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March 24, 2010

DRUG AND DEVICE PROVISIONS OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

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MEMORANDUM

Drug and Device Provisions of the
Patient Protection and Affordable Care Act

On March 23, 2010, President Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act (the "Act").[1] A companion bill, the Health Care Education Affordability Reconciliation Act of 2010 (H.R. 4872)[2] (the "reconciliation bill"), which was passed by the House of Representatives along with H.R. 3590 on March 21 and is expected to pass the Senate in the near future, contains amendments to the Act that reconcile the Senate and House versions of the legislation. Together, these bills represent the most comprehensive overhaul ever enacted of both the public and private health care systems in the U.S.

Although this legislation will have a far-reaching impact on all segments of the health care and insurance industries, the medical community, and health care consumers, this memorandum focuses more narrowly on some of the provisions that most directly affect pharmaceutical and medical device manufacturers. While these manufacturers will most likely see an increase in revenues by virtue of an additional 30 million Americans who will have access to health insurance, the legislation imposes on manufacturers a variety of rebates, discounts, fees, taxes, and reporting and regulatory requirements, which are described below.

In view of the importance of this legislation, we have prepared this memorandum despite the fact that the reconciliation bill has yet to be passed by the Senate and signed into law. The memorandum refers to H.R. 3590 and the reconciliation bill together as the "Act", and describes provisions of the Act as it will be amended by the reconciliation bill if the latter passes the Senate, as expected. It is possible, though unlikely, that certain provisions of the reconciliation bill described below will be amended in the Senate. In that event, we will distribute an update describing the pertinent changes.

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1 Pub. Law No. 111-148.

2 Pub. Law No. 111-152.

I. MEDICAID PRESCRIPTION DRUG REIMBURSEMENT AND REBATES

A. Expansion of Medicaid (§ 2501)[3]

Beginning in 2014, state Medicaid programs will be required to extend eligibility to all individuals who are not already eligible for Medicaid or Medicare and whose income does not exceed 133 percent of the federal poverty level for the size of the family involved. This is expected to increase Medicaid enrollment by approximately 16 million individuals.

B. Federal Upper Limits (FULs) (§2503)

Under currently effective regulations of the Centers for Medicare & Medicaid Services (CMS), Federal Upper Limits (FULs) are established for multiple source drugs at 150% of the least costly therapeutic equivalent, as reported in available pricing compendia.[4] The Act replaces this formula with a new formula for calculating FULs: no less than 175% of the weighted average (based on utilization) of the most recent average manufacturer prices (AMPs) for pharmaceutically and therapeutically equivalent multiple source drugs available in commercial pharmacies nationally. The use of the term "no less than" implies that the Department of Health and Human Services (HHS) has discretion to set FULs at a higher level. HHS must implement a "smoothing process" for AMPs similar to that used to determine average sales price (ASP) under Medicare Part B. The latter requirement appears to codify the 12-month averaging methodology currently required for calculating monthly AMP under CMS regulations. The new FUL formula will become effective on October 1, 2010 – regardless whether there are implementing regulations.

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[3] Section references are to H.R. 3590 unless otherwise indicated.

[4] 42 C.F.R. § 447.332 (2006). The implementation of a new FUL formula enacted in section 6001(a)(2) of the Deficit Reduction Act of 2005 (DRA), Pub. L. No. 109-171 (250% of the lowest AMP among the multiple source drugs) was enjoined by the court in National Association of Chain Drug Stores et al. v. U.S. Dep't. of Health and Human Services (D.D.C.), Civ. No. 07-02017 (RCL), and has therefore not been implemented.

C. Excludable Drugs (§ 2502)

Effective January 1, 2014, the Act removes smoking cessation drugs (including OTC drugs), barbiturates, and benzodiazepines from the current statutory list of drugs excludable from Medicaid coverage.[5]

D. Medicaid Rebate Program

1. Increase in minimum rebate (§ 2501(a) and (b))

Effective January 1, 2010, the minimum Medicaid rebate for innovator drugs is increased from the current 15.1% to 23.1% of AMP, except for clotting factors and drugs for exclusively pediatric indications, which increase to only 17.1%. The current rebate for non-innovator drugs is increased from the current 11% to 13% of AMP. It is uncertain how CMS will implement this new requirement retroactively for the monthly and quarterly AMPs for the first quarter of 2010. Note that this increase may also affect state supplemental rebate agreements whose rebate formulae are tied to the minimum Medicaid Rebate.

