ARNOLD & PORTER LLP

ADVISORY

September 2009

SENATE FINANCE COMMITTEE CHAIRMAN BAUCUS REVEALS MUCH-AWAITED LEGISLATIVE PROPOSALS

On September 16, 2009, US Senate Finance Committee Chairman Max Baucus (D-MT) released his "Chairman's Mark," the America's Healthy Future Act, which will likely serve as the basis for the Senate Finance Committee's healthcare reform legislation.

The US$856 billion package is financed through a number of policies focused on improving quality, efficiency, and prevention, and by making payment adjustments for many federal health programs. The Mark includes insurance market reforms, payment and delivery system reforms, and initiatives to address fraud and abuse in the Medicare program. It is notable that the Chairman's Mark does not include the public plan option, which has been a topic of intense debate in the past months for congressional leaders and for the public, but does include an alternative plan, which would create nonprofit Consumer Owned and Oriented Plans (CO-OPs) to compete with traditional insurance plans.

The Senate Finance Committee is scheduled to begin to mark up its legislative proposals on Tuesday, September 22, 2009, when it will walk through the current proposals and consider amendments. The committee has made available lists and descriptions of the amendments that will be considered, divided into the categories of healthcare delivery system reform, coverage and financing. Those amendments can be accessed on the Senate Finance Committee's website at http://www.finance.senate.gov/sitepages/legislation.htm.

This advisory summarizes major provisions in the Chairman's Mark that may be of interest to pharmaceutical and device manufacturers and healthcare providers, among others.

INSURANCE MARKET REFORMS

The Chairman's Mark would impose far-reaching reforms on the individual and small group health insurance markets, where individuals and small businesses purchase insurance coverage. Issuers in those markets would be required to offer coverage on a guaranteed issue basis and to offer guaranteed renewal (rated on the same factors initially used when issuing the policies). They also would be barred from denying coverage for pre-existing health conditions, rescinding health coverage, or imposing annual or lifetime limits on benefits. Further plans would not be able to require cost-sharing for preventive services, except in cases where they use "value-based insurance design" to set cost-sharing.

Brussels
+32 (0)2 290 7800

Denver
+1 303.863.1000

London
+44 (0)20 7786 6100

Los Angeles
+1 213.243.4000

New York
+1 212.715.1000

Northern Virginia
+1 703.720.7000

San Francisco
+1 415.356.3000

Washington, DC
+1 202.942.5000

arnoldporter.com

The Mark would also set rating rules for coverage offered in the individual or small group markets. It would set standard ratios by which insurance premiums would be allowed to vary, and such variations would only be permitted for tobacco use, age, family composition, and to account for geographic differences.

The Mark defines four benefit categories (bronze, silver, gold, and platinum) that health plans could offer with actuarial values ranging from 65% (bronze) to 90% (platinum). All plans in the individual and small group markets (except "grandfathered" plans) would be required to offer policies meeting these actuarial standards. In addition, all insurance plans offered in the individual and small group market would be required to cover a certain basic benefits package, including preventive and primary care, prescription drugs, and a variety of other specified services. Plans offered in the state exchanges (described in the next section) would be required to apply parity for cost-sharing for treatments within certain benefit categories.

Existing health plans would be "grandfathered," meaning that individuals and groups could renew existing health policies, even if they did not meet the new benefits, coverage, and rating standards. New federal rating rules would be phased in to apply to grandfathered plans, beginning January 1, 2013.

The Mark would allow states to form "healthcare choice compacts," which would, starting in 2015, allow for the purchase of individual health insurance across state lines. A healthcare choice compact could exist between two or more states, allowing individuals to buy health insurance within any of the states participating in the compact. The National Association of Insurance Commissioners would be required to develop model rules for healthcare choice compacts by 2013.

The Mark also would allow insurers to offer national plans, which must meet the benefit levels and coverage categories defined in the Mark, but would not be subject to state benefit mandates; thus, insurers could offer national plans with uniform benefit packages.

The Mark would also create a high-risk pool to enroll, within a year of enactment, individuals who previously have been denied coverage because of pre-existing health conditions. The high-risk pool would exist until 2013, when, presumably, individuals would be able to enroll in plans offered under a state exchange (which would be required to cover individuals with pre-existing conditions).

