ARNOLD & PORTER UPDATE

Sweeping Legislation Creates New Medicare Drug Benefit, Reforms Traditional Medicare Program

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Today, President Bush signed the "Medicare Prescription Drug Improvement and Modernization Act of 2003," which adds a voluntary prescription drug benefit to Medicare. The legislation also creates a temporary drug discount card program; makes significant changes in the existing Medicare program, including the payment rules for drugs already covered under Medicare; and changes the rules under which innovator companies can challenge the entry of generics into the market. This summary briefly describes some of the major provisions of the new legislation, focusing on issues relevant to drug manufacturers.

TIMETABLE FOR KEY CHANGES IN DRUG BENEFITS

The new Medicare prescription drug benefit (Medicare "Part D") will not become available until January 1, 2006. To provide interim relief until the Part D benefit takes effect, the legislation mandates that new Medicare-endorsed drug discount cards be made available within six months of enactment. In addition, the legislation changes the payment rules for drugs currently covered by Medicare beginning January 1, 2004, and requires manufacturers to begin compiling new pricing data beginning on January 1, 2004.

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PRIOR LAW

Coverage of Drugs Under Medicare. The traditional fee-for-service Medicare program (which provides health insurance to persons 65 and over and to certain persons with disabilities) does not cover most outpatient prescription drugs. Rather, coverage is limited to drugs generally administered in a physician's office and a small number of additional drugs specified by statute (collectively referred to as "Part B" drugs). (Like all Medicare-covered items and services, these drugs must also be "reasonable and necessary.") Approximately 10% of Medicare beneficiaries are enrolled in managed care plans under the Medicare+Choice program; some of these plans cover outpatient prescription drugs that go beyond Part B drugs, although they are not required by law to do so. Under the new legislation, Medicare+Choice plans are now called "MedicareAdvantage" plans.

Coverage of Drugs Under Medicaid. Medicaid, a joint federal-state program that provides health insurance to the poor, provides broad drug coverage. Given the limited categories of drugs currently covered by Medicare, persons who are eligible for both Medicare and Medicaid ("dual eligibles") receive coverage for most drugs under the Medicaid program.

BASIC PART D PRESCRIPTION DRUG COVERAGE

The legislation creates a voluntary prescription drug benefit under a new Part D of the Medicare program. For 2006, beneficiaries enrolling in Part D would typically pay a premium (estimated at $35 per month), an annual $250 deductible, and the following co-payments:

Prescription drug costs	Beneficiary co-payment
$250-$2,250	25%
$2,250-$3,600	100%
$3,600 and above	Approximately 5%

Additional subsidies are provided to persons with incomes below 150% of the federal poverty level. As noted above, most beneficiaries will have no coverage for drug expenditures between $2,250 and $3,600; this is commonly referred to as the Part D "doughnut hole."

"Covered Part D drugs" ("Part D drugs") are defined to include most prescription drugs, biologics, vaccines, and insulin. Part D drugs do not include: certain drugs such as drugs for weight gain or loss, infertility, or hair growth; Part B drugs; drugs that would not meet Medicare's "reasonable and necessary" requirements (subject to provisions for reconsideration and appeal); drugs prescribed for uses that are not "medically accepted indications" (as that term is defined in the Medicaid rebate statute); and drugs not prescribed as required under the plan or Part D.

Role of Private Health Plans

The new drug benefit will be provided by private entities under contract with the Department of Health and Human Services (HHS). These entities will bear significant financial risk in providing

the benefit and receive federal payments and enrollee premiums. Only companies authorized as risk-bearing insurance plans under state law will generally be eligible. Plans will submit bids and compete for contracts based on factors such as the coverage offered (including the deductible and other cost sharing) and the level of risk assumed. HHS has authority to negotiate the terms of plans' participation similar to the Office of Personnel Management under the Federal Employees Health Benefits Program. Plans can subcontract with pharmacy benefit managers (PBMs) or other entities to administer the benefit.

Two types of prescription drug plans will be available. First, health plans can establish stand-alone plans providing coverage for Part D drugs ("prescription drug plans" or "PDPs"). Second, MedicareAdvantage plans may provide coverage for Part D drugs to their members ("MedicareAdvantage prescription drug plans" or "MA-PDPs"). Health plans may provide supplemental coverage consisting of either certain reductions in cost sharing (*e.g.*, reduction in deductibles or co-pays) or coverage of drugs that are excluded from Part D.

