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Advisory

December 3, 2003

HEALTH LAW

The New Medicare

After many years of failed attempts by Congress to overhaul Medicare and add a prescription drug benefit, the United States Senate, last week, gave final approval to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (H.R. 1, the "Act"), which will implement the greatest changes to the Medicare program since its inception in 1965. The bill is now headed to President Bush, who is expected to sign it shortly.

After months of contentious negotiations between House and Senate conferees, the final bill, which is predicted to cost approximately $395 billion over the next ten years, aims to help Medicare beneficiaries cover the costs of prescription drugs. Beginning in 2006, the bill adds a prescription drug benefit for all Medicare beneficiaries. In the interim, a temporary drug discount card program will be established.

In addition to adding a prescription drug benefit to the Medicare program, the bill: provides more than $86 billion in payments and tax advantages to employers to encourage them to continue providing drug benefits to retired workers; increases payments to doctors and hospitals; provides $25 billion in assistance to rural health care providers over the next 10 years; and establishes tax breaks for persons who set aside money in designated savings accounts for medical expenses. Furthermore, beginning in 2007, for the first time, higher income beneficiaries will be required to pay higher Medicare Part B premiums on a sliding scale. The legislation also takes steps to make low-cost generic medicine more readily available.

Because the Act is so extensive, it is impossible to detail each provision; this advisory is intended to highlight some of the key provisions that may affect health care providers. Mintz Levin plans to publish additional advisories on specific provisions of the Act in the coming months.

Voluntary Drug Benefit

The Act carves out a significant role for private health plans in the provision of the new drug benefit. Beneficiaries may obtain coverage by purchasing a separate private insurance policy for drugs or by joining a preferred provider organization (PPO), health maintenance organization (HMO), or other type of private health plan that offers such coverage. The federal government will rely on private plans to provide drug coverage and to bear some of the financial risk for drug costs. Plan premiums will be determined through a bid process, pursuant to which plans will compete based on premiums and negotiated prices. Outpatient drugs covered under the benefit include drugs dispensed pursuant to a prescription, biological products, vaccines, insulin, and drugs covered under the Medicaid program. For the most part, drugs excluded from coverage under Medicaid are also excluded from the new Part D coverage.

The drug benefit will have average monthly premiums of $35, depending on the type of plan chosen, and a $250 deductible. The Act establishes several types of premium and cost-sharing subsidies for low-income beneficiaries. The amount of subsidy provided depends on the beneficiary's income and asset levels. In addition, the Act provides for subsidies to private plans to encourage their participation in the program, reduce the changes of adverse selection among plans, and decrease premiums for all beneficiaries. These payments will be made as direct subsidies and through insurance. The Act also provides for tax-free subsidies to employers who maintain drug coverage for retirees once the Medicare drug benefit begins. The government hopes to encourage employers to continue retiree coverage, which is often more generous than Medicare's benefits.

Beneficiary Enrollment

Medicare beneficiaries will have the opportunity to obtain prescription drug coverage by enrolling in a prescription drug plan (PDP) or Medicare Advantage [MA, formerly, Medicare+Choice (M+C)] prescription drug plan ("MA-PD plans") in their geographic area. Individuals entitled to Medicare Part A or enrolled in Medicare Part B will be entitled to obtain qualified prescription drug coverage through enrollment in a PDP. A beneficiary already enrolled in a MA-PD plan will obtain coverage through that plan. MA enrollees are not permitted to enroll in a PDP under Part D unless they are participants in a fee-for-service MA plan that does not offer prescription drug coverage, or are enrollees in Medicare medical savings accounts. Beneficiaries eligible for both Medicare and Medicaid (so-called "dual-eligibles") will receive coverage through the Medicare program. Coverage will begin January 1, 2006.

The Secretary of the Department of Health and Human Services (HHS) is required to establish a process for enrollment, disenrollment, termination, and change of enrollment of eligible beneficiaries in PDPs. The initial enrollment period will begin on November 15, 2005 and will continue for six months. Congress has stated that the enrollment process must be administratively simple to encourage enrollment in the new plans. Moreover, the Act requires the Secretary to establish and implement both a public information campaign designed to make beneficiaries aware of and encourage them to make use of their new benefits, and a comparative information program to assist beneficiaries in comparing their drug coverage options.