STATE EXCHANGES

The Mark would require states to establish exchanges for the individual and small group insurance markets, and all private insurers in the individual and small group markets would be required to offer plans in exchanges established in the states where the insurers are licensed. States would be required to establish exchanges in 2010. States could, through regional compacts, form multistate exchanges. After an exchange in a given state operated for at least three years, the state could permit other entities to establish an exchange.

State exchanges initially would receive federal funding but would become self-sustaining "in future years."

CREDITS FOR INDIVIDUALS AND SMALL BUSINESSES

The Mark would provide healthcare affordability tax credits to lower income individuals and families, to allow those individuals and families to purchase health insurance through the state exchanges. Credits would be calculated on a sliding scale based on income, to individuals and families with income up to 400% of the federal poverty level (FPL). Individuals with incomes at or below 200% of the FPL would also be eligible for cost-sharing subsidies.

The Mark also would provide tax credits to small businesses that offer health insurance to their employees.

INDIVIDUAL MANDATES AND EMPLOYER PENALTIES

The bill would generally require individuals, by 2013, to have health insurance, obtained either through their employers, purchased individually, or received through a government program (e.g., Medicare, Medicaid, the Children's Health

Insurance Program, the Veteran's Healthcare Program, or TRICARE). Such insurance would need to meet certain minimum standards. Uninsured individuals would be subject to a penalty in the form of an excise tax, based on income. Exemptions from the penalty would be allowed for individuals with religious objections, individuals with incomes below 100% of the FPL, if coverage is deemed unaffordable (i.e., the lowest cost premium exceeds 10% of the individual's income), individuals experiencing "hardship situations," and Native Americans. Individuals enrolled in grandfathered plans would not be subject to this penalty.

Employers with at least 200 employees would be required to enroll employees automatically in health plans offered by the employer, although employees may opt out if they show they have other health coverage. Employers would *not be required to offer health insurance*, but they would be required to pay a penalty for any of their full-time employees who receive tax credits to obtain insurance from an exchange. Smaller employers (50 or fewer employees) would not be subject to that penalty. Certain benefit requirements would apply to any employer offering health coverage, such as first-dollar coverage for prevention services.

HEALTHCARE COOPERATIVES

In contrast to the public plan included in other proposed health reform legislation, the Mark would create a CO-OP program to foster creation of nonprofit, member-owned cooperatives that would offer health plans in the individual and small group markets. These CO-OPS would compete with other insurers in these markets. The bill would authorize US$6 billion in funding to establish the CO-OP program. Federal funds would be distributed as loans and grants to CO-OP plans.

The CO-OPs would be structured as nonprofit entities governed by their members, and CO-OPs could not be organizations (or affiliates) existing prior to July 16, 2009. In addition, CO-OPS could not be sponsored by state, county, or local governments, or any government instrumentalities. Any profits generated in such CO-OPs would be used to lower premiums, improve benefits, or for other programs designed to improve the quality of healthcare delivered to members of the CO-OP.

The Mark would not require creation of CO-OPs in every state, nor would it authorize the federal government to create CO-OPs in states where no CO-OPs form. If CO-OP organizations do not form in every state, the Secretary of the US Department of Health and Human Services (HHS) would be authorized to use "planning grants" to encourage formation of new organizations or expansion of currently-participating organizations.

MEDICAID EXPANSION

The Mark would expand Medicaid eligibility for non-elderly, non-pregnant individuals otherwise ineligible for Medicaid, effective in 2011, and would establish 133% of the FPL as the new mandatory minimum Medicaid eligibility level for all non-elderly individuals, beginning in 2014. In addition, beginning in 2014, individuals with income below the FPL would be eligible for Medicaid and ineligible for tax credits in the state exchanges. Non-elderly, non-pregnant adults between 100% and 133% of the FPL could choose between Medicaid and coverage through an exchange. States will be entitled to new federal payments to cover the cost of newly-eligible Medicaid beneficiaries.