To assure beneficiary choice, HHS must contract with at least two plans (at least one of which must be a PDP) in each geographic region. In areas where two plans are not otherwise available, HHS must provide a "fallback" mechanism. Medicare would contract with private entities to provide the "fallback" benefit, although the entity would essentially be paid on a cost reimbursement basis for its drug costs, with management fees tied to performance measures.

Formularies

PDPs and MA-PDPs (collectively "plan sponsors") can establish formularies, subject to certain requirements.

P&T Committees. Formularies must be developed and reviewed by a pharmacy and therapeutics committee. A majority of P&TC members shall be practicing physicians, pharmacists, or both. In addition, each P&TC must include one physician and one pharmacist who are independent and free of conflict with respect to the plan sponsor and have expertise in the care of elderly or disabled people.

In developing and reviewing the formulary, the P&TC must "base clinical decisions on the strength of scientific evidence and standards of practice, . . . pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate and . . . take into account whether including . . . particular covered Part D drugs has therapeutic advantages in terms of safety and efficacy."

Therapeutic categories and classes. Formularies must include "drugs" within each therapeutic category and class of covered Part D drugs, but need not include all drugs within such categories or classes. Thus, the language appears to require that formularies include at least two drugs within each category or class. The legislation directs HHS to request the U.S. Pharmacopoeia to develop "a list of categories and classes that may be used in prescription drug plans . . . ." USP may periodically revise such classifications "to reflect changes in therapeutic uses of covered Part D drugs and the addition of new covered Part D drugs." Whether plan sponsors will use the USP guidelines – given the phrase "may be used" – is not clear. However, the legislation creates incentives for plans to use the USP guidelines.

Beneficiary protections. Plan sponsors may change therapeutic categories and classes only at the beginning of each year, except as permitted by HHS to take into account new therapeutic uses and newly approved covered Part D drugs. In addition, plan sponsors may not remove a drug from the formulary or change a drug's preferred or tiered cost-sharing status unless they have notified HHS, affected enrollees, physicians, and pharmacies.

Each plan sponsor must establish minimum procedures for coverage determinations, reconsiderations, and appeals. Beneficiaries are entitled to appeal to receive a non-formulary drug if the prescribing physician determines that formulary drugs would not be as effective or would have adverse effects for that beneficiary. HHS must establish guidelines for plan sponsors to resolve such appeals.

Government Non-Interference in Price Negotiations

In order to promote competition, HHS may not "interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" or "require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs." The formulary rules discussed above, which could give plan sponsors leverage in price negotiations with manufacturers, represent one of the cost containment mechanisms under Part D.

DRUG DISCOUNT CARDS

The legislation directs HHS to establish a program under which private-sector entities offer Medicare-endorsed drug discount cards to Medicare beneficiaries. Discount card sponsors would negotiate discounts and rebates with manufacturers and pharmacies, thereby allowing beneficiaries to purchase reduced-price covered Part D drugs. The Centers for Medicare and Medicare and Medicaid Services (CMS) estimates that these discount cards will provide savings of 10%-25%. The program would be voluntary, and sponsors could charge beneficiaries an annual fee of up to $30. HHS must establish the program within 6 months of enactment of the legislation under expedited rulemaking proceedings that are not subject to review. With limited exceptions, the program would expire on December 31, 2005, when the new Part D benefit begins. Most dual eligibles (*i.e.*, persons eligible for both Medicare and Medicaid) cannot participate in discount card programs. Certain low-income beneficiaries who enroll in a discount card program will receive "transitional assistance" (up to $600 per year) to help subsidize drug costs.

A wide range of private-sector entities would be eligible to become card sponsors, including PBMs, wholesalers, pharmacies, health insurers, and MedicareAdvantage plans. Interested entities must submit bids to HHS that meet certain standards specified in the legislation and its implementing regulations. HHS must ensure that at least two discount cards are available in each PDP region. The Conference Report on the legislation encourages, but does not require, manufacturers to maintain their existing discount cards until the new Part D benefit takes effect.

