered for FY 2005.
Geographic Reclassification	• Requires Secretary to establish a process and payment adjustment to recognize the out-migration of hospital employees who reside in a county and work in a different area with a higher wage index. Qualifying hospitals could receive a blended increase in their wage index beginning in FY 2005. Any adjustments would not be part of budget-neutral updates to the wage index. • Requires Secretary to establish a process for hospitals to appeal their wage index classification. This one-time appeal requires hospitals to file the appeal between December 8, 2003 and February 15, 2004. Reclassifications would be effective only for discharges on or after April 1, 2004, and in effect for a three-year period only. $900,000,000 has been set aside for these reclassifications, which will not be part of the budget-neutral annual update to the wage index.

OUTPATIENT HOSPITAL

Outpatient PPS

- Extends the effective date of the hold-harmless provision, for rural hospitals with 100 or less beds and Sole Community Hospitals (SCHs) of any size, for two more years (CALENDAR years 2004 and 2005, since the OPPS is updated on a calendar year basis). By adding the sole community hospitals over 100 beds to the hold harmless provision, the drug bill makes that change effective with cost reporting periods on or after January 1,2004. If a SCH has a cost report date that is the same as the calendar year, they will be held harmless for the two full calendar years (2004 and 2005). All other large SCHs would be held harmless for something less than two years, depending on their actual cost reporting period.
- Requests a study by the Secretary to determine if rural providers experience higher costs under outpatient PPS than urban providers. Based on its study, Secretary to make recommendations for adjustments to OPPS rates effective January 1, 2006 to reflect higher costs.

Hospital Outpatient Department Drug Payment

- Provides payment for outpatient drugs at either 95% average wholesale price (AWP) or a transition percentage for 2 years from 2004-2005. Transition percentage is (excludes orphan drugs; drugs for which payment is first made on or after 1/1/03; and those drugs for which no temporary HCPCS code has been assigned.:

Drug Category	2004	2005
Sole Source	88% AWP	83%
Multisource	68%	68%
Generic	46%	46%

  - o 2006 rates based on GAO survey on hospital acquisition cost.
  - o Rates after 2007 and beyond would be determined by the Secretary based on periodic acquisition cost surveys.
  - o Reduces the threshold for establishing separate APCs for drugs and biologicals to $50 for 2005 and 2006.
  - o Orphan drugs to be paid at a rate determined by the Secretary for 2004-2005. Covered drugs for which no HCPCS code has been assigned shall be paid at 95% of AWP.
  - o Requires MedPAC, by 7/1/05, to issue a report on whether and how adjustments should be made to drug APC payment rates to take into account overhead and related expenses.
- Brachytherapy would be paid based on charges adjusted to costs for three years from 2004-2006, with a GAO study to determine appropriate payment amounts by 2005.
- Limits the application of a functional equivalence standard used to establish eligibility for pass-through payments.
- Requires GAO to study hospital acquisition costs for drugs greater than $50 in a representative sample of hospitals by 2006.
- Reduces the threshold for establishing separate APCs for drugs and biologicals to $50 for 2005 and 2006.

Clinical Diagnostic Lab Services

- Effective with cost reporting periods on or after July 1, 2004, provides for rural hospitals under 50 beds to receive cost reimbursement. Similar to CAHs, these hospital may not charge deductibles/insurance to the beneficiary for these services.

SPECIALTY HOSPITALS

Specialty Hospitals

Provides an 18-month moratorium on physician self-referrals under Medicare and Medicaid to certain new specialty hospitals while MedPAC and HHS study the issue; grandfathers existing specialty hospitals and those under development prior to November 18, 2003; prevents grandfathered facilities from adding physician investors and from expanding to other specialty categories; limits bed expansions at grandfathered facilities to the greater of 50 percent or 5 beds.