2. Average Manufacturer Price (§ 2503(a)(2))

Narrowing the sweeping definition of AMP under current CMS regulations,[6] the Act amends the statutory definition of AMP to include only sales to wholesalers for drugs distributed to retail community pharmacies, and direct sales to retail community pharmacies. Specifically excluded are not only prompt pay discounts, as under current law, but also: (1) bona fide service fees, which include, among other things, distribution service fees, inventory management fees, and product stocking allowances; (2) reimbursement for unsalable returned goods (including reimbursements for the costs of reverse logistics and drug destruction); (3) direct sales and rebates to pharmacy benefit managers (PBMs), HMOs, managed care organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or community retail pharmacy. However, notwithstanding this list of exclusions, rebates, discounts, payments and other financial transactions that are received by or passed through to retail community pharmacies are included in AMP. "Wholesalers" are defined more narrowly than under current regulations,[7] and include only entities engaged in wholesale distribution to community

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5 See 42 U.S.C. § 1396r-8(d)(2).

6 See 42 C.F.R. § 447.504.

7 See 42 C.F.R. § 447.504(f), in which "wholesaler" is defined as any entity other

retail pharmacies. Community retail pharmacies are defined to exclude mail order pharmacies and long term care pharmacies, among other things. The new definition of AMP will become effective on October 1, 2010 – regardless whether there are implementing regulations. The new definition, which has been advocated by pharmacists, will likely increase FULs and therefore Medicaid reimbursement to pharmacies for generics, but it will also increase manufacturers' Medicaid Rebate liability.

3. Public disclosure of AMP (§ 2503(b))

A DRA provision authorizing HHS to disclose manufacturer AMPs on a web site[8] (which has yet to be implemented due to a court injunction) is amended to permit only disclosure of "weighted" AMP. This indicates that, for multisource drugs, what would be disclosed is a weighted average of AMPs rather than each manufacturer's AMP. For single source drugs, it is unclear what a "weighted AMP" would be. This provision will become effective on October 1, 2010 – regardless whether there are implementing regulations.

4. Rebates on managed care units (§ 2501(c))

Reversing current law,[9] the Act imposes Medicaid rebates on covered outpatient drugs dispensed to enrollees of Medicaid managed care organizations. Because Medicaid Managed care enrollment is over 70% of total Medicaid enrollment,[10] this provision is likely to increase manufacturers' Medicaid Rebate liability substantially, particularly in states with large Medicaid managed care enrollment (e.g., Michigan, Kentucky, Colorado, Arizona).

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than a repackager/relabeler that purchases from the manufacturer.

8 See DRA § 6001(b), 42 U.S.C. § 1396r-8(b)(3)(A).

9 See 42 U.S.C. § 1396r-8(j)(1).

10 See Kaiser Family Foundation, Medicaid and Managed Care: Key Data Trends and Issues (Feb. 2010), http://www.kff.org/medicaid/upload/8046.pdf

5. Additional rebate for new formulations (reconciliation bill § 1206)

For a line extension (defined as a "new formulation, such as an extended release formulation") of an innovator, oral dosage form drug, the per-unit Medicaid Rebate (the unit rebate amount, or URA) is the greater of (1) the URA of the new formulation, or (2) the highest additional (i.e., inflation penalty) rebate of any strength of the original drug, calculated as a percentage of AMP. This formula saddles the line extension with the pricing history of the original drug, by virtue of the fact that unit rebate amount for the line extension could be increased if the original drug underwent substantial price increases. Note, however, that the provision does not require the line extension to use the baseline AMP of the original drug. This provision applies to drugs that are paid for by a state after December 31, 2009.

