

# Congress Approves Medicare, Medicaid Changes

July 18, 2008

In what is becoming an annual ritual, Congress on July 15, 2008, approved legislation (H.R.6331) that reverses a 10.6 percent reduction in Medicare payments to physicians. This year's process, however, was more exciting and unpredictable than most, because Congress approved the measure over a presidential veto.

In addition to the physician payment relief, the legislation also makes various other changes that provide payment and regulatory relief to dozens of other Medicare and Medicaid stakeholders, including medical equipment suppliers, clinical laboratories, hospitals, therapy providers and dialysis facilities.

As the name would suggest, the Medicare Improvements for Patients and Providers Act of 2008 (the Act) is mostly good news for program beneficiaries and health care service providers, but less welcomed by managed care organizations, which were forced to bear much of the cost of the physician payment bail-out.

This *White Paper* provides an overview of the most significant Medicare- and Medicaid-related provisions in the Act.

## Physician Services

### PAYMENT UPDATE

The centerpiece of the legislation is a provision that blocks the Centers for Medicare & Medicaid Services (CMS) from implementing a 10.6 percent reduction in Medicare payment amounts for physician services. Medicare statute requires CMS to adjust the payments to physicians up or down depending on how actual expenditures compare to a variety of inflation indices. In recent years, the update formula has repeatedly required negative updates; for 2008, the payment formula required that payments for physician services be reduced by 10.1 percent. Because the update formula repeatedly requires that physician payments be reduced, Congress has intervened each year since 2003 to block the payment reductions.

In late 2007, Congress stepped in again with legislation blocking this 10.1 percent reduction, but the approved bill provided relief for only the first six months of 2008. Congress worked throughout much of the first half of the year to avoid what had grown to a 10.6 percent reduction that would become effective July 1, 2008. On June 24, 2008, the House approved a bill that would have avoided the cut with overwhelming bipartisan support, 355-59. The Senate, however, failed to muster enough votes when it considered the same bill two days later, and Congress adjourned the next day for its annual July 4 recess without approving the needed relief.

Consequently, CMS implemented the 10.6 percent cut effective July 1, but directed its contractors to temporarily withhold payments in anticipation of congressional action following the recess. The Senate voted again on the House-approved bill on July 9, this time easily approving the measure, 69-30. Nine Republicans, who previously voted against the bill, succumbed to intense lobbying pressure from physicians and voted for the bill the second time around.

The President, who had consistently objected to the mechanism by which the bill would offset the increased expenditures necessary to reverse the physician pay cuts, vetoed the legislation on July 15. For just the third time during the Bush presidency, Congress overrode the President's veto that same day, thereby making the legislation law.

The Act reverses the 10.6 percent cut that became effective July 1 and instead continues payments at the same level as set for the first half of the year. The Act further averts a payment fall-off in 2009 by providing for a 1.1 percent update in lieu of the statutory formula-driven update.

### PHYSICIAN QUALITY REPORTING INITIATIVE

The Act also directs CMS to continue to offer an incentive payment to physicians and other eligible professionals who report quality information consistent with measures established by the agency. The legislation increases the incentive payment from 1.5 percent to 2 percent for 2009 and 2010. The current pay-for-reporting program is viewed by many as the precursor to a pay-for-performance program. Consistent with this expectation, the legislation requires CMS to provide Congress by May 1, 2010, with a plan and recommendations for legislation necessary to transition to a value-based purchasing program.

## INCENTIVES FOR E-PRESCRIBING

Previous efforts to encourage adoption of e-prescribing technology did not provide a financial incentive to the health care professional or group practice, for whom the technology represented an expense with unquantified benefits. Promotion efforts were typically directed at Medicare Part D plan sponsors and other organizations that were better situated to administer an electronic prescribing program or to create a user community with donated technology. However, the most recent electronic prescribing initiative delivers a tangible benefit directly to professionals and group practices in the form of increased compensation.

