George/Jo/Terry/Paul

TO: Members, Roundtable for the Development of Drugs and Vaccines Against AIDS

FROM: Leslie Hardy

DATE: December 15, 1993

SUBJECT: Materials for Your Information

COVINGTON & BURLING
1201 PENNSYLVANIA AVENUE, N.W.
P.O. BOX 7566
WASHINGTON, D.C. 20044-7566
(202) 662-6000

TELEFAX: (202) 662-6291
TELEX: 89-593 (COVLING WSH)
CABLE: COVLING

LECONFIELD HOUSE
CURZON STREET
LONDON W1Y 8AS
ENGLAND
TELEPHONE: 071-495-5655
TELEFAX: 071-495-3101

BRUSSELS CORRESPONDENT OFFICE
44 AVENUE DES ARTS
BRUSSELS 1040 BELGIUM
TELEPHONE: 32-2-512-9890
TELEFAX: 32-2-502-1598

PETER BARTON HUTT
DIRECT DIAL NUMBER
(202) 662-5522

November 24, 1993

MEMORANDUM

Enclosed is our summary of provisions of the Administration's Health Security Act that are of interest to our pharmaceutical and medical device clients. The summary is based on the draft of the legislation that was presented to Congress on October 27, 1993. The bill was introduced to Congress on November 20, 1993 and does differ slightly from the draft. We will continue to monitor these changes.

Peter Barton Hutt

November 16, 1993

SUMMARY OF HEALTH SECURITY ACT PROVISIONS RELATING TO PHARMACEUTICALS AND MEDICAL DEVICES

The Administration's Health Security Act (the "Act") was released in draft form on October 27, 1993. The Act would implement a health reform plan under which all U.S. citizens and legal residents would be entitled to a comprehensive benefit package from a health plan offered through a regional health care alliance. This memorandum summarizes the provisions of the Act that would most directly affect manufacturers of pharmaceuticals and medical devices. After providing a brief overview of the structure of the Act's health reform proposal in Section I, the memorandum focuses in Sections II through VII on the provisions that directly relate to pharmaceuticals and medical devices.

I. OVERVIEW OF THE HEALTH SECURITY ACT

The Act mandates universal access to a nationally guaranteed package of health care benefits through the establishment of a system of regional and corporate alliances in each state. These alliances would act as buying agents, negotiating with health plans in order to offer a choice of health plans to employers and individuals.

A. Eligibility

All American citizens, nationals, legal residents, and long-term non-immigrants would be guaranteed access to a comprehensive package of health benefits. Each eligible

individual would receive a health security card issued by the alliance or other entity that offers the health plan in which the individual is enrolled. § 1001(b) and (c). Individuals who are eligible for the Medicare program would be entitled to coverage through that program, unless they are "qualifying employees" or spouses of qualifying employees.[1] § 1001(d).

Every eligible individual (other than individuals entitled to remain covered under Medicare) would be required to enroll in a health plan. § 1002(a). All members of a nuclear family would be required to enroll in the same health plan. § 1011(a). Each family would enroll in a regional alliance health plan for the geographical area in which the family resides, unless a family member is eligible for a corporate alliance health plan (discussed below), in which case the entire family would enroll in that plan. § 1004(a). Military personnel and their families, veterans and their families, and Native Americans would have the option of enrolling in a health plan or a program established especially for their group. § 1004(b).

B. Comprehensive Benefit Package

The comprehensive benefit package would include hospital services; services of health professionals; emergency and ambulatory medical and surgical services; clinical

---

[1] A "qualifying employee" is defined as one who is employed by an employer for at least 40 hours during the month. § 1901(b)(1)(A).

preventive services; mental health and substance abuse services; family planning services and services for pregnant women; hospice care; home health care; extended care services; ambulance services; outpatient laboratory, radiology, and diagnostic services; outpatient prescription drugs and biologicals; outpatient rehabilitation services; durable medical equipment and prosthetic and orthotic devices; vision care; dental care; health education classes; and certain investigational treatments. § 1101(a). (Part II of this memorandum describes in greater detail the coverage of outpatient drugs and other drugs and medical devices.) Items or services that were not medically necessary would not be included in the comprehensive benefit package. § 1141(a). Certain other items and services, such as custodial care (other than hospice care), cosmetic surgery, private duty nursing, and orthodontic care, would also be excluded. § 1141(b). The National Health Board could expand the comprehensive benefit package before January 1, 2001, as long as the resulting increase in per capita health care expenditures would not cause any regional alliance to exceed its per capita target. § 1152. Benefits included in the comprehensive benefit package would be subject to cost sharing requirements as described in Section II.E, below.

C. Health Alliances

1. Regional Alliances

Each state would be required to establish one or more regional alliances. § 1201(1). Each regional alliance would be governed by a Board of Directors composed of members representing employers whose employees purchase health coverage through the alliance and members who represent individuals who purchase such coverage. § 1302(a). Individuals who have a conflict of interest (e.g., who derive substantial income from the provision of health care) could not serve on the Board. § 1302(c). Each regional alliance would establish a provider advisory board. § 1303.