- Clarifies "whole hospital" and "rural" exceptions to the prohibitions on physician self-referrals to entities in which they have an ownership interest. Specifically:
  - Excludes specialty hospitals from the whole hospital exception for 18 months beginning on the date of enactment.
    - Defines specialty hospital as being primarily or exclusively engaged in the care/treatment of cardiac conditions, orthopedic conditions, patients receiving a surgical procedure, or any other specialized category designated by HHS as inconsistent with the purpose of the statute.
    - Excludes from the moratorium those specialty hospitals in operation or under development as of November 18, 2003. To maintain their exemption from the moratorium, such hospitals:
      1. Must not increase the number of physician investors at any time on or after November 18 beyond the number as of November 18, 2003;
      2. Must not expand or change the type of specialty categories after November 18;
      3. Must not expand their operations outside their main campus;
      4. Must limit any expansion of beds on their main campus to no more than 50 percent of the number of beds in the hospital as of November 18, or 5 beds, whichever is greater; and
      5. Must meet other requirements set by HHS.

    Directs HHS to consider several factors in defining "under development," including completion of architectural plans, receipt of funding, compliance with zoning requirements, receipt of regulatory approvals, and any other evidence required by the Secretary.
  - Excludes specialty hospitals from use of the general rural exception to the ban on physician self-referrals.

- Within 15 months of enactment, MedPAC (in consultation with GAO) and HHS are required to perform studies and submit reports with recommendations to Congress. Specifically:
  - MedPAC will conduct a study comparing physician-owned specialty hospitals with local full-service community hospitals with respect to:
    - Differences in the cost of serving patients within specific DRGs.
    - The extent to which specialty hospitals treat patients in certain DRGs within categories and an analysis of the selection.
    - The financial impact of physician-owned specialty hospitals on local full-service community hospitals.
    - How the current DRG system should be updated to better reflect the cost of delivering care in a hospital setting.
    - The proportions of payments received, by type of payer.
  - HHS will conduct a study of a representative sample of specialty hospitals to:
    - Determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest.
    - Determine the referral patterns of physician owners regarding referrals to their specialty hospitals and to full-service community hospitals for the same condition.
    - Compare the quality of care furnished in physician-owned specialty hospitals and full-service community hospitals for similar conditions and patient satisfaction with such care.
    - Assess differences in uncompensated care, as defined by the Secretary, between specialty hospitals and local full-service community hospitals, and the relative value of any tax exemption available to such hospitals.

PHYSICIAN	
Key Medicare Physician Provisions	• Physician Payment Update – The physician fee schedule payment update factor for 2004 and 2005 shall not be less than 1.5% and will be exempt from budget neutrality adjustment of –0.2% in 2004 and 0.8% in 2005. • Medicare Incentive Payment (MIP) Program (Bonus Payment) – Physicians will be paid a new 5% bonus payment for certain underserved counties for services furnished in 2005-2007. Counties will be defined based on the number of primary care and specialty care physicians. The Secretary is required to establish procedures to determine when a physician can be paid a Medicare (MIP) bonus payment when providing services in health professional shortage areas (HPSA). • Work Index Floor – For localities with a work index of less than 1.00, the index is increased to 1.00 for services furnished in 2004-2006. • Allows grandfathered independent labs to continue to bill Medicare directly for the technical component of physician pathology services provided to hospital inpatients and outpatients in 2005 and 2006. • Requires MedPAC report within one year on increases in the volume of physician services and their impact on beneficiary health. • Requires GAO study to be completed within 18 months on beneficiary access to physician services. • Provides coverage for additional screening tests.
POST-ACUTE AND OTHER	
Home Health	• Provides an inflation update of market basket minus 0.8 percentage points for the last three calendar quarters of 2004, then calendar years 2005 and 2006. • 1-year increase of payments of 5% for rural providers beginning April 1, 2004. • Demonstration project to clarify homebound criteria. • Changes payment cycle from fiscal year to calendar year starting in 2004. • Requires MedPAC study on home health payment margins under PPS. • Temporarily suspends OASIS patient assessment for non-Medicaid/Medicare patients and calls for HHS study. • Expands home health agency definition to include “religious nonmedical health care institutions.” • 3-year, 5-site demo permitting adult-day services to substitute for a portion of home health services.
Skilled Nursing Facilities (SNF)	• Adds new consolidated billing exemptions for federally qualified health centers. • Increases per diem payment by 128% for residents with AIDS. • Comptroller General shall conduct a feasibility study on providing portable diagnostic ultrasound services to Medicare beneficiaries in SNFs.
Hospice	• Recognizes nurse practitioners as allowable providers of hospice services. • Proposes for a 5-year demonstration program for up to three hospital-based hospices. • Effective January 1, 2005, provides for consulting services to be paid at rate paid under physician fee schedule for an office visit of moderate severity requiring medical decision making of low complexity.
Therapy Services	• Applies moratorium on therapy caps for remainder of 2003, 2004 and 2005. • Requires study by March 2004 on therapy cap alternatives and outpatient therapy utilization. • By October 1, 2004, requires a Comptroller General study on conditions appropriate for cap exemptions. • MedPAC shall conduct a study on direct access to outpatient physical therapy.