OTHER MEDICAID PROVISIONS

Effective in 2014, the Mark would also make prescription drug coverage a mandatory benefit category for both categorically needy and medically needy Medicaid beneficiaries. (Currently, prescription drug coverage is an optional benefit, and when states do provide Medicaid drug coverage, they must cover all categorically needy beneficiaries but they do not need to cover the medically needy.) The Mark also would remove several classes of drugs (smoking cessation drugs, barbiturates, and benzodiazepines) from the list of classes currently excludable from coverage under Medicaid.

The Mark would bar payments to states for Medicaid services related to "healthcare acquired conditions"—potentially broader than the current Medicare definition of "hospital acquired conditions" (i.e., conditions identified by Centers for Medicare & Medicaid Services (CMS)that are (1) high cost, high volume, or both; (2) identified as complicating conditions or major complicating conditions

in Medicare's diagnosis-related group system; and (3) reasonably preventable through the application of evidence-based guidelines). HHS would define "healthcare acquired conditions," and such a definition would not be limited to conditions acquired in hospitals.

The Mark would authorize a Medicaid-bundled payment demonstration project, in which the unit of payment for hospital acute care would be expanded to include post-acute care provided in hospitals and nonhospital settings, as well as hospital and concurrent physicians' services. Under the demonstration, all of these services would be rolled into a single bundled payment.

Disproportionate share hospital (DSH) payments to states would be decreased for states that experience a drop of at least 50% in the uninsured rate, and DSH payments would be reduced in subsequent years for states where the uninsured rate continues to fall.

MEDICAID REBATES

The Mark would significantly modify how drug manufacturers calculate Medicaid rebates. The Mark does not specify, however, when these changes would take effect. A summary of relevant Mark provisions on Medicaid rebates follows.

Medicaid rebates for innovator drugs currently include two components, the basic rebate and the additional rebate. The basic rebate for innovator drugs currently is Average Manufacturer Price (AMP) minus Best Price, or 15.1% of AMP, whichever is greater. Thus, the minimum basic rebate for innovator drugs currently is 15.1% of AMP. Under the Mark, the minimum basic rebate for innovator drugs generally would increase from 15.1% of AMP to 23.1% of AMP, "except for clotting factors…and outpatient drugs that are approved by the Food and Drug Administration exclusively for pediatric indications, for which the basic rebate would increase to 17.1 percent." (Non-innovator drugs' Medicaid rebates would also increase from 11% of AMP to 13% of AMP.)

The additional rebate component would also change, with respect to "new formulations" of existing drugs. The additional rebate for a drug is currently calculated as the difference between the current quarter AMP for that drug minus that drug's base date AMP (generally the first full quarter after a product's launch), as adjusted for inflation. Under the Mark, the additional rebate for "a new version of an existing drug" would be calculated using the *existing* drug's base date AMP, rather than the new drug's base date AMP. New formulations of orphan drugs would be excluded from this change. The Mark does not define what would qualify as a "new formulation" of an existing drug for purposes of this provision.

The Mark would "clarify what transactions, discounts, and other price adjustments [are] included in the definition of AMP," but does not specify how the definition of AMP might change. The Chairman's Mark would also cap total Medicaid rebate liability for innovator drugs at 100% of AMP.

Medicaid rebates currently are paid only on Medicaid fee-for-service drug utilization. The Mark would expand manufacturer Medicaid rebate obligations by requiring rebates on drug utilization under Medicaid managed care plans. (In addition, manufacturers could continue to pay rebates to Medicaid managed care plans voluntarily.)

Under the Mark, Medicaid Federal Upper Limits (FULs)—which cap Medicaid programs' reimbursements to pharmacies for certain multiple source drugs—would equal 175% "of the weighted average (determined on the basis of utilization) of the most recent AMPs for pharmaceutically and therapeutically equivalent multiple source drugs available nationally through commercial pharmacies."

DRUG AND DEVICE MANUFACTURER FEES

The Mark would assess a fee "on any person that manufactures or imports prescription drugs for sale in the United States." The aggregate fee would be US$2.3 billion payable annually beginning in 2010. Under the Mark, the aggregate fee would be apportioned among "covered entities" each year based on each entity's relative market share of "covered domestic sales" for the prior year. The Mark defines a 'covered entity' as "any manufacturer or importer of certain drugs or biologics offered for sale under prescription in the United States," and notes

that covered entities "would include both domestic and foreign manufacturers and importers of such products." "Covered domestic sales" would include sales of branded prescription drugs (excluding orphan drugs) made to or funded by Medicare, Medicaid, Veterans Administration, and TRICARE. A sliding scale would be used in determining a manufacturer's relative share of covered domestic sales, with a manufacturer's first US$400 million in sales not fully counting in the calculation. This fee would not be deductible for US income tax purposes.