Regional alliances would be required to establish procedures to ensure that every eligible individual who resides in an alliance's area is enrolled in a regional alliance health plan. § 1323(a). Alliances would be required to offer a choice of plans to eligible individuals, including at least one fee-for-service plan under which no prior approval is necessary to obtain non-primary health care. § 1322. Each regional alliance would solicit bids from, and negotiate with, any willing state-certified health plan to enter into a contract with the alliance to provide health care coverage to eligible individuals in the alliance area. § 1321(a). However, a regional alliance could refuse to contract with a health plan if (i) the proposed premium exceeded 120 percent of the weighted average premium within

the alliance, or (ii) the plan had previously failed to fulfill its responsibilities under a contract. § 1321(b).

Regional alliances would be responsible for issuing health security cards to eligible individuals, collecting premiums from them, and paying the health plans. § 1324. Regional alliances also would be required to provide to eligible individuals certain information about the available health plans, including information on cost and restrictions on access, descriptions of the participating providers, and summaries of annual quality performance reports. § 1325.

Each employer that is a member of a regional alliance would be required monthly to pay to the alliance on behalf of its employees an amount equal to the base employer monthly premium (1/12 of 80 percent of the alliance's weighted average premium) multiplied by the number of its employees covered by that alliance. §§ 6121 - 6122. The required contribution from a regional alliance employer for any year could not exceed 7.9 percent of the employer's average annual wages paid for that year. § 6123. The required contribution from an employer that employed an average of 75 full-time equivalent employees[2] or less would be capped at a percentage of average annual wages, ranging from 3.5 to 7.9 percent,

---

[2] A "full-time equivalent employee" is a qualifying employee who is employed by an employer for at least 120 hours in a month. § 1901(b)(2).

based on the employer's average number of full-time equivalent employees and average annual wages per employee. Id.

2. Corporate Alliances

Companies with over 5,000 full-time employees and sponsors of multiemployer plans with more than 5,000 active participants would, as an alternative to joining a regional alliance, be eligible to sponsor a "corporate alliance" and offer coverage under a self-insured health plan. § 1311. Each corporate alliance would be required to offer a minimum of three health plans, including at least one fee-for-service option and at least two plans that are not fee-for-service plans. § 1382. If a corporate alliance failed to make premium payments to a health plan, the plan could terminate coverage, and the corporate alliance would be responsible for enrolling the affected individuals in another health plan. § 1383(d)(2). The Secretary of Labor would be required to establish a Corporate Alliance Health Plan Insolvency Fund from which payments would be made to providers if a corporate alliance health plan became insolvent. § 1396(c). The Secretary would also be appointed as trustee of insolvent corporate alliance health plans. § 1395.

Individuals eligible for membership in a corporate alliance would not be eligible to enroll in a regional alliance health plan. § 1311(c)(4). AFDC recipients, SSI recipients, and individuals who elect to enroll in special health programs for veterans, military personnel, or Native

Americans would not be eligible for a corporate alliance. § 1311(d).

D. Health Plans

Each state-certified or self-insured health plan would be required to provide the nationally guaranteed comprehensive benefits package to its enrollees on a risk-adjusted, capitated basis. § 1400. Each health plan would be required to accept every alliance-eligible individual seeking enrollment, regardless of the individual's health, although plans could establish overall limits on enrollment based on service capacity. § 1402(a). Health plans would be obligated to cover emergency and urgent care services without regard to whether the provider had a contract with the plan. § 1406(b).

E. National Health Board

The National Health Board would consist of seven full-time members appointed by the President, with the advice and consent of the Senate. § 1501(b). The Board's responsibilities would include, among other things, determining the details of the comprehensive benefit package, recommending revisions to the package, overseeing cost containment, developing and implementing standards relating to eligibility for coverage, establishing minimum capital requirements for health plans, establishing and administering a performance-based system of quality management, and establishing and monitoring compliance with requirements for

participating states. § 1503. The Board could apply sanctions to non-complying states, including notifying the Secretary of Health and Human Services ("Secretary") to reduce certain payments to the state or terminating its approval of the state system if the non-compliance "substantially jeopardizes" the ability of eligible individuals to obtain coverage. § 1512.

In the event that a state did not submit a document for the establishment of a state health care system by January 1, 1998, the Board would notify the Secretary, who would establish regional alliances to provide coverage for eligible individuals of that state. § 1522(b). The Secretary would also establish a guaranty fund to provide financial protection to health care providers in the event that a health plan associated with a regional alliance established by the Secretary failed. § 1522(d). These funds would be derived from assessments imposed on the other health plans in a regional alliance in which one plan had failed. Id.

F. Long-Term Care Services

Each state would be required to submit a plan for home and community-based services for individuals with disabilities. § 2101(a). The new benefit would not create an individual entitlement, but states would be forbidden to limit eligibility based on income; age; geography; residential setting; the nature, severity, or category of disability; or other grounds specified by the Secretary. §§ 2101 - 2102.

States would be required to ensure that recipients of long-term care services under Medicaid would continue to receive an appropriate level of services, either through Medicaid or the new plan. § 2102(a)(1)(d).

G. Medicare and Medicaid

Under proposed amendments to the Social Security Act, states could submit an application for the integration of Medicare into state health security programs. § 4001. Under an integrated system, Medicare-eligible individuals would be enrolled in regional alliance health plans serving the areas in which they reside. They would have the same choice of health plans as other alliance-eligible individuals and be charged the same premiums as other individuals within the same premium class. The health plans in which Medicare-eligible individuals would be enrolled would be required to cover at least the items and services for which payment would otherwise be made under Medicare. Id. Under an integrated system, individuals would continue enrollment in an alliance health plan after reaching age 65, with Medicare making payments to the plan equal to 95 percent of the adjusted average per capita cost of covered services. § 4002.