6. Rebate capped at 100% of AMP (§2501(e))

The Medicaid rebate (including any additional rebate) for an innovator drug may not exceed 100% of AMP. This provision, which is effective January 1, 2010, will avoid situations were a large additional (i.e., inflation penalty) discount causes a per unit rebate to exceed the AMP of the drug.

7. Best Price and AMP exclusion for Medicare coverage gap discounts (§ 3301(d)(2) and reconciliation bill § 1101(c))

Exclusions from AMP and best price are added for discounts provided by manufacturers under the new Medicare coverage gap discount program (see below).

II. MEDICARE PART D

A. Closing the Part D Donut Hole (§ 3301 as amended by reconciliation bill § 1101)

1. One-time rebate in 2010

Part D enrollees who reach the coverage gap in 2010 will receive a one-time rebate of $250.

2. Coverage gap discount (§ 3301 as amended by reconciliation bill § 1101)

Then, beginning January 1, 2011, Part D beneficiaries in the coverage gap who do not qualify for the low income subsidy will receive a 50% point-of-sale discount off the negotiated price for brand drugs (i.e., drugs approved under a new drug application

(NDA) or biologics license application (BLA)) covered under their Part D plan. The negotiated price is the price beneficiaries pay to network pharmacies for Part D drugs, net of price concessions passed through by the Part D plan to beneficiaries.[11] Despite the 50% discount, 100% of the negotiated price will count toward the beneficiary's true out of pocket (TrOOP) expenses, which count toward the catastrophic coverage threshold (i.e., the upper limit of the coverage gap). The 50% discount on brand drugs will be subsidized directly by manufacturer rebates, as described in section II.B, below. The 50% discount is not required for drugs approved under an Abbreviated New Drug Application (ANDA).

2. Reduction in coinsurance

By virtue of the 50% reduction in the price of brand drugs, the coinsurance of an enrollee who reaches the coverage gap will be 50% for a brand drug in 2011. Over the next ten years, that amount will be reduced annually or bi-annually such that, by 2020, the coinsurance will be 25%. In other words, between the time the enrollee meets the deductible and the time he or she reaches the catastrophic coverage threshold, the coinsurance will be a uniform 25%.

Although generic (i.e., ANDA) drugs are not subject to the 50% discount, the coinsurance for generics within the coverage gap will also be gradually reduced from the current 100% in 2010 to 25% in 2020.

B. Part D Rebates

Effective January 1, 2011, drug manufacturers will be required, as a condition of having their drugs covered under Part D, to have in effect an agreement with HHS agreeing to offer the above-described 50% discount on brand (i.e., NDA or BLA) drug prices at the pharmacy or through a mail order service. HHS is required to issue a model agreement within 180 days following enactment (i.e., by September 23, 2010), and manufacturers must sign an agreement within 30 days after that in order for the agreement to be effective by January 1, 2011. Coverage gap discounts are exempt from the federal health care program antikickback law, and excluded from Medicaid Rebate best price and AMP.

HHS must establish procedures for beneficiaries to receive the 50% discount at the point of sale, but HHS is permitted to provide for the discount after the point of sale (which presumably means through a rebate mechanism) for a temporary period until December 31, 2011. The Act leaves it up to HHS to determine the process by which the

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[11] See 42 C.F.R. § 423.100.

50% discount will be provided to enrollees at the point of sale at the pharmacy, except that, interestingly, HHS may not (except during an initial transitional period) receive or distribute any funds of a manufacturer under the program. This means that the process will have to involve manufacturer payments to Part D plans or their agents, or to pharmacies. Civil monetary penalties may be imposed on manufacturers that fail to comply with the discount requirement.

C. Required Classes Under Formularies (§ 3307)

Part D plans are generally required to include in their formularies at least two drugs within each therapeutic category and class.[12] CMS has issued guidance requiring that, for six specific classes of drugs, all or substantially all of the drugs in the class must be covered under Part D formularies. The six classes are immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.[13] The Medicare Improvements for Patients and Providers Act of 2008 requires HHS to publish regulations to identify protected classes.[14] The Act codifies these six classes until CMS issues a rule regarding protected classes.

