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# Advisory

August 1, 2003

## HEALTH LAW

### Recently Passed House and Senate Medicare Reform Bills Would Significantly Affect Health Care Providers

On June 27, 2003, the House and Senate passed different versions of Medicare legislation, either of which would implement the greatest changes to the Medicare program since its creation in 1965. The bills would set aside slightly more than \$400 billion over the next decade to help Medicare beneficiaries cover the cost of prescription drugs. The Senate bill (S. 1) was passed by a bipartisan vote of 76-21, with 40 Republicans, 35 Democrats and one independent voting for the bill. The House narrowly approved its version (H.R. 1) by a vote of 216-215, with 207 Republicans and nine Democrats voting for the bill, and 195 Democrats, 19 Republicans and one independent voting against it. The House and Senate recently began the conference process that, if successful, will lead to a Medicare prescription drug bill that Congress will send to President Bush, most likely in the fall.

Beginning in 2006, both bills would provide \$400 billion over the next decade to add a prescription drug benefit for Medicare beneficiaries. In the meantime, a temporary drug discount card endorsement program would be established until the program is implemented. The House and Senate proposals each carve out a significant role for private health plans, and both are voluntary, involving significant beneficiary cost-sharing provisions until expenses reach a certain amount, at which point catastrophic coverage would kick in. Each bill would require annual premiums (\$420) and deductibles (\$250 for the House plan, \$275 for the Senate plan). Furthermore, both measures provide extra assistance for low-income beneficiaries, and are designed to assure access to plans in all areas, with increased federal assistance authorized where necessary to encourage participation. While the Senate bill includes a fallback mechanism in areas where private plans are not available, the House bill does not.

Only the House bill calls for some means testing to determine eligibility for benefits: individuals with annual incomes over \$60,000, and couples with incomes over \$120,000, would pay a larger share of their own drug bills before they qualify for catastrophic drug coverage. While the Senate bill has no similar provision, there is some support in the Senate for requiring higher income beneficiaries to pay higher Medicare Part B premiums on a sliding scale. Both of these issues are expected to be addressed during the conference.

The most contentious provision facing conferees is a House proposal that would phase in a premium support system under which private health plans and traditional fee-for-service Medicare would directly compete in areas where at least two private plans are offered. Beginning in 2010, beneficiaries

who chose a plan that costs less than a benchmark amount (calculated as the average of all plan bids and the estimated cost of the fee-for-service plan) would be able to retain 75 percent of the savings, whereas those who chose the more expensive plan would have to pay the difference themselves. Supported by House Republicans but extremely unpopular with Senate Democrats, this provision could threaten to unravel the fragile coalitions that enabled both Chambers to pass their bills. When the Medicare bill goes back to the Chambers for a final vote, the inclusion of the provision in its current form is likely to create significant concerns in the Senate. Likewise, its exclusion could threaten the bill in the House.

House and Senate conferees have admitted that negotiations may be extremely difficult given the number of major differences between the bills. Further complicating the negotiations, preliminary Congressional Budget Office (CBO) estimates released July 22, 2003 found that both bills exceed the \$400 billion set aside in the budget resolution: the House bill by \$8 billion and the Senate bill by \$61 billion. Leaders of the House conferees have vowed to produce an agreement that abides by the \$400 billion ceiling. Despite these formidable obstacles, conferees remain optimistic that an agreement will be reached given the strong desire of lawmakers to finally enact a Medicare prescription drug plan, the Administration's strong support of the effort, and the enormous political pressure, especially from elderly voters. Because both bills are so extensive, it is impossible to detail each provision; however, this advisory highlights some of the key provisions that may affect health care providers if they are enacted in the final legislation.

## Pharmaceutical Manufacturers, Pharmacies and Health Care Providers

Both the House and Senate bills include provisions that will significantly impact pharmaceutical manufacturers and providers. Both bills aim to reform the payment system for outpatient drugs and biologicals currently paid under Medicare, but there are significant differences between the two. Currently, outpatient drugs and biologicals are paid at 95% of Average Wholesale Price (AWP). Under the House bill, each physician would elect for payment for outpatient drugs or biologicals to be based either on a new reimbursement system tied to the manufacturers' Average Sales Price (ASP) (an average of all final sales prices in the U.S., net of rebates, discounts or chargebacks), or on a new competitive bidding system. (H.B. §303). If the physician chooses the ASP system, the payment would be 112% of the ASP for 2005 and 2006, and 100% of ASP for 2007 and thereafter. Under the competitive bidding system, the physician would select a supplier who has been awarded a contract by the U.S. Department of Health and Human Services (HHS) to provide outpatient drugs and biologicals for a two-year period based on various factors, including bid prices, ability to ensure product integrity, customer service, and past experience. Under this bid system, the supplier, not the physician, would be reimbursed by Medicare. Under the Senate bill, payment for outpatient drugs and biologicals furnished in 2004 would be based on the lesser of the current AWP or 85% of the listed AWP as of April 2003. (S.B. §432). For 2005 and each year thereafter, the payment amount would be increased by the Consumer Price Index for medical care. HHS also would be able to substitute a "widely available market price" for a drug if it is found to be less than the AWP-based amounts.