The approved legislation includes electronic prescribing incentives that allow for payment of an additional 2 percent of the allowed charges for covered professional services in 2009 and 2010; 1 percent in 2011 and 2012; and 0.5 percent in 2013, provided that the professional or group practice meets the criteria of a “successful electronic prescriber.” Eligible professionals and group practices that are not successful electronic prescribers shall receive a reduced percentage of the fee schedule amount: 99 percent in 2012, 98.5 percent in 2013 and 98 percent for 2014 and each subsequent year, unless they apply for and receive a hardship exception. No incentive will be paid if the allowed charges for the codes to which the electronic prescribing incentive applies are less than 10 percent of the total of the allowed charges for covered professional services furnished by the professional or group practice, or, if determined appropriate by the Secretary, the professional or group practice does not submit a sufficient number of electronic and non-electronic prescriptions under Part D. To be a successful electronic prescriber, a professional or group practice must report electronic prescribing quality measures in at least 50 percent of the professional’s or group practice’s applicable cases, or, alternatively at the Secretary’s option, the professional or group practice must electronically submit a sufficient number, as determined by the Secretary, of prescriptions under Part D. The electronic prescribing systems used must be in compliance with standards established under the Part D Electronic Prescribing Program. The incentive amounts paid to physicians could potentially range from \$2,000 to \$4,500, depending on final implementation details approved by the Secretary.

The availability of a tangible financial incentive should prompt professionals and group practices to more readily adopt electronic prescribing solutions. The incentives may offset costs associated with adopting electronic prescribing technology, and, in combination with other recent initiatives such as electronic prescribing of controlled substances and adoption of interoperable electronic prescribing standards, enable professionals and group practices to adopt more complete electronic prescribing capabilities. The benefits accrued from wider adoption of electronic prescribing will potentially be enjoyed throughout the health care system in the form of reduced errors, more efficient transactions and lower cost.

## GEOGRAPHIC ADJUSTMENT FACTORS

Medicare adjusts payments to physicians to reflect geographic variations in the costs of furnishing services. Through the Medicare Modernization Act (MMA), Congress set a floor whereby the geographic adjustment factor used to determine locality-specific payments could not be below 1.0. Congress has several times acted to extend this provision. The Act not only extends the floor for 18 months, through December 31, 2009, but also increases the minimum geographic adjustment factor to 1.5 beginning January 1, 2009.

## IMAGING SERVICES

Increased program expenditures for imaging services, particularly advanced imaging services such as magnetic resonance (MR) and computed tomography (CT), have been a source of controversy and scrutiny in recent years. Congress and CMS each have taken action to address perceived over-utilization of these services. In the Act, Congress further addresses perceived concerns by providing that effective January 2012, Medicare may only make payment for specified advanced imaging modalities to suppliers that are accredited by an approved accrediting organization. The accreditation restriction will apply to diagnostic MRI, CT and nuclear medicine (including positron emission tomography), although CMS is vested with the authority to expand the list to other modalities. The law specifies that accrediting organizations must be selected for this purpose by January 1, 2010. Suppliers who are accredited before January 1, 2010, by an accrediting organization that ultimately is selected will not need to be re-accredited.

## MENTAL HEALTH SERVICES

The legislation increases payments by 5 percent for specified mental health-related services (*i.e.*, those that are insight oriented, behavior modifying or supportive of interactive psychotherapy) furnished during the period July 1, 2008, through December 31, 2009.

## Medicare Advantage and Part D

The legislation adopts several changes for the Medicare Advantage (MA) and Medicare Part D programs, including new restrictions and prohibitions on MA and Part D plan marketing activities, new regulatory requirements for MA Special Needs Plans (SNPs) and private fee-for-service (PFFS) plans, and a prompt-pay provision for Part D plan sponsors. These changes and others reflect Congress' continued focus on these programs in recent months, as well as the changing dynamics on Capitol Hill since enactment of the MMA.