Beneficiary Access to Plans

Beneficiaries eligible for the benefit will be guaranteed their choice of at least two qualifying plans, from two different sponsors, in their area of residence. A "qualifying plan" includes a PDP or MA-PD that provides either basic prescription drug coverage or qualified prescription drug coverage that does not include an MA monthly supplemental beneficiary premium. When an area does not have sufficient qualifying plans, beneficiaries will have the option of enrolling in limited risk or fallback plans, which provide for greater cost sharing or complete cost coverage by the government. The purpose of these plans is to encourage (and ensure) private plans to offer coverage in underserved (including rural) areas. Fallback PDPs are permitted to offer only standard prescription drug coverage, must pass on negotiated discounts, and must meet other requirements specified by the Secretary.

Qualified drug plans will be required to provide beneficiaries with access to negotiated drug prices (which take into account all discounts, direct or indirect subsidies, rebates, etc.), even if no benefits are payable. Plans are permitted to provide supplemental prescription coverage for cost-sharing amounts and excluded drugs. However, a PDP sponsor may not offer a plan that provides supplemental benefits unless it also offers a basic plan in the area. For 2006, "standard prescription drug coverage" will have a $250 deductible, 25% coinsurance up to $2,250, and catastrophic coverage of 95% after an individual incurs $3,600 in out of pocket expenses. After the catastrophic limit, Medicare will pay all costs, except for nominal cost sharing by all but low-income beneficiaries. Amounts for which no benefits are provided because they are not on the applicable drug formulary would not be considered incurred costs. In addition, costs would only be considered incurred if they were paid by the individual (or by a family member on behalf of the individual); on behalf of a low-income beneficiary in the form of a subsidy; or by a state pharmaceutical assistance program.

It is possible that some beneficiaries will decide that the costs of obtaining prescription drug coverage (*i.e.*, premiums and deductibles) are higher than the benefits they will receive under such plans. If beneficiaries (other than those who already have drug coverage from another source) decide to join plans after the effective date, they would be required to pay higher premiums. In this way, the Act attempts to ensure that people with high drug costs are not the only beneficiaries who participate in the plans.

Disclosure Requirements and Beneficiary Protections

PDPs and MA-PD plans will be permitted to offer alternative coverage that is at least actuarially equivalent to the standard Part D benefit, so long as it provides for no more than the standard plan deductible and threshold for catastrophic coverage. PDP sponsors and MA-PD entities are required to disclose to the Secretary the aggregate negotiated price concessions made available and passed through in the form of lower subsidies,

lower monthly beneficiary premiums, and lower prices offered by pharmacies and other dispensers. Manufacturers are also required to disclose pricing information to the Secretary, but the information will remain confidential.

The Act also establishes a variety of beneficiary protections, similar to those required under the current M+C program. For instance, PDP plan sponsors must disclose certain information to beneficiaries about the plan's benefit structure. In addition, the Act contains an "any willing provider" provision that requires PDP sponsors to permit any pharmacy that meets the plan's terms and conditions to participate in the plan. PDP sponsors must also secure enough pharmacy participation in their networks (other than mail order) to ensure convenient access for beneficiaries. In addition, the Act requires the Secretary to develop electronic prescription standards, and sets a deadline of September 1, 2005 for the initial set of standards.

Establishment of Regions and Plan Approval Processes

The Secretary has the authority to establish and revise PDP regions, consistent with the requirements for establishing and revising MA regions. The goal is for the PDP regions to be the same as the MA regions, to the extent possible. The Act provides for anywhere between 10 and 50 regions. Bush Administration officials have stated that they believe larger regions are necessary to prevent plans from excluding rural areas and other less profitable markets.

Each PDP sponsor is required to submit to the Secretary a bid containing specified information on the prescription drug coverage to be offered. The Secretary will review the submitted information and negotiate with the plan. Ultimately, the Secretary will approve or disapprove the plan. The Secretary may only approve a plan if the plan and benefits are not likely to discourage enrollment by certain beneficiaries.

In order to promote competition, the Secretary may not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors. The Secretary may not require a particular formulary or price structure for covered drugs. Congress expects PDPs to negotiate price concessions directly with manufacturers.

Medicare Prescription Drug Discount Card and Transitional Assistance Program

In 2001, the Bush administration, through regulations released by HHS, announced a national drug discount card program for Medicare beneficiaries. However, implementation of the program was suspended after it was successfully challenged in court on procedural grounds. Remedying any alleged deficiencies in legislative authority, the Act expressly establishes the voluntary Medicare Prescription Drug Discount Card and Transitional Assistance Program (the "Program"). It is estimated that the card will reduce beneficiaries' pharmaceutical costs by 10% to 25%.

