

## **Teaching Hospital and Physician-Related Provisions in the “Medicare Prescription Drug, Improvement and Modernization Act of 2003”**

### **AAMC Summary and Analysis**

On November 22 and 25, 2003 the House and Senate passed H.R. 1, the “Medicare Prescription Drug, Improvement and Modernization Act of 2003.” The President signed the \$395 billion (over 10 years) legislation into law (P.L. 108-173) on December 9, 2003. In addition to providing a discount prescription drug card and voluntary prescription drug benefit; expanding private plan choices for Medicare beneficiaries; improving Medicare fee for service benefits; combating waste, fraud and abuse; and reforming regulatory procedures, the bill includes a number of provisions that will affect teaching hospitals and academic physicians. P.L. 108-173 includes some provisions that address the AAMC's top 2003 priorities: ameliorating recent reductions to Medicare Indirect Medical Education payments, Medicare physician payment updates and Medicaid Disproportionate Share Hospital allotments to states, and ensuring full inflation update adjustments to Medicare reimbursements for inpatient services.

Other important changes include provisions that redistribute unused residency slots, freeze Medicare Direct Graduate Medical Education per resident amounts for hospitals with per resident levels above 140 percent of a locality adjusted national average per resident amount; and provide a temporary moratorium on new physician-owned “niche” hospitals.

### **I. Medicare Hospital Payment Provisions**

#### ***Provisions Pertaining to IME and DGME Payments***

- **Indirect Medical Education Payments**

*Current Law.* In FY 2003 and subsequent years, the Medicare Indirect Medical Education (IME) adjustment to teaching hospitals was reduced from 6.5 percent for every 10 percent increment in a hospital’s resident-to-bed ratio to 5.5 percent.

*P.L. 108-173.* Section 502 increases the IME adjustment from 5.5 to 6.0 percent on April 1, 2004; 5.8 percent in FY 2005; and 5.55 percent in FY 2006. In FY 2007, IME payments are reduced to 5.35 percent before being set at 5.5 percent in FY 2008 and beyond. (See table). It is estimated that this provision will provide \$400 million to teaching hospitals over ten years.

**IME Add-On Percentage As Set Forth by P.L. 108-173  
 “Medicare Prescription Drug, Improvement and Modernization Act of 2003”**

Period	IME%	IME Multiplier
April – September 2004	6.0%	1.47
FFY 2005	5.8%	1.42
FFY 2006	5.55%	1.37
FFY 2007	5.35%	1.32
FFY 2008 & Beyond	5.5%	1.35

- **DGME, IME and Nursing and Allied Health Payments Associated with Medicare Advantage Enrollees**

*Current Law.* Medicare currently pays teaching hospitals for residency and nursing and allied health training programs through DGME, IME, and Nursing and Allied Health payments for every fee for service (FFS) and Medicare+ Choice enrollee treated.

*P.L. 108-173.* Section 201 establishes by January 1, 2006, a Medicare Advantage (MA) program. The program will replace Part C of the Medicare program, known as Medicare Plus Choice. Because the bill’s language literally replaces any reference in the statute to Medicare Plus Choice with the words “Medicare Advantage,” Direct Graduate Medical Education (DGME), IME and Nursing and Allied Health Payments will continue to be paid to teaching hospitals when they treat Medicare Advantage enrollees.

- **Redistribution of Unused Resident Limit Positions**

*Current Law.* None.

*P.L. 108-173.* Section 422 requires the portion of teaching hospitals’ resident limits (as mandated by the Balanced Budget Act of 1997 (BBA)) that is "unused" to be redistributed to teaching hospitals seeking to increase their resident limits. The redistributed slots would be eligible for both DGME and IME payments.

According to the law’s language, a resident "pool" would be created based on the difference between hospitals’ actual historical resident counts and their resident limits, to the extent the actual count is lower. Specifically, with limited exceptions (see below), if a hospital's resident count for “the most recent cost reporting period ending on or before September 30, 2003, for which a cost report has been settled (or, if not, submitted (subject to audit))” is below its corresponding resident limit, effective July 1, 2005, its resident limit would be permanently reduced by 75 percent of the difference between its

resident limit and its resident count. (Note: It is not clear from this legislative language which cost reporting period will be used. This issue will be addressed with more clarity in the forthcoming regulations.) Both the DGME and IME resident limits would be reduced. Rural teaching hospitals with less than 250 beds and teaching hospitals participating in the Voluntary Reduction Program, as set forth by the BBA and the Centers for Medicare and Medicaid Services' (CMS) New York demonstration project, are exempted from these reductions.

There are two exceptions in which the resident count used to compare to the resident limit could be modified:

- The Secretary of the Department of Health and Human Services (DHHS), subject to his discretion, may use a hospital's cost reporting period that includes July 1, 2003 if the resident count is higher due to an expansion of an existing residency training program that is not reflected on the most recent settled cost report;
- The DHHS Secretary is required to adjust the resident count to include residents that were approved in a residency training program application by the appropriate accrediting body before January 1, 2002, but which was not in operation during the relevant cost reporting period;

In addition, hospitals that are members of the same resident limit affiliation agreement will receive special consideration. The AAMC expects that additional information will be provided in regulation.

The one-time pool of resident slots created by the retroactive resident limit reductions would be available to hospitals through an application process that would be administered by the DHHS Secretary. The resident limit increases would be effective for portions of cost reporting periods occurring on or after July 1, 2005. Increases in resident slots would be granted under the following priority order:

- 1) hospitals located in rural areas;
- 2) hospitals located in small urban areas; and
- 3) hospitals where a residency training program is the only resident program in the state.

The DHHS Secretary must also take into account the likelihood that a hospital will fill the positions. A hospital's resident limit could not be increased by more than 25 positions. DGME payments for the additional residents would be paid based on a locality-adjusted national average per resident amount rather than the hospital's current per resident amount. IME payments for the additional residents would be paid based on an add-on percentage of 2.7 percent.

The Congressional Budget Office (CBO) has scored the provision at providing \$800 million in additional DGME and IME payments over 10 years.

- **Extension of Freeze in DGME Payments for Hospitals with “High Cost” Residency Programs**

Current Law. Medicare pays hospitals for its share of DGME costs in approved training programs based on a 1984 hospital specific per resident amount, updated to the current year for inflation, and a hospital’s number of full time equivalent (FTE) residents, not to exceed a hospital’s resident limit.

Beginning FY 2001, a new methodology for determining DGME payments was applied, centering around a “locality-adjusted” national average per resident amount (PRA), and the calculation of a “floor” and a “ceiling” PRA. In FY 2001 and FY 2002, hospitals with PRAs below 70 percent and 85 percent of the national average PRA had their PRAs increased to that floor amount and then updated annually thereafter by the Consumer Price Index (CPI) increase. PRAs for hospitals above the 140 percent ceiling amount were frozen at FY 2001 levels for FYs 2001 and 2002. In FYs 2003-2005, the per resident amount was to be updated by the CPI increase minus two percentage points.

Hospitals with PRAs between the floor and ceiling amounts were unaffected by this methodology.

P.L. 108-173. Section 711 freezes in FYs 2004-2012 the PRAs for those teaching hospitals with per resident limits above 140 percent of the locality-adjusted national average at the FY 2003 level. This provision is estimated to save \$1.3 billion over 10 years.

- **Exception to Initial Residency Period for Geriatric Residency or Fellowship Programs**

Current Law. For purposes of calculating Medicare DGME payments, Medicare counts residents in the initial residency period (the lesser of the minimum number of years required for board eligibility in the physician’s specialty or 5 years) as 1.0 Full Time Equivalent (FTE); afterwards, the resident is counted as a 0.5 FTE. In order to be certified in geriatrics, a subspecialty of family practice, internal medicine and psychiatry, requires 1 year of additional training beyond the initial residency in one of these areas. Additional years of training are often sought to pursue careers in academic medicine.

P.L. 108-173. Section 712 clarifies, effective October 1, 2003, that an exception to the initial residency period for geriatric residency or fellowship programs will be allowed for approved geriatric training programs “where a particular approved geriatrics training program requires a resident to complete 2 years of training to initially become board eligible in the geriatric specialty.” While the language is not as clear as the AAMC would have liked, the AAMC believes the intent of the section is to require CMS to count geriatric residents as one full time equivalent for two years for purposes of calculating DGME payments. DHHS is required to promulgate regulations for notice and comment to become effective for cost reporting periods beginning on or after October 1, 2003.