Under proposed changes to the Medicaid program, Medicaid-eligible individuals under age 65 who do not receive AFDC or SSI payments would no longer receive medical assistance under the Medicaid program, but instead would enroll in regional or corporate alliance health plans.

§ 4201. These families could apply for cost sharing subsidies in alliance areas where there are not sufficient low-cost plans available. § 1371. Families receiving AFDC or SSI would also be enrolled in regional alliance plans, but Medicaid would pay the alliances to provide the comprehensive benefit package to individuals in these families. § 4201. Eligibility for nursing facility services under Medicaid would be expanded through increased income and resource disregards. §§ 4211 - 4212. States would have the option of combining Medicaid community long-term care services for low-income individuals with the new state program for home and community-based services. § 4213.

H. Premium Limitations

The Act does not establish global budgets for overall spending on health care services. Instead, the primary means of controlling health care costs under the Act would be premium controls. The National Health Board would establish a per capita premium target for each regional alliance based on a national per capita baseline premium target, the regional alliance inflation factor, and the adjustment factor for the regional alliance, as described below. § 6003(a).

The national per capita baseline premium target would be based on total expenditures for items and services in the comprehensive benefit package in 1993, adjusted for expenditures for individuals who would not be eligible for

alliances, projected expenditures for currently uninsured and underinsured individuals, estimated administrative costs for health plans and alliances, and cost sharing. § 6002. The Board would compute an inflation factor for each regional alliance, based on the increase in general inflation adjusted for changes in the demographic characteristics and health status of alliance enrollees. § 6001. The Board would establish an adjustment factor for each regional alliance based on variations in premiums across states and across alliance areas within a state, variations in per capita health spending by a state, variations across states and across alliance areas within a state in per capita spending under the Medicare program, and area rating factors commonly used by actuaries. § 6003(c). If an alliance exceeded its per capita premium target for the year, a prorated assessment would be imposed on those health plans within that alliance that had premiums in excess of the allowable average. § 6011.

II. COVERAGE OF DRUGS AND MEDICAL DEVICES UNDER THE COMPREHENSIVE BENEFIT PACKAGE

As discussed in Section I.B, above, the Health Security Act would require each health plan to offer a uniform comprehensive benefit package covering specified items and services. The benefit package would include coverage for drugs and medical devices, as described below. § 1001(a).

A. Covered Outpatient Drugs

Under the Act, a health plan would be required to include coverage for "covered outpatient drugs." §§ 1122(a)(1), 2001(b)(2). A "covered outpatient drug" is generally defined as (1) any prescription drug or biological product approved or licensed by the Food and Drug Administration (FDA) (or a drug commercially available prior to 1962 that has not been determined to require approval); (2) insulin; or (3) a "covered home infusion drug." § 2001(b). A covered home infusion drug is an outpatient drug with respect to which the Secretary has determined that the drug generally can be intravenously administered safely and effectively in a home setting. § 2001(b).

In order to meet the definition of a "covered outpatient drug," a drug also would have to be used for a "medically accepted indication." § 2001(b). A drug would be deemed to be so used if (1) the use of the drug has been approved by the FDA, or (2) the use has not been approved, but the drug itself has been approved and the use is supported by a citation in at least one authoritative compendium (so long as this is not contradicted by another authoritative compendium), or by clinical evidence in peer-reviewed medical literature identified for this purpose by the National Health Board. § 1122(a)(1). Thus, for unapproved uses, the Board would have authority to determine which drugs were covered for which uses by a health plan because it could delist a use by

determining that it was not medically appropriate, even if it was supported by a compendium citation, or by revising the lists of authoritative compendia and reliable medical literature. §§ 1122(a)(1) and (b).

There would be no frequency or quantity limitations on the coverage of outpatient prescription drugs and biologicals. Contrary to earlier indications contained in an explanation of the Act issued by the Administration in September 1993 (the "September Draft"), the Act does not specifically authorize the establishment of formularies, drug utilization review, and generic substitution. See September Draft at 25. However, the Administration has indicated that this omission is the result of an inadvertent error, and that the Act will be revised to contain such authorization before it is introduced in Congress.

B. Immunizations

Under the comprehensive benefit package, coverage would be required to be provided for immunizations specified in lists set forth in the Act for each of seven age groups, and for such additional immunizations as would be specified by the National Health Board. §§ 1114; 1153(a)(3).

C. Other Drug Coverage and Medical Device Coverage

In addition to covered outpatient drugs and immunizations, the comprehensive benefit package would cover drugs and medical devices furnished incident to other services, including the following:

1. Hospital Inpatient Services. Drugs, biologicals, supplies, appliances, and equipment furnished to hospital inpatients. § 1111.

2. Physicians' Services. Supplies, including drugs and biologicals that cannot be self-administered, furnished incident to health professional services. § 1112.

3. Mental Health. Drugs, biologicals, supplies, appliances, and equipment furnished to individuals receiving inpatient and residential mental health and substance abuse treatment, and diagnostic or therapeutic items or services provided to individuals receiving intensive nonresidential treatment, subject to time and other limits. §§ 1115(b)-(d).

4. Hospice Care. Medical supplies, including drugs and biologicals, provided under a hospice care program. § 1117.

5. Home Health Care. Medical supplies (excluding drugs and biologicals) furnished incident to home health care. § 1118.

6. Extended care. Drugs, biologicals, supplies, appliances, and equipment furnished to an inpatient of a skilled nursing facility or rehabilitation facility, subject to an annual limit of 100 days. § 1119.

