



Health care reform

Five challenges life sciences companies must face and address

With the recent enactment of sweeping health care reform legislation, the US is undertaking a major overhaul of the health care system that will affect everyone — life sciences companies, insurance companies, health care providers, individuals and employers. This summary is intended to provide an overview of the key implications for life sciences companies in the final health care reform legislation (the “Act”), which is described below.

The Act will accelerate the transformation of the overall health care ecosystem and will change the way life sciences companies do business. To help you begin this process, we focus on the top five things that life sciences companies should know about the Act.



About health care reform

The Patient Protection and Affordable Care Act (P.L. 111-148), including the changes in the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152), (collectively the “Act”), provides the legal framework for the implementation of health care reform through 2020.

Primary goals for the legislation

The primary goals of the Act are to: (i) expand coverage to an estimated 32 million Americans without health insurance; (ii) reform the delivery system to improve quality; and (iii) lower the overall costs of providing health care.

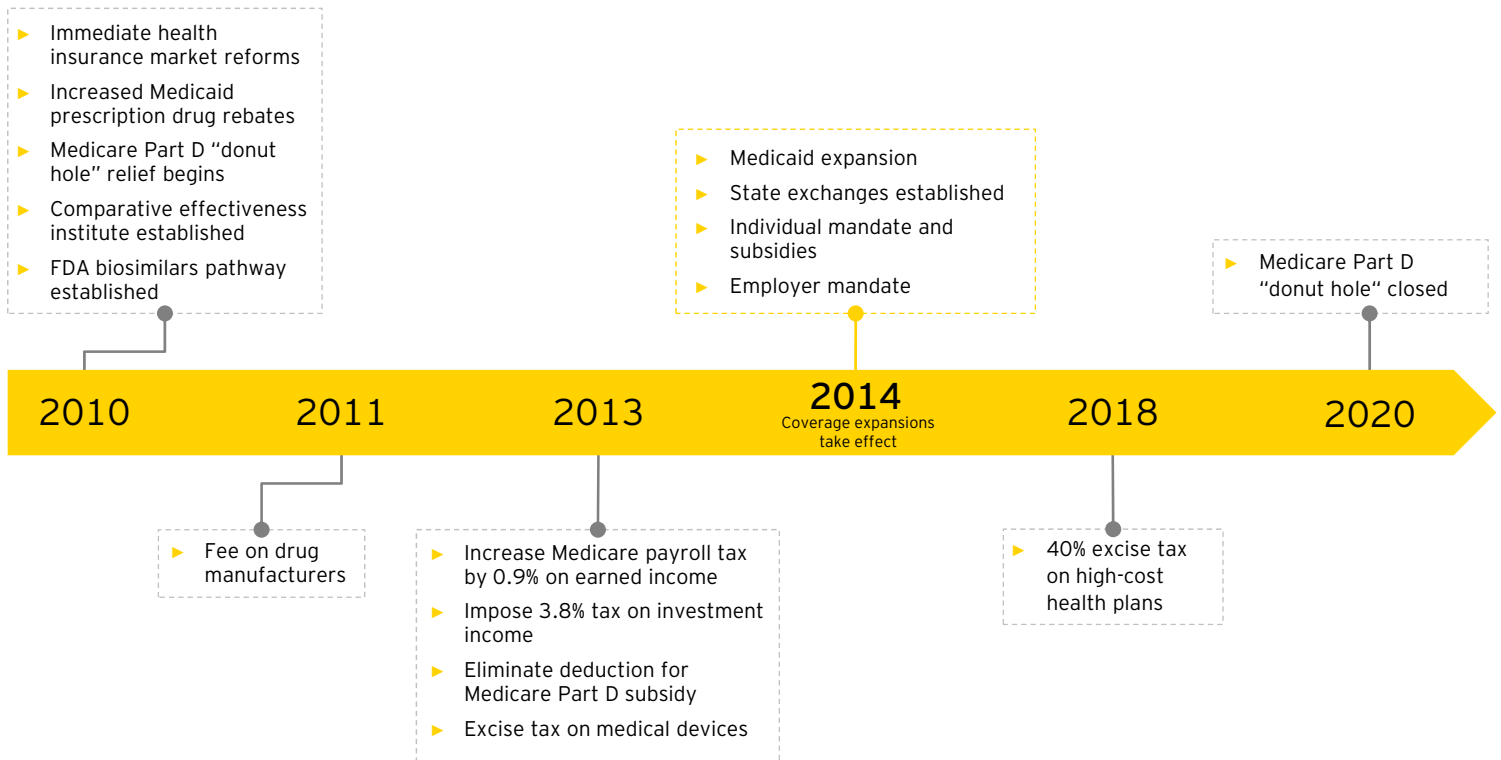
To expand coverage, the Act mandates that all Americans maintain a minimum level of health coverage. It expands Medicaid and provides federal subsidies to help low-income individuals buy health insurance. The legislation also implements insurance market reforms, including mandatory coverage of preventive services and a ban on exclusions for pre-existing conditions. It also mandates, for the first time, that employers with 50 or more full-time employees provide certain minimum benefits or pay penalty fees.