- **Clarification of Initial Residency Periods for Preliminary or General Year of Training**

*Current Law.* Medicare’s policy for DGME payments is to count residents during the number of years required to achieve first board eligibility as a 1.0 FTE, though no resident can be counted as a 1.0 FTE for more than 5 years. The period leading to initial board eligibility is called the initial residency period (IRP). For any training beyond the IRP, residents are counted as 0.5 FTE. Under the Medicare statute, the IRP is “determined, with respect to a resident, as of the time the resident enters the residency training program.”

Under CMS’ current interpretation of the statute, hospitals providing specialty training for residents who select a specialty that requires a general clinical year may not be able to count those residents as a 1.0 FTE for the full length of the specialty training. This is because CMS determines the IRP based on the specialty in the first year of training, regardless of the specialty in which the resident actually intends to train. Thus, a resident who enrolls in a preliminary year internal medicine program is assigned the internal medicine IRP of 3 years. For a resident who intends to train in radiology (many of whom have already been “matched” to a radiology program prior to commencing any residency training), for example, this means that for the first 3 years of training (preliminary medicine year plus 2 years of radiology), the hospital counts the resident as a 1.0 FTE and that for the required years 4 and 5 of radiology training, the resident is counted as only a 0.5 FTE. By contrast, a resident who meets the general clinical year requirement through a “transitional year” program is assigned an IRP based on the specialty in which the resident is training in the second year—for residents entering radiology, this would be five years.

*P.L. 108-173.* Conference report language accompanying Section 712 clarifies that the initial residency period for any residency for which the Accreditation Council of Graduate Medical Education requires a preliminary or general clinical year of training is to be determined in the resident’s second year of training. While conference report language is not binding, it does express the wishes of Congress and is helpful in persuading the DHHS Secretary to take action.

- **Treatment of Volunteer Supervision**

*Current Law.* Medicare makes DGME and IME payments to teaching hospitals for residents in non-hospital sites if they incur "all or substantially all" the training costs at that site. Before 1999, hospitals could meet this requirement if they paid the residents stipends and benefits. In 1999, CMS added a regulation that said hospitals also had to incur "physician supervisory costs" and include in the agreement between the hospital and non-hospital site how much the hospital is paying for physician supervision in the non-hospital site. There has been some controversy as to whether physicians can “volunteer” their supervisory time, such that hospitals would not pay these costs.

P.L. 108-173. Section 713 specifies for one year beginning on January 1, 2004, hospitals will be allowed to count residents in osteopathic and allopathic residents in family medicine programs in existence as of January 1, 2002, who are training in non-hospital sites without regard to the financial arrangement between the hospital and the supervisory physician. Report language accompanying section 713 also requires the DHHS Secretary to “clarify in future regulation its definition of reasonableness of payment for supervisory physicians” for programs established after January 1, 2002.

Section 713 also requires the Inspector General of DHHS to conduct a study on the appropriateness of “alternative payment methodologies” for the costs of training residents in non-hospital settings and issue a report with any potential recommendations to Congress no later than one year of the law’s enactment (December 8, 2004.) The accompanying conference report language also requires that the study examine the effect of the change in the BBA that allowed payment by Medicare “for graduate medical education in non-hospital settings, including whether access and numbers of physicians placing in rural and underserved areas has increased”; examination of programs regarding “evidence of possible misuse of federal money with respect to volunteering supervising physicians”; “a determination whether supervisory physicians are freely volunteering their time”; and a description of incentives are offered to physicians who volunteer their times as supervisory physicians (Continuing Medical Education credit hours, hospital privileges, etc.).

- **Clinical Psychology Training Programs**

Current Law. On January 12, 2001, the DHHS Secretary published a proposed rule to provide Medicare pass-through cost payments for clinical psychology training programs. A final rule has yet to be published.

P.L. 108-173. Conference report language accompanying Section 712 directs the DHHS Secretary to implement a final rule six months from the date of the law’s enactment, which is June 8, 2004. Further, the report language states that “it is the intention of Congress” that hospital-based clinical psychology training programs be reimbursed. While conference report language is not binding, it does express the wishes of Congress and is helpful in persuading the DHHS Secretary to take action.

### ***Medicare Provisions Related to Inpatient Services***

- **Inpatient Payment Update**

Current Law. Standardized payments for inpatient services are updated each year using an “update factor” which is based on the hospital market basket (MB). The MB measures

the increase in the cost of goods and services purchased by hospitals in a given year. In FY 2004 and thereafter, the update to hospital inpatient Medicare prospective payment rates is the full market basket percentage increase.

P.L. 108-173. Section 501 maintains the hospital inpatient update at a full MB in FY 2004. In FYs 2005-07, hospitals will receive a full MB update if they submit data to the CMS on 10 quality indicators established by the DHHS Secretary. For hospitals that do not submit data, the MB update will be reduced by 0.4 percentage points. The reduction will only apply to the fiscal year involved. In FY 2005, hospitals will have a 30-day grace period to submit the data. This provision is estimated to save \$200 million over 10 years.

Section 501 also includes a study by the General Accounting Office (GAO) on the appropriate level and distribution of payments in relation to costs for inpatient hospital services and whether there is a need to adjust such payments to reflect legitimate differences in costs across different geographic areas, kinds of hospitals, and types of cases. The report, due to Congress on December 8, 2005, will include legislative and administrative recommendations.

In addition, section 404 requires the DHHS Secretary to increase the frequency (currently, it is once every five years) for revising the weights used in the hospital market basket, including the labor share to reflect more current data.

- **Standardized Payment Amount**

Current Law. Medicare pays for inpatient services using two standardized amounts: one for hospitals located in rural and small urban areas (metropolitan statistical areas less than 1 million population) and a higher rate for hospitals in large, urban areas. Legislation enacted in 2003 temporarily increased, through March 31, 2004, the standardized amount for discharges of hospitals in rural and small urban areas by 1.6 percent to equal the large urban rate.

P.L. 108-173. Section 401 permanently equalizes the standardized amount for hospitals in rural and small urban areas with the rate for hospitals in large urban areas. Hospitals in rural and small urban areas will be paid based on the large urban rate for discharges beginning in FY 2004, a 1.6 percent increase in the standardized amount. The provision is estimated to increase payments to hospitals in rural and small urban areas by \$7.6 billion over 10 years.

- **The Wage Index**

Current Law. The hospital wage index is used to adjust the “labor share” of the national standardized Medicare per case payment amount to account for the wage level in the area where a hospital is located. Presently, approximately 71 percent of the standardized amount for each hospital discharge is adjusted by the area wage index. A hospital can

seek to have its wage index changed by submitting an application to the Medicare Geographic Classification Review Board (MGCRB).

*P.L. 108-173.* Section 403 decreases the percentage of the standardized amount of each discharge that is adjusted by the area wage index from 71 percent to 62 percent, but only for hospitals that would benefit from such a provision, i.e. whose payments would increase as a result of decreasing the percentage of the wage index applied to the standardized amount. This will result in increased inpatient payments to such hospitals. The provision is estimated to increase payments for this group of hospitals by \$5.2 billion over 10 years.

Section 505 requires the DHHS Secretary to establish a process by which qualifying hospitals with certain wages and employee commuting patterns could receive an increase in their wage index by FY 2005. Specifically, the DHHS Secretary shall establish criteria by which a county would qualify for another wage index based on out-migration of hospital employees and differences in area wage indices. The process will be similar to reclassification used by the Medicare Geographic Classification Review Board. Any such wage index increases shall be effective for 3 fiscal years and will not affect the wage indices of other hospitals. The DHHS Secretary shall establish a process by which a hospital could waive the application of the wage index increase. Section 505 is estimated to increase hospital payments by \$400 million over 10 years.

Section 508 requires the DHHS Secretary to establish a one-time appeals process under which a hospital may appeal its wage index classification and select another area to which to be reclassified. The appeals process established will require an appeal to be filed by not later than April 1, 2004. If the Medicare Geographic Reclassification Review Board determines that a hospital is a qualifying hospital, the hospital shall be reclassified to the area selected for three years beginning with discharges during FY 2005. A qualifying hospital is a hospital not eligible for a wage index classification on the basis of distance and/or commuting and meets other criteria, such as “quality”, as the DHHS Secretary may specify. The bill language does not define what quality means in this instance. Section 508 limits increases in hospital payments due to the one time appeals process to \$500 million.

