Healthcare Reform and the Pharmaceutical Industry

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EXECUTIVE SUMMARY

Several sections within the Patient Protection and Affordable Care Act (PPACA) contain provisions that have or will directly affect the bottom line of pharmaceutical companies. The better known are those that expand drug coverage, require additional fees or rebates, or otherwise change the way that drugs are managed, patent protected, and promoted. Overviews of these direct provisions are summarized in the Appendix of this report.

Of equal importance but not as well known are provisions with