The Program, which must commence within six months of enactment and concludes when the new drug coverage goes into effect, will be available on a voluntary basis to those persons entitled to or enrolled under Medicare Part A or enrolled under Part B (subject to certain exclusions). An individual may be enrolled in one endorsed program at a time, and for an annual fee of $30, he or she will have access to discounted drugs offered by the card "sponsor." Individuals with incomes below 100% of the poverty line qualify for "transitional assistance," which means that HHS will cover the annual enrollment fee and 95% of drug costs up to $600 per year during the transition period. Individuals with incomes between 100% and 135% of the poverty line will receive similar assistance.

HHS is charged with publishing regulations to implement the Program and may do so on an Interim Final basis, as was done with the implementation of the M+C program. Regardless, as the Program is scheduled to commence within six months of enactment of the new legislation, organizations that may qualify as "sponsors" are left with little time to analyze the benefits of participation, prepare systems and procedures, and execute any contracts necessary for administering a card program. Pursuant to the Act, any of the following types of organizations (or any combination thereof) may qualify as a sponsor of a discount drug card if it has "demonstrated experience and expertise in operating such a program or a similar program and [it] meets such business stability and integrity requirements as the Secretary may specify":

- Pharmacy Benefit Managers (PBMs);
- wholesale pharmacy delivery systems;
- retail pharmacy delivery systems;
- insurers, including offers of Medicare supplemental policies; and
- M+C plans.

Sponsors must provide enrollees with access to both negotiated prices and traditional pharmacies. Negotiated prices offered to enrollees must take into account price concessions including discounts, subsidies, rebates, and other remuneration, and include any dispensing fees. These negotiated prices will not be considered for purposes of making best price calculations under the Medicaid rebate program.

With respect to pharmacy access, card sponsors (except M+C organizations) that enroll individuals in any part of a state would be required to permit eligible individuals in all parts of the state to participate. To this end, each sponsor must secure the participation of a sufficient number of retail pharmacies to

satisfy access requirements (*i.e.*, access may not be satisfied by mail order alone). Sponsors also must employ drug utilization mechanisms to reduce the likelihood of medication and adverse drug reactions. In addition, sponsors will have significant reporting and compliance obligations as part of their participation in the program.

Finally, sponsors will be required to comply with the Health Insurance Portability and Accountability Act's administrative simplification provisions, including the Privacy Rule and Security Standards. Interestingly, the Act specifies that "the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of [HIPAA]." Although HHS may waive temporarily the privacy-related compliance obligations to encourage participation in the Program, ultimately this will have significant implications for PBMs and wholesale pharmacy sponsors, as these organizations have not been required to comply with many of these onerous requirements.

Reimbursement for Outpatient Drugs

Currently, Medicare provides limited coverage for certain outpatient drugs and biologicals, including drugs furnished incident to a physician's service, drugs used with durable medical equipment, vaccines, and a narrow set of self-administered medications. Payments for covered outpatient drugs are made under Medicare Part B and are generally calculated as a percentage (*e.g.*, 95%) of the manufacturer's reported average wholesale price (AWP).

Payment based on AWP has been scrutinized by Congressional and Senate committees, the Office of the Inspector General (OIG) and the General Accounting Office (GAO), as there are no uniform criteria for reporting these prices and evidence shows that the AWPs for some Medicare-covered products may sometimes exceed the cost paid by other purchasers. There are also allegations that this system has influenced physician prescribing practices (through profits resulting from the "spread" – *i.e.*, the difference between the price paid and the reimbursement amount), and has resulted in comparatively high costs to both the Medicare program and its beneficiaries. To remedy these issues, in August of this year, CMS published a proposed rule that solicited comments on four different approaches to Medicare reimbursement for covered drugs. Two of these approaches are now required under the Act. By January 1, 2005, the Act requires that existing sources of market-based prices must be used and additional sources for market monitoring must be developed. By January 1, 2006, a competitive acquisition program and Average Sales Price (ASP) system must be established. In the interim, beginning in 2004, the Act provides that outpatient drugs will be reimbursed at the rate of AWP minus 15%, and gives the Secretary the authority to increase or decrease reimbursement based on market surveys.