- **New Technologies Under the Medicare Inpatient Hospital PPS**

*Current Law.* As set forth by the “Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000” (BIPA), Medicare makes special payments for expensive new technologies under the Medicare inpatient prospective payment system (PPS). According to current regulations, a special payment will be made for a new technology that "represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." Additionally, in order to qualify for the payments, the costs of the new technology must be one standard deviation beyond the mean standardized charge for all cases in the Diagnostic-Related Group (DRG) to which the technology is assigned. The payment will be 50 percent of the amount by which the costs of a case that involves

the new technology exceeds the comparable per case payment, up to 50 percent of the costs of the new technology. CMS has set a target limit on these payments to be one percent of projected total inpatient PPS payments. The one percent amount is financed by a reduction to the base standardized amount for all inpatient cases. If the special payments are estimated to be higher than this amount, they will be reduced on a pro rata basis to ensure the target is not exceeded.

*P.L. 108-173.* Section 503 increases payments to hospitals for new technologies by reducing the cost threshold by which new technologies would be eligible for payment. The threshold is reduced from one standard deviation to the lesser of 75 percent of the standardized amount or 75 percent of one standard deviation for the DRG involved.

Section 503 also requires the DHHS Secretary to try and identify one or more DRGs associated with such technology based on similar clinical or anatomical characteristics and cost. Within such groups, the DHHS Secretary shall assign an eligible new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. Such identification shall take place before the DHHS Secretary establishes an add-on payment.

The section also requires the DHHS Secretary to provide for the addition of new diagnosis and procedure codes in April 1 of each year, but such codes are not required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date.

The section expands the process by which the public can provide input related to new technology payments, including requiring the DHHS Secretary to: update a list of services and technologies applying for additional payment; accept comments, recommendations and data from the public as to whether the service or technology represents a substantial improvement beyond the existing technology or service; and hold stakeholder meetings before publication of a notice or proposed rulemaking related to technology.

The section also requires the DHHS Secretary to automatically reconsider applications reviewed for approval in FY 2004, but were denied.

The provisions are estimated to increase inpatient payments by \$500 million over 10 years and are scheduled to take effect with classifications beginning FY 2005.

- **Physician-Owned “Niche” Hospitals**

*Current Law.* Existing federal law, known as “Stark”, sets some limits on physicians’ abilities to refer patients to facilities in which they have a financial interest. However, a current exception under the physician self-referral law allows physicians to refer patients for designated health services to a hospital in which they are an owner so long as their

ownership is in the “whole hospital,” not just a distinct part or department at the hospital. This provision has allowed the development of physician-owned hospitals that specialize in providing care for a limited set of conditions, such as cardiac care, or performing certain procedures, such as orthopedic surgery.

*P.L. 108-173.* Section 507 limits the ownership and investment interests in a “specialty” hospital for 18 months beginning November 18, 2003. The section defines a specialty hospital as a hospital primarily or exclusively engaged in the care and treatment of one of the following categories: patients with a cardiac or orthopedic condition; patients receiving a surgical procedure; and any other specialized category of services that the DHHS Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests.

The section includes a number of exceptions to the definition of specialty hospital. The exceptions are as follows: any hospital determined by the DHHS Secretary that was in operation before November 18, 2003 or under development as of such date. In determining whether a hospital under development would be exempt from the 18 month moratorium, the DHHS Secretary shall consider whether architectural plans have been completed, funding has been received, zoning requirements have been met and necessary approvals from State agencies have been received as well as any other evidence the DHHS Secretary determines.

In order for exempt specialty hospitals to maintain their exception during the moratorium period, a specialty hospital may not increase the number of physician investors as of November 18, 2003; change or expand the field of specialization it treats; expand beyond the main campus; or increase the total number of beds in its facilities by more than the greater of 5 beds or 50 percent of the number of beds in the hospital as of November 18, 2003. Report language accompanying section 507 clarifies that for purposes of this section, long-term acute care hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children’s hospitals are not considered specialty hospitals.

Section 507 also requires the Medicare Payment Advisory Commission (MedPAC) in consultation with the GAO to study the issue and report back to Congress within 15 months.

- **Provisions Related to Inpatient Rehabilitation Facilities**

*Current Law.* Under current regulations, to be paid under the Rehabilitation PPS, hospitals and units must meet specified criteria, including serving a patient population of whom at least 75 percent require intensive rehabilitation services for one of a designated list of conditions. A survey by CMS indicated that most rehabilitation hospitals were not meeting these criteria. CMS published a proposed rule modifying the list of conditions and temporarily reducing the patient percentage to 65 percent.

*P.L. 108-173.* Conference report language accompanying section 501 urges the CMS to delay implementation of its Medicare Rehabilitation Proposed Rule, known as the "75

percent rule," that would tighten the eligibility criteria for inpatient rehabilitation facilities. The language directs GAO to issue a report, in consultation with experts in the field of physical medicine and rehabilitation, to review "whether the current list of conditions represents a clinically appropriate standard for defining IRF [inpatient rehabilitation facility] services and, if not, which additional conditions should be added to the list. During the study period, the Committee urges the DHHS Secretary to delay implementation of the rule and not accept new IRF applications until the report is finished."

### ***Medicare Provisions related to Hospital-Based Outpatient Department Payments***

- **Hospital Outpatient Prospective Payment System (OPPS) Drug Payment**

Current Law. The OPPS provides that hospitals may receive "pass through" payments for a period of two to three years for specific items. These include orphan drugs; current drugs, biologic agents, and brachytherapy devices used in cancer treatment; current radiopharmaceutical drugs and biological products; and those new medical devices, drugs, and biologic agents that were not paid as outpatient services as of December 31, 1996 and where the cost of the item is "not insignificant" in relation to the corresponding Ambulatory Payment Classification (APC) amount.

Transitional pass-through payments are available for only for a limited period of time, between two and three years. After that period, the device/drug/biological and its associated costs are "packaged into" a current APC or a new APC is created. The two-to-three-year time frame was established because it generally takes CMS this amount of time to collect the claims data and allow CMS staff to analyze the device/drug/biological costs and incorporate those costs into the APC rate calculations.

For drugs and biologicals, the pass-through amount is equal to the difference between 95 percent of the item's average wholesale price (AWP) and the portion of the APC amount determined by CMS to be associated with the item. For devices, the additional payment is the difference between a hospital's charges adjusted to costs and the portion of the applicable APC amount associated with the device. Both of these payment types, however, are contingent on the total monies available for these payments.

Pursuant to current law, the total amount of additional payments available for pass through payments cannot exceed 2.5 percent of total outpatient payments through 2003; for 2004 and beyond the payments cannot exceed more than 2 percent of total payments. These amounts are funded through a reduction in the conversion factor for all outpatient services. If the amount of pass-through payments exceeds the authorized level (for example, 2.5 percent in 2003) CMS has the authority to make a prospective uniform pro rata reduction to the pass-through payments to ensure that the level is not exceeded.

P.L. 108-173. Section 621 modifies how covered drugs are reimbursed under the OPPS according to drug type. For services furnished on or after January 1, 2004, "specified"

hospital outpatient department covered drugs will be paid based on a percentage of the reference average wholesale price (AWP) for the drug. The reference AWP is the average wholesale price for the drug as of May 1, 2003.

- Payment for Sole Source Drugs in CYs 2004 and 2005: OPPS payments for sole source drugs can be no less than 88 percent and no greater than 95 percent of the reference AWP in CY 2004 and no less than 83 percent and no greater than 95 percent in CY 2005.
- Payment for Innovator Multiple Source Drugs in CY 2004 and 2005: Payments for innovator multiple-source drugs can be no greater than 68 percent of the reference AWP in CY 2004 and CY 2005.
- Payment for Noninnovator Multiple Source Drugs in CYs 2004 and 2005: OPPS payments for non innovator multiple source drugs can be no greater than 46 percent of the reference AWP.
- Payment for Drugs in CY 2006 and Beyond: In subsequent years, payment will be equal to the average acquisition cost for the drug for that year, or if hospital acquisition cost data are not available, the average price for the drug in the year established under Sections 1842(o), 1847A or 1847B as calculated and adjusted by the DHHS Secretary.

The section defines “specified” drugs as a covered drug for which a separate APC has been established and that is a radiopharmaceutical, or a drug or biological for which a pass-through payment was made on or before December 31, 2002. “Specified” drugs do not include a drug or biological for which pass-through payments are first made on or after January 1, 2003; those drugs for which a Healthcare Common Procedure Coding System (HCPCS) code has not been assigned; or orphan drugs furnished in 2004 and 2005. (Payment for orphan drugs during 2004 and 2005 will be paid at an amount specified by the DHHS Secretary; drugs for which a temporary HCPCS code has not been assigned will be reimbursed at 95 percent of the AWP.)