NEW PAYMENT RULES FOR PART B DRUGS

Part B Drugs Generally

As noted earlier, Medicare Part B covers a limited category of drugs, which are generally reimbursed at 95% of Average Wholesale Price (AWP). The new legislation directs CMS to prepare recommendations (due by January 1, 2005) on folding Part B drugs into the new Part D drug benefit. Unless these recommendations ultimately spur legislative changes, however, Part B drugs will remain in Part B.

Payments for 2004[1]

During 2004, most drugs will be reimbursed at 85% of their April 1, 2003 AWP. Thus, Medicare payments will still be based on AWP; because the payment formula uses a historical AWP figure, however, changes in AWP will no longer affect Medicare payments. Certain drugs that had a high AWP relative to their market prices will be reimbursed at a lower rate, but not below 80% of the April 1, 2003 AWP. Manufacturers also may request CMS to set a different payment rate than would otherwise apply to a particular drug, by submitting supporting pricing data to CMS by the end of 2003; there is no guarantee that CMS will grant such requests.

Payments for 2005

Under a new payment methodology that takes effect beginning in 2005, payment for most drugs will depend partly on their Average Sales Price (ASP)[2]. The ASP for a drug is a quarterly figure, which basically equals the average net price at which the manufacturer sells the drug in the U.S. during that quarter. Certain sales are excluded from ASP calculations. Manufacturers must report ASPs (and certain other data) to CMS "for calendar quarters beginning on or after January 1, 2004." Given this schedule, implementing systems to capture this data should be a top compliance priority.

The basic payment formula for single source drugs is the lesser of: (1) 106% of ASP; or (2) 106% of Wholesale Acquisition Cost (WAC). The basic payment formula for multiple source drugs is 106% of the volume-weighted ASP for all of the multiple source products within the same Medicare billing code. Payments will be lower than 106% of ASP (or 106% of the lesser of ASP or WAC) in some cases. This will occur if the ASP exceeds the Widely Available Market Price (WAMP) or the Average Manufacturer Price (AMP) by a threshold percentage. The threshold percentage is 5% for 2005, and may be adjusted by CMS in subsequent years. AMP

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[1] This section and the sections below discuss the payment rules that will apply to most Part B drugs; the special payment rules that apply to certain categories of drugs are not discussed here. This discussion also does not cover drug payments in the hospital outpatient setting.

[2] This methodology, described in a new Section 1847A of the Social Security Act, is referred to below as the "Section 1847A" payment methodology.

has the same definition it has under the Medicaid rebate statute. WAMP is "the price that a prudent physician or supplier would pay for the drug, "taking into account " the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers."

The HHS Office of Inspector General (OIG) will conduct studies to determine WAMP, and will notify CMS if the ASP for a drug exceeds its WAMP or AMP by the applicable threshold percentage. Upon receiving this notice, CMS "shall" substitute an alternative payment formula for the basic payment formula. This alternative payment is the lesser of: (1) WAMP; or (2) 103% of AMP.

Payments for 2006 and Subsequent Years

CMS will phase in a "competitive acquisition program" for certain drugs beginning in 2006. While the competitive acquisition program is yet another new payment methodology, it is much more than a payment reform - essentially, it will create a new drug distribution system.

Once the competitive acquisition program starts, physicians make an annual election about whether to participate in the program. For physicians who do not participate (or for drugs that are not included in the competitive acquisition program), reimbursement is based on the Section 1847A payment methodology described above in connection with 2005 payments. Physicians who do participate obtain drugs from a competitive acquisition contractor in their area. The competitive acquisition contractor bills Medicare (and collects beneficiary co-payments) for the drug. Under this system, the physician neither pays for the drug nor obtains reimbursement for the drug.

Certain drugs (*e.g.*, specified types of vaccines) are not "competitively biddable drugs." CMS may exclude additional drugs from the competitive acquisition program if competitive bidding is unlikely to produce significant savings, or is likely to have an adverse impact on access.