D. OIG Study of Part D Drug Pricing (§ 3313)

The OIG is directed to conduct a study comparing net prices paid by Part D plans with those paid by state Medicaid programs for the top 200 drugs based on volume and expenditures.

III. ANNUAL FEE FOR MANUFACTURERS AND IMPORTERS OF BRAND DRUGS AND EXCISE TAX ON DEVICES

A. Annual Fee for Brand Drugs (§ 9008 as amended by reconciliation bill § 1404)

Beginning in calendar year 2011 and annually thereafter, a fee will be imposed on any person that manufacturers or imports branded prescription drugs or biologics (i.e., those approved under an NDA or BLA) for sale in the U.S. In each year between 2011 and 2018, the aggregate fee for all such manufacturers will range from $2.5 billion to $4.1 billion, then will remain at $2.8 billion in 2019 and subsequent years. Each manufacturer's share of the fee will be based on the ratio of its branded drug sales to the

12 42 C.F.R. § 423.120(b)(2).

13 Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.2.5.

14 Pub. L. No. 110-275, § 176.

branded drug sales of all covered entities during the prior year. However, in calculating this ratio, manufacturers in different sales dollar tiers will take into account differing percentages of their branded sales. For example, companies in the highest tier (over $400 million in brand sales) will take into account 100% of their branded sales in calculating the ratio; those in the next highest tier (between $225 and $400 million in branded sales) will only take 75% of their sales into account, etc. Companies with less than $5 million in branded sales will not be required to pay a fee.

Branded drug sales are sales of brand (i.e., NDA or BLA) prescription drugs (excluding orphan drugs) made to or reimbursed by Medicare, Medicaid, the Department of Veterans Affairs (VA), the Department of Defense (DoD), or the TRICARE retail pharmacy program. The respective agencies will report to the Department of the Treasury each year the sales of each drug of each manufacturer covered by the program for the prior year. For Medicaid, Medicare, and TRICARE, which reimburse but do not purchase drugs, the "sales" reported by the agency generally will be the units of each drug dispensed to beneficiaries multiplied by the payment amount. The fee is not tax deductible.

B. Excise Tax on Medical Devices (reconciliation bill § 1405)

Beginning in 2013, an excise tax of 2.3% will be imposed on the sale of any medical device (as defined under the Federal, Food, Drug, and Cosmetic Act (FDC Act) by the manufacturer or importer. Exemptions are provided for eyeglasses, contact lenses, hearing aids, and other devices determined by Treasury to be of a type that is generally purchased by the general public at retail for individual use.

IV. SUNSHINE PROVISIONS

A. Reporting Requirement for Payments to Physicians and Teaching Hospitals (§ 6002)

Beginning on March 31, 2013, and annually thereafter, each manufacturer of a covered drug, device, biological, or medical supply (for convenience, "product") that is operating in the U.S. or its territories or possessions will be required to electronically report information on payments or other transfers of value made during the prior year to (1) physicians and (2) teaching hospitals. A "manufacturer" is defined as an entity engaged in the production of a product, but also includes another company under common ownership with the entity that assists it with production, promotion, sale, or distribution. Certain payments are exempt from reporting, including, among others: transfers of $10 or less unless the aggregate annual transfers to a recipient exceed $100 (both dollar amounts to be indexed); samples intended for patients; patient educational materials; a short-term (i.e., less than 90 days) loan of a device for evaluation; items or

services provided under a warranty; discounts and rebates; and returns on publicly traded securities or mutual funds. Reportable information includes the recipient's name, the amount, the form (e.g., cash, stock, in-kind item) and nature (e.g., consulting fee, food, royalty, travel, research grant) of the payment, the name of any product involved, and any other information specified by regulation.

Reported information must be made available by HHS on the Internet in searchable format no later than September 30, 2013. However, public disclosure of payments made under a product development agreement or clinical trial will be delayed until product approval or four years after the payment is made, whichever is earlier. Manufacturers will have an opportunity to review their information before it is posted.

