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Health Care Reform: Key Legislative Changes Impacting the Pharmaceutical, Biotechnology, and Medical Device Industries

Last week, Congress adopted comprehensive health care reform through the passage of the Patient Protection and Affordable Health Care Act (H.R. 3590) (signed into law on March 23) and the Health Care and Education Reconciliation Act (H.R. 4872) (signed into law on March 30) (together, the "Act"). The Act, which is estimated to bring an additional 32 million individuals into the health insurance market, brings significant challenges and opportunities to the pharmaceutical, biotechnology, and medical device industries.

Ropes & Gray will continue to monitor implementation of the Act in the coming months and will provide more in-depth analysis in separate alerts on specific topics of interest. See Ropes & Gray's Health Reform Resource Center and specifically our Pharmaceutical and Device Industry section for all of the latest analyses and updates.

Below is a summary of the key elements of the Act that relate to the pharmaceutical, biotechnology, and medical device industries.

- **Industry Fees.** The Act imposes tax-deductible fees on pharmaceutical and medical device companies that are expected to raise $54 billion.

  Pharmaceutical Companies

  An annual fee will be levied on pharmaceutical manufacturers and importers of brand name prescription drugs, effective in 2011. This fee will be allocated among companies according to the percentage of each company's branded pharmaceutical sales to certain government programs, including Medicare and Medicaid, against all aggregated pharmaceutical sales to such programs. Orphan drugs are excluded from the definition of branded pharmaceutical. The aggregate fee amount will equal the following:

  • $2.5 billion in 2011;

  • $2.8 billion in 2012 and 2013;

  • $3 billion in 2014 through 2016;

  • $4.1 billion in 2018; and

  • $2.8 billion in 2019 and thereafter.

Medical Device Companies

- An annual 2.9% excise tax will be levied on the medical device manufacturer or importer of any taxable medical devices, excluding eyeglasses, contact lenses, and hearing aids, effective for all sales after December 31, 2012.
- **Sunshine Reporting Provisions.** The Act provides for new "Sunshine Provisions," requiring pharmaceutical, medical device, biological, and medical supply manufacturers to begin reporting to the federal government the payments they make to physicians and teaching hospitals, and physician ownership interests in those entities. Additionally, the law requires the Secretary to make this payment and ownership interest information available on a publicly accessible, searchable, and downloadable website. As a result, manufacturers' payments to consultants, researchers, and others, and other important financial information will now be a matter of public record. Please click here for a more in-depth analysis of the Sunshine Reporting Provisions.
- **Biosimilars.** The Act establishes an abbreviated regulatory pathway for FDA approval of biosimilars and interchangeable biosimilar products. Biosimilar products may be approved by FDA on the basis of analytical tests and certain clinical studies demonstrating that they are highly similar to the corresponding innovator product. FDA may find that a biosimilar product is interchangeable with an innovator product if it is likely to produce the same clinical results

and switching between the innovator product and biosimilar does not result in diminished safety or efficacy. Reference products are granted a twelve year period of exclusivity and an additional six months of exclusivity if pediatric studies are conducted. The Act also adopts a complex scheme for the resolution of disputes involving patents belonging to innovator companies, including imposing stiff penalties on innovators who make mistakes in the process. Such penalties may include barring an innovator from bringing an infringement action. Please click here for a more in-depth analysis of the Biosimilars Provision.

- **340B Program**. The Act expands the 340B Drug Pricing Program to children's hospitals, free-standing cancer hospitals, critical access hospitals, and rural referral centers, effective January 1, 2010. For these newly-eligible providers, the discounts will not apply to orphan drugs. The Act also creates new program integrity requirements for manufacturers and covered entities to reduce overcharging and other violations of the 340B Program. The provisions require that the Secretary establish a system for verifying drug ceiling prices, and that manufacturers establish internal processes for returning payments to overcharged covered entities. The Act also assesses civil monetary penalties ("CMPs") for violations involving intentional overcharging. The Reconciliation Act removed an expansion of the program to inpatient drugs that had been included in H.R. 3590.
- **Closing the "Donut Hole."** The Act closes the Medicare Part D "donut hole" by lowering the beneficiary coinsurance from 100% to 25% over ten years. For generic drugs, the coinsurance will drop to 93% in 2011, and will continue to be reduced annually until reaching 25% in 2020. Manufacturers will provide a 50% discount on brand-name drugs, effective in 2011. Additional federal subsidies will phase in, beginning in 2013.
- **Drug Rebates.** The Act also increases drug rebates under Medicaid. Effective in 2010, minimum percentage rebates on brand-name drugs will increase to 23.1% of average manufacturer price, with exceptions for certain clotting factors and pediatric drugs, and rebates for other drugs will increase to 13%. The Act also creates an additional rebate for new formulations of brand-name drugs and extends the rebate requirement to drugs reimbursed under Medicaid managed care organizations.
- **False Claims Act.** The Act expands the jurisdiction of the False Claims Act to payments made by, through, or in connection with the Health Insurance Exchange if payments include any federal funds. The Act also expands the powers of individuals to bring civil actions as relators under the False Claims Act by narrowing the application of the public disclosure bar. Under the Act, a relator who has independent knowledge that materially adds to the publicly disclosed allegations is permitted to serve as an original source. Please click here for more a more in-depth analysis of the False Claims Act and other anti-fraud provisions.
- **Anti-Kickback Statute.** The Act amends the Federal Anti-Kickback Statute intent standard to provide that a person may violate the Anti-Kickback Statute without actual knowledge of or specific intent to violate the statute. This less stringent intent standard may result in more lawsuits under the Anti-Kickback Statute because such lawsuits will be easier to prosecute in some jurisdictions which previously required a heightened intent standard.
- **Enhanced Penalties for Federal Health Care Offenses**. The Act requires that the Federal Sentencing Guidelines be amended to increase sentences for defendants convicted of federal health care offenses, and adds violations of the Anti-Kickback Statute and the Federal Food, Drug, and Cosmetic Act to this category of offense. The Act also expands enforcement tools and administrative penalties for violations of federal fraud and abuse laws, including permitting suspension of payments during pending investigations, expanding the grounds for permissive exclusion of suppliers or manufacturers from federal programs, and expanding the grounds for CMPs.
- **Compliance Programs.** The Act mandates that providers and suppliers enrolled in Medicare, Medicaid, and CHIP establish and maintain compliance programs that satisfy requirements to be established by the Secretary, but the Act does not provide further guidance on the content or timing of this requirement.

If you have any questions about the new requirements or related issues, please contact your usual Ropes & Gray attorney.