Section 621 also requires GAO to conduct a survey in 2004 and 2005 to determine the acquisition cost for each of the specified covered drugs. Not later than April 1, 2005, the GAO will provide to the DHHS Secretary the data for use in setting payment rates for 2005. Upon completion of the 2004 and 2005 surveys, the GAO shall recommend to the DHHS Secretary the frequency and methodology of subsequent surveys to be conducted by the DHHS Secretary. The section requires the DHHS Secretary to take into account GAO's recommended methodology and frequency and conduct periodic subsequent surveys to determine hospital acquisition costs. The GAO and Secretarial surveys shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified drug. The GAO shall report to Congress if there is, and the extent of, any variation in hospital acquisition costs for drugs among hospitals based on the volume of services performed or other relevant characteristics determined by the GAO.

MedPAC is also required to submit a report to the DHHS Secretary on the payment adjustment to APCs for specified covered outpatient drugs that take into account overhead and related expenses.

Section 621 also reduces the threshold from \$150 to \$50 per administration for establishing separate APC payments for drugs and biologicals furnished in 2005 and 2006. The separate APC groups are not eligible for outlier payments. Starting in CY 2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract will equal the average price of the drug or biological for all competitive acquisition areas calculated and adjusted by the DHHS Secretary for that year.

For brachytherapy devices consisting of a seed or seeds furnished on or after January 1, 2004 and before January 1, 2007, payments will be based on the hospital's charges for each device furnished, adjusted to cost. Charges for such devices shall not be included in determining any outlier payment. The GAO is required to conduct a study and report to Congress no later than January 1, 2005 on an appropriate payment amount for such devices.

The provision is estimated to increase HOPD payments by \$700 million over 10 years. The additional expenditures that result from the changes will not be taken into account in establishing the conversion, weighting and other adjustment factors for 2004 and 2005, but will be taken into account in subsequent years.

## **II. Medicaid Hospital Payment Provisions**

- **Increase in State Medicaid DSH Allotments**

Current Law. The provisions in BIPA that prevented BBA-scheduled cuts to state Medicaid Disproportionate Share Hospital (DSH) allotments expired on October 1, 2002. The subsequent FY 2003 cuts eliminated over \$1.3 billion in allotments (10 percent) and affected 37 states.

Current law establishes a “floor” whereby a state’s Medicaid DSH allotments cannot fall below 1 percent of its Medicaid spending. It also caps a state’s allotment at 12 percent of its Medicaid spending. State Medicaid DSH payments to hospitals may not exceed 100 percent of a hospital’s uncompensated care costs.

P.L. 108-173. Section 1001 sets FY 2004 state Medicaid DSH allotments at 116 percent of FY 2003 levels. The provisions then freeze allotments at FY 2004 levels until the year in which they fall below BBA-scheduled levels. State allotments will then increase by inflation. In addition, the provisions temporarily raise the 1 percent “floor” by 16 percent over five years (FY 2004 through FY 2008).

### **III. Provisions Related to Physicians**

- **Revised Physician Payment Update for CY 2004 and CY 2005**

Current Law. Under the annual Medicare Physician Fee Schedule, CMS assigns relative value units (RVU)s to each service to reflect the physician work, practice expenses, and malpractice costs of providing that care. The RVUs are subsequently adjusted for geographic cost variations and then converted into a payment by an annually updated conversion factor.

To calculate the conversion factor update, CMS uses the Sustainable Growth Rate (SGR) methodology, which sets an annual spending target for Medicare expenditures on physician services. If overall physician spending misses the target in any given year, payments are adjusted upward (positive update) or downward (negative update) in subsequent years to compensate for the disparity.

In February 2003, Congress granted CMS legal protection to correct past calculation errors, which subsequently revised the CY 2003 conversion factor update from an initial negative 4.4 percent to a positive 1.6 percent. Flaws in the SGR methodology remained unaddressed, including a problematic link to changes in the national Gross Domestic Product (GDP). Primarily because the SGR problems remained unresolved, the initial CY 2004 conversion factor was set at negative 4.5 percent.

P.L. 108-173. Section 601 sets the conversion factor update for CYs 2004 and 2005 at “not less than 1.5%.” In CY 2006, the update calculation reverts to the SGR methodology as if the two positive updates did not occur. While the CBO estimates that the provision adds \$2.4 billion in Medicare spending over 5 years, the provisions add \$200 million over ten years, implying substantial reductions in physician updates starting in CY 2006.

In addition, Section 601 replaces the current GDP component in the SGR methodology (which reflects only the GDP for the previous year) with a 10-year rolling average of the GDP. While not stated, the 10-year average is intended to mitigate the impact of sudden declines in the national economy as occurred in 2002, resulting in a disproportionate negative affect on the CY 2003 physician update.

- **Temporary Increase in the “Work GPCI”**

Current Law. In the calculation of Medicare physician payments, the physician work component, practice expense component, and malpractice expense component are each modified by a Geographic Practice Cost Index (GPCI). The GPCI accounts for cost differences in a particular area, versus a national average. Subsequently, areas with costs below the national average (e.g., rural areas) have a GPCI of less than 1.00.

If changes in the GPCI increase total Medicare expenditures on physician services by over \$20 million, CMS must proportionately reduce RVUs for all services to assure budget neutrality.

P.L. 108-173. Section 412 temporarily increases to 1.00 any GPCI for the physician work component that falls below 1.00. The increase applies to physician services provided from January 1, 2004 until January 1, 2007. According to the CBO estimate of P.L. 108-173, CMS will fund the temporary increase with \$1 billion in new money over ten years (i.e., the budget neutrality requirement will not apply). However, the provision contains no language that explicitly prevents a budget neutrality adjustment.

As discussed below, Section 413(c) requires the GAO to evaluate how the location and retention of physicians were affected by the temporary increase in the work GPCI.

- **GAO Study of Geographic Differences in Physician Payments**

Current Law. None.

P.L. 108-173. Under Section 413(c), the GAO will within one year deliver a study to Congress that evaluates geographic payment disparities under the Physician Fee Schedule. The GAO must make recommendations regarding the timeliness of data used to calculate GPICs. It must also address the use of “directly representative” cost data versus the use of cost proxies.

In addition to assessing the “validity” of the geographic adjustment factors for each Fee Schedule component, the GAO will evaluate the elements used in the adjustments (including how frequently elements are revised). The GAO will review how professional liability insurance (PLI) costs in the malpractice component are determined, including any adjustments for premium increases and variations in premium increases among specialties and states. The GAO will also review how PLI premium increases are reflected in the practice expense GPCI and the appropriateness of relative weights for the malpractice component.

As mentioned in the previous section, the study will also evaluate how the location and retention of physicians are affected by the temporary physician work GPCI increase in Section 412. The analysis of the GPCI increase will include all specialties and must account for variations in recruitment costs and retention rates between large urban areas and “other areas”. It must also account for “the mobility of physicians over the last decade.”

- **New Payments and Regulatory Relief for Physicians Serving Shortage Areas**

Current Law. Physicians qualify for a 10 percent add-on to their payment when they provide services in Health Professions Shortage Areas (HPSAs). Physicians must indicate eligibility on their billing forms.

P.L. 108-173. Under section 413(b), the DHHS Secretary is now responsible for identifying claims that qualify for the 10 percent HPSA add-on payment. The provisions only apply to services provided on or after January 1, 2005 in a full-county primary care geographic HPSA. Eligible claims will be identified by the service location’s zip code. The DHHS Secretary must designate all qualifying HPSAs before the start of each calendar year.

Section 413(b) does not explicitly require similar treatment of claims for services furnished in partial-county HPSAs. However, the accompanying conference report language states that the DHHS Secretary would not be precluded from including partial-county HPSAs in the new process “if the DHHS Secretary determines that it is feasible to do so based on information on the Medicare claim form.” In the interim, the CMS website must assure physician access to the partial-county HPSA modifier they must use to identify claims eligibility.

Section 413(a) establishes new “Physician Scarcity Areas.” It also creates a new, temporary 5 percent add-on to physician payments for services provided in the Scarcity Areas from January 1, 2005 until January 1, 2008. According to the accompanying conference report language, the new add-on payment will “make it easier to recruit and retain physicians” in areas with low physician-to-beneficiary ratios. The CBO estimates the new incentive program will cost \$700 million over ten years.