The Act provides that, with the exception of certain drugs and biologicals that will continue to be reimbursed at 95% of AWP, Medicare will reimburse covered outpatient drugs using an ASP methodology. Similar to the methodology established by the OIG in its Corporate Integrity Agreement with TAP Pharmaceuticals and subsequently set forth in the CMS August 20th Proposed Rule, under the Act a manufacturer's ASP is calculated by NDC code for each calendar quarter by dividing a manufacturer's total sales by the total number of units sold in that quarter. Certain sales are exempt from the calculation, including those that are also exempt from the "best price" determination under the Medicaid drug rebate program. Volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and certain rebates (not including Medicaid rebates) will be factored in the calculation of ASP.

To ensure that manufacturers accurately report sales data, the OIG will conduct studies to determine the "widely available market price" (WAMP) for a covered drug. If the OIG finds that the ASP for a drug or biological exceeds the WAMP or average manufacturer price (AMP) by a certain threshold, HHS in the next calendar quarter will substitute a payment amount equal to the lesser of the WAMP or 103% of the AMP. Moreover, manufacturer misrepresentations of ASP is punishable by civil monetary penalties in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

The Secretary is also required to establish a competitive acquisition program to acquire and pay for "competitively biddable drugs and biologicals," which includes covered drugs furnished on or after January 1, 2006 with certain significant exceptions (*e.g.*, pneumococcal, influenza, and hepatitis B vaccines, and most drugs or biologicals furnished in connection with renal dialysis services). Under the program, which will be phased in beginning in 2006, HHS will establish competitive acquisition areas and entities will bid to supply drugs to physicians in one or more of these areas. A physician could choose annually to receive payment based on the ASP model described above or to acquire drugs from one of these entities and then the entity would be responsible for billing Medicare and collecting beneficiary coinsurance amounts. Contractors will compete annually for each competitive acquisition area for each applicable category of competitively biddable drugs and biologicals in

accordance with provisions established by the Secretary.

The Act also mandates a two year demonstration project to study the impact of paying differently for certain drugs, including cancer chemotherapy drugs, that are already covered under Medicare Part B, when they are furnished as part of a physician's services and not usually self administered. The demonstration will be conducted in six states, cover up to 50,000 patients, and provide up to $500 million in funding. The demonstration would pay for these drugs using the cost sharing and deductible requirements established under the new Part D, rather than as under the current system. At least 40% of the funding must be used for oral cancer drugs. The study is also intended to include certain drugs used to treat multiple sclerosis, which are administered by injection. HHS is to study the impact of the project on patient access and health outcomes, as well as evaluate any cost savings from reduced physician and outpatient visits.

Medicare Advantage

The Act replaces the current M+C program with the Medicare Advantage program under Part C of Medicare. The goal of this new program is to modernize and revitalize the role of private plans under Medicare, and increase beneficiary choice. Beginning in 2004, all private plans will be paid at a rate at least as high as the rate for traditional fee-for-service (FFS) Medicare, with certain adjustments. In addition, private plan rates would increase at the same rate as growth in FFS Medicare.

Establishment of MA Regional Plans

Regional plans, which encourage private plans to serve beneficiaries in larger regions and which are intended to benefit beneficiaries in more rural areas, will be established beginning in 2006. The Secretary must establish between 10 and 50 regions across the nation on or before January 1, 2005; plans that desire to participate in this program must serve an entire region.

To encourage plans to enter the regional market (a significant problem under the M+C program) and to assist those plans with their start-up costs, during years 2006 and 2007 Medicare will share risk with MA regional plans if costs fall above or below a specific risk corridor. In addition, beginning in 2006, the Secretary will compute a "blended benchmark" amount for each region to respond to market conditions in the region by allowing plan bids to influence the final benchmark amount. The Act also establishes a $10 billion fund (to be used through 2013) to provide incentives for plan entry in each region and to retain MA regional plans in regions with below-national-average MA market penetration.

Competition and Premium Support

The most controversial provision throughout conference negotiations related to a House proposal designed to create a premium support system to encourage competition between the Medicare program and private plans. Democrats, in particular, objected to the proposal because in their view, it represented an ill-conceived privatization of the Medicare program. The House proposal was especially controversial because of its requirement that if Medicare's cost is more than private plans, Medicare beneficiaries will have to pay higher premiums than those receiving coverage from private plans. Ultimately, the conferees agreed upon a pilot program to begin in 2010 and last six years, in which traditional government-run Medicare will compete directly with private plans in up to six metropolitan areas where at least 25 percent of Medicare beneficiaries are in private plans.