By October 1, 2011, HHS must establish procedures for manufacturers to submit this information, and procedures for HHS to make it available to the public. The Act establishes civil penalties for non-compliance with reporting requirements.

B. Reporting Requirement for Physician Ownership Interests (§ 6002)

Beginning March 31, 2013, the manufacturers described above as well as group purchasing organizations (GPOs) operating in the U.S. or its territories or possessions will be required annually to electronically report information regarding any ownership or investment interest (other than publicly traded securities) held by a physician or his/her immediate family member in the manufacturer or GPO during the preceding year. The information reported must include the amount invested by each physician, the value and terms of the ownership or investment interest, and any payments from the manufacturer or GPO to such physician. The information must be disclosed by HHS in searchable form on a web site no later than September 30, 2013.

C. Preemption (§ 6002)

The Act preempts state laws that require reporting of the types of information covered in the Act. However, the Act does not preempt state requirements to report information of a type not required to be reported under the Act or exempted under the Act; requirements applicable to reporting entities and recipients other than those covered by the Act; or requirements to report information to a federal, state, or local government for public health purposes.

D. Other Transparency Provisions

1. Sample reporting (§ 6004)

By April 1, 2012 and each subsequent year, manufacturers and authorized distributors of record will be required to report to HHS the identity and quantity of samples requested by and distributed to each requesting practitioner, for drugs covered under Medicare or Medicaid. The statute does not indicate the purpose of this report or describe what is to be done with this information.

2. PBM transparency (§ 6005)

The bill requires any PBM that manages the drug benefit for a Medicare Part D plan or any plan offered through a health insurance exchange to disclose to HHS, and the plan the PBM contracts with, the aggregate amount and types of rebates, discounts, and other price concessions negotiated on behalf of the plan, the amount passed through to the plan, and the aggregate difference between the amount the plan pays the PBM and the amount the PBM pays retail and mail order pharmacies. This information must be kept confidential by HHS and by the plan that receives disclosure.

V. COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH (§ 6301)

An independent, non-profit Patient-Centered Outcomes Research Institute will be established and funded to establish and carry out an agenda for comparative clinical effectiveness research on medical treatments, services, and items, including drugs and devices. A Methodology Committee will be established within the Institute to develop methodological standards for comparative effectiveness research. The Institute will have access to Medicare and Medicaid data. Any research findings of the Institute must be broadly disseminated to the medical community and the general public. The Act permits CMS to use the Institute's comparative effective research findings in making Medicare coverage or reimbursement determinations if such use is through a transparent process that includes public comment, but CMS may not deny Medicare coverage based solely on clinical effectiveness research.

VI. APPROVAL PATHWAY FOR BIOSIMILARS (§§ 7001-7003)

The Act amends the Public Health Service Act (PHS Act) to create a new pathway for the approval of applications for biological products shown to be biosimilar to or interchangeable with a licensed reference product. A biosimilar product is defined in the Act to mean a biological product that is both "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and for which "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." The Act defines an interchangeable product to mean a biological product that "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." The Act also creates market exclusivity for the

reference product and the first interchangeable product, establishes patent dispute procedures, and amends the FDC Act to make user fees under the Prescription Drug User Fee Act applicable to biosimilar and interchangeable biological products.

The bill provides for up to 12.5 years of market exclusivity for a biological product approved under a BLA, consisting of an initial 12-year exclusivity period that may be extended by 6 months of pediatric exclusivity. The first 4 years (or 4.5 years with pediatric exclusivity) is a period of data exclusivity during which time an application for a biosimilar or interchangeable version of the reference product may not be submitted to the Food and Drug Administration (FDA). The 12-year exclusivity period would not be available with respect to the approval of a supplement or subsequent application filed by the sponsor of the reference biological product for certain changes or modifications. The licensure of a biosimilar or interchangeable version of a reference product that was designated and approved as an orphan drug may only occur after the later of the expiration of any applicable 7-year orphan drug exclusivity or the 12-year market exclusivity period (or 7.5 years and 12.5 years with pediatric exclusivity).