Both bills contain provisions to establish a federally-endorsed interim drug discount card program for 2004 and 2005 that would be voluntary for Medicare beneficiaries. (S.B. §111; H.B. §105). Under both bills, pharmaceutical benefit management companies, wholesale and retail pharmacy delivery systems, insurers, and other entities with experience in the area would be eligible to sponsor the discount cards. Sponsors would be required to provide beneficiaries with access to negotiated prices, including discounts and other direct or indirect remunerations. The annual enrollment fee under the Senate bill could not exceed \$25, and would be \$30 under the House bill. Under both the House and Senate bills, assistance would be furnished to low-income beneficiaries.

In an attempt to lower drug prices in the U.S., the House and Senate bills both incorporated provisions whereby HHS must promulgate regulations allowing pharmacists and wholesalers to reimport prescription drugs from Canada, where they are sold for lower prices. (S.B. §801; H.B. §1121). 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. However, subsequent to the passage of the House Medicare bill, the House reconsidered a more expansive drug reimportation bill. On July 25, the House voted 243-186 to approve a measure that would make it easier for consumers, pharmacists and wholesalers to import inexpensive prescription medicines from FDA-approved facilities in 25 industrialized countries, including Canada, the European Union and Israel. This bill does not include any requirement that HHS certify that the imported medicines "pose no additional risk" to consumers — an issue of concern for drug

manufacturers. Since approved, the provisions in this bill supersede the original House provision in the Medicare bill and now represent the House conferees' official position during the Medicare conference.

Both the House and Senate bills further aim to reduce drug prices by amending a key provision in the Hatch-Waxman Act. Some legislators have expressed concern that some brand name drug manufacturers have entered into agreements with generic drug manufacturers that arguably could prevent or delay entry of the generic drug into the market. Therefore, the House and Senate bills would require both the generic company and the brand name company to file with federal authorities notice of any agreement regarding the manufacturing, marketing or sale of either the brand name or generic drug, which is the subject of the generic drug applicant's drug application. Both bills provide for civil penalties up to \$11,000 per day of noncompliance. (S.B. §§901-908; H.B. §§1111-1115).

### **Pharmacy Benefit Managers (PBMs)**

Both bills envision the administration of the Medicare prescription drug benefit by private entities such as Pharmacy Benefit Managers (PBMs). They both impose certain requirements on PBMs, but the Senate bill is the more restrictive of the two. Specifically, the Senate bill includes a provision that would prohibit an entity offering a Medicare drug plan from entering into a contract with any PBM that is owned by a pharmaceutical manufacturing company. (S.B. §133). The Senate bill also would require a PBM that manages prescription drug coverage to disclose certain information annually to the Antitrust Division of the Department of Justice and the Inspector General of HHS. For example, the PBM

would be required to disclose (1) the aggregate amount of any rebates, discounts, administrative fees, promotional allowances, or other payments received or recovered from a pharmaceutical manufacturer; (2) the amount of payments received from each pharmaceutical manufacturer for each of the top 50 drugs; and (3) the percentage differential between the price the PBM paid to pharmacies for a drug versus the price the PBM charged a Medicare drug plan for the same drug. The Congressional Budget Office has estimated that these requirements, proposed by Senator Cantwell (D-Wash), would cost the Medicare system \$40 billion.