The DHHS Secretary will identify Physician Scarcity Areas according to the number of practicing primary care physicians (PCPs), practicing specialists, and Medicare beneficiaries in every county. Counties/tracts with the lowest PCP-to-beneficiary ratios (up to an aggregate of 20 percent of all Medicare beneficiaries) are identified as “Primary Care Scarcity Counties.” Those with the lowest specialist-to-beneficiary ratios (up to an aggregate of 20 percent of all Medicare beneficiaries) are considered “Specialist Care Scarcity Counties.” Qualifying counties must be identified in the proposed and final

update to the physician fee schedule. They must also be posted on the CMS website. As in the new HPSA claims process, CMS will identify qualifying claims by zip code.

Services provided in counties that are both a Scarcity Area and a full-county HPSA will receive both incentive payments (i.e., a total add-on of 15 percent).

- **Physician Payment Reform for Covered Outpatient Drugs**

*Current Law.* In general, the reimbursement rate for covered outpatient drugs provided in a physician's office is 95 percent of a drug's Average Wholesale Price (AWP). The AWP reflects prices reported by drug manufacturers. However, neither statute nor regulation defines reporting criteria. Physician payment for the administration of such drugs is reflected in the RVUs assigned to relevant services. The DHHS Secretary must periodically review and revise RVUs as necessary. Any changes that increase overall spending by more than \$20 million require offsets from other physician payments to maintain budget neutrality.

*P.L. 108-173.* Under Title III ("Combating Waste, Fraud, and Abuse"), Sections 303 and 304 alter the level of reimbursement for most outpatient drugs provided in a physician's office. The sections also revise payments for administration of drugs by adjusting the Practice Expense component used to calculate physician reimbursement under the Medicare Fee Schedule. The provisions specify when a particular revision will require offsets from other physician payments to maintain budget neutrality. The DHHS Secretary has relatively broad authority to establish exceptions, timelines, deadlines, and adjustments to the reforms outlined below. According to CBO estimates, the reimbursement changes are expected to save the government \$4.2 billion over 10 years.

***Payments Related to Drug Costs***

In general, Sections 303 and 304 set CY 2004 reimbursement for most covered outpatient drugs at 85 percent of their April 1, 2003 AWP. Drugs that the GAO and the Office of Inspector General (OIG) identified as being sold at large discounts (i.e., Medicare significantly overpaid for the drugs) are reimbursed at percentages below 85 percent, but not less than 80 percent of AWP. Certain exceptions apply to clotting factors, several vaccines, and other explicitly defined products, which will continue to be reimbursed at 95 percent of AWP. To help mitigate CY 2004 reductions in reimbursement, Section 303 provides a temporary "transitional" 32 percent add-on to payments for covered drugs.

In CY 2005, covered outpatient drugs are, in general, reimbursed at 106 percent of their Average Sales Price (ASP). The ASP is calculated by dividing the manufacturer's actual sales revenue by the number of units sold. The calculation excludes sales to the government, Public Health Service grantees, and certain other entities, but includes discounted payments, rebates, and similar payment mechanisms. Also in CY 2005, single-source drug costs are reimbursed at the lower of either 106 percent of ASP or 106 percent of the wholesale acquisition cost. Physicians receive a second year of transitional add-on payments in CY 2005, but at a significantly lower level (3 percent) versus the previous year.

The DHHS Secretary has authority to adjust reimbursement levels, including reduction of an ASP that “exceeds the widely available market price or the average manufacturer price” for a drug.

In CY 2006, CMS begins phasing in a new option that allows physicians to purchase covered outpatient drugs from entities selected by DHHS through a competitive bidding process. Physicians may select from the two options on an annual basis. A DHHS impact study of the new option is due to Congress by July 1, 2008.

### ***Payments for Administration of Drugs***

Sections 303 and 304 modify the Practice Expense component related to the administration of certain drugs. The modifications adjust for oncology nurse salaries and sets the Physician Work RVUs for non-chemotherapy and chemotherapy drug administration codes at a Level I visit for an established patient. The initial changes should be reflected in the CY 2004 Fee Schedule. They are exempt from the budget neutrality provisions which otherwise might require offsets from other physician payments. Specialties that derive at least 40 percent of their Medicare revenues from drug-related services may propose additional changes in the Practice Expense component by submitting supplemental practice expense data to the DHHS Secretary.

The provisions in Section 303 also direct the DHHS Secretary to “promptly” review reimbursement policies in effect as of October 1, 2003 for multiple chemotherapy agents furnished on a single day through the “push technique”. Neither the statutory language nor the accompanying conference report language defines “promptly” as it relates to timetables and deadlines. According to the provisions, the DHHS Secretary will modify the payment policy as he/she “determines to be appropriate.” While its recommendations are non-binding, the accompanying conference report language strongly urges CMS to pay for “multiple pushes”. If the DHHS Secretary’s decision triggers significant payment increases, they will not require cost offsets in CY 2004, CY 2005, or CY 2006.

### ***Impact Studies for Congressional Review***

Under Section 303, Congress will, by January 1, 2006, receive a report from MedPAC regarding the impact of payment changes on oncologists. MedPAC will deliver a similar study regarding other affected specialties by January 1, 2007. The provisions also call for studies by the OIG and other entities regarding payment adequacy, the cost efficiencies of the new direct-purchase option, and other issues of concern to physicians.

- **Electronic Prescribing Program**

Current Law. Current Medicare statute does not address the creation of standards for an electronic prescribing program. However, the “Administration Simplification” provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) directed the DHHS Secretary to develop transaction and security standards for electronic medical records and claims. The standards, which were intended to reduce administrative costs to health plans and providers, include uniform transaction formats, code sets for transaction

data, unique health identifiers, security standards, and electronic signatures for verification. Plans and providers must comply with the standards and face strong penalties for non-compliance and accessing/disclosing personally identifiable information.

*P.L. 108-173.* Section 1860 D-4 calls for the implementation of electronic prescribing standards to reduce medical errors and improve efficiencies in the health care system. The standards, which must be implemented no later than April 2009, will help serve as the foundation for electronically transmitted medical histories.

By September 1, 2005, the DHHS Secretary must develop initial electronic prescribing standards for drugs covered by the new Medicare benefit (“Part D drugs”). The standards must encompass the transmission of eligibility and benefit information, prescribed drug information, patients’ medication histories, and details on potentially lower-cost alternative drugs. They must also support quality assurance systems (e.g., drug interaction alerts) and allow beneficiaries to designate their pharmacies of choice. The electronic prescription standards may supercede state laws, with some exceptions.

The standards must reflect recommendations from the National Committee on Vital and Health Statistics, which will work in consultation with industry experts, physicians, hospitals, pharmacies, and other entities. The standards must be compatible with HIPAA’s administrative simplification standards, and language in both Section 1860 D-4 and the accompanying conference report language state that “to the extent practicable” the standards may not impose “undue administrative burden” on prescribing physicians and pharmacists. The standards must also permit the electronic exchange of drug labeling and drug listing information from the Food and Drug Administration and the National Library of Medicine. Additionally, both the law’s provisions and the accompanying conference report language state that, “to the extent feasible”, the standards should support the creation of a prescribing program that operates on an interactive, real-time basis.

On January 1, 2006, prior to the promulgation of final standards, the DHHS Secretary must implement a one-year pilot project to test the initial standards. Practice groups, hospitals, pharmacies, drug benefit plans, and other prescribing entities may volunteer to participate in the pilot. Section 1860 D-4 exempts the pilot testing of standards already having “adequate industry experience”. The HIPAA privacy rule applies to any information disclosed via an electronic prescribing program. The DHHS Secretary must evaluate the pilot and report to Congress before April 1, 2007, with final standards published by April 1, 2008.

With the understanding that hospitals, physician practices, Medicare drug benefit sponsors, and Medicare managed care plans could likely raise self-referral concerns by providing medical staff, practice members, network pharmacists, and network providers with hardware, software, information technology, and training services, Section 1860 D-4 directs the DHHS Secretary to exempt the activities from the self-referral law in Section 1877 of the Social Security Act (SSA). The exemptions apply only if the items are used

solely to receive and transmit electronic prescription information in accordance with Part D standards. The DHHS Secretary will also establish legal “safe harbors” from the anti-kickback laws in Section 1128B(b) of the SSA.

Section 108 authorizes the DHHS Secretary to award \$50 million in grants in FY 2007 to help physicians comply with the new electronic prescription standards. Preference is given to physicians serving a disproportionate number of Medicare patients or rural/underserved areas. “Such sums as may be necessary” are authorized for FY 2008 and FY 2009. Physicians must cover at least 50 percent of their own implementation/compliance costs, and they must assure the grants are used as intended. They may use the funds to: purchase, lease, and install hardware and software; make upgrades and other improvements; and provide education and training to eligible physician staff on the use of technology.

