AKIN GUMP
STRAUSS HAUER & FELD LLP
Attorneys at Law

November 25, 2003

HEALTH INDUSTRY ALERT

CONGRESS ENACTS COMPREHENSIVE MEDICARE PRESCRIPTION DRUG LEGISLATION

Congress today enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Act"), ending a contentious, partisan debate over the form and substance of adding an outpatient prescription drug benefit under the Medicare Program.

This historic legislation, which represents the most significant expansion of Medicare since the advent of the program in 1965, comes on the heels of the House and the Senate passing separate bills earlier this year, which were reconciled by a congressional conference committee this week after months of negotiations. On November 22, the conference agreement narrowly passed the House in a dramatic 220-215 vote and cleared the Senate today by a vote of 54-44. The measure now goes to President Bush, who has promised to sign it.

In general, the Act implements a Medicare prescription drug benefit to provide coverage for outpatient prescription drugs normally purchased in retail pharmacies and previously not covered by Medicare. The Act implements the benefit in phases, initially through a prescription discount card program similar to the President's discount card program that was enjoined by a federal court in September 2001, and, subsequently, through establishment of an outpatient prescription drug benefit program administered through private drug-only plans or through integrated health plans, similar to existing Medicare+Choice plans. In addition, the Act addresses a longstanding prescription drug reimbursement issue — reform of the "average wholesale price" reimbursement methodology for drugs under Medicare Part B. The Act also mandates changes to the Medicare payment methodologies for nearly every provider type, and attempts to improve beneficiary access to lower cost drugs through amendments to the Hatch-Waxman Act and by authorizing drug reimportation.

MEDICARE PRESCRIPTION DRUG BENEFIT

Transitional Assistance

The Medicare prescription drug benefit will be provided first through a prescription drug discount card program. This program, to be implemented by the Secretary of Health and Human

Services through the Centers for Medicare & Medicaid Services (CMS), is to take effect within six months of enactment of the Act. Enrollment is voluntary, and beneficiaries will be afforded access to price discounts negotiated by the card sponsor. Card sponsors may charge an annual enrollment fee of up to $30, and beneficiaries may enroll only in one card program at a time.

Under the discount card program, additional transitional assistance is available for beneficiaries whose income is at or below 135 percent of the poverty line. Qualifying individuals will be eligible to have their enrollment fees paid by the government and will receive $600 annually in financial assistance, with any unused assistance rolling over into the next year (although any leftover funds may not be used for drugs purchased after December 31, 2005 — the last effective date of the discount card program).

Any nongovernmental entity that meets the requirements published by the Secretary may be endorsed as a qualifying card sponsor under the discount card program. While the full details of the program will be announced through an agency rulemaking, the Act requires that card sponsors obtain sufficient participation by pharmacies to ensure that card enrollees have convenient access to covered drugs. Also, the Act mandates that this requirement be met by entities that do not rely solely on mail-order pharmacies, with an express statement of intention that beneficiaries have access to "bricks and mortar" pharmacies.

Full Prescription Drug Benefit

On January 1, 2006, the full Medicare prescription drug benefit will become effective, offering coverage for prescription drugs for all Medicare beneficiaries under a new Medicare Part D. Enrollment in the new program will be voluntary, and beneficiaries will have the option of choosing between standard coverage and alternate coverage with actuarially equivalent benefits. Under standard coverage, a beneficiary is responsible for the first $250 in prescription drug costs. Once that deductible is met, Medicare will pay 75 percent of costs up to $2,250, and then will pay all but nominal cost-sharing costs once the beneficiary reaches the catastrophic coverage limit of $3,600 (leaving beneficiaries with the so-called "doughnut hole" in their coverage). As with the discount card program, low-income beneficiaries are eligible for additional subsidies.

Beneficiaries may obtain coverage either through private drug-only plans (known as prescription drug plans or PDPs) or through Medicare Advantage (formerly Medicare+Choice) plans. While plans generally must bear some financial risk, federal subsidies are available to encourage plan participation.

In order to participate, PDP sponsors must submit bids outlining the prescription drug coverage to be provided, including its actuarial value, service area and level of risk assumed. The Secretary is responsible for ensuring that each enrollee has access to at least two plans in his or her region, one of which must be a PDP. If a choice between two plans does not exist in an enrollee's area, then the enrollee may enroll in a "fallback" plan. Under a fallback plan, the federal government pays the actual costs of the covered drugs to the plan, based on negotiated price concessions.