Premium Support

Beginning in 2006, MA organizations (other than MSA plans) will be required to submit bids to provide services to Medicare beneficiaries on either a local or a regional level. However, the Secretary may not require any MA organization to contract with a particular hospital, physician, or other entity or individual. Bids will be compared to a benchmark amount. Plans that submit bids below the benchmark will be paid their bids plus 75% of the difference between the benchmark and the bid, which must be returned to beneficiaries as additional benefits or reduced premiums. The government will keep the remaining 25% of the savings. Plans that bid above the benchmark amount will receive the benchmark amount as payment, with beneficiaries to pay the difference between the benchmark amount and the bid amount as a premium.

Competition Demonstration

Beginning in 2010, the Act requires a six-year demonstration in which FFS Medicare will compete directly against private plans for patients based on price. The study's goal is to determine whether direct competition between private plans and the original FFS Medicare program will enhance competition in Medicare, improve health care delivery for all Medicare beneficiaries, and provide for greater beneficiary savings and reductions in government costs. This requirement is one of the most controversial provisions in the Act. Some policymakers contend that such competition will save money for Medicare in the long run, but others believe it will increase premiums for beneficiaries who remain in traditional Medicare.

The Secretary will select demonstration areas from among qualifying metropolitan areas. The number of demonstration areas is limited to six, or 25% of the total number of qualifying areas, whichever is lower. To qualify for selection, the area

must have at least 25% of eligible Medicare beneficiaries enrolled in a local coordinated care plan, and at least two coordinated MA local plans offered by different organizations. The details of the demonstration are complex, but the general purpose is to encourage plans to offer lower premiums and allow beneficiaries to share in any savings realized over traditional FFS Medicare.

Effect on Other Providers in the Health Care System

Pharmacy Benefit Managers

In addition to the provisions described above, which will have a significant impact on PBMs, the Act calls for the Federal Trade Commission (FTC) to conduct a study to assess the differences in payment amounts for pharmacy services, including mail-order drugs, provided to enrollees in group health plans that use PBMs versus those plans that do not use PBMs. The study must also determine whether group health plans that use PBMs are acting in a manner that maximizes competition and results in lower prescription drug prices for their enrollees. The report is due to Congress within 18 months of enactment. The study must compare the activities of mail order pharmacies owned by PBM-owned mail order pharmacies to other mail order pharmacies to determine whether PBM pharmacies:

- dispense fewer generic drugs versus single-source drugs within the same therapeutic class;
- routinely switch patients from lower priced drugs to higher priced drugs (in the absence of a clinical indication);
- sell a higher proportion of repackaged drugs; or
- sell repackaged drugs at prices above the manufacturer's average wholesale price.

Furthermore, the FTC must consider whether competition or drug pricing behavior would be affected if PBMs were to bear financial risk for drug spending.

Neither the original House bill nor the original Senate bill contained a provision similar to this, even though both bills envisioned the administration of the Medicare prescription drug benefit by private entities such as PBMs. It is worth noting that the evaluation of the dispensing and switching activities contemplated are strikingly similar to conduct that is the subject of a suit filed by the United States under the False Claims Act. *See United States v. Merck-Medco Managed Care, L.L.C*, No. 00-CV-737 (E.D. Pa. filed Sept. 29, 2003).

Durable Medical Equipment Suppliers

Under the Act, the Secretary, after consultation with industry representatives, must establish quality standards for suppliers of durable medical equipment (DME) (as well as certain other items and services), to be applied by recognized independent accreditation organizations. In addition, the Secretary must establish standards for clinical conditions for payment for covered DME, including the specification of the types or classes of covered DME that require a face-to-face examination of the individual by a physician, physician assistant, nurse practitioner, or a clinical nurse specialist and a prescription for the DME. As a result of concerns about misuses of motorized wheelchairs, as of the date of enactment of the Act, the Medicare program will not pay for motorized or power wheelchairs unless a physician, physician assistant, nurse practitioner, or a clinical nurse specialist has conducted a face-to-face examination of the individual and has written a prescription for the item.