CMS will conduct competitions to select competitive acquisition contractors, based on bid prices and certain other factors. CMS can limit the number of competitive acquisition contracts it awards for a particular category of drug and particular geographic area, but not below two. Based on the bids it accepts, CMS will set "a single payment amount for each competitively biddable drug . . . in the area" (which suggests that a competitive acquisition contractor might have to accept a payment differing from its bid price).

FUNCTIONAL EQUIVALENCE STANDARD

CMS may not use the "functional equivalence" standard to determine drug payments unless: (1) it had already applied that standard to the drug before the legislation's enactment; and (2) it applies the functional equivalence standard only for purposes of determining the drug's eligibility for hospital outpatient pass-through payments.[3]

[3] This provision does not prevent CMS from treating two drugs as identical if they are classified by FDA as pharmaceutically equivalent and bioequivalent.

DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN DRUGS

CMS is to conduct a demonstration project, beginning 90 days after the legislation's enactment and concluding by December 31, 2005, that will pay for certain drugs not currently covered by Medicare. The project cannot involve more than 50,000 patients, or cost more than $500 million.

The project will pay for drugs prescribed as replacements for Medicare-covered drugs described in 42 U.S.C. § 1395x(s)(2)(A) (physician-administered drugs), 42 U.S.C. § 1395x(s)(2)(Q) (a limited category of oral cancer drugs, which must have the same active ingredients as physician-administered cancer drugs), or both. The Conference Report states that at least 40% of the project's funding should be used for oral anticancer chemotherapeutic agents, and that the demonstration is intended to "provide immediate Part B coverage for all immunomodulating drugs and biologicals used when treating multiple sclerosis."

CMS must submit a report to Congress on the project by July 1, 2006, which is to analyze: (1) patient access to care and patient outcomes under the project; and (2) the project's cost effectiveness (including any cost savings to Medicare attributable to reduced physicians' services and hospital outpatient services for drug administration).

MEDICAID AND THE MEDICAID REBATE STATUTE

Generally, dual eligibles will receive prescription drug benefits under the new Medicare Part D (although States will finance a portion of the Part D costs for dual eligibles under a "federal clawback" mechanism). This is significant because dual eligibles account for roughly 50% of Medicaid drug costs. Providing drug benefits to these individuals through Medicare should lessen budget pressure on the states and lessen state interest in further Medicaid drug price control mechanisms and coverage restrictions -- but not until 2006.

A key issue for manufacturers is the treatment of negotiated prices under the Part D benefit in Medicaid rebate calculations. The legislation provides that prices negotiated by a plan sponsor with respect to covered Part D drugs (as well as prices negotiated by a Medicare-endorsed drug discount card sponsor) are excluded from Best Price calculations under the Medicaid rebate statute. The legislation does not appear to exclude prices for Part B drugs that a manufacturer negotiates with "competitive acquisition contractors" from Best Price calculations (or from ASP calculations).

FRAUD & ABUSE PROVISIONS

Many of the most controversial "fraud and abuse" provisions in the House- and Senate-passed bills were removed in conference, including provisions requiring mandatory reporting of manufacturer rebates to the Department of Justice, increasing the HHS OIG's civil money penalty authority, and boosting funding for healthcare fraud enforcement agencies. Nevertheless, the legislation includes a number of fraud and abuse provisions, including the following:

- Authority for HHS to conduct audits of the "financial statements and records" of PDP or MA-PDP sponsors with respect to prescription drug plans.

- A requirement that each plan sponsor establish "a program to control fraud, waste, and abuse."

- Civil money penalties for misrepresentations in manufacturers' quarterly ASP reports to CMS.

- A directive to HHS to conduct a demonstration project in at least two states on the use of "recovery audit contractors" to identify and recoup overpayments to providers. HHS may pay the contractors on a contingency fee basis.

COST-EFFECTIVENESS RESEARCH

The legislation directs the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research designed to meet the needs of the Medicare, Medicaid, and SCHIP programs on the "outcomes, comparative clinical effectiveness, and appropriateness of health care items and services" and "strategies for improving the efficiency and effectiveness of such programs." For FY 2004, AHRQ will receive $50 million to carry out this effort.

AHRQ must establish an initial list of research priorities within six months of the legislation's enactment, and then complete the research on the initial priority list within 18 months of developing the list. AHRQ shall disseminate its findings to PDPs and MA-PDPs, other health plans, and the public.