7. Laboratory, Radiology, and Diagnostic Services. Laboratory, radiology, and diagnostic services provided on prescription to outpatients. § 1121.

8. Blood Clotting Factors. Blood clotting factors provided on an outpatient basis. § 1122(a)(2).

9. Durable Medical Equipment. Durable medical equipment, prosthetic devices, braces, and artificial limbs and eyes. § 1124

D. Investigational Treatments

Under the Act, a health plan would be permitted, at its discretion, to cover any item or service provided to an individual in the course of a treatment that is under clinical investigation as part of an "approved research trial." An "approved research trial" is defined as a research trial approved by the Department of Health and Human Services, the National Institutes of Health, the FDA, the Department of Veterans Affairs, or the Department of Defense; or a peer-reviewed and approved research program conducted for the purpose of determining whether a treatment is safe or effective. § 1128. The definition would include an investigation under an investigational new drug (IND) application or an investigational device exemption (IDE) approved by the FDA.

E. Cost Sharing

Items and services covered by the comprehensive benefit package, including medical devices and prescription drugs and biologicals, would be subject to different cost sharing provisions depending on the cost sharing schedule selected by the enrollee (as described below), and also whether the enrollee received "in-network" or "out-of-network" care. In-network care is defined as that provided by a health

care provider that is part of a provider network that has contracted with the health plan to provide items and services in the comprehensive benefit package to enrollees of the plan or to provide services to enrollees on a fee-for-service basis. §§ 1402(f)(1), (f)(3). Out-of-network care is defined as care provided to a health plan enrollee by a provider who is not a member of the plan's provider network. § 1402(f)(2).

A plan would be required to offer to enrollees a choice of three cost sharing schedules: higher cost sharing; lower cost sharing; and combination cost sharing. Each of the cost sharing schedules would impose a $1,500 annual out-of-pocket limit on cost sharing for individuals and a $3,000 annual out-of-pocket limit for families. §§ 1132(a)(2), 1133(8), 1134(a)(1).

1. Higher Cost Sharing Schedule

An enrollee who selected the higher cost sharing option could choose any provider, but, for most items and services, would be required to meet an annual individual deductible of $200 and an annual family deductible of $400. § 1133(1). However, in order to begin receiving benefits for outpatient drugs and biologicals, each individual would, in addition, have to incur an annual expense for these products of $250. § 1133(3). For most items and services, including outpatient drugs and biologicals, the higher cost sharing option would require that the enrollee pay coinsurance equal to 20 percent of the applicable payment rate (see section F,

below).[3] § 1135(a). However, no coinsurance would be required for immunizations included in the comprehensive benefit package (see section I.B, above). § 1133(5).

2. Lower Cost Sharing Schedule

An enrollee who selected the lower cost sharing option would not be required to meet any deductible or pay any coinsurance. §§ 1132(a)(1), (a)(3)(A). If the enrollee used an in-network provider, he or she would have to make small copayments for some (but not all) items and services, as specified in the copayment table appearing in the Act. § 1135. For example, an enrollee who purchased outpatient drugs and biologicals from an in-network provider would be subject to a copayment of $5 per prescription. §§ 1132(a)(3)(B), 1135(a).

An enrollee who selected the lower cost sharing option but used an out-of-network provider would not have to pay a deductible or copayment, but would be required to pay coinsurance for any item or service that was subject to coinsurance under the higher cost sharing schedule (i.e., the great majority of health care items and services, including outpatient drugs and biologicals). § 1132(a)(4). The amount

---

[3] The term "coinsurance" refers to the percentage of the payment rate owed by a plan participant under the higher cost sharing option. "Copayment" refers to the out-of-pocket cost that a participant under the lower cost sharing option pays at the time that care is sought.

of coinsurance would be a percentage of the "applicable payment rate" (see section F, below). § 1132(a)(4). The percentage would be determined by the National Health Board but could not be less than 20 percent. § 1132(b).

Under both the lower and higher cost sharing options, the above rules would not apply to investigational treatments. Instead, the cost sharing rules for such treatments would be determined by the health plan. § 1135(a).

3. Combination Cost Sharing Schedule

Under a combination cost sharing schedule, the enrollee's cost sharing contribution would vary depending on whether the enrollee received in-network or out-of-network care. The lower cost sharing provisions would apply to in-network items and services, and the higher cost sharing provisions (including all deductibles and coinsurance payments) would apply to out-of-network items and services. § 1134(b) and (c).

4. Reduced Cost Sharing For Low Income Individuals

Families that receive AFDC or SSI, or whose adjusted family income is below 150 percent of the federal poverty level, would be eligible for reductions in cost sharing as specified in the Act. §§ 1371, 1902(25).

F. Plan Payments to Providers and Suppliers For Drugs, Devices, and Other Items and Services

Each health plan would be responsible for entering into such agreements with health care providers (and presumably suppliers) as would be necessary to assure the provision to enrollees of benefits covered by the comprehensive benefit package. § 1406(a). Thus, wide latitude is provided for plans to negotiate with providers and suppliers the terms of payment for services and supplies provided to enrollees. However, for health plans that pay for services on a fee-for-service basis, the Act specifies that the plan must pay providers according to a fee schedule established by the regional alliance, or, at a state's option, a statewide fee schedule established by the state. §§ 1132(a)(4); 1322(c)(1) and (3); 1406(c). The Act is unclear whether fee schedules would include health care goods (e.g., drugs and devices) in addition to services.

