Proskauer

Provisions of Interest to Life Sciences Companies

April 16, 2010

Much of the attention concerning health reform has understandably focused on coverage and payment issues. However, several provisions are of particular interest to life sciences companies (in addition to Medicare reimbursement provisions). For early-stage companies without products on the market, the health care reform act (the Reform Act) includes incentives to accelerate bench-to-bedside progress. For established companies, the Reform Act imposes costs and disclosure obligations but also incentivizes faster development. The message of the Reform Act for drug, biologics, and medical device companies is to accelerate business as usual.

Early-Stage Companies

The Reform Act contains three provisions of particular interest to early stage companies.

- **Therapeutic Discovery Tax Credit**. Companies with no more than 250 employees (including employees of affiliates) are eligible to receive a federal income tax credit equal to 50 percent of certain expenditures made in their tax years ending in 2010 or 2011. To obtain the credit, the company must obtain certification for the project from the Department of the Treasury, in consultation with the Secretary of Health and Human Services (HHS). Total credits certified may not exceed $1 billion over the two-year period of the program. Qualifying projects include projects designed to: treat or prevent diseases by conducting pre-clinical activities and clinical trials; diagnose diseases, including through molecular diagnostics; or develop a product or process to administer therapeutics. Expenditures qualifying for the credit do not include compensation for the chief executive officer and certain other employees, interest, mortgage or rent, property insurance, utility and maintenance costs. The Secretary of the Treasury may specify other expenditures that are not eligible for the credit. Grants may be awarded in lieu of credits; however, no tax-exempt or governmental entity, or pass-through entity with one of these entities as an owner, is eligible for a grant. The program to consider and award certification for projects is to be in place sixty days after enactment of the Reform Act. Thus, companies that may qualify for the credit and are interested in pursuing certification should move quickly.

- **Cures Acceleration Network**. The Reform Act establishes a Cures Acceleration Network. The National Institutes for Health is to determine drugs, biologicals and devices related to "high-need cures," which are a priority to diagnose or treat a disease but for which the incentives of the commercial market are unlikely to result in adequate or timely development. The network's activities are to be directed by a review board made up of scientists, experts in private equity investment, and disease advocacy organizations. Grants and contracts are to be awarded on a competitive basis to accelerate the development of high need cures, with expedited regulatory approvals. These may be awarded to universities, academic medical centers, pharma and device companies, or other research organizations.
- **Comparative Effectiveness Research**. The Reform Act accelerates the development of comparative effectiveness research. It directs the Secretary of HHS to establish a Patient-Centered Outcomes Research Institute, as a nonprofit corporation, to conduct, support, and synthesize research that identifies the manner in which diseases can be prevented, diagnosed, or managed most effectively and appropriately. Research findings are not to include practice guidelines or coverage or payment recommendations. The institute's findings are to be widely disseminated. The work of the institute is to be funded in part by the fees the Reform Act imposes on health plans. The institute replaces the recently established Federal Coordinating Council for Comparative Effectiveness Research.

Companies with Products in the Market

Life sciences companies with products that are generating revenue, or products that are reimbursable by Medicare or Medicaid, will face several requirements.

Fees on Drug and Biological Companies. Each manufacturer or importer of branded prescription drugs or biologicals, other than orphan drugs, must pay a fee to the Secretary of the Treasury starting in calendar year 2011. The Reform Act establishes the aggregate payment to be paid by all affected entities, which increases from $2.5 billion in 2011 to $4.1 billion in 2018. The Secretary of the Treasury is to calculate the amount of each affected entity's portion of the fee. The fee is allocated based on relative levels of branded product sales to government-related buyers by all affected entities. For purposes of determining each affected entity's branded product sales, sales of up to $5,000,000 are disregarded and only a percentage of sales over that amount are counted until sales reach $400 million. Sales over $400 million are counted in full. This calculation is of significance because in determining each entity's total sales, controlled groups will be aggregated.

Sales included are sales to government programs, including Medicare Parts B and D, Medicaid, Veterans Affairs, the Department of Defense, and TRICARE. The government agencies operating these programs are to report applicable sales for each affected entity to the Department of the Treasury. The Reform Act specifies that the fees are not deductible for income tax purposes.

Tax on Medical Device Companies. Each manufacturer or importer of human medical devices must pay a manufacturer's excise tax of 2.3 percent of total sales of such products. This provision is applicable for sales in calendar year 2013 and subsequent years. The tax is imposed on total sales, not just those to government buyers. Items excluded from the tax are eyeglasses and contact lenses, hearing aids, and other devices determined by the Secretary of the Treasury to be generally purchased at retail by the general public for individual use. The scope of this exclusion was narrowed in the reconciliation process. Before amendment by reconciliation, automatic exclusions from the tax were provided for Class I devices as well as Class II devices primarily sold at retail to consumers for less than $100 per unit. As amended, the only items automatically excluded are eyeglasses, contact lenses, and hearing aids; guidance will be needed from Treasury to exclude other items. The reconciliation act also removed a provision prohibiting the manufacturer from deducting the tax payment in computing its own income taxes.

Disclosure of Hospital and Physician Payments. Effective in 2013 for payments made in calendar year 2012, manufacturers, marketers, or distributors of drugs, devices, biologicals, or medical supplies covered by Medicare or Medicaid must disclose payments to physicians and teaching hospitals. These payments must be reported on an annual basis to HHS (by March 31 for the previous calendar year). The manufacturer must make the information publicly available on a website, in electronic and easily manipulable form, by June 30 for the previous calendar year (September 30 in 2013). Manufacturers that are not publicly traded, and physician-owned group purchasing organizations, are also required to disclose details of their ownership by physicians. Procedures for disclosure are to be in place by October 1, 2011.

Payments for the following items would be reportable: research; grants; consulting fees; other compensation for services; honoraria; gifts; entertainment; food; travel; education funding; royalties or licenses; charitable contributions; and current or prospective ownership or investment interests. Indirect payments (payments to an entity or individual at the request of, or designated on behalf of, a covered recipient) would also have to be reported, in the covered recipient's name. Payments consisting of loan of a device for evaluation; discounts and rebates; in-kind items used for the provision of charity care; product samples; educational materials for patient use; payments for health services to manufacturer's employees under self-insured plan; and payments to physicians for services with respect to civil or criminal action or administrative proceeding would not have to be reported. Payments below $10 would not have to be reported so long as total payments to that recipient for the year did not exceed $100. If a payment is related to a specific drug, device, biological, or medical supply item, the name of the item must be reported. The Reform Act includes some provisions for delayed reporting if the payments are for the development of a new item or for clinical investigation.

The legislation preempts similar state reporting laws that require reporting of transfers valued at less than $10, as well as those that are identical to the federal reporting requirements. Those state laws that require additional reporting by other types of entities or disclosure of information not covered by the Reform Act are not preempted. Civil money penalties can be imposed for violations.

Biosimilars. Finally, the Reform Act contains provisions intended to stimulate innovation and price competition for biologics. The Reform Act provides a twelve-year period of exclusivity for an original biological product. It further provides a mechanism for the licensure of biosimilar follow-on products following the expiration of the original product's exclusivity. The first biosimilar product that is interchangeable with the original product has a short period of exclusivity.

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