MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND MODERNIZATION ACT OF 2003

After much fanfare, on December 8, 2003, President Bush signed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, P.L. 108-173, (“Medicare Act” or “Act”), legislation that promises to have a substantial impact on the health care industry. The measure is being touted as the largest change to the Medicare system in decades and has an estimated price tag of roughly $400 billion in the next few years, with some analysts estimating the changes could cost over $1 trillion in the next decade. Although the centerpiece of the legislation is the implementation of a prescription drug plan for senior citizens who qualify for Medicare benefits, the legislation also includes a panoply of provisions that affect Medicare reimbursement and related regulations. The following is a very brief summary of a few of the highlights of this 800+ page bill.

Medicare Prescription Drug Benefit

The centerpiece of the Medicare Act is dedicated to establishing a voluntary plan providing expanded prescription benefits under new Medicare Part D. The plan will be implemented through a progressive roll-out, with substantial components of the program being added in 2006 and 2010. In 2004 and 2005, Medicare beneficiaries will be allowed to purchase a prescription discount card that government agencies estimate will provide an average of 15-25% savings on drug prices. Starting in 2006, Medicare recipients will be given a choice to sign up for a stand-alone drug plan or a private health plan that would offer drug coverage in addition to regular health services. Under either plan, beneficiaries will be charged a premium of $420 per year, and after a $275 deductible, insurance will pay 75% of the cost of drugs up to $2200. In the case that a participant’s out-of-pocket costs exceed $3600, insurance would then pay 95% of drug costs, with the possible requirement of a modest co-payment by the beneficiary. At this time, there is no coverage provided for out-of-pocket costs that fall between the $2200 and $3600 amounts. For qualifying low-income beneficiaries, the premium, deductible and coverage gap will be waived. Employers that maintain
existing prescription coverage for retirees who would otherwise qualify for the Medicare plans will also receive generous subsidies to continue that coverage. Private providers will run the prescription programs, as well as the discount cards, on a regional basis.

Re-Importation of Prescription Drugs

A hot issue in the prescription drug savings debate has been regulation of the re-importation of prescription drugs from other countries offering lower pricing—such as Canada. A number of parties sought to have the authorization of re-importation included in the Act, with others arguing that it should be strictly outlawed. The final result is that the Act contains a provision that maintains the importation ban, with an exception for drugs imported from Canada after the Department of Health and Human Services (“HHS”) provides a safety certification of the drug. In the end, it is unlikely that the provision will have any impact on the current situation. Re-importation of prescription drugs remains prevalent today despite an existing ban, and HHS has made no indication that it will be willing to provide the safety certifications that would authorize importation. Without an increase in enforcement or a change of position by HHS, maintenance of the status quo is the likely result of this section. The Act also directs HHS to conduct studies of the current problems associated with the importation of drugs and drug pricing policies of other nations.

Competition from Private Health Organizations

One of the more controversial components of the Medicare Act involves pilot programs that will be put into place to “test” the viability of private sector competition with traditional Medicare plans. Beginning in 2010, private insurance plans in six as yet undetermined metropolitan areas would offer an alternative (where at least two private plans enroll at least 25 percent of Medicare beneficiaries in the area) to senior citizens that wished to waive coverage in the traditional Medicare program. The competition would be guaranteed to operate for six years, with continuation of the program subject to congressional authorization. Opponents of the legislation argue that the provision is the beginning of an effort to privatize Medicare, while proponents suggest that the competition between private companies and Medicare will encourage better services with reasonable premiums. There are, however, some groups of beneficiaries who would experience an increase in premiums under the new plan due to the implementation of a graduated payment scale that will be tied to an individual’s annual income.