Health care cost reductions stem from cuts to Medicare and Medicaid payments, provisions to reduce fraud, waste, and abuse in those public programs, and other delivery reforms to their payment systems.

Important effective dates for life sciences companies

The implementation of the Act will take place over a 10-year period with a number of provisions important to life sciences companies taking effect in 2010. In their planning process, life sciences companies should consider that some provisions, such as new taxes and fees and an increase in Medicaid prescription drug rebates, will take effect before insurance coverage is expanded in 2014.

Many agencies, including the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services, the Department of Treasury, the Internal Revenue Service and the Department of Labor, are already writing and issuing regulatory guidance. Numerous regulations will guide the long-term implementation process, and technical corrections and additional legislation are expected. The timeline below highlights a number of important provisions for life sciences companies and their effective dates.



Key provisions of health care legislation

01. Coverage expansion

Increased access to coverage will provide life sciences companies with new consumers and new channels for products.

The expansion of coverage will be realized through a series of policy changes generally effective in 2014 that require most individuals to maintain health insurance, expand Medicaid eligibility and provide federal subsidies to help individuals purchase coverage through insurance exchanges.

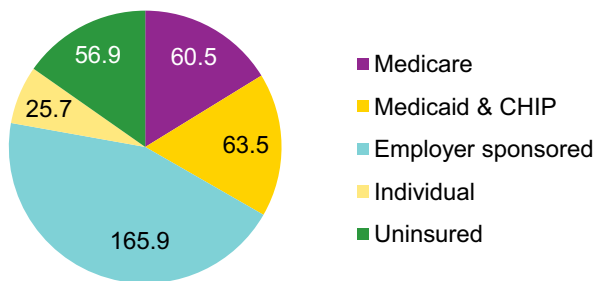
Drug manufacturers and medical device manufacturers will see an increase in demand for products as the number of insured individuals increases and health plans are required to offer prescription drug coverage.

As previously uninsured individuals enter the health care system as insured consumers, the utilization of drugs and products related to primary and preventive care will increase. The Act's emphasis on chronic disease management will fuel the demand for drugs and devices related to diabetes, hypertension, asthma and other chronic conditions.

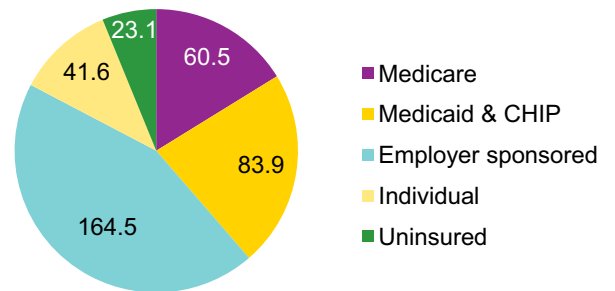
For life sciences companies, operating in a market where more people are insured will present both challenges and opportunities. Strategic companies will refocus marketing and consumer education programs to align with the needs of these new customers.

As illustrated in the chart below, nearly one-half of the newly insured are expected to be covered through Medicaid. Life sciences companies will need to assess how the change in the composition of their customer base will affect their business given Medicaid's historically low reimbursement rates.

Estimated 2019 coverage without health care reform
(in millions)



Estimated 2019 coverage with health care reform
(in millions)



Source: Centers for Medicare and Medicaid Services, Office of the Chief Actuary, Estimated Financial Effects of the "Patient Protection and Affordable Care Act" as Amended, April 22, 2010.

02. Pressures on earnings

While the volume of product sales may increase, pricing pressures, payment changes, and new fees and taxes will create stress on margins and add pressure on earnings.