### NEW MARKETING PROVISIONS FOR MA AND PART D PLANS

In response to numerous reports and testimonials about marketing abuses, Congress included in the Act a variety of new regulatory requirements and prohibitions on certain activities intended to better protect Medicare beneficiaries from inappropriate marketing conduct. The list of prohibited marketing activities by MA organizations and Part D plan sponsors as well as entities acting on their behalf includes the following new (and some old) ideas:

- There may be no "unsolicited means of direct contact" with Medicare beneficiaries, including cold-calling and door-to-door solicitation (the latter already is prohibited by the Medicare Marketing Guidelines).
- No meals may be offered at promotional or sales events, regardless of the meal's value. It is unclear whether CMS will adopt its previously proposed exception to this prohibition (as set forth in its May 2008 proposed rule) to allow snacks and refreshments to be served.
- There may be no cross-selling of non-health-related products during appointments with Medicare beneficiaries.
- No sales or marketing activities may be conducted at educational events or in health care settings where health care is delivered (such as physician offices), although marketing activities in "common areas" of such health care settings may continue.

These statutory prohibitions apply to plan years beginning January 1, 2009, and therefore would not take effect until after the Fall 2008 marketing and annual enrollment period for the 2009 benefit year.

Measures to increase regulatory oversight of agents and brokers marketing MA and Part D plans include several new requirements for MA organizations and Part D plan sponsors: (i) only agents and brokers licensed under state law to sell the respective Medicare products may be used; (ii) MA organizations and Part D plan sponsors must report to the applicable state the termination of any agent and broker, including the basis for termination; and (iii) MA organizations and Part D plan sponsors must comply with any state's request for information about an agent or broker. Although such requirements take effect with the 2009 benefit year, the requirement that MA organizations and Part D plan sponsors train and test (and annually retrain and retest) agents and brokers takes effect upon CMS's adoption of applicable standards (and no later than November 15, 2008).

### MA PLAN PAYMENT REDUCTIONS

One of the cost-savings provisions adopted by Congress is a phase-out of the Indirect Medical Education (IME) component within MA plan payments. Currently, the benchmark amounts established by CMS against which MA plans' bid submissions are compared to determine the plans' monthly capitation rates automatically include an IME payment amount that MA plans may pass on to hospitals for resident training. Effective with the 2010 benefit year, this IME component will be reduced annually until it is phased out entirely. The incremental reduction in the IME component will be an increasing percentage that is intended to reflect the proportion of per capita IME costs that are factored into each benchmark amount.

The Act also reduces the balance of the MA Regional Plan Stabilization Fund. Established under the MMA to provide supplemental funds to regional PPO plans that participate in geographic areas with low MA plan penetration, the fund's initial balance of \$10 billion is supplemented through savings derived through the annual bidding process. Congress already reduced the initial balance twice, and the Act further reduces the balance to \$1, although the supplemental funding mechanism remains in place.

## REGULATORY CHANGES FOR PFFS PLANS AND SNPS

PFFS plans face new provider network requirements as a result of H.R. 6331, which are designed to increase beneficiary access to health care providers. Currently, PFFS plans may meet MA program provider network access standards by establishing payment rates for non-contracted providers that equal or exceed the rates such providers would receive for the same services under traditional Medicare FFS. If a non-contracted provider knows (or has reason to know) that the beneficiary is enrolled in a PFFS plan and the provider renders the service, the provider is “deemed” to participate in the PFFS plan’s network and required to accept the plan’s payment rate.

Effective with the 2011 benefit year, individual market PFFS plans that operate in a geographic area with two or more “network plans” (defined as MA coordinated care plans, network-based MSA plans and reasonable cost reimbursement plans) must meet MA program network access standards through written contractual arrangements. “Deeming” providers to participate in the network would only be a permissible method for meeting access standards in areas served by fewer than two network plans. PFFS plans sponsored by employers also would be required to meet access standards through written contracts with providers, beginning with the 2011 benefit year. Additionally, Congress clarifies that PFFS plan payment rates may vary by specialty, geographic location and other factors, but not utilization.