The Mark would also assess fees on device manufacturers and importers. The aggregate device manufacturer fee would be US$4 billion payable annually beginning in 2010. The aggregate fee would be apportioned among "covered entities" each year based on each entity's relative market share of "covered domestic sales." For purposes of the device manufacturer fee, a covered entity would be "any manufacturer or importer of medical devices offered for sale in the United States and would include both domestic and foreign manufacturers and importers of such products." Covered domestic sales would "include U.S. sales of medical devices regulated by the [FDA] as a medical device and subject to premarketing and postmarketing regulatory controls," but would not include sales "attributable to Class I products" or sales of products intended for use on animals. A sliding scale would be used in determining a device manufacturer's relative share of covered domestic sales, with a manufacturer's first US$25 million in sales not fully counting in the calculation. This fee would not be deductible for US income tax purposes.

Finally, the Mark would assess fees on clinical laboratories and health insurers.

MEDICARE PART D REFORMS

The Baucus proposal includes a number of Medicare Part D provisions, generally intended to improve coverage and reduce costs for Part D enrollees and to improve care for low-income subsidy enrollees (by increasing the number of plans that can serve LIS enrollees, and improving the transition to new plans for LIS enrollees who must change plans).

Specifically, the proposal would establish a discount program for Part D beneficiaries during the coverage gap, or "donut hole," that occurs after the initial coverage limit is reached and before the beneficiary reaches the catastrophic benefit. Beginning July 1, 2010, manufacturers would provide discounts of 50%of the drug's "negotiated price" (minus dispensing fees) on brand name Part D drugs that are on the plan's formulary. The manufacturer discount (like the remainder of the drug's "negotiated price") would count toward a beneficiary's annual out-of-pocket threshold. (thus helping the beneficiary to reach catastrophic coverage more easily). The discount program would not apply to LIS enrollees, people enrolled in an employer-sponsored retiree drug plan, and Part D enrollees with income high enough that they must pay higher Part B premiums (for 2009, those income levels are US$85,000 for singles and US$170,000 for a couple).

The Mark would also change the standards for designating "protected" classes of drugs. Protected classes (also called "classes of clinical concern" are classes in which all or substantially all of the drugs in the class must be included on Part D formularies. The proposal would remove criteria specified in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that CMS was supposed to use to identify protected classes, and would give CMS the discretion to identify such classes via rulemaking. Until CMS issues a regulation, the Mark would codify the current six classes of clinical concern that are specified in sub-regulatory guidance (i.e., immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretroviral, and antineoplastics).

The Mark also would increase Part D premiums for higher-income beneficiaries. Income-based increases in Part B premiums were included in the Medicare Modernization Act of 2003. The income thresholds under the Part D proposal are based on those used under Part B. (As noted above, the 2009 Part B thresholds are US$85,000 for singles and US$170,000 for couples.)

The Mark would generally prevent Part D plans from removing a covered drug from a formulary, or otherwise restricting its coverage (e.g., through new utilization management

restrictions or increased cost-sharing) "other than [on] the date on which Part D sponsors begin marketing their plans with respect to the immediately succeeding plan year." (Presumably the intent is to allow plans to adopt new coverage restrictions only at the beginning of a new year, but the language is unclear.) This rule would not apply to replacing a brand drug with a newly-available generic, or to imposing new access restrictions in response to a safety issue identified by FDA or the plan's Pharmacy and Therapeutics (P & T) Committee.