### **Physicians and Hospitals**

Many of the House and Senate bill provisions would have an impact on physicians and hospitals. Physicians would benefit from a House bill provision that would update the conversion factor used in calculating physicians' fees by no less than 1.5% for 2004 and 2005. (H.B. §601). The House bill also contains a controversial provision that would allow HHS to adopt a new ICD-10 coding system as a standard if the National Committee on Vital and Health Statistics does not make a recommendation regarding the code within one year after the day of enacting this provision. (H.B. §942). In addition, the House bill would decrease the market basket index adjustment used for hospital inpatient Prospective Payment System (PPS) payments. Under current law, hospital payments in 2004 would increase by a full market basket index adjustment factor (a measure of inflation). However, the House bill would change the inpatient hospital update to market basket minus 0.4% for fiscal years 2004-2006. (H.B. §501). While the Senate bill is silent on all of these issues, it contains a provision that

would affect specialty or "boutique" hospitals by narrowing the "whole hospital" exception to the Stark self-referral law. Physicians with an ownership interest in a specialty hospital would be limited in their ability to refer Medicare or Medicaid patients to that hospital. The bill would, however, exempt specialty hospitals already in operation or under development as of June 12, 2003. (S.B. §453). The House bill takes a more tentative approach to the subject, calling for a study of specialty hospitals to examine whether there are excessive self-referrals to these hospitals, the quality of care furnished, whether specialty hospitals adversely impact general acute care hospitals, and any differences in the scope of services, Medicaid utilization and uncompensated care furnished. (H.B. §505).

Rural hospitals would benefit under either bill. One common goal of both bills is to equalize the standardized amounts for payment received by rural hospitals and urban hospitals under the PPS system. (H.B. §402; S.B. §401). Both bills also call for adjustments to the payment amounts made to disproportionate share hospitals; that is, those hospitals that serve a large share of poorer patients. (H.B. §401; S.B. §404).

### **Home Health Providers**

The primary, contentious issue for home health providers is a House bill provision that calls for a beneficiary co-payment for each 60-day episode of care. The co-payment would equal 1.5% of the national average payment estimated by HHS for the year involved, and is set at \$40 for 2004, unless HHS timely provides otherwise. (H.B. §702). This co-payment would not apply to certain low-income or low-usage patients (patients for whom an episode of care does not exceed four visits).

## Laboratories

Laboratories will be concerned primarily with two provisions: a 20% co-payment under the Senate bill, and a demonstration project for a competitive bidding program for clinical laboratory services under the House bill. The Senate bill proposes a 20% co-payment for clinical diagnostic laboratory tests, which would likely translate into about \$5 per claim. (S.B. §431). The co-payment would go into effect January 1, 2004, and is estimated to save the Medicare program \$18.6 billion over 10 years. The House bill would require 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. (H.B. §302). Under the bill, HHS would be required to submit an initial report on the project to Congress by December 31, 2005. Both the House and Senate bills contain provisions that allow Medicare to pay for cholesterol and blood lipid screening tests every two years (H.B. §612, S.B. §450D), and the House bill also provides coverage for diabetes laboratory diagnostic tests, (H.B. §630).

## DME and Orthotic Suppliers

Durable medical equipment (DME) suppliers have voiced concern about a House bill provision that would require HHS to implement a competitive bid-

ding program over a three-year period. (H.B. §302). The program would apply to durable medical equipment and medical supplies, including items used in infusion and drugs and supplies used in conjunction with DME, but excluding Class III devices under the Federal Food, Drug and Cosmetic Act. It would also apply to other items, equipment and supplies (except enteral nutrients), and to off-the-shelf orthotics that require minimal self-adjustment and no expertise in customizing the fit for the patient. Under the House bill, HHS has discretion to exempt rural areas, areas with low population density in urban areas, and items and services for which competitive bidding is not likely to result in significant savings. The bill also allows HHS to establish a process under which a physician may still prescribe a clinically-superior item or service. The Senate bill does not include a competitive bidding requirement, but does include a provision that would freeze the inflationary increases in Medicare payments for DME products and off-the-shelf orthotics (that are not custom-fabricated) from 2004 to 2010. (S.B. §430). The Senate bill also would require DME providers to meet quality standards established by independent accreditation organizations selected by HHS in consultation with industry representatives.

## Fraud Provisions

There has been speculation that the new Medicare provisions, particularly the prescription drug benefit, may create even greater confusion in the health care industry and may increase fraud and abuse enforcement. The Senate bill would strengthen efforts to reduce fraud by increasing appropriations to the Health Care Fraud and Abuse Control Account and the Office of the Inspector General of HHS, and significantly increasing the range of civil penalties under the False Claims Act to not less than \$7,500 or more than \$15,000 per false claim, plus three times the amount of damages that the Government sustains. The Senate bill would also increase civil penalties under section 1128A of the Social Security Act from \$10,000 to \$12,500; from \$15,000 to \$18,750; and from \$50,000 to \$62,500. These amendments would apply to violations occurring on or after January 1, 2004. (S.B. §§611-613).

*The full text of H.R. 1 and S. 1 are available at <http://thomas.loc.gov>.*

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