The Act also eliminates the quality improvement program exception for PFFS and MSA plans, all of which must maintain such programs beginning with the 2010 benefit year.

Congress extends the authority for SNPs through 2010 and maintains the existing moratorium on designation of new disproportionate-share SNPs through the 2010 benefit year. Congress also imposes a new requirement on all SNPs, mandating that all individuals enrolling in the plan for the 2010 benefit year and thereafter must meet the plan’s special needs eligibility criteria. (This is a more stringent enrollment standard than the 90 percent threshold CMS had proposed in its May 2008 proposed rule.) Additionally, SNPs will have to develop and implement care management requirements that are designed specifically for their populations as well as satisfy quality reporting requirements developed by CMS.

Other revisions to SNP provisions, such as a modification to the standard defining a severe or disabling chronic condition and additional requirements for SNPs serving dual-eligible individuals, also are included within the Act.

## PROMPT-PAY REQUIREMENTS AND OTHER NEW STANDARDS UNDER MEDICARE PART D

One of the more significant changes the Act makes to the Medicare Part D program is adoption of a prompt-pay standard for clean claims, effective with the 2010 benefit year. Part D plan sponsors will be required to pay electronic claims within 14 days and paper claims within 30 days of receipt from pharmacies (other than mail-order and long-term care pharmacies), and a financial penalty shall be applied for failure to meet this standard. Additionally, effective with the 2010 benefit year, Part D plan sponsors must incorporate into their contracts with long-term-care pharmacies a provision permitting the pharmacy to have at least 30 days (but not more than 90 days) to submit claims for reimbursement.

The Act also requires that Part D plan sponsors that rely on a standard (such as AWP-15 percent) for pharmacy payment rates must update the standard no less frequently than once per week in order to “accurately reflect the market price of acquiring the drug.” This requirement takes effect with the 2009 benefit year.

Provisions addressing Part D drugs also are amended by the Act. Effective with the 2013 benefit year, the definition of a Part D drug permits coverage of barbiturates used to treat “epilepsy, cancer or a chronic mental disorder” as well as benzodiazepines. Additionally, the Act codifies CMS’s existing requirement that Part D plan formularies include all drugs in those classes and categories of drugs that are of clinical concern, and modifies the “medically accepted indication” standard for Part D, including directing the Secretary to revise the list of drug compendia used to determine medically accepted indications.

Other Medicare Part D-related changes include the permanent elimination of the application of the late enrollment penalty to individuals eligible for low income subsidies, and codification of permissible uses of Part D data.

## Hospitals

The Act includes several provisions that will benefit hospitals, and primarily those in rural areas. The legislation includes two provisions that would substantially improve Medicare reimbursement to hospitals with the sole community hospital (SCH) designation. The first provision allows these hospitals to use cost data from cost reporting years beginning in federal fiscal year 2006 (*i.e.*, October 1, 2005, through September 30, 2006) to determine the hospital-specific, cost-based payment rate, if using such data would improve payment to the hospital. Previously, these facilities could use only cost reports beginning in fiscal years 1982, 1987 or 1996 to determine the most advantageous hospital specific rate.

Additionally, Congress restored hold-harmless protection under the hospital outpatient prospective payment system (HOPPS) for SCHs with not more than 100 beds, and extended it for other rural hospitals also with not more than 100 beds. Under this provision, eligible hospitals with adjusted costs in excess of HOPPS payments receive a supplemental payment equal to 85 percent of the amount by which the cost amount exceeds the HOPPS payment.

Further, the Act extends by 12 months a provision included in the MMA that reclassified approximately 120 hospitals for purposes of the wage index geographic adjustment factor. Under the new law, these reclassifications will be effective through September 30, 2009.