All plan sponsors must negotiate and provide beneficiaries with access to negotiated prices, even if no benefits are otherwise payable. PDP sponsors may develop and implement formularies, subject to certain restrictions, in order to achieve price concessions. All sponsors also must disclose to the Secretary the aggregate discounts negotiated and provided to beneficiaries. Notably, these negotiated prices are not included in manufacturers' "best price" for purposes

of the Medicaid drug rebate program. Plan sponsors also are required to allow any pharmacy willing to accept the plan's terms and conditions to participate in the plan and must secure participation by a sufficient number of pharmacies to provide convenient access to enrollees. Plans cannot rely solely on mail-order pharmacies.

Full-benefit dual eligibles — beneficiaries eligible for both Medicare and full Medicaid benefits — who do not voluntarily enroll in a Part D plan will automatically be enrolled in a plan whose premium is equal to the subsidized premium for beneficiaries with incomes below 135 percent of poverty.

To encourage employers not to drop existing retiree prescription drug coverage, the Secretary is required to make subsidy payments to qualifying plans. The subsidies — in the amount of 28 percent for drug costs between $250 and $5,000 — are not taxable. To be eligible for the subsidy, the retiree plan must be actuarially equivalent to the standard coverage described above.

OUTPATIENT PRESCRIPTION DRUG REIMBURSEMENT REFORM

The Act also addresses the longstanding issue of drug reimbursement for outpatient prescription drugs and biologicals under the average wholesale price (AWP) methodology. This methodology, considered by many to be flawed, was the subject of a proposed rulemaking by CMS in August of this year. Currently, covered Medicare Part B drugs are reimbursed at 95 percent of AWP. Under the Act, AWP will continue to be the basis for reimbursement in 2004, but reimbursement (for most drugs) will be set at 85 percent of AWP. Beginning in 2005, reimbursement will be based on the lesser of the average sales price (ASP) or wholesale acquisition cost, plus 6 percent. The ASP is to be calculated each quarter by dividing the total sales (with some statutory exceptions) of a drug by the number of units of the drug sold for that quarter. The Department of Health and Human Services Inspector General also is to conduct market studies in order to determine the market price of drugs and biologicals reimbursed by Medicare. If, based on these studies, the ASP exceeds the widely available market price (WAMP) or average manufacturer price (AMP) by a predetermined threshold (5 percent for 2005), reimbursement will be reduced to the lesser of the WAMP or AMP.

As an alternative to the ASP methodology, the Secretary is required to phase in, beginning as early as 2006, a competitive acquisition program for Medicare Part B drugs. Under this program, successful bidders will provide drugs to physicians, and the bidder (not the physician) will be reimbursed by CMS based on the successful bids. Physicians will have the option of participating in the competitive bidding system or continuing to be reimbursed under the ASP methodology.

HOSPITAL OUTPATIENT DEPARTMENT PAYMENT REFORM

Currently, Medicare reimburses drugs provided in a hospital outpatient department in one of three ways: through a transitional pass-through payment, currently 95 percent of AWP, which is available only for new drugs; through their own code (known as an ambulatory payment classification or APC) in the outpatient prospective payment system (OPPS); or as part of an APC code under OPPS that is "packaged" with other services. For 2004 and 2005, the Act would preserve the current reimbursement rate for pass-through drugs (i.e., 95 percent of AWP), and would set floor reimbursement rates for single-source drugs that have their own APC. The floor reimbursement rates for such drugs are 88 percent of AWP and 83 percent of AWP for 2004 and 2005, respectively. In 2006, payment rates for these

single-source drugs will be set based upon a General Accounting Office survey of provider acquisition costs, and, in subsequent years, outpatient drugs will be reimbursed at the drug's average acquisition cost as determined by the Secretary through periodic surveys. If acquisition cost data is not available for a drug, reimbursement will be based upon the payments under the outpatient prescription drug reforms described above.

COMPARATIVE COST ADJUSTMENT DEMONSTRATION

The Act requires the implementation of a six-year demonstration project, beginning in 2010, to study the effect of direct competition between private plans and traditional Medicare fee-for-service. The demonstration project is to be conducted in a maximum of six metropolitan statistical areas as selected by the Secretary. Under the demonstration project, the traditional Medicare fee-for-service program and private plans will compete to offer beneficiaries benefits based on competitive bids for private plans and calculated per capita costs for traditional Medicare. In order to avoid dramatic increases in premiums to beneficiaries, the Act limits premium increases to 5 percent per year for beneficiaries remaining in Medicare fee-for-service.

