STRATEGIC HEALTH CARE

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KEY PROVIDER ISSUES IN HEALTH CARE REFORM

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SELECT PHARMACEUTICAL PROVISIONS

Under the new health care law, the expansion of health care coverage will result in an increase in the number of drug consumers. As a result of the law, pharmaceutical companies will also see changes in reporting requirements and the first-ever pathway for FDA approval of biosimilar biologic compounds.

Drug Sample Reporting and Relationship Disclosures

On April 1, 2012 and annually thereafter, manufacturers and authorized distributors are required to report to HHS information on the identity and quantity of drug samples distributed. Additionally, the new law requires all pharmaceutical and device manufacturers to submit annual reports disclosing payments to physicians and teaching hospitals beginning March 31, 2013. Companies must also disclose ownership interests by physicians in manufacturers. Payments of less than $10 are excluded from disclosure unless such payments add up to more than $100.

Biosimilar Application Process

The biosimilars pathway created by the new health care reform law generally resembles the Hatch-Waxman Act that established an abbreviated pathway for generic drug approvals. But some key differences exist between the abbreviated pathway for biosimilars and that for small molecule drugs, such as divergent patent listing processes.

To be interchangeable with the reference product, a biosimilar must meet more stringent criteria. "In order to meet the higher standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once, that the risk of alternating or switching between use of the biosimilar product and the reference product is not greater than the risk of maintaining the patient on the reference product," according to an FDA statement. "Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing health care provider."

The law also gives newly approved and existing original biologics 12 years before a biosimilar product can reference the original biologic's data on an FDA application.

Insurance Coverage through Exchanges

Commencing January 1, 2014, insurance coverage will adopt standards developed by the National Association of Insurance Commissioners. An established uniform outline of coverage documents for health insurance plans offered through state exchanges will include a description of pharmaceutical coverage to facilitate comparison among plans. Also under the new law, an inclusion of prescription drugs in essential benefits will be required. All plans in the individual and small group markets offered through state exchanges must include prescription drug coverage.

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