Finally, the accompanying conference report language clearly states that an electronic prescribing program should not be used “as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians.”

- **Voluntary Chronic Care Improvement Programs**

*Current Law.* None. However, CMS coordinates several ongoing disease management demonstration projects that serve Medicare beneficiaries with congestive heart failure, diabetes, or coronary heart disease. The CMS demos include both fee-for-service and managed care models. The disease management programs are intended to improve the health of Medicare beneficiaries and reduce program costs.

*P.L. 108-173.* Section 721 directs the DHHS Secretary to develop, test, and implement chronic care improvement (CCI) programs for Medicare fee-for-service beneficiaries diagnosed with congestive heart failure, diabetes, chronic obstructive pulmonary disease, or other conditions to be determined. The purpose of the programs will be to improve the clinical quality, patient satisfaction, and cost efficiencies associated with chronically ill beneficiaries. Beneficiary participation in a CCI program is voluntary, and beneficiaries may withdraw at any time.

Under Section 721, Chronic Care Improvement Organizations (CCIOs) will contract with DHHS to provide CCI programs (directly or via subcontractors). Eligible contractors include disease management organizations, insurers, integrated delivery systems, physician groups, a consortium of such entities, or others determined by the DHHS Secretary. The contract agreement will include performance standards, including clinical quality and spending targets.

Each CCIO must provide beneficiaries with resources to assure compliance with a care plan, including self-care education and interactive monitoring technologies. The CCIOs will adhere to evidence-based practice guidelines and other criteria determined by the DHHS Secretary. They must also develop a clinical information database to track patients and evaluate outcomes (the new law does not include funding for information

technology). The CCIOs will enhance collaboration with community providers by conducting education programs.

In general, payments to CCIOs are computed on a per member/per month basis. A CCIO must refund any payments that exceed the estimated Medicare savings generated by CCI programs. Additionally, payments may be adjusted if a CCIO fails to meet the performance standards specified in their contract. The chronic care initiative is budget-neutral, placing CCIOs at financial risk for costs that exceed their payments.

### ***Demonstration Projects***

The new law states that by December 9, 2004 at least one CCIO must be enrolled in a 3-year DHHS demonstration project to develop and evaluate CCI programs “using randomized controlled trials.” Demonstration projects must be located in areas representing at least 10 percent of all Medicare beneficiaries. The areas must contain at least 10,000 eligible CCI program beneficiaries, as well as a “control population” enrolled in Medicare Part A and/or Part B.

A contractor with experience in chronic care management programs will evaluate each demonstration project. The evaluation will assess a demonstration project’s quality improvement measures (e.g., rehospitalization rates), patient and provider satisfaction rates, health outcomes, and financial outcomes.

### ***Program Expansion***

If the demonstration projects prove effective in meeting clinical, customer service, and spending targets, the DHHS Secretary will expand the program into additional geographic areas (or nationally). The expansion will occur at least two years after the first demonstration project begins, but no later than six months after the last project concludes. The DHHS Secretary will evaluate the new CCI programs in a manner similar to that used in the demonstration projects. While the new law states that it will appropriate “such sums as necessary” for CCI program expansion, total program costs may not exceed \$100 million over 3 years (beginning October 1, 2003)

### ***Reports***

The DHHS Secretary must, no later than December 2005, submit an interim report to Congress on the scope, design, preliminary costs, and quality findings of the existing CCI programs. An updated report must be submitted no later than June 2007.

Within two years of submitting the updated report, the DHHS Secretary shall provide Congress with two additional biennial reports on the CCI programs. The two reports will address the scope, design, financial efficiencies and outcomes related to CCI programs and organizations.

- **Medicare Care Management Performance Demonstration**

Current Law. None. However, CMS coordinates several ongoing Medicare case management demonstration projects (“demos”), particularly regarding chronic care. The

CMS demos include both fee-for-service and managed care models. The programs are intended to improve the health of Medicare beneficiaries and reduce program costs.

*P.L. 108-173.* Section 649 establishes a three-year pay-for-performance demonstration program to encourage physician adoption of health information technology and evidence-based outcomes measures. Physician use of information technology and outcomes measures are expected to promote continuity of care, help stabilize conditions, maximize management of chronic conditions, and reduce adverse outcomes such as drug interaction.

The demo is limited to four sites, with two in an urban area, one in a rural area, and one in a state having a medical school with a Department of Geriatrics. The urban demonstration programs may enroll any Medicare beneficiary who receives Part A and B and is not in a managed care plan. The beneficiaries must have at least one chronic condition (which may include “cognitive impairment”). The rural and medical-school-related sites must enroll beneficiaries having at least two chronic conditions. One condition must be dementia.

Section 649 directs the DHHS Secretary to contract with quality improvement organizations (QIOs) to enroll and evaluate physician participants. Physicians must agree to adopt pre-selected clinical health information technology over the three-year period and also consent to electronic reporting requirements (to be established by the DHHS Secretary). The QIOs will provide related technical assistance and training as needed. Participating physicians must serve as the patient’s primary source for accessing Medicare services. Additional responsibilities include assuring a continuity of care across providers/settings, using evidence-based guidelines and outcome measures to be determined by the DHHS Secretary, promoting self-care, and referring beneficiaries to appropriate community service organizations.

Under Section 649, physicians who meet or exceed “specific performance standards” (to be determined by the DHHS Secretary) will receive a per beneficiary amount. The amount may vary based on performance levels. The payments are funded by the Medicare Trust Fund, but do not represent “new money.” The provisions state that “aggregate payments made by the Secretary” may not “exceed the amount which the Secretary estimates would have been paid if the demonstration program was not implemented.”

Within 12 months of program completion, the DHHS Secretary must submit a report to Congress, including related administrative and legislative recommendations.

#### **IV. Regulatory and Contracting Reforms**

The Bush Administration consistently pressed Congress to include provider regulatory relief and contracting reform in any Medicare modernization legislation that came under consideration. Strong bipartisan and bicameral support for regulatory relief and contracting reforms allowed an early and relatively uncontested agreement on the

provisions in Title IX of P.L. 108-173 (“Administrative Improvements, Regulatory Reduction, and Contracting Reform”).

The provisions in Title IX address inconsistencies, lack of clarity, and excessive provider burdens related to Medicare audits and appeals, the regulatory process, and the selection of administrative contractors. Of the numerous reform provisions are several that teaching hospitals and academic physicians will find noteworthy.

- **Provisions Related to Regulatory Issuance and Compliance**

Current Law. Despite a lack of explicit statutory language regarding the addition of new material to final rules, the courts have repeatedly agreed that the DHHS Secretary may add new material to a final rule if the material is a “logical outgrowth of the proposed rule.” Also, while case law has established a strong presumption against the retroactive application of regulations, no explicit statutory language exists.

P.L. 108-173. Sections 902 and 903 establish that, in general, any measure added to a final rule that is not a “logical outgrowth” of the proposed/interim final rule should be treated as a proposed rule (e.g., solicit public comment). The sections also establish that compliance actions against a provider are limited to services furnished on or after the effective date of the relevant regulatory change. Additionally, the language states that if a provider follows written, yet inaccurate, guidance when offering services or submitting a claim, the provider is not subject to penalty or interest (with some exceptions).

- **Provisions Regarding Contractor Reforms**

Current Law. Part A and Part B contractors are distinct entities that essentially function independently. Insurers are the only entities that may enter into contracts to make Medicare physician payments.

P.L. 108-173. Section 911 consolidates the functions of the Fiscal Intermediaries and Carriers and then places them under the authority of new “Medicare Administrative Contractors” (MACs). The DHHS Secretary must implement a competitive system for selecting/renewing MACs by FY 2006. The DHHS Secretary will select and renew contractors based on performance standards and an evaluation methodology that must be reported to Congress by October 1, 2004. Performance standards will include provider satisfaction levels, claims payment error rates, and the ability to provide DHHS with timely access to records and information. By FY 2012, all contracts will be awarded through the competitive bidding/performance evaluation process.

Additionally, as of October 1, 2004, all Medicare contractors must offer clear, concise, and accurate responses to written provider inquiries within 45 business days. Medicare contractors must also have a toll-free telephone number and website where providers can promptly obtain answers to common billing, coding, claims, and coverage questions.

- **Provisions Regarding Provider Appeals**

***Process for Expedited Access to Review***

Current Law. Generally, administrative appeals must be exhausted prior to judicial review.