COMPARATIVE EFFECTIVENESS RESEARCH

The Chairman's Mark would establish a private, not-for-profit corporation to conduct comparative effectiveness research (CER), comparing the clinical effectiveness of two or more medical treatments, items or services. This entity, which would be called the "Patient-Centered Outcomes Research Institute," would be run by a board of governors, including both public and private stakeholder representatives. Among the Institute's responsibilities would be identifying national priorities for CER, establishing and carrying out a research agenda, adopting methodological standards, coordinating research activities, and disseminating results. The Institute would be required to have a standing methodology committee of scientific experts that would be responsible for ensuring adherence to sound methodological and reporting standards.

The proposal would require the Institute to disseminate research findings in a manner that is useful to patients, clinicians and the public in making healthcare decisions. The Institute would be prohibited from mandating coverage or reimbursement, or other payment policies for any public or private payer, and the Secretary of HHS would be prohibited from denying coverage based solely on the findings of a CER study. The HHS Secretary would be prohibited from using the Institute's research to develop coverage, reimbursement, or other incentives that would discriminate against elderly, disabled, or terminally ill patients. The Institute would be prohibited from developing or using a standard such as dollars per quality-adjusted life year to establish what healthcare is cost-effective or recommended, and the Secretary would likewise be prohibited from using such a measure as a threshold for coverage, reimbursement, or incentive programs.

The Institute's activities would be funded from general revenues, the Medicare trust funds, and fees on insured and self-insured health plans.

MEDICARE COMMISSION

The Chairman's Mark would establish an independent Medicare Commission (Commission) that would be charged with developing proposals for Congress designed to slow the growth of Medicare spending and improve quality of care. The Commission would be prohibited from presenting proposals to Congress that would ration care, increase revenues or make other changes to Medicare benefits, cost-sharing or eligibility requirements. The provision describes the composition of the Commission and qualifications for membership, and makes clear that this new Commission would operate separately from the existing Medicare Payment Advisory Commission (MedPAC), which currently serves as an advisory body to Congress.

The Commission would be required to submit proposals to Congress that reduce or eliminate "excess" Medicare cost growth (per capita growth in Medicare costs exceeding the growth in the Consumer Price Index and the Consumer Price Index of medical care), based on projections by the CMS Office of the Actuary. If the Commission fails to meet the statutory deadline for submitting its proposal, the HHS Secretary would be required to submit a proposal to Congress that achieves the same reductions. The Mark lays out a complicated process with very specific timelines, under which these activities must occur, beginning in 2014. If the timeframes are not met, and a legislative proposal is not signed into law by August 15 of that year, the Commission's original proposal (or the Secretary's proposal if the Commission fails to submit a proposal) would go into effect automatically. In subsequent years, the Commission would be required to submit additional proposals, but the targeted level of Medicare savings would increase each year (from

0.5 percentage point the first year, to 1.5 percentage points by the fourth year, 2015 through 2018). In 2019, Congress would be required to pass a joint resolution in order to continue this process.

QUALITY INFRASTRUCTURE

Baucus' proposal would require the HHS Secretary to develop a national quality improvement strategy that includes developing priorities for improving the delivery of healthcare services and patient outcomes. As part of this process, the Secretary would be required to establish an interagency working group on healthcare quality, and to improve the process for developing quality measures by identifying gaps where measures are still needed or where existing quality measures need to be updated or improved. The proposal would require this process to include consultation with a qualified, consensus-based entity as well as with stakeholders, in order to ensure appropriate selection of measures that will be used for reporting to and payment under Federal health programs, including Medicare. The proposal would provide funding for these activities through 2014.

FRAUD AND ABUSE

The Chairman's Mark eliminates the "whole hospital" exception to the Stark law, but grandfathers in those hospitals with a provider agreement in operation effective November 1, 2009 (exempt hospitals). Thus, the bill would halt further development of specialty hospitals. The bill imposes extensive requirements on those exempt hospitals, however, such as making disclosures to patients of physician ownership, and advising patients before admission that a physician is not available on the premises at all hours that the hospital provides services. Exempt hospitals would not be allowed to increase the number of operating rooms, procedure rooms, or beds for which they are licensed after enactment of this legislation, subject to limited exceptions relating to the need for additional facilities in a geographic location. Exempt hospitals also would be required to file an annual report, identifying each physician owner and other information related to ownership interests in the hospital.