Finally, the new law revokes the exclusive deeming authority traditionally bestowed upon the Joint Commission. Since the inception of Medicare, the Joint Commission was the sole accrediting organization granted authority by statute to survey hospitals for compliance with Medicare's conditions of participation. Since then, the American Osteopathic Association also has been granted deeming authority. The law revokes the Joint Commission's exclusive statutory authority, thereby encouraging CMS to permit other accrediting organizations comparable authority, and requiring the Joint Commission to compete for deemed status along with other accrediting organizations.

## Laboratories

Among the more noteworthy changes in the new law is a provision repealing a demonstration project establishing a competitive acquisition model for clinical laboratory services. The original demonstration project language was first established under the MMA, but was still being designed and implemented by CMS. The legislation repeals the authorization and mandate outright, thereby stopping the demonstration in its tracks.

In exchange for this much-sought-after relief, the clinical lab community also received a significant reduction in the annual update for lab services. Under the new law, lab service payments under the clinical lab fee schedule will be updated by the consumer price index for urban areas minus 0.5 percent in each of the years 2009 through 2013, rather than by the previously prescribed CPI-U.

The legislation also extends a change originally made by the Benefits Improvement and Protection Act of 2000 (BIPA), and extended three times since by subsequent legislation, that permits independent laboratories with arrangements with hospitals in effect as of July 22, 1999, to bill for the technical component of pathology services provided to inpatients or outpatients of such hospitals. This special exception expired on June 30, 2008, but now is restored retroactively to July 1, 2008, and extended through December 31, 2009.

## Therapy Services

Legislation enacted in 1997 capped annual payments for all outpatient therapy services provided by non-hospital providers at \$1,500 per beneficiary. The payment limits apply to physical, speech and occupational therapy. Subsequent legislation delayed implementation of the therapy caps until 2006. The Deficit Reduction Act of 2005 established a one-year exceptions process whereby beneficiaries can request and be granted an exception from the cap and receive an unlimited amount of therapy services deemed medically necessary by Medicare. Congress acted again in 2006 and 2007 to extend the exceptions process through June 30, 2008. The Act extends this exceptions process for another 18 months, through December 31, 2009.

## Dialysis Services

The Act requires CMS to inflate the composite rate component of the payment formula by 1.0 percent effective January 1, 2009, and by another 1.0 percent effective January 1, 2010.

The new law also requires CMS to implement by January 1, 2011, a payment system under which Medicare would make a single bundled payment for renal dialysis services that would reimburse the facility for all costs related to the composite rate, erythropoiesis stimulating agents, and other drugs and biologicals furnished to the patient, as well as diagnostic laboratory tests.

The new legislation also establishes a pay-for-performance mechanism whereby, effective in 2012, facilities that fail to meet established quality standards will have payments reduced by 2 percent. The law requires CMS to develop quality measures around specified categories. Performance scores used to determine payment penalties will be made available to the public.

## Durable Medical Equipment Suppliers

The MMA required CMS to establish and implement a competitive acquisition program to establish reimbursement rates for select items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). CMS began implementing the competitive acquisition program in 10 markets effective July 1, 2008.

The Act suspends and delays the DMEPOS competitive acquisition program and requires CMS to rebid agreements that took effect in 10 areas effective July 1, 2008. Specifically, the approved Act terminates all contracts awarded before the date of enactment and forbids CMS from making any payments pursuant to such contracts. CMS is now required to rebid all contracts for these areas in 2009. The new bidding process would occur in the same areas initially selected by CMS (except that CMS could no longer include Puerto Rico) and with respect to the same items identified by CMS (except that CMS could no longer include negative pressure wound therapy-related items and services).

The MMA required CMS to expand the competitive acquisition program to 80 areas by 2009. The Act postpones that mandate by two years, thereby requiring the agency to expand the competitive acquisition program to 70 additional areas in 2011. CMS identified the additional areas in June 2008; the agency is not required to re-identify new areas, although CMS is now barred from extending the program to rural and small urban areas, among others.