P.L. 108-173. Under Section 932, the DHHS Secretary must establish a process whereby a provider, supplier, or beneficiary may obtain access to judicial review when a review entity (up to 3 qualified reviewers drafted from the Administrative Law Judges or Department Appeals Board) determines, within 60 days of a complete written request, that it does not have authority to decide the question of law or regulation and where material facts are not in dispute. The decision is subject to review by the Secretary. This provision is effective for appeals filed on or after October 1, 2004.

***Requirements for “Reviewing Professionals” and Written Notices***

Current Law. None, although determinations and appeal decisions currently address the policy, regulatory, or legal reasons for denials, as well as how to appeal the decisions. BIPA created a new second level of appeal that permits review by healthcare professionals (coordinated by Qualified Independent Contractors), but their role is not yet fully implemented.

P.L. 108-173. Section 933 establishes that written notices of determination, redetermination, or appeal decisions that result in claims denial must address the reasons for denial, how to obtain additional information about the decision, and how to initiate the next step in the appeals process. Notices of redetermination and appeal decisions must also summarize any clinical/scientific evidence used in the decision-making process. All notices must be written in a manner that Medicare beneficiaries would understand.

The Section also requires that “reviewing professionals” (physicians or other healthcare professionals on a review panel) must be legally authorized to provide the services under review and must possess medical expertise in the related field of practice. The DHHS Secretary may not use contingency fees to compensate the Qualified Independent Contractors responsible for coordinating the services of reviewing professionals.

***Provider Enrollment Process: Right of Appeal***

Current Law. None, although CMS has administrative authority to establish enrollment processes in its instructions to contractors.

P.L. 108-173. According to Section 936, within six months of enactment (June 9, 2004), the DHHS Secretary will establish a provider enrollment process that includes a right to hearings/judicial reviews for provider application/enrollment denials or non-renewals. The hearings will apply to denials that occur one year after enactment. The DHHS Secretary will also set contractor deadlines for acting on provider enrollment applications and renewals (the timeliness of contractors will be a performance measure during the competitive bidding process discussed in “*Provisions Regarding Contractor Reforms*”). As of January 1, 2004, any changes in provider enrollment forms must be made in consultation with Medicare providers.

- **Provisions Related to Provider Audits**

***Random Prepayment Reviews (audits without cause)***

Current Law. None, although CMS has administratively granted contractors the right to use random prepayment reviews to develop program-wide and contractor-wide error rates.

P.L. 108-173. Section 934 explicitly limits random prepayment reviews by MACs to program-wide or contractor-wide analyses. MACs must adhere to a review process to be established by the DHHS Secretary.

***Non-Random Prepayment Reviews***

Current Law. None, although such reviews are permitted by CMS under certain circumstances.

P.L. 108-173. Section 934 states that within one year of enactment, initial identification of a provider billing error may not trigger a prepayment review unless “there is a likelihood of sustained or high level payment error.” The DHHS Secretary must establish regulations regarding the termination of a non-random prepayment review (including maximum duration). The DHHS Secretary may vary the duration of such reviews “based upon differences in the circumstances triggering prepayment review.”

***Post-Payment Audits***

Current Law. None.

P.L. 108-173. Section 935 states that if a contractor plans to conduct a post-payment audit, the provider must receive a written notice of the contractor’s intent (electronic notification is acceptable). Unless such information would compromise related law enforcement activities, the contractor must give the provider an “understandable” explanation of findings, their right to appeal, and any consent settlement options. The contractor must also allow the provider to present additional information.

***Notice of Over-Utilizing Billing Codes***

Current Law. None.

P.L. 108-173. Section 935 directs the DHHS Secretary to (within one year of enactment) establish a process for notifying providers that their contractor has identified their possible over-utilization of certain billing codes. The DHHS Secretary will work in consultation with providers when developing the process.

- **Provisions Related to Recovery of Overpayments**

***Extrapolation of Overpayment Amounts to be Recovered***

Current Law. None.

P.L. 108-173. Beginning one year after enactment, Section 935 limits the use of extrapolation unless there is a “sustained or high level of payment error,” as defined by the DHHS Secretary. Extrapolation is also allowed when documented educational intervention has failed to remedy the cause of such errors.

### ***Provider Repayment Plans***

Current Law. CMS has the authority to negotiate extended provider repayment plans. However, no explicit statutory language exists.

P.L. 108-173. Section 935 establishes a new recovery option if repayment within 30 days constitutes a “hardship” for a provider. To qualify, a provider that files Medicare cost reports must show that the overpayments exceed 10 percent of the provider’s Medicare payments, according to the most recently filed cost report. If the provider does not file cost reports, the overpayments must exceed 10 percent of the provider’s Medicare payments for the previous calendar year.

Under the new option, providers could repay the amount over 6 months to 3 years, as determined by the DHHS Secretary. If the DHHS Secretary determines that the provider faces “extreme hardship” (no explicit definition), the repayment plan could last up to 5 years. If the DHHS Secretary suspects that the provider may cease business or discontinue Medicare participation, the option is withdrawn and the DHHS Secretary may demand immediate repayment of the outstanding balance (with interest).

- **Other Provisions of Interest**

### ***Correcting Minor Claims Errors and Omissions without Appeals Process***

Current Law. None.

P.L. 108-173. Section 937 directs the DHHS Secretary to work with contractors and providers to establish (within one year of enactment) a process whereby providers may correct minor claims errors without initiating an appeals process. “Minor errors” include a provider’s omissions or other errors as defined by the DHHS Secretary. The process must include allowing a provider to resubmit a corrected claim.

### ***Mediation Process for Local Coverage Determinations***

Current Law. Only beneficiaries may appeal local coverage decisions by Medicare contractors. Medicare-related disputes between any entities are not resolved via mediation.

P.L. 108-173. Section 940A directs the DHHS Secretary to establish a mediation process for resolving disputes between providers and contractors. The process will be led by a CMS-employed physician trained in mediation, and it may be implemented when a CMS regional administrator identifies a large number of complaints from providers regarding a decision by a contractor’s medical director.

### ***Pilot Testing New E&M Documentation Guidelines***

Current Law. None.

P.L. 108-173. Section 941 states that the DHHS Secretary may not implement any new or modified E&M documentation guidelines unless they are developed in collaboration with practicing physicians and tested via one-year voluntary pilot projects to be analyzed by MedPAC. The pilot programs must conclude within one year. At least one pilot must be conducted in a “teaching setting”. Under Section 941, the changes must reduce paperwork burdens on physicians.

### ***EMTALA Improvements***

Current Law. Hospitals that violate the Emergency Medical Treatment and Labor Act (EMTALA) requirements may face subsequent fines or termination of their provider agreement. Before imposing a civil monetary penalty, the DHHS Secretary must request a review by a Peer Review Organization (PRO). With some exceptions, the DHHS Secretary allows a 60-day period for a PRO review.

P.L. 108-173. Section 944 states that, upon enactment, the DHHS Secretary must request a PRO review before issuing an EMTALA compliance determination that would terminate program participation (unless the delay threatens health or safety). The DHHS Secretary must allow 5 business days for the review and notify the hospital and physician(s) when the investigation concludes. The PRO must provide the hospital and physician(s) with a copy of their final report.

Under Section 944, when determining payment for EMTALA-mandated services provided after January 1, 2004, Medicare must establish whether a service was “reasonable and necessary” based on the information available to the treating provider at the time the services were ordered (e.g., a patient’s presenting symptoms or complaints, not their principal diagnosis). In its analysis, Medicare must exclude the frequency with which the service was provided to a patient before or after the visit/admission.

Section 945 creates an EMTALA Technical Advisory Group to review related issues and advise the DHHS Secretary accordingly. While Section 945 requires at least one public hospital and several physician specialty members on the Advisory Group, it does not mandate representation by teaching hospitals or teaching physicians.

## **V. Miscellaneous Provisions**

- **Federal Reimbursement for Emergency Services for Undocumented Aliens**

Current Law. From FY 1998 through FY 2001, the BBA made available \$25 million annually to fund emergency services provided to undocumented aliens. The funding was directed to the 12 states with the highest number of undocumented aliens (California, Texas, New York, Florida, Illinois, New Jersey, Arizona, Massachusetts, Virginia, Washington, Colorado, Maryland). A state’s allotment was based on its share of total

undocumented aliens within the 12 states (using Immigration and Naturalization Service data).