The Act freezes payment rates for DME from 2004 through 2008. Furthermore, the Act requires the Secretary to establish and implement a competitive bidding program (the "Bidding Program") for DME (as well as other items and supplies) to replace the Medicare fee schedule payments beginning in 2007. Certain items, including inhalation drugs and class III devices will be excluded from the Bidding Program. The Bidding Program is to be phased-in with competition occurring in 10 of the largest metropolitan areas beginning in 2007 and 80 of the largest metropolitan areas in 2009, with additional areas to be added after 2009. Rural areas and areas with low population density within urban areas that are not competitive may be exempted from the Bidding Program. The Secretary may initially phase-in items and services with the highest cost and volume, or which the Secretary determines have the largest savings potential, and may exclude items for which the Bidding Program would not likely generate significant savings. Payment for competitively priced items and services will be based on bids submitted and accepted, and the Secretary will determine a single payment amount for each item or service in each competitive acquisition area. The Medicare payment will be 80% of the payment amount, with the beneficiary to pay the remaining 20% (after meeting the Part B deductible).

Home Health Services

Home health patients and rural home health agencies benefit as a result of the final provisions of H.R.1. The controversial provision of the initial House Bill requiring a beneficiary co-payment for each 60-day episode of care was not incorporated into the Act. In addition, rural home health providers will receive a 5% increase in payment for services rendered for episodes of care ending between April 1, 2004 and April 1, 2005.

Physicians and Hospitals

The Act benefits physicians by providing for an increase in their Medicare payment rates, rather than the decrease in rates that CMS announced earlier this year. The physician fee schedule

is based on relative value units, which are determined by, and adjusted according to factors such as the type of work, the practice expenses, and the geographic location of the physician's practice. Once a relative value is established and adjusted, a conversion factor is used to determine the dollar amount Medicare will pay for the service. Congress updates the conversion factor annually. In 2004, the conversion factor was expected to decrease by 4.5%. Instead, the Act provides for no less than a 1.5% increase to the conversion factor in 2004 and 2005.

Like Medicare's payment system for physicians, Congress regularly updates the payments Medicare makes to hospitals. Under current law, hospitals are scheduled to receive a full update based on the market basket for fiscal year 2004. The currently planned update for 2004 does not change under the Act. However, for fiscal years 2005-2007, in order to receive the full market basket update, hospitals must submit data to the Secretary regarding the quality of inpatient care at the hospital, based on all ten factors developed by the National Quality Foundation and established by the Secretary on November 1, 2003. If a hospital does not submit the data by the beginning of the fiscal year (including applicable grace periods), then the hospital will receive an update of market basket minus 0.4%. However, these reductions will not be taken into account in computing the increase in subsequent years.

Under current law, there is a disparity between payments received under the Medicare Inpatient Hospital Prospective Payment System by acute hospitals for inpatient services in large urban areas and those received by hospitals in rural or smaller urban areas. Large urban areas receive 1.6% more than the standardized amount used to pay hospitals in other areas. The Act equalizes the amount paid by Medicare, beginning with discharges in fiscal year 2004, such that acute hospitals in all areas – rural and urban – will receive the higher, standardized amount currently used for payments to hospitals in large urban areas. Similarly, hospitals that serve a disproportionate share of poorer patients ("disproportionate share hospital" or "DSH") that are not located in large urban areas will be eligible to use the same DSH adjustment factor that is currently used for disproportionate share hospitals in large urban areas, subject to a 12% cap for all hospitals except rural referral centers. This new adjustment, which doubles the cap for many hospitals, will take effect for any discharges occurring after April 1, 2004.

The Act also temporarily amends the "whole hospital" exception to the Stark law, which prohibits physician referrals of Medicare patients to facilities in which the physician or physician's family has a financial interest. For 18 months following enactment, the whole hospital exception will not cover specialty hospitals, which include hospitals devoted primarily or exclusively to certain specialty areas, such as cardiac, orthopedic and surgical care hospitals. During this time, the Medicare Payment Advisory Commission (MedPAC) would study the effects of the whole hospital exception for physician ownership in specialty hospitals. Specialty hospitals in existence or under development as of November 18, 2003 are exempt from the effect of this amendment.

Finally, the Act prohibits the Secretary from requiring a hospital to ask questions or obtain information relating to the Medicare secondary payor provisions in the case of reference laboratory services, unless the same requirements are imposed upon independent clinical laboratories. Currently, an entity furnishing Part B services must obtain information from the beneficiary about whether he or she has insurance coverage other than Medicare. The Act releases hospital labs from this burden with regard to "outreach testing" unless independent labs are also required to collect the information.