Medicare Advantage Program

The Medicare Act aims to modernize and revitalize Medicare+Choice, beginning with renaming the program as “Medicare Advantage.” Largely as a result of the acknowledged unpredictable and insufficient payments under Medicare+Choice, Medicare Advantage provides that all plans would be paid at a rate at least as high as the rate for traditional fee for service (“FFS”) Medicare. After 2004, private plans’ capitation rates would increase at the same rate as FFS Medicare.
Fraud and Abuse Provisions

Significant measures are included in the legislation aimed specifically at combating fraud and abuse. Some highlights include:

- **Durable Medical Equipment.** DME rates will be frozen for three years from 2004-06. Close scrutiny will be given to and standards set for payment of DME items requiring a face-to-face exam; DME items for which there has been a proliferation of use, consistent findings of charges for items that are not delivered or of falsified documentation; and power wheelchairs.

- **Physician Investors in New Specialty Hospitals.** The Act imposes an 18-month moratorium of the whole hospital exemption under the Stark Law for new specialty hospitals. During this period, the Medicare Payment Advisory Commission (“MedPAC”) and HHS are to study referral patterns and the costs and benefits of specialty hospitals.

- **Education and Outreach.** Medicare contractors will be required to provide responses to written inquiries within 45 business days of receipt of an inquiry. Contractors will be required to maintain Internet sites to answer frequently asked questions and provide published materials, and their payment accuracy will be monitored.

- **Medicare Recovery Issues.** The Act mandates limits on the use of non-random prepayment review, it prevents extrapolating overpayments based on a small sample of claims, it requires the Secretary to allow extended repayment (of at least six months) where repaying an overpayment within 30 days would be hardship, and it requires HHS to provide notice to providers who it discovers are overusing a particular code.

- **Average Wholesale Price (“AWP”) Reform.** Although certain drugs and biologicals will continue to be paid at 95% of AWP in 2004, payments for most drugs will equal 85% of the AWP. Beginning in 2005, drugs and biologicals, except for pneumococcal, influenza and hepatitis B vaccines and those associated with certain renal dialysis services, will be paid using either the newly established average sales price (“ASP”) methodology or, for physicians, through the newly established competitive acquisition program. Manufacturers will be required to report ASP data, and reporting of false ASP information will be a violation of the False Claims Act. The Office of the Inspector General (“OIG”) is required to regularly audit manufacturer submitted ASPs and compare them with market prices and Medicaid Average Manufacturer Prices. The OIG will investigate drug pricing to identify overpriced drugs, and HHS will institute fines on drug companies who misrepresent or inflate drug prices.

Physician Issues

Physicians and hospitals will also benefit from the Act, with special assistance earmarked for rural health care providers. Although the bill has been touted as increasing payments to hospital providers, it remains unclear whether all types of hospitals will see these increases. Some observers
have noted that nearly all of the $25 billion dedicated to these increases will be distributed to rural hospitals, and the average hospital will only experience a 1.5% over the next ten years.

However, physicians will see an across-the-board increase. The 2004 Physician Fee Schedule is changed so that the scheduled 4.5% cut in reimbursement is blocked, and effective January 1, 2004 physicians will receive a 1.5% increase in payments. Further, another 1.5% increase in reimbursement is scheduled to take effect in 2005. For physicians in qualifying rural hospitals, there is an allowance for an additional 5% increase in payments in addition to the standard increase in order to provide an incentive for physicians to practice in these areas.

Therapy Caps

The Act places an additional two-year moratorium on the caps for outpatient physical, speech, and occupational therapy that had originally been mandated by the Balanced Budget Act of 1997. Although application of therapy limits had been suspended from 1999 through 2002, the caps finally became effective in September 2003. However, as of the date of the Act’s enactment through calendar year 2005, the caps will again be suspended. Meanwhile, the Secretary must report to Congress by March 31, 2004 on alternatives to a single annual dollar cap on outpatient therapy and the utilization patterns for outpatient therapy.

Hospitals

Most of the Act’s most touted benefits for hospitals will go to rural hospitals, with increases intended to redress years of financial problems at rural hospitals. The following are among the provisions that will impact all hospitals:

- **Disproportionate Share Payments**
  
  The Act establishes a temporary increase in Medicaid disproportionate share (“DSH”) allotments in FY 2004 and for certain subsequent fiscal years. Allotments for FY 2004 will be set at 116% of the allotment for FY 2003. In subsequent years the rate will remain equal to the 2004 amounts, with an alternative funding formula available in limited circumstances. The Act also raises the floor for extremely low DSH states for fiscal years 2004 through 2008 by 16%.