In another self-referral related change, the Chairman's Mark proposes that effective January 1, 2010, for certain imaging services—MRI, CT, and PET—plus any other designated health service as determined by the Secretary of HHS, the referring physician must inform the patient that the service is available from someone other than the referring physician (or his/her practice), and the patient must be provided with a written list of suppliers providing the service in the area.

The legislation also incorporates a physician payments sunshine provision. Similar to prior legislation, this provision would require disclosure of a broad range of payments or transfers of value from manufacturers to physicians. The Chairman's Mark contains a *de minimis* exception, excluding payments under US$10 unless the annual aggregate amount to a physician exceeds US$100. Reporting requirements would begin on March 31, 2012, and would continue annually thereafter. The Secretary of HHS is directed to establish procedures to assure public access to this information no later than September 30, 2012. Manufacturers would be subject to civil monetary penalties of US$1,000–US$10,000 for each failure to report, although the penalties increase to US$10,000–US$100,000 for each *knowing* failure to report. Addressing concerns about the potential conflict with the several state disclosure laws that have been passed recently, the Chairman's Mark provides for pre-emption of any state law imposing disclosure, except as the state law may related to disclosures not covered by the federal law.

In the title on "Fraud, Waste, and Abuse," the Chairman's Mark mandates extensive data coordination among several federal agencies and databases, as well as state agencies. The Mark would require completion of CMS's cross-agency integrated data repository for claims and payment data and other data sources. The Mark also proposes changes to the existing provider databases to expand and consolidate with a national patient abuse/neglect registry that would be accessible by state licensure boards and federal and state law enforcement agencies. States also would have reporting obligations related to their Medicaid Management Information Systems database; penalties would apply for non-compliance. In cooperation with this enhanced data

capacity any provider and supplier would be subject to screening before being granted Medicare billing privileges. Providers and suppliers would be required to pay an application fee to cover the costs of the screening.

Adopting a recommendation of Inspector General Levinson in recent congressional testimony, the Chairman's Mark would require Medicare and Medicaid providers and suppliers to implement compliance programs as a Condition of Participation, the core elements of which would be established by the Secretary of HHS in consultation with the Office of Inspector General and CMS. The legislation proposes an affirmative obligation on providers to return program overpayments, an expansion of the Recovery Audit Contractor Program to Medicare Parts C and D and Medicaid, and directs CMS to establish a self-disclosure program to cover any Stark law violation as well as kickback violations of less than US$50,000. In an effort to further tighten the Anti-Kickback Statute, the Mark defines the term "willfully" to cover conduct that violates the law, even if the person did not know that the conduct was a violation.

Finally, the legislation increases the funding for fraud control efforts.

NEXT STEPS

Again, the Senate Finance Committee begins debate on these and other proposals contained in the "America's Healthy Future Act" on September 22, 2009. Hundreds of amendments have already been filed with the Committee and are available on the Committee's website (http://www.finance.senate.gov/sitepages/legislation.htm). Once Senate Finance has reported its bill out of the Committee, the process of melding the bill with the US Senate Commitee on Health, Education, Labor & Pensions (HELP) bill and reconciling those with the House bill will begin.

Arnold & Porter LLP will continue to monitor the health reform legislative activities and to review and analyze the proposals that are being offered that will have substantial impact on our clients. We hope that you had found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

Daniel A. Kracov
+1 202.942.5120
Daniel.Kracov@aporter.com

Jeffrey L. Handwerker
+1 202.942.6103
Jeffrey.Handwerker@aporter.com

Alan E. Reider
+1 202.942.6496
Alan.Reider@aporter.com

Allison W. Shuren
+1 202.942.6525
Allison.Shuren@aporter.com

Rosemary Maxwell
+1 202.942.6040
Rosemary.Maxwell@aporter.com

Chandra N. Branham
+1 202.942.5659
Chandra.Branham@aporter.com

John Gould
+1 202.942.6281
John.Gould@aporter.com

Brandi A. Kupchella
+1 202.942.5673
Brandi.Kupchella@aporter.com

Benjamin H. Wallfisch
+1 202.942.5601
Benjamin.Wallfisch@aporter.com

Thomas A. Gustafson*
+1 202.942.6570
Tom.Gustafson@aporter.com

*Not admitted to the practice of law