After the demonstration is completed, the Secretary is required to submit a report to the Congress describing the outcome of the demonstration and making recommendations on whether to expand the program. Regardless of the outcome of the demonstration project, additional congressional action is required before such a program can be extended to the balance of the Medicare Program.

OTHER PROVIDER ISSUES

The Act also includes a number of changes in Medicare policies affecting providers. These provisions include the following:

- All PPS hospitals will receive a full market-basket update for inpatient reimbursement in fiscal year 2004. For fiscal years 2005 through 2007, hospitals will receive full market-basket updates if they submit data on 10 quality of care indicators to the Secretary. The update for hospitals not submitting these data in those years will be market basket minus 0.4 percent.
- The Act includes numerous changes enhancing Medicare reimbursement for rural hospitals, including the equalization of the standardized payment amount for Medicare inpatient reimbursement at the large urban rate and, for hospitals with a wage index of less than one, reducing the labor-related share of the standardized amount to 62 percent.
- Hospitals located in counties that meet certain requirements relating to wages and commuting patterns are eligible to receive a blended increase in their wage index reflecting the number of residents in the qualifying county employed by hospitals in higher wage index areas and the wage indices for the higher wage index areas.

- Hospitals are granted a limited one-time appeal right to seek reclassification to another wage index area within the hospital's state (or to a contiguous state at the Secretary's discretion). This appeal right applies to hospitals that do not otherwise qualify for a change in their wage index classification under current distance or commuting requirements. Such hospitals also must meet other criteria as specified by the Secretary. Reclassification is for a three-year period, and the additional expenditures available under this provision for all hospitals are limited to $900 million.
- The indirect medical education adjustment to PPS hospital payments is increased to 6 percent in the last six months of fiscal year 2004. It is then reduced to 5.8 percent in fiscal year 2005; 5.55 percent in fiscal year 2006; and 5.35 percent in fiscal year 2007, before reverting to the current 5.5 percent in fiscal year 2008.
- For an 18-month period following enactment, the Act prohibits physicians referring patients to specialty hospitals (e.g., hospitals engaged primarily in care for cardiac or orthopedic conditions or surgical procedures) in which the physicians have an ownership interest. The Act includes a "grandfathering" provision for hospitals in operation prior to November 18, 2003, or "under development" as of that date, if certain conditions are met. The Act provides the Secretary with significant discretion to define specialty hospitals and the term "under development."
- The Secretary is required to phase in a competitive acquisition program for durable medical equipment to replace the existing fee schedule system.
- The Act reimposes the moratorium on enforcement of the outpatient rehabilitation therapy cap through 2005.

OTHER REFORMS

Hatch-Waxman Reform

The Act amends existing law in order to allow generic drugs to enter the market more quickly. Specifically, brand-name drug manufacturers are limited to one 30-month stay to block generic drug market entry during patent disputes. In addition, a generic drug manufacturer will be able to seek a declaratory judgment that its product does not violate a brand-name drug patent if the brand-name manufacturer does not sue for patent infringement in a timely fashion.

Reimportation

The Secretary is granted the authority to create a system allowing drugs to be reimported from Canada. Prior to implementing such a reimportation system, the Secretary must certify the safety and cost savings of the system. While similar to existing reimportation law, the Act significantly narrows the scope of reimportation to Canada. Supporters of reimportation believe that, by limiting the scope of the law, it will be easier to certify the safety of the drugs being imported. In addition, the Secretary must conduct a study on reimportation, which must be submitted to Congress within 12 months of enactment.

AKIN GUMP
STRAUSS HAUER & FELD LLP
Attorneys at Law

CONTACT INFORMATION

Health Industry Team

For general information regarding our health industry practice and capabilities, please contact our practice group chairman:

David H. Eisenstat. . . . . 202.887.4056. . . . . deisenstat@akingump.com . . . . . .Washington

For specific questions on the new Medicare prescription drug legislation, please contact either of the following lawyers:

Jorge Lopez Jr. . . . . 202.887.4128. . . . . jlopez@akingump.com . . . . . .Washington

Michael J. Parini . . . . . 202.887.4449. . . . . mparini@akingump.com . . . . . .Washington

Albany Austin Brussels Chicago Dallas Houston London Los Angeles Moscow New York
Northern Virginia Philadelphia Riverside/Inland Empire Riyadh (Affiliate) San Antonio San Francisco Washington, D.C.

www.akingump.com