The first company to obtain approval of an interchangeable product would be eligible for a period of exclusivity that would expire on the earlier of (1) one year after first commercial marketing of the interchangeable product, (2) 18 months after the resolution of patent litigation, or (3) 42 months after initial approval of the interchangeable product if patent infringement litigation is ongoing.

Patent disputes would be initiated and resolved after a reference product sponsor and a follow-on applicant exchange required information on applicable patents covering the reference product. The submission by a biosimilar or interchangeable biologic sponsor of a statement challenging certain patents identified by the patent holder constitutes an act of infringement of the patents that cover the biological product.

VII. 340B DRUG DISCOUNT PROGRAM

A. Additional Covered Entities (§ 7101 as amended by reconciliation bill § 2302)

Effective as of January 1, 2010, the drug discount program established under section 340B of the PHS Act[15] is extended to the following additional covered entities: free-standing cancer hospitals and children's hospitals that are excluded from Medicare's prospective payment system and that meet disproportionate share requirements;[16] critical

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15 42 U.S.C. § 256b.

16 Children's hospitals are currently identified as covered entities in the Medicaid

access hospitals; and rural referral centers. However, orphan drugs purchased by these additional covered entities are not subject to 340B pricing. A provision in H.R. 3590 to extend 340B prices to inpatients of the above hospitals and also disproportionate share hospitals was deleted in the reconciliation bill.

B. 340B Program Integrity (§ 7102)

Effective for drugs purchased on or after January 1, 2010, pharmaceutical manufacturers are required to submit to HHS quarterly reports of 340B ceiling prices and the components used to calculate them. It is uncertain how this requirement will be implemented for the first quarter of 2010. The Act expands the compliance oversight authority of HHS by authorizing the Secretary, among other things, to publish standards for, and verify the accuracy of, manufacturer 340B ceiling price calculations; establish procedures for manufacturers to refund overcharges; publish 340B prices on a database accessible only to covered entities and state Medicaid agencies; audit manufacturers and covered entities; establish an administrative process for dispute resolution; and issue regulations establishing civil monetary penalties for knowing and intentional violations by manufacturers, which may not exceed $5,000 per violation.

VIII. DRUG AND DEVICE RESEARCH AND CLINICAL TRIALS

A. Tax Credit to Encourage New Therapies (§ 9023)

Tax credits will be available to small companies (250 employees or less) for 50% of investments made in 2009 and 2010 in "qualified investments." These are projects to conduct pre-clinical or clinical studies to obtain marketing approval; develop molecular diagnostics to guide therapeutic decisions; or develop technologies to advance the delivery of therapeutics. The Department of Treasury must certify projects as eligible, taking into account whether the project has the potential to result in new therapies to treat unmet medical needs, reduce health care costs, advance the goal of curing cancer, create jobs, or advance U.S. competitiveness.

B. Cures Acceleration Network (§ 10409)

The Act establishes and provides for funding of the Cures Acceleration Network (CAN), which will be administered by the National Institutes of Health (NIH). CAN will award grants and contracts to eligible entities "to accelerate the development of high need cures, including through the development of medical products and behavioral therapies."

Rebate statute but not in PHS Act section 340B. See 42 U.S.C. § 1396r-8(a)(5)(B).

A "high need cure" is defined as a drug, device, or biologic, that, as determined by NIH, "is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition," and "for which the incentives of the commercial market are unlikely to result in its adequate or timely development." The functions of CAN include conducting and supporting "revolutionary advances in basic research;" providing needed resources for entities, such as government agencies, biotechnology companies, or academic research institutions, to develop high need cures; and facilitating FDA's review of the high need cures funded by CAN. The goal of CAN's involvement in FDA review matters is to expedite "the development and approval of countermeasures and products."

Grants authorized under this provision are available to any government, private, or non-profit entity, for the purpose of, among other things, promoting innovation and helping the recipient to establish protocols that comply with FDA's standards and permit the recipient to meet regulatory requirements "at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product." The grant application process requires the submission of, among other things, "a description of the protocols the entity will follow to comply with [FDA] standards …." Awards may be granted in amounts not to exceed $15,000,000 per project per fiscal year.