CMS may not "use data obtained [under the new AHRQ provisions] to withhold coverage of a prescription drug." While there is no explicit prohibition on Medicare carriers or intermediaries using AHRQ's findings to develop local coverage policies that withhold coverage of prescription drugs, these contractors traditionally have been considered agents of CMS, and presumably would be subject to the same limitations as CMS.

HATCH-WAXMAN REFORMS

The legislation makes changes to various aspects of the Hatch-Waxman provisions of the Food, Drug and Cosmetic Act. These provisions include: changing FDA's recently issued regulation to require notice to patent and NDA holders of all paragraph IV patent challenges, but to limit 30-month stays of approval related to patent litigation to patents listed before the ANDA is submitted, permitting the patent notice when non-infringement is alleged to include an offer to provide review of the generic application under a confidentiality agreement, and making a perhaps ineffectual change in the law with respect to the standards for declaratory judgment actions. In addition, the legislation rewrites the 180-day exclusivity provisions to eliminate court decisions as a trigger for the 180-day exclusivity, to specify that first applicants who file on the same day share exclusivity, to limit 180-day exclusivity to patents in the paragraph IV certifications submitted on the first day such certifications are submitted for a product, and to define circumstances under which a first applicant forfeits its eligibility for exclusivity. The legislation also requires that certain agreements involving generic products be submitted to the

government for review under the antitrust laws. For a more detailed discussion, see our Client Advisory on the legislation's Hatch-Waxman provisions on the Arnold & Porter website at http://www.arnoldporter.com/pubs/files/Hatch-Waxman_Reforms.pdf.

IMPORTATION PROVISIONS

The legislation provides for importation of drugs by pharmacists and wholesalers in accordance with a regulatory scheme to be put in place by FDA. The law differs from prior law (which was never implemented) in that it is restricted to imports from Canada, it excludes more categories of drugs, and it does not contain a prohibition against agreements preventing the sale or distribution of imported drugs. The new provision also restricts enforcement with respect to imports by individuals. Like the prior law, however, the entire import program only becomes effective if the Secretary of Health and Human Services certifies to Congress that its implementation will pose no additional risk to the public's health and safety and will result in significant cost savings to American consumers. At this stage, such a certification seems unlikely.

The Secretary is, however, required to submit to Congress, within 12 months of enactment of the statute, a report of a study on the importation of drugs into the United States under the statutory provision. While the statutory language is not clear, it appears that that report will be required, even if the program is not put into place. An additional study and report on issues related to trade in pharmaceuticals is also to be prepared by designees of the President.

COMPLIANCE IMPLICATIONS FOR PHARMACEUTICAL MANUFACTURERS

The new legislation imposes an array of new requirements – and associated compliance risks – on pharmaceutical manufacturers. While many of these risks will only become clear when HHS issues implementing guidance, several generalizations can safely be made at this point:

- *Calculation of Average Sales Price.* The legislation imposes yet another price reporting obligation on manufacturers. Any reimbursement formula that relies wholly or partly on manufacturer-reported data creates significant risks for manufacturers, particularly if there is a lack of clear-cut guidance on what information should be reported. And under the Medicaid rebate statute, CMS has a long history of failing to provide clear-cut guidance.

- *Manufacturer Relationships with Plan and Discount Card Sponsors*. For several years now, federal prosecutors and investigators have focused intense scrutiny on financial relationships between manufacturers and PBMs. This scrutiny is likely to increase given the central role that PBMs will play in administering the Part D benefit.

- *Role of the HHS OIG in Drug Payment Policy.* In a number of areas, the legislation provides an operational role for the HHS OIG in drug payment policy (*e.g.,* the HHS OIG will conduct studies to determine WAMP, which may trigger reduced payments). Significantly, there is no provision for judicial review or administrative review of such OIG actions.

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ARNOLD & PORTER'S PHARMACEUTICAL REGULATORY PRACTICE

With 700 lawyers in the United States and Europe, Arnold & Porter provides full-service representation on regulatory, transactional, and litigation matters to pharmaceutical, biotechnology, and medical device companies. For more information about the new Medicare prescription drug legislation or related issues, please contact one of the following:

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