  Medicare DSH payments for small rural and urban hospitals will more than double from 5.7% to 12% of total Medicare inpatient payments.

- **Undocumented Aliens Receiving Emergency Care**

  A provision that is aimed at promoting fair compensation to hospitals is a provision that allocates funds to pay for the services given to undocumented aliens that are required under the Emergency Medical Treatment and Labor Act (EMTALA). Medical care for undocumented aliens has often gone uncompensated because its recipients were not eligible for payment. The Act allocates funds to the states on an annual basis beginning in 2005, with each state’s share determined by the size of its illegal immigrant population. In cases where a provider could prove it had not been compensated for such services (by insurance or other means), the Secretary
of HHS is given the authority to compensate them directly. It is estimated that approximately $1 billion will be allocated to support this.

- **New Technologies**

  The Act also makes changes to payment rates and DRG classification of new technologies. The Secretary is required to add new diagnosis and procedure codes by April 1 of each year, with payment under those changes effective the start of the following fiscal year. The Secretary is also required to publish pending applications for evaluation of new services, accept comments from the public on the classification of those services, and provide an opportunity for individuals and organizations to voice concerns. Funding for new technology will no longer be budget neutral. The Secretary is required to implement these changes for FY 2005, and any application that was denied for FY 2005 is to be reconsidered under the new rules.

### Skilled Nursing Facility Appeals

Under the Act, the Secretary must establish a process to expedite appeals of provider terminations, and other remedies imposed on skilled nursing facilities (“SNFs”), including denial of payment for new admissions and the imposition of temporary management, and disapproval of a SNF’s nurse aide training program. Sufficient money is to be appropriated to reduce by 50% the average time for administrative determinations, and to increase the number of ALJs and appellate staff for the DAB.

### Inpatient Rehabilitation Facilities

In response to the September 2003 proposed regulation governing inpatient rehabilitation facilities (“IRF”), the Act instructs the GAO to report on whether the existing list of conditions required to classify a facility as an IRF represents a clinically appropriate standard whether additional conditions should be included on the list. The committee drafting the legislation also urges that implementation of any new rules be delayed until the GAO findings are announced. Critics of the bill argue that the bill does not do enough to prevent the implementation of the proposed rule changes, and that implementation of the rules would force many IRFs out of business because it would restrict the types of procedures for which they could receive payment.

### Beneficiary-Related Issues

- **Health Savings Accounts**

  The Act also establishes “Health Savings Accounts” (“HSAs”) that provide a means of setting aside money used for lifetime health care needs on a tax-free basis. Individuals, employers and family members can make tax-free contributions to a special account up to 100% of the amount of the insured’s deductible, so long as the annual amount does not exceed $2600 for individual policies and $5150 for family policies. The HSAs are aimed primarily at people who are in high-deductible insurance plans, and distributions from the account are tax-free so long as they are used for un-reimbursed medical expenses, retiree health insurance, Medicare expenses, prescription drugs, and related expenses. For individuals age 55-65 there is an extra $1000 contribution allowed each year to allow them to “catch-up” in their accounts.
• **Expanded Coverage**

The Act provides the following additional Medicare coverage for beneficiaries:

- Initial voluntary physical when becoming eligible for Medicare.
- Screening for diabetes and cardiovascular disease.
- Improved payments for mammography.
- Disease management program to assist beneficiaries with chronic illnesses.

**Looking Forward**

It is important to note that this summary is a cursory and preliminary examination of the changes that are instituted by this landmark legislation. It is our impression that there are widely varying interpretations of this legislation in the media, which underscores the complexity of the Act. In the months to come, we will continue to provide you with information, updates and analysis of the Act. In the meantime, if you have more specific questions or concerns regarding the new law, please feel free to contact our office for assistance.