Ambulance	• Temporary increase in the mileage base rate (as determined by the Secretary) for ground ambulance services originating in a rural area with a low population density for services furnished on or after July 1, 2004 and before January 1, 2007. • Provides payment at the greater of either the national fee schedule or a blended rate of the national fee schedule and a regional fee schedule. The new regional fee schedule will be determined by the Secretary for each of the 9 Census divisions using a methodology that includes calculating a regional conversion factor and a regional mileage payment rate. The blended rate is: For CY 2004 (on or after July 1, 2004): 20% of the national fee schedule, and 80% of a regional fee schedule For CY 2005: 40% national, 60% regional For CY 2006: 60% national, 40% regional For CY 2007-CY2009: 80% national, 20% regional For CY 2010 and thereafter: 100% of the fee schedule • Provides a 25% increase in the per-mile rate for trips over 50 miles (regardless of whether they originate in an urban or rural setting) for services furnished on or after July 1, 2004 and before January 1, 2009. • Rural air ambulance service will be paid at the air ambulance rate if the service is reasonable and necessary based on the health condition of the patient needing transport and the air ambulance service complies with the equipment and crew requirements established by the Secretary. • Initial GAO report on ambulance cost and access by CY 2006, with a final report by CY 2008.
Durable Medical Equipment (DME)	• Phases in implementation of a competitive bidding process for acquisition of durable medical equipment beginning with 10 of the largest MSAs in 2007. All other areas to be phased in by 2010, although Secretary may exempt rural areas and other low population density urban areas that are deemed to be not competitive.
MEDICAID AND OTHER	
Medicaid Disproportionate Share Payments (DSH)	• **DSH Cliff -** Eliminates the DSH cliff in FY 04 with an increase in the DSH allotment of 16% over FY 03 levels. Subsequent years are frozen at FY 2004 levels until the allotment level intersects with where it would have been absent relief from BBA. Increases thereafter are tied to the change in the Consumer Price Index. • **Low DSH -** Very low-DSH states, with DSH spending under 3% of total spending as of 08/31/03 will have their DSH allotment for FY 2004 increased by 16% and subsequent allotments increased by 16% of the previous year amount through FY 2008. DSH allotment increases for FY 2009 and in the future will be increased by the change in the Consumer Price Index based on the previous year amount. • **DSH Reporting -** States, as a condition of receiving Medicaid funding, must submit annual reports to the Secretary of HHS detailing DSH spending. States must also submit to the Secretary an independent audit report of DSH spending to include whether DSH payments appropriately offset the costs of uncompensated care services provided to low-income populations.
Federal Allotments to States for Emergency Services for Undocumented Aliens	• Establishes temporary federal allotments to states to help pay for emergency health care services provided undocumented aliens. $250 million will be allocated, from FY 2005-FY 2008, to states with high levels of undocumented aliens. States must use funds to pay local government, hospitals, and other providers of care for emergency medical services. Funds can be used to pay for the health services of documented aliens permitted to enter the country to receive emergency health care services.