While pharmaceutical, biotechnology, and medical device companies may see increased demand for products, the Act's push for greater efficiency and lower health care costs likely will cut into revenue gains generated by the increase in volume. New provisions that will create stress on margins and add pressures on earnings include:

1. Increased Medicaid drug rebates
2. Closing of the Medicare "donut hole"
3. Annual industry fees and excise taxes

Increased Medicaid drug rebates

Provisions that increase Medicaid drug rebates from 15.1% to 23.1% for certain drugs and from 11% to 13% for others will result in a net loss on each dollar currently reimbursed. The pricing pressure from the rebates is compounded by the Act's heavy reliance on Medicaid to expand coverage. Depending on a company's payor mix, the increased rebates could have significant impact on margins.

Closing the 'donut hole'

The phased-in elimination of the Medicare Part D coverage gap ("donut hole") also will push life sciences companies to take a closer look at their bottom line. In 2010, Part D beneficiaries who hit the donut hole will receive a one-time \$250 rebate from the federal government. Beginning in January 2011, the Act requires drug manufacturers to provide a 50% discount to Part D beneficiaries for brand-name drugs and biologics purchased during the coverage gap. A drug manufacturer selling or marketing products in the US must agree to participate in the discount program to be included in the Part D program. By 2020, the donut hole will be replaced with the standard 25% coinsurance rate, potentially resulting in improved compliance with drug regimens by Medicare beneficiaries.

Opportunity: Therapeutic discovery tax credit

The Act offers an offset to some financial pressures with a therapeutic discovery project credit for companies engaged in defined research that advances science, as well as creates jobs. Companies with fewer than 250 employees are eligible to apply for the program. The funds are limited to \$1 billion and will be allocated based on an application to and approval from the Department of the Treasury. Companies interested in leveraging this opportunity should act quickly to prepare applications for the credit, which is retroactive to January 1, 2009, but expires at the end of 2010.

Industry fees and taxes

Branded drug manufacturers will be required to pay new annual fees that will increase costs and add pressure to already shrinking operating margins. The fees will be apportioned among the covered entities each year based on an individual entity's relative market share of covered domestic sales to government programs for the prior year. These fees are not deductible for US tax returns.

The medical device industry faces an excise tax equal to 2.3% of the first sale-for-use sales price of their products, excluding glasses, contacts, hearing aids and similar products. The excise tax for the medical device industry will be deductible for US tax returns.

Annual fees on drug manufacturers

Annual Fees	Calendar Year
\$2.5 billion	2011
\$2.8 billion	2012–2013
\$3.0 billion	2014–2016
\$4.0 billion	2017
\$4.1 billion	2018
\$2.8 billion	2019 and thereafter

Implications

Individually, these reimbursement changes, fees and taxes represent significant costs for the life sciences industry. Together, they add to existing pricing pressures, squeeze operating margins, and further pressure earnings, creating a more dynamic pricing environment. The impact on companies will differ and depend on their product mix and the payment mechanisms. Life sciences finance personnel will need more sophisticated tools to support analysis and decision-making as growing uncertainty enters financial and operational forecasting.

03. Transparency

Pricing, financial relationships and claims data will be under the government microscope.

Life sciences companies will face new compliance obligations under provisions of the Act aimed at increasing transparency and preventing fraud, waste and abuse. The Act provides for an expanded role for the HHS Inspector General, as well as new data collection initiatives by the government and more stringent public reporting requirements.

Provisions focused on transparency and fraud, waste and abuse that will affect life sciences companies include:

1. “Sunshine provisions,” which require increased reporting of financial relationships (payment or other transfers of value) between manufacturers of covered drugs, devices, biologics, and medical supplies under government programs and physicians and other health care entities
2. A new 90-day period of enhanced oversight for initial claims of DME suppliers, which requires withholding of payments of initial claims for DME suppliers
3. Pharmacy benefit manager (PBM) reporting requirements, which require PBMs to report the percentage of branded drugs sold where a generic alternative was available, as well as all rebates, discounts, fees and pricing concessions
4. Enhanced penalties and fraud sentencing guidelines

These requirements will enhance the volume of data collected within life sciences companies as well as shared externally. This new degree of transparency will increase the level of monitoring with a particular impact on how life sciences companies manage their sales and marketing functions. The availability of this data could help life sciences companies take steps to identify improvements to their performance and financial reporting.

As the government expands public health insurance programs, life sciences companies will be subject to an increasing number of reporting requirements and pricing mechanisms. Finance, government pricing, and IT personnel should take the necessary steps to ensure price reporting systems are in compliance. In the end, life sciences companies will face increased administrative burdens, reporting requirements and government scrutiny.