The Act establishes various new rules that CMS must obey in soliciting and considering bids under the competitive acquisition program. The Act also would require the Inspector General of the U.S. Department of Health and Human Services to monitor and report on the bidding process.

For 2009, Medicare payments for the items initially selected to be subject to a competitive acquisition program would be cut by 9.5 percent; payments for all other items would be inflated by an amount equal to the consumer price index.

## Ambulance Services

Medicare pays for ambulance services on the basis of a blend between a fee schedule. The MMA established enhanced payments for certain ground ambulance services through 2006. The Act extends and improves these enhanced payments. For ground ambulance services furnished between July 1, 2008, and December 31, 2009, payments that would otherwise be made under the fee schedule are increased by 3 percent if furnished in a rural area and by 2 percent if furnished in an urban area.

## Devices

Under current law, brachytherapy devices consisting of radioactive sources (or seeds) are paid on the basis of a hospital's cost for such a device. Congress extended this treatment last year through June 30, 2008. The Act extends payment for brachytherapy sources on the basis of costs through December 31, 2009.

## Beneficiaries

Congress has substantially broadened Medicare coverage in recent years to include preventative services, which otherwise are excluded from coverage because they do not meet the general “reasonable and necessary for the diagnosis or treatment” standard that is a hallmark of the Medicare program. Under the Act, Congress has now given the Secretary the authority to cover “additional preventive services” that the Secretary deems are reasonable and necessary (through the regular national coverage decision-making process) to “identify medical conditions or risk factors ... for the prevention or early detection of an illness or disability,” and that meet other criteria.

The Act also establishes program benefits for items and services furnished under cardiac and pulmonary rehabilitation programs. To be covered, the services and patient must satisfy various specified characteristics. Covered items and services might include physician-prescribed exercise, cardiac risk factor modification (including education, counseling and behavioral intervention), psychosocial assessment and outcomes assessment.

Further, the Act establishes a new benefit for kidney disease education services available to individuals with stage IV chronic kidney disease who require dialysis or a transplant.

The legislation also seeks to make Medicare more affordable and more accessible for low-income beneficiaries. The Qualified Individuals (QI) program, which pays for Part B premiums for certain low-income seniors, is extended and funded through 2009. The legislation also increases the amount of assets an individual may have and still be eligible to enroll in the Medicare Savings Program (MSP) such that the MSP asset requirement is now the same as for the Medicare Part D Low-Income Subsidy (LIS) program. The MSP Program assists low-income beneficiaries by helping to pay Medicare premiums and, in certain cases, cost-sharing for other Medicare services. Historically, the MSP Program and the Part D LIS program have experienced problems enrolling all of those eligible. Accordingly, the legislation requires that applications for both programs be made more available and accessible to those who are potentially eligible through, for example, translation of the MSP application form into at least 10 languages other than English and funding for outreach to low-income beneficiaries who may be eligible for these programs. The bill also provides for judicial review of final Part D LIS eligibility decisions, exempts the value of life insurance policies from the eligibility test and eliminates the late enrollment penalty. Funding is provided to state and local programs to help seniors and those with disabilities navigate the Medicare program.

## Medicaid and Selected Other Provisions

With respect to Medicaid, the legislation extends Transitional Medical Assistance (TMA) and the Abstinence Education Program through June 30, 2009, and Temporary Assistance for Needy Families (TANF) through fiscal year 2009.

The bill forestalls payment cuts to retail pharmacies by delaying the application of new payment limits for multiple source (*e.g.*, generic) drugs under Medicaid. In addition, the Secretary is instructed to temporarily suspend the public availability of average manufacturer price (AMP) submissions.

This *White Paper* summarizes the most significant changes made by the Act; it does not address all of the changes. For more information, contact your regular McDermott lawyer or:

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