III. ADVISORY COUNCIL ON BREAKTHROUGH DRUGS

The Act directs the Secretary of Health and Human Services (HHS) to appoint a 13-member Advisory Council on Breakthrough Drugs to examine the reasonableness of launch prices for new drugs that represent a breakthrough or significant advance over existing therapies. One of the Council members would be required to be a representative of the pharmaceutical industry, and no other member would be

permitted to have any direct or indirect financial ties to the pharmaceutical industry. § 1572(a) and (c).

At the request of the Secretary or a Council member, the Council would make a reasonableness determination with respect to a drug price based on (1) the prices of other drugs in the same therapeutic class; (2) prices of the drug in the 21 foreign countries specified in the Drug Export Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act);[4] (3) cost information supplied (presumably voluntarily) by the manufacturer;[5] and (4) projected prescription volume, economies of scale, product stability, special manufacturing requirements, and research costs. § 1572(b). The Secretary would review the Council's determinations and publish the determinations and results of the review in the Federal Register. § 1572(b)(2). The Council would not be authorized to set or control drug prices.

It is noteworthy that the Act would place the Council under the jurisdiction of the Secretary of HHS, rather than the National Health Board as proposed in the September Draft. Under the Act's Medicare amendments, the Secretary

---

[4] See FD&C Act § 802(b)(4)(A)). These countries are listed in note 13, below.

[5] The Act does not provide the Council with authority to inspect or subpoena a manufacturer's information regarding cost. The Act is unclear whether the Council would have access to information obtained by the Secretary from a manufacturer pursuant to the Secretary's authority under the Medicare program. See, e.g., sections V.A and V.C, below (relating to a manufacturer's reporting obligations under the Medicare rebate program and to Medicare rebate negotiations).

would be granted authority to negotiate prices for new drugs under the Medicare program and exclude from the program any drug whose price to Medicare was determined to be excessive (see Section V.C, below). § 2003(a), adding SSA § 1850(c)(3)). Though the Act does not grant the Council price setting authority, a Council determination that a price is unreasonable could be expected to effectively limit the price that the Secretary would be willing to reimburse for the drug under Medicare.

IV. MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

The Act would retain Medicare as the basic benefit package for the elderly. At age 65, an individual could enroll in Medicare rather than remain in a health plan that provides the comprehensive benefit package, unless the state had elected to integrate Medicare into its alliance system, as described in Section I.G, above. § 1001(d).

A. Covered Drugs and Biologicals

With few exceptions, the Medicare program currently does not cover outpatient prescription drugs. The Act would expand Medicare to provide coverage for these drugs, effective January 1, 1996. § 2001, 2009. The definition of "covered outpatient drugs" for purposes of the new Medicare benefit is substantially similar to that used for the comprehensive drug benefit package discussed in section I.A, above -- i.e., FDA-approved prescription drugs and biological products, insulin,

and covered home infusion drugs, when "used for a medically accepted indication." § 2001(b).[6] A drug would be excluded from coverage as a covered outpatient drug if it were furnished as part of or incident to any other item or service covered under Medicare (and thus reimbursable as part of the reimbursement for that item or service). § 2001(c)(3). In addition, the Secretary could, at her discretion, exclude from Medicare coverage certain categories of drugs that are excludible under Medicaid. Id.[7]

B. Payment Rules for Covered Outpatient Drugs

Medicare beneficiaries would be required to pay a $250 annual deductible for covered outpatient drugs before receiving any benefits. § 2002, amending SSA § 1834(d)(1).[8] The deductible would be applied to the "payment basis" for the drug (discussed below) rather than the actual expenses the patient incurs. SSA § 1834(d)(1)(C). Once the deductible had

---

[6] The definition of "medically accepted indication" for purposes of the Medicare outpatient prescription drug benefit is almost identical to that for the comprehensive benefit package except that the Secretary of HHS, rather than the National Health Board, has ultimate authority to determine which drug uses are covered. § 2001(b)(4).

[7] These include drugs used for anorexia, weight gain, infertility, cosmetic purposes, hair growth, cough and colds, smoking cessation; prescription vitamins and minerals, nonprescription drugs, benzodiazepines, and drugs sold on condition that related tests be purchased from the manufacturer. SSA § 1927(d)(2), 42 U.S.C. § 1396r-8(d)(2).

[8] The payment rules described in this Section IV.B would be added to SSA § 1834 (42 U.S.C. § 1395m) by § 2002 of the Act. For convenience, subsequent citations in this Section IV.B refer only to the SSA section number.

been met, Medicare would pay 80 percent of the "payment basis" for each prescription until the beneficiary reached the $1,000 annual limit on out-of-pocket expenditures. SSA § 1834(d)(2)(A)(i). Thereafter, Medicare would pay 100 percent of the "payment basis" for each prescription for the remainder of the year. SSA § 1834(d)(2)(A)(ii).