04. Comparative effectiveness

This new research will impact decision-making in care delivery and pricing.

Comparative effectiveness research (CER) has been an industry hot topic over the past several years. Many stakeholders believe CER has the potential to improve clinical decision-making and help bend the cost curve. The Act establishes a private, nonprofit institute to conduct research on the comparative effectiveness of diagnostics, pharmaceuticals, devices and other medical treatments.

The Secretary of HHS is prohibited from relying solely on the reports of the CER Institute in issuing coverage mandates, guidelines, or policy recommendations. Even with government limitations, patients, providers, and payors will have more access to CER data, shifting coverage and use decisions for non-government entities. Stakeholders are seeing changes in purchasing and prescribing patterns from physicians and group purchasing organizations.

Life sciences companies are looking to leverage the benefits of CER and integrating the practice into their strategic plans. Companies see incentives for improving how data is captured, disseminated and reported, as well as an approach that can demonstrate the value of their products to payors, providers, and consumers.

Life sciences companies also need to assess IT and other systems to ensure that they have the necessary capabilities to prepare for CER. As CER becomes a reality, the findings of this research will help with the difficult task of demonstrating a product's effectiveness. This is a key consideration in an era in which the cost of developing new drugs is high and profitability depends on effective R&D and clinical trial processes, as well as obtaining regulatory approval and expediting market entry.

05. Business model

Life sciences companies are entering a period of changing priorities within the health care system, which increases the need for reductions in health care costs.

Health care costs account for approximately 17% of the US's GDP, a measure far above other industrialized countries and a source of concern for many stakeholders. While some reform provisions may serve to control costs, the US's high level of spending on health care likely will continue to draw scrutiny from policymakers.

These concerns only accelerate life sciences companies' imperative to reinvent the business model, which is already changing as a wave of patent expirations end the era of the blockbuster drug. Companies will face greater competition, increased pricing pressures, and new priorities as policymakers continue to explore means to reduce costs.

A new ecosystem is emerging, one that is focused on health outcomes and that is centered on patients and payors, rather than the life sciences sector's current orientation toward products and physicians.

The business of health care is being transformed as policies shift toward preventive care, wellness, consumer empowerment, and a greater focus on outcomes. The change is resulting in new opportunities for creative first-movers. To develop new business models, pharmaceutical companies will need to team with nontraditional partners, such as health IT, telecommunications, and large retailers to test innovative market offerings and target new customer segments.

A new policy that creates an approval pathway for biosimilar products, which the government sees as an effective option to control drug costs, will begin to change consumption patterns. These provisions create incentives for the development of biosimilars, while guaranteeing 12 years of market exclusivity for branded biologics.

As the health care ecosystem becomes more interdependent and defined by rapid change, life sciences companies will need to examine strategies to address R&D pipelines, consider the desired balance of generics and branded products in product portfolios, and support commercialization goals.

Finally, certain components of the new provisions will have accounting and financial reporting implications and non-financial disclosures for life sciences companies. Some issues life sciences companies should consider include the implications of the excise tax on medical devices and the annual pharmaceutical fees, increased drug rebates for Medicaid, the 50% discount for Medicare Part D drugs, and elimination of the deduction for Medicare Part D subsidies. The specific application of these issues may evolve as the regulations are promulgated.



Conclusion

This is just the beginning of change.

The passing of the Act will result in dramatic changes to the current life sciences business model and operating strategies for most life sciences companies. By encouraging greater efficiency in health care spending and delivery, the Act will accelerate the ongoing transformation of the health care ecosystem.

Life sciences companies must be prepared to deal with both increased patient demand and pressure on earnings in a challenging regulatory and reimbursement environment. Making the necessary changes to processes and infrastructure should be a top-of-mind concern for life sciences company management teams for the foreseeable future. Payors and providers will have incentives to stretch their health care dollars — and share risk — as they face reduced margins of their own. This will cause a natural tension among life sciences companies, payors, and providers. Managing the commercial risk will be added to the portfolio of managing development risk and regulatory hurdles.

The rising trends of health IT, the availability of data to understand comparative effectiveness, and the consumers' roles in managing their personal health will all grow in importance in the wake of the Act. In many respects, for life science companies on the long journey of moving from developing pills and devices to delivering health outcomes, health care reform is just the starting bell.

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