Clinical Laboratories

Throughout the consideration of the House and Senate versions of the legislation and the hotly contested conference process, clinical laboratory interests battled a proposed copayment for laboratory services. Ultimately, the conferees gave up on the idea of a copayment and decided instead to impose a five-year freeze on laboratory payments. Laboratories were scheduled to receive a Consumer Price Index (CPI) update, but that update will now not come again until 2009. The freeze is estimated to save the Medicare program nearly $7.8 billion. In addition, the bill requires HHS to conduct a demonstration project on a competitive bidding program for clinical diagnostic laboratory tests performed by entities that do not have face-to-face encounters with patients. CLIA standards will apply to the demonstration project. Under the bill, HHS is required to submit an initial report on the program to Congress by December 31, 2005. The Act will also require Medicare to pay for the following preventive services:

- cholesterol and blood lipid screening tests every two years;
- diabetes screening tests, including fasting plasma glucose tests for certain beneficiaries; and
- screening pap, PSA, cardiovascular, and colorectal cancer screening tests as part of coverage of initial preventive physician exams.

The Act also requires the Secretary to establish procedures for determining the basis for and amount of payments for new clinical diagnostic laboratory tests.

Finally, the Act extends the grandfather granted to clinical laboratories for billing

certain physician pathology services. In general, clinical laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. The Beneficiary Improvement and Protection Act of 1997 (BIPA) permitted independent laboratories with certain existing arrangements with such hospitals to bill Medicare directly for the technical component of pathology services provided to patients. The Act permits Medicare to continue to pay laboratories directly for these services through 2006.

Hatch-Waxman Reforms

The Act includes provisions designed to close loopholes in the Hatch-Waxman Act, which governs how generic drugs are brought to market. These new provisions are intended to ultimately benefit consumers by enabling generic drugs, which are less costly than their brand-name counterparts, to enter the market in a more timely fashion. First, the Act changes the existing 30-month stay and 180-day exclusivity provisions. Branded drug companies will only be able to obtain one 30-month stay period to block a generic drug from entering the market based on a patent dispute. In addition, multiple generic companies may qualify for the 180-day exclusivity period because, under the new provisions, any company that files an application on its first day of eligibility qualifies for the exclusive period. The primary goal of this provision is to encourage competition among generic manufacturers.

Moreover, under the Act a generic manufacturer may seek a declaratory judgment that its drug does not infringe an established patent if a patent owner, or branded company that holds an approved New Drug Application does not sue for patent infringement within 45 days after the generic drug manufacturer filed its Abbreviated New Drug Application, and complied with all related requirements. This provision is intended to facilitate the timely resolution of patent disputes, which ultimately helps both generic drug companies and consumers by sending cheaper generic alternatives to the market more quickly.

Drug Reimportation Issues

In an effort to lower drug prices in the United States, the Act requires HHS to promulgate regulations allowing pharmacists and wholesalers to reimport prescription drugs from Canada, where they are sold for lower prices. However, these sections would only become effective if HHS certified to Congress that implementation of the provision would not pose any additional risk to the health and safety of the public and that it would result in a significant cost savings for American consumers. HHS, however, has consistently taken the position that reimportation poses a risk to public health and safety. The agency is not expected to change this position in the near future, and thus it is not expected that regulations permitting reimportation will be promulgated any time soon.

Conclusion

Although Democrats narrowly lost the votes in the House and the Senate, the fight over prescription drug coverage may not be over – they have vowed to continue the fight to improve Medicare in the ways they prefer. Minority Leader Daschle has announced plans to introduce legislation early in the next session that would give greater leverage to the U.S. government to use its purchasing power to negotiate discounts on drug prices, create a form of the drug benefit that would be run directly by the government, and enact federal protections for Medicare patients and younger people who get care through private health plans. In fact, Daschle has already introduced legislation to effect some of these changes. Several House Democrats are also poised to introduce similar legislation. In addition, many observers predict that when future sessions of Congress are forced to make changes to the Act's complex requirements or authorize expenditures to fund its initiatives, political differences could continue to plague the process. There is no doubt that the health care industry will be anxiously waiting to see how the drama unfolds as the Act's provisions are implemented over the next decade.

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