For a prescribed brand name drug (i.e., a single source drug, or a multiple source drug specified on the prescription by the prescriber with a "brand medically necessary" or similar notation), the "payment basis" is defined as the lower of (i) the actual charge to the patient; (ii) the 90th percentile of actual charges for the drug during the six-month period beginning at least one year previous; or (iii) the "estimated acquisition cost" plus a $5 dispensing fee. SSA §§ 1834(d)(3); (d)(4)(A)(i); (d)(8)(C). The Secretary would determine the estimated acquisition cost based on price information provided by drug wholesalers and retailers, but it could not exceed 93 percent of the average manufacturer non-retail price for the drug during the payment calculation period. SSA § 1834(d)(4)(C)(i).[9] The dispensing fee would be adjusted annually for inflation and could be reduced for drugs dispensed through a mail order pharmacy. SSA § 1834(d)(5).

---

[9] The Administration has indicated that this provision will be revised to limit the estimated acquisition cost to 93 percent of the average wholesale price, rather than the average non-retail manufacturer price.

For generic drugs, Medicare would reimburse the lower of (i) the actual charge to the patient, or (ii) the estimated acquisition cost plus a $5 dispensing fee. SSA §§ 1834(d)(3), 1834(d)(4)(B). As with brand name drugs, the dispensing fee would be adjusted annually for inflation and could be reduced for drugs dispensed through a mail order pharmacy. SSA § 1834(d)(5).

One aspect of this reimbursement scheme is especially noteworthy. The Secretary of HHS would be authorized to adjust the dollar amounts for both the deductible and the out-of-pocket limit each year to ensure that the percentage of beneficiaries who receive coverage does not increase over time. SSA §§ 1834(d)(1)(B), (d)(2)(B). While this provision is apparently intended to control Medicare expenditures on outpatient drugs, it would limit the number of elderly individuals who would be able to take advantage of drug therapy with Medicare coverage, and possibly result in an increase in the use of more invasive (and expensive) therapies.

The Act also contains provisions under which the Secretary would establish standards and educational programs on prescribing and dispensing drugs, including the appropriate use of generic products. SSA § 1834(d)(6). For example, the Act calls for the creation of a drug use review program (similar to the Medicaid counterpart) to ensure that prescriptions are appropriate, medically necessary, and

unlikely to result in adverse medical results. SSA § 1834(d)(6(C).

V. MEDICARE PRESCRIPTION DRUG REBATE

In order for a manufacturer's covered outpatient drugs to be reimbursed under the Medicare program, the manufacturer would be required, by January 1, 1996, to enter into a rebate agreement with the Secretary. § 2003(a), adding SSA § 1850(a).[10] Under the agreement, which would be effective for one year and renewed automatically thereafter, a manufacturer would be required to pay to Medicare quarterly rebates on covered outpatient drugs dispensed by pharmacies to individuals "eligible for benefits under [Medicare Part B]." SSA § 1850(b)(1).[11] Rebates would be payable only with respect to single source and innovator multiple source drugs; no rebates would be required for generics. SSA § 1850(c)(4) and (f)(4). The "manufacturer" for purposes of the rebate requirement is generally defined as the entity whose National Drug Code Number appears on the label of the drug. SSA § 1850(f)(5).

---

[10] All of the Medicare rebate provisions would be added by § 2003 of the Act. For convenience, subsequent citations in Sections V and VI of this memorandum will continue to refer only to the SSA section number.

[11] It is unclear whether the phrase "eligible for benefits" is intended to include individuals who are eligible for Part B benefits (see SSA § 1836, 42 U.S.C. § 1395o) and have paid the required premiums but have not yet met the applicable deductibles. If so, rebates would be payable on covered drugs dispensed to such beneficiaries, even though the drugs would not be reimbursed by Medicare.

A. Rebate Mechanics

The system for the payment of rebates would be similar to that currently used under the Medicaid Prescription Drug Rebate Program. See SSA § 1927, 42 U.S.C. § 1396r-8. Within 30 days after the end of a quarter, each manufacturer would be required to submit to the Secretary information on the average manufacturer retail price (AMRP) and average manufacturer non-retail price (AMNP) (both discussed below) for each covered drug. SSA § 1850(b)(3). Within 60 days after the end of the quarter, the Secretary would provide the manufacturer with utilization data for each of its covered drugs (i.e., information on the total number of units of each dosage form, strength, and package size dispensed under Medicare during the quarter), which would be used to calculate the total rebate owed for each covered drug for the quarter. SSA § 1850(b)(2).

The Secretary would have the authority to inspect a manufacturers' records to verify the AMRP and AMNP data submitted. SSA § 1850(b)(2)(C). Severe civil monetary penalties could be imposed on a manufacturer for submitting false AMRP and AMNP data, failing to submit this data on a timely basis, or refusing to provide pricing information requested by the Secretary. SSA § 1850(b)(2)(D).

B. Amount of the Rebate

The amount of the basic rebate for each covered drug would be the greater of (1) 17 percent of the AMRP of the

drug, or (2) the difference between the AMRP and the AMNP. SSA § 1850(c)(1). The AMRP is defined as the average price paid to the manufacturer for the drug in the U.S. by the retail pharmacy class of trade. The AMNP is the weighted average price paid to the manufacturer for the drug in the U.S. by hospitals and other institutional purchasers that purchase drugs for institutional use and not for resale. Both the AMRP and AMNP are to be determined taking into account rebates (other than the Medicare rebate) and discounts for cash payment, prompt payment, and volume purchases, but excluding "nominal prices".[12] SSA § 1850(f)(1) and (2). Apparently, the Medicaid rebate and rebates to other governmental entities are to be taken into account in determining AMRP and AMNP.