C. Health Insurance Coverage for Clinical Trial Costs (§ 10103)

Section 10103 amends the PHS Act by adding section 2709, which covers certain costs of individuals participating in approved clinical trials. Under this provision, a group health plan or a health insurance issuer offering group or individual health insurance coverage ("health plan") may not deny a "qualified individual" participation in an "approved clinical trial" and may not deny (or limit or impose additional conditions on) coverage of "routine patient costs" for items and services furnished in such trial. Further, a health plan may not discriminate against the individual for participating in a trial.

"Routine patient costs" include all items and services consistent with the health plan's coverage for an individual who is not enrolled in a clinical trial, but do not include the investigational item, device or service; items and services provided solely to satisfy data collection and analysis needs; or a service inconsistent with established standards of care for a particular diagnosis. A health plan is not required to provide benefits for services outside of the plan's provider network unless out-of-network benefits are covered.

A "qualified individual" must meet the trial protocol's eligibility criteria and participation must be appropriate as determined by the referring health care professional or by medical and scientific literature. An "approved clinical trial" is a clinical trial for the prevention, detection, or treatment of cancer or other life-threatening disease or

condition. The trial must be either federally funded, conducted under an investigational new drug application (IND), or IND-exempt.

IX. DRUG LABELING

A. Labeling Changes and Generic Drug Approval (§ 10609)

The Act amends the FDC Act's ANDA provisions at section 505(j) to permit FDA to approve an ANDA notwithstanding certain changes to the Reference Listed Drug (RLD) labeling approved within 60 days of anticipated ANDA approval – that is, within 60 days before the expiration of a period of patent or non-patent market exclusivity or a 30-month stay blocking final ANDA approval. Changes to the "Warnings" labeling section of the RLD are not included, and FDA may decide not to grant final ANDA approval based on the unamended RLD labeling if the Agency determines that the presence of such labeling in interstate commerce "adversely impacts the safe use of the drug." The ANDA sponsor must agree to quickly submit revised labeling to FDA.

This provision is essentially an exception to the statutory requirement for generic drugs that their labeling be the same as that of the RLD. A predecessor bill has been dubbed the "Generic Loophole Bill" and was reportedly introduced after a change to the labeling of CASODEX (bicalutamide) Tablets allegedly delayed generic drug approval.[17]

B. Presentation of Prescription Drug Benefit and Risk Information (§ 3507)

The Act requires HHS to determine whether "the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers." In making such a determination, the Secretary must "review all available scientific evidence and research on decision making and social and cognitive psychology" and consult with various stakeholders and experts. By March 23, 2011, HHS must report to Congress on whether such quantitative summaries would improve health care decision making and the reasoning and analysis of that determination. If the Secretary determines that quantitative summaries would improve health care decision making, then the

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[17] See Shaheen, Vitter Introduce Legislation To Get Affordable Drugs In Consumer Hands Faster (Oct. 14, 2009), *available at* http://shaheen.senate.gov/news/press/release/?id=8a5894e3-9a69-439a-bcf6-8c929bd4fd8e.

Secretary would be required to issue proposed regulations not later than three years after submitting the report to Congress.

X. ANTIKICKBACK LAW AMENDMENTS

A. Kickbacks as Violation of False Claims Act (§ 6402(f)(1))

Codifying the holdings of a number of judicial opinions, the federal health care program antikickback law[18] would be amended to provide that a claim submitted to a federal health care program that includes items or services resulting from an antikickback law violation constitutes a false claim for purposes of the Federal False Claims Act.[19]

B. Intent Requirement Revised (§ 6402(f)(1))

Resolving differences among federal circuit courts concerning the intent standard under the antikickback law, the statute would be amended to provide that a person need not have actual knowledge of the antikickback law or specific intent to commit a violation.

C. Exemption for Coverage Gap Discounts (§ 3301(d))

A new exemption would be added to the antikickback law for discounts offered to beneficiaries under the Medicare Part D coverage gap discount program (see section II.B, above).

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[18] 42 U.S.C. § 1320a-7b(b).

[19] 31 U.S.C. § 3729 et seq.