*P.L. 108-173.* Section 1011 establishes \$250 million in temporary state allotments for each of FYs 2005, 2006, 2007, and 2008 to pay physicians, hospitals, and ambulance services for health care services provided to undocumented aliens. Qualifying services include those required under EMTALA, as well as “related hospital inpatient and outpatient services and ambulance services” as identified by the DHHS Secretary. The Section states that the funds are to be appropriated out of “any funds in the Treasury not otherwise appropriated.”

The temporary allotments will be divided among all 50 states (as described below), but disbursed directly from the DHHS Secretary to providers. Hospitals are granted the option of receiving payments for both hospital and physician services. They must then disburse the appropriate physician payments without charging an administrative fee. Alternatively, hospitals may opt to receive payments for their services, plus a portion of any on-call physician payments they made.

In each of the specified years, \$167 million (about two-thirds) will be distributed among the 50 states according their share of the total undocumented alien population, using Immigration and Naturalization Service (INS) data. A January 2003 INS report suggests that California, Texas, New York, Illinois, Florida, and Arizona might receive the greatest percentages of the \$167 million in FY 2005.

The remaining third of allotment funds (\$83 million) is distributed among the 6 states with the highest number of “undocumented alien apprehensions,” as reported by the Department of Homeland Security. The January 2003 INS report indicates that California, Texas, Arizona, Michigan, Louisiana, and New York would likely qualify, and that California and Texas would receive over one-half of the \$83 million.

The DHHS Secretary is directed to establish a new reimbursement methodology for services rendered to illegal aliens. If the actual cost of service is less than the newly established payment level, the provider will receive the lower reimbursement. Under the new methodology, The DHHS Secretary may establish different formulas for different provider types and may use cost-to-charge ratios to calculate individual hospital reimbursements.

Under Section 1011, payments are made quarterly, and the DHHS Secretary may impose a “pro-rata” reduction on a state’s payments if reimbursement levels exceed a state’s allotment. In some instances, providers may apply for advance payments.

- **Medicare Quality Demonstration Programs**

*Current Law.* None. However, CMS has already coordinated/collaborated with several initiatives intended to improve the health of Medicare beneficiaries and reduce program costs.

P.L. 108-173. Section 646 establishes five-year “Medicare Healthcare Quality Demonstration Programs” to examine what healthcare delivery factors promote quality and cost efficient Medicare services. The programs will evaluate the effectiveness of incentives to improve safety of care, “best practices,” utilization and outcomes research, shared decision-making (patient-physician), and culturally/ethnically sensitive care. The programs should also evaluate the financial impact of altering incentives/resource allocation within markets.

“Health Care Groups,” defined as physician groups, integrated delivery systems, regional coalitions of health systems and other appropriate entities determined by the DHHS Secretary would be eligible to participate in the demonstration program. (The section dictates that the DHHS Secretary may designate a hospital as an appropriate “health care group.”) Participating entities must maintain continuous quality improvement mechanisms to integrate community-based support services, primary care and referral care; actively promote effective care delivery; encourage “patient participation in preference-based decisions;” have mechanisms to coordinate/integrate service delivery; and be able to measure and document the financial impact of altering incentives and re-allocating resources in order to improve quality and efficiencies.

Although Section 646 allows participating providers to propose “alternative payment systems,” the provision is budget neutral (i.e., it provides no additional funding for increasing reimbursements or assisting with program expenses). Participating “health care groups” would be allowed to modify benefits under Medicare Fee for Service or Medicare Advantage.

Section 646 also authorizes the DHHS Secretary to request the Director of the National Institutes of Health to expand its efforts to evaluate medical technologies and evidence-based practices. The DHHS Secretary may allow the Agency for Healthcare Research and Quality Administrator to “use the program ... as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate” relevant information to program participants. Section 646 also authorizes the DHHS Secretary to link demonstration program participants to relevant CMS claims data, when appropriate.

- **Coverage of Costs Associated with Clinical Trials**

Current Law. No explicit statutory authorization regarding clinical trials. Under existing authorities, Medicare covers the routine costs of qualifying clinical trials which includes items or services typically provided absent a clinical trial and items or services needed for the diagnosis of treatment of complications. Medicare does not pay for certain aspects of the clinical trial including: the investigational item or service, items and services not used in the direct clinical management of the patient, and items and services customarily provided by the research sponsor free of charge for any enrollee in the trial. Under separate regulation, trials are put into Category B, for which payment may be available, or Category A, for which no payment is available.

P.L. 108-173. Section 731 extends coverage of routine costs incurred on and after January 1, 2005 associated with “qualifying” clinical trials of Category A (experimental/investigational) devices if certain conditions are met. One of the criteria for a qualifying clinical trial is that the device “has been determined by the DHHS Secretary” to be “intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.” The provision does not apply to or affect Medicare coverage or payment for a non-experimental/investigational (Category B) device.

Section 733 also requires the DHHS Secretary to conduct a clinical investigation of pancreatic islet cell transplantation which includes Medicare beneficiaries. Beginning no earlier than October 1, 2004, the DHHS Secretary is required to pay for routine costs as well as transplantation and appropriate related items and services for Medicare beneficiaries who are participating in such a trial.

- **Including the Costs of Indirect Medical Education in Payments to Medicare Advantage Plans**

Current Law. Under current law, Medicare Plus Choice plans are paid monthly for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: 1) a minimum payment rate; 2) a rate calculated as a blend of an area-specific (local) rate and a national rate; or 3) a rate reflecting a minimum increase from the previous year’s rate.

P.L. 108-173. Section 211 adds a fourth payment mechanism so that Medicare Advantage (previously known as Medicare Plus Choice) plans will be paid the highest of the floor, minimum percent increase, the blend, or a new amount beginning in 2004. The new MA payment amount will “equalize payments with fee for service” and base plan payments on approximately 100 percent of fee for service costs. The costs associated with Indirect Medical Education, but not direct graduate medical education will be included in the calculation of the payment rate. The increase in plan payments will not affect IME payments that teaching hospitals will receive when they treat MA enrollees.

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Group on Faculty Practice Representatives  
Group on Resident Affairs

## Glossary of Acronyms

<b>AAMC</b>	Association of American Medical Colleges
<b>APC</b>	Ambulatory Payment Classification
<b>ASP</b>	Average Sales Price
<b>AWP</b>	Average Wholesale Price
<b>BBA</b>	The Balanced Budget Act of 1997
<b>BIPA</b>	The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000
<b>CBO</b>	Congressional Budget Office
<b>CCI</b>	Chronic Care Improvement
<b>CCIO</b>	Chronic Care Improvement Organization
<b>CMS</b>	The Centers for Medicare and Medicaid Services
<b>CPI</b>	Consumer Price Index
<b>CY</b>	Calendar Year
<b>DGME</b>	Direct Graduate Medical Education
<b>DHHS</b>	The Department of Health and Human Services
<b>DRG</b>	Diagnostic Related Group
<b>DSH</b>	Disproportionate Share Hospital
<b>E&amp;M</b>	Evaluation and Management
<b>EMTALA</b>	Emergency Medical Treatment and Labor Act
<b>FFS</b>	Fee for Service
<b>FTE</b>	Full Time Equivalent
<b>FY</b>	Fiscal Year (refers to the Federal Government's Fiscal Year (October 1-September 31))
<b>GAO</b>	General Accounting Office
<b>GDP</b>	Gross Domestic Product
<b>GPCI</b>	Geographic Practice Cost Index
<b>HCPCS</b>	Healthcare Common Procedure Coding System
<b>HIPAA</b>	Health Insurance Portability and Accountability Act of 1996
<b>HPSA</b>	Health Professions Shortage Area
<b>IME</b>	Indirect Medical Education
<b>INS</b>	Immigration and Naturalization Service
<b>IRF</b>	Inpatient Rehabilitation Facility
<b>IRP</b>	Initial Residency Period
<b>MA</b>	Medicare Advantage
<b>MAC</b>	Medicare Administrative Contractor
<b>MB</b>	Market Basket
<b>MedPAC</b>	Medicare Payment Advisory Commission
<b>MGCRB</b>	Medicare Geographic Classification Review Board
<b>OIG</b>	Office of the Inspector General
<b>OPPS</b>	Outpatient Prospective Payment System
<b>PCP</b>	Primary Care Physician
<b>PLI</b>	Professional Liability Insurance
<b>PRO</b>	Peer Review Organization
<b>PPS</b>	Prospective Payment System

<b>PRA</b>	Per Resident Amount
<b>QIO</b>	Quality Improvement Organization
<b>RVU</b>	Relative Value Unit
<b>SGR</b>	Sustainable Growth Rate
<b>SSA</b>	The Social Security Act