The minimum basic rebate is greater than that proposed in the September Draft, which was 15 percent of the AMRP. It is also greater than its Medicaid counterpart, which is currently 15.7 percent of the average price to wholesalers. SSA § 1927(c)(1)(B)(i)(II), 42 U.S.C. § 1396r-8(c)(1)(B)(i)(II). However, unlike the Medicaid rebate, the Medicare rebate amount (when it exceeds the minimum rebate) is not influenced directly by the "best price" offered by the manufacturer to any entity, since it is based instead on the weighted average price to

---

[12] Under the Medicaid rebate statute, which contains similar language, the Secretary has interpreted "nominal prices" as meaning less than 10 percent of the average manufacturer price. See Medicaid Rebate Agreement § I(s), 56 Fed. Reg. 7049, 7051 (Feb. 21, 1991).

institutional buyers. This would provide manufacturers with somewhat more latitude to negotiate substantial discounts without dramatically affecting the Medicare rebate.

In addition to the basic rebate, the Act would require an additional rebate for drugs whose prices increase at a rate greater than inflation. The additional rebate would be equal to the amount by which the percentage increase in the current AMRP over the AMRP for a specified base quarter (i.e., April - June 1993) exceeded the percentage increase in the Consumer Price Index for urban consumers from the base quarter to the current quarter. SSA 1850(c)(2).

Covered drugs furnished to an individual eligible for benefits under both Medicare and Medicaid would be subject to rebate under the Medicare, rather than the Medicaid, rebate program. § 2008(a)(2)(B).

C. Negotiated Rebate for New Drugs

The Act would authorize the Secretary to negotiate special rebates for drugs first marketed after June 30, 1993 that were deemed to be excessively priced. If the drug were marketed in any of the foreign countries specified in the Drug Export Amendments to the FD&C Act,[13] the authority to negotiate an additional discount would be triggered if the price of the drug

---

[13] See FD&C Act § 802(b)(4)(A). Those countries are Australia, Austria, Belgium, Canada, Denmark, Germany, finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

in one of those countries were significantly lower than the AMRP. If the drug were not marketed in one of those countries, the Secretary could still negotiate an additional rebate if she determined that the AMRP was excessive. SSA § 1850(c)(3)(A). The rebate negotiated under this provision could not exceed the difference between the AMRP and the price at which the drug was available to wholesalers in one of the specified countries. SSA § 1850(c)(3)(B).

In determining whether a price is excessive and in negotiating an additional rebate, the Secretary would be required to take into account the prices of other drugs in the same therapeutic class, cost information requested by the Secretary and supplied by the manufacturer (presumably voluntarily) or estimated by the Secretary, prescription volumes, economies of scale, product stability, special manufacturing requirements, prices of the drug in the specified countries, and other relevant factors. If the Secretary were unable to negotiate an acceptable rebate for a covered drug, she could exclude the drug from coverage under Medicare. SSA § 1850(c)(3)(C) and (D).

VI. EQUAL ACCESS TO DISCOUNTS

As a further prerequisite for having its covered outpatient drugs reimbursed under Medicare, a manufacturer would be required, under the rebate agreement, to guarantee that it would offer the same price for a drug to each wholesaler, retailer, or purchasing group that purchased the drug on like terms. The provision would not preclude the manufacturer from

offering differential discounts for prompt payment, cash payment, volume purchase, single-site delivery, the use of formularies, and other terms providing economic advantage to the manufacturer, as long as such terms were applied equally to all types of purchasers. Terms offered to the Department of Veterans Affairs, the Department of Defense, or any public program would not be taken into account in determining compliance with the equal access requirement. SSA 1850(e).

VII. ANTIKICKBACK VIOLATIONS

Currently, the Medicare/Medicaid antikickback statute imposes criminal penalties for the payment of kickbacks, bribes, rebates, or "other remuneration" in connection with the provision of goods or services reimbursed under Medicare or Medicaid. SSA 1128B(b), 42 U.S.C. § 1320a-7b(b). The broad prohibition of this statute is potentially applicable to many marketing programs of drug and device manufacturers and suppliers of other goods reimbursed under these federal programs. The Act would change the antikickback law in numerous respects, both with regard to its substantive and penalty provisions and its scope of applicability.

A. Substantive Amendments Relating to Exemptions

The antikickback statute currently exempts from its prohibitions "a discount or other reduction in price" obtained by an entity on reimbursable goods, if the discount is properly reflected in the costs claimed under Medicare or Medicaid. SSA

§ 1128B(b)(3)(A), 42 U.S.C. § 1320a-7b(b)(3)(A). The Act would narrow this exemption by excluding from its coverage (1) the furnishing of one item or service free or at a reduced charge in exchange for an agreement to buy another item or service (i.e., bundled items); (2) a discount applicable to one payor but not providers under Medicare or Medicaid; and (3) cash payments. § 4041(b). (These exclusions from the discount exemption already appear in implementing regulations issued by the HHS Office of the Inspector General ("OIG"). See 42 C.F.R. § 1001.952(h)(3).)

The Act would also narrow the scope of the current exemption for payments by employers to bona fide employees "for employment in the provision of covered items or services." SSA § 1128B(b)(3)(B), 42 U.S.C. § 1320a-7b(b)(3)(D). Under the Act, payments to employees would be exempted only if the amount of remuneration were (1) consistent with the fair market value of the services and (2) not related to the volume of any referrals, except that productivity bonuses would be permissible. § 4041(b)(2). This amendment would appear to preclude suppliers such as drug and device companies from compensating their sales representative employees based solely on commission, though the "productivity bonus" language leaves room for some remuneration based on volume of sales.