Medicaid Best Price Exclusion for 340B Clinics and Hospitals	• Clinics and hospitals that qualify as 340B entities will be able to negotiate discounted drug prices with manufactures for both inpatient and outpatient drugs that fall outside the Medicaid best price determination (the maximum allowable statutory price.) Hospitals qualifying as 340B entities are hospitals that are publicly owned by state or local governments or hospitals that contract with state or local governments to serve indigent patients not eligible for Medicare and Medicaid. These hospitals must have a Medicare DSH adjustment of greater than 11.75% and cannot have arrangements to purchase outpatient drugs through a group purchasing organization. Rural and small urban hospitals, with a Medicare DSH adjustment greater than 11.75%, now may be able to qualify as a 340B entity if these hospitals meet all other qualifying requirements. Effective December 8, 2003.
REGULATORY RELIEF	
Regulatory Relief ***Regular Timeline for Publication of Final Rules***	Requires the Secretary in consultation with the OMB Director to establish a regular timeline for the publication of final regulations. The timeline can vary based on complexity of regulations, number and scope of comments received and other relevant factors.
Regulatory Relief ***Interim Final Rule***	Establishes that upon the expiration of the regular timeline established between the Secretary and OMB, an interim final rule shall not continue in effect unless the Secretary publishes a notice of continuation of the regulation that includes an explanation of why the regular timeline was not complied with. If such a notice is published, the regular timeline for publication of the final regulation shall be treated as having been extended for one year.
Regulatory Relief ***Limitations on New Matter in Final Regulations***	If the Secretary publishes a notice of proposed rulemaking (NPRM) and, if, the final regulation includes a provision that is not a logical outgrowth of such NPRM, that provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.
Regulatory Relief ***No Retroactive Application of Substantive Changes***	A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability shall not be applied retroactively subject to compliance with statutory requirements and any concerns with the "public interest."
Regulatory Relief ***Effective Date of Substantive Changes***	With specific exception, CMS may not apply new regulations or other policy decisions until 30 days after the change has been issued.
Regulatory Relief ***Reliance on Guidance***	CMS is prohibited from levying penalties or interest on providers who have shown to have reasonably relied on erroneous written guidance.
Regulatory Relief ***GAO Study on Advisory Opinions***	Requires GAO to study the feasibility of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of regulations under the Medicare Program.
Regulatory Relief ***Contractor Reform***	Permits the Secretary to enter into contracts with any entity eligible to serve as a Medicare contractor for one or more functions. Requires that the Secretary use competitive procedures for contracting with Medicare administrative contractors. Permits the Secretary to consult with providers of services in developing specific performance requirements for the Medicare contractors. Requires the Secretary to consult with organizations representing providers to establish standards relating to the accuracy, consistency, and timeliness of information provided by the fiscal intermediaries.

Regulatory Relief ***Medicare Provider Ombudsman***	Requires the Secretary to create a new Medicare ombudsman program for providers to furnish assistance on a confidential basis concerning complaints, grievances, and resolution of unclear or conflicting guidance given by the Secretary and Medicare contractors. Also creates a Medicare ombudsman program for beneficiaries.
Regulatory Relief ***Medicare Secondary Payor (MSP) and Laboratories***	Prohibits the Secretary from requiring hospitals serving as reference labs to ask questions regarding the Medicare Secondary Payor requirements that are not required for independent labs.
Regulatory Relief ***Medicare Disproportionate Share Hospital (DSH) Information***	The Secretary shall furnish directly to hospitals the SSI and Medicaid patient days data used in the computation of the Medicare DSH payment formula.
Regulatory Relief ***EMTALA Reforms***	Clarifies current law to require that any emergency care services provided to a Medicare fee-for-service beneficiary shall be covered by the Medicare program. Requires prior review by peer review organizations in EMTALA cases involving termination of a hospital from participation under Medicare. Requires notification to hospitals when EMTALA investigation is closed. Requires the Secretary to establish an advisory group comprised of CMS and OIG officials, providers and beneficiaries to review EMTALA and its implementation.
Regulatory Relief ***Expedited Access to Review***	Secretary shall establish a process for providers to obtain access to judicial review when a review panel has decided that they don't have the authority to decide the question of law or regulation or that there is no material issue of fact in dispute. Review panel shall make determination within 60 days. Provider may file for civil action within 60 days of determination if review panel determines that there is no material issue of fact in dispute, the review board doesn't have authority to decide, or it fails to make prompt determination.