A new exemption would be added for payments to a provider, and discounts or reductions in price offered by a provider to a health plan enrollee, when the provider is paid by a plan on an at-risk, prepaid, capitated basis. § 4041(b)(3). A

second new exemption would cover remuneration by a health plan to a provider for the referral of patients or the use or procurement of space, equipment, goods or services, if the payment were pursuant to a written agreement, did not inure to the private benefit of the recipient, and did not preclude the patient's freedom of choice of providers (within the limits of the terms of the patient's health plan). § 4041(b)(4).[14]

B. Additional Penalties for Medicare/Medicaid Related Kickback Violations

For antikickback violations relating to the Medicare and Medicaid programs, the criminal fine for each offense would be increased from $25,000 to $50,000 plus an assessment of up to three times the amount of illegal remuneration offered or received. § 4041(a)(3). The Act also would authorize a court to order a person convicted of a "Federal health care offense" (defined to include a violation of the Medicare/Medicaid antikickback law and the new Health Care Fraud statute described in Section C.1, below) to forfeit any property used in the commission of the offense or derived from proceeds traceable to the offense. § 5432(a); 5402(e).

In addition, new civil monetary penalties would be authorized. Currently under the Medicare and Medicaid programs, the Secretary has authority to impose civil monetary penalties

---

[14] These two new exemptions, which are not specifically limited to Medicare and Medicaid, reflect the expansion of the scope of the antikickback law to other payors, as discussed in Section C, below.

for certain illegal activities with respect to the Medicare and Medicaid programs, but not for antikickback violations. SSA § 1128A, 42 U.S.C. § 1320a-7a. The Act would extend the Medicare/Medicaid civil monetary penalty authority to antikickback violations. § 4041(a)(1). It would mandate a $50,000 penalty for each violation, plus an assessment of up to three times the total amount of remuneration offered or received. § 4041(a)(2) and (4). In addition, a new provision would be added authorizing civil monetary penalties against any person that offers remuneration (including free or discounted goods or services) to a Medicare or Medicaid beneficiary that is likely to influence the individual "to order or receive from a particular provider, practitioner, or supplier any item or service" reimbursable under Medicare or Medicaid. This new prohibition (which would not be added to the criminal antikickback prohibitions) appears to be directed at free goods, rebates and the like offered by vendors directly to patients. § 4043.

C. Penalties for Kickback Violations Relating to Health Plans

1. No Criminal Antikickback Penalty

The September Draft stated that the Act would expand the scope of the antikickback statute beyond Medicare and Medicaid to cover all health payers. Draft at 25. As described below, the Act does authorize exclusion and civil monetary penalties for kickback violations in connection with health plans. Nevertheless, despite the description in the September

Draft, criminal penalties for kickback violations would not be expanded beyond offenses in connection with Medicare and Medicaid.

However, the Act would impose a new criminal penalty for executing or attempting to execute a scheme or artifice to "defraud any health alliance, health plan, or other person, in connection with the delivery of payment for health care benefits, items, or services." Violation would be punishable by fine, or imprisonment of not more than 10 years, or both. § 5431(a). It is possible that criminal prosecutions of certain kickback activities relating to health plans could be brought under this new health care fraud prohibition.

2. Civil Monetary Penalties

The Act would expand the new civil monetary penalties for antikickback law violations beyond Medicare and Medicaid. Under the Act, any actions, including kickback activities and the offer of remuneration to beneficiaries as described in section B, above, that are subject to civil monetary penalties when engaged in under the Medicare and Medicaid programs would become subject to penalty when taken in connection with any health plan. § 5412(a)(1); 4041(a)(1); 4043(a)(1).

3. Exclusion

Currently, a person convicted of a criminal offense relating to Medicare or Medicaid (such as a kickback violation or fraudulent billing practices) is subject to mandatory exclusion

by the Secretary from participating in those federal programs. SSA § 1128(a), 42 U.S.C. § 1320a-7(a). The Secretary is permitted to exclude from Medicare and Medicaid any person who, even if not criminally convicted, is determined by the Secretary to have committed kickback violations or fraud. SSA § 1128(b)(7), 42 U.S.C. § 1320-7(b)(7).

The Act would extend these provisions so that an entity determined to have engaged in kickback or fraud activities with respect to a health plan could be excluded from participation in any health plan. §§ 5411(a) and (b). While the Inspector General of HHS has interpreted the Medicare/Medicaid exclusion provisions not to apply to suppliers like drug and device companies (see 57 Fed. Reg. 3298, 3300 (Jan. 29, 1992)), the language of the Health Security Act is sufficiently broad to authorize exclusion from plans of suppliers determined to have engaged in kickback activities, if HHS were to change its policy on this issue.

D. Health Care Fraud and Abuse Control Program

The Act would establish an all-payer health care fraud and abuse control program under the direction of the OIG and the Department of Justice. The purpose of the program would be to coordinate the functions of the OIG, the Justice Department, and other organizations to control and prevent health care fraud and abuse, and to facilitate enforcement of fraud and abuse laws. § 5401(a). The Act directs the OIG and the Justice Department to arrange for information sharing with other federal, state, and

local law enforcement agencies, as well as health alliances and health plans. § 5401(b) and (c). The OIG and the Department would have access to all pertinent records of health alliances and health plans during the course of a fraud and abuse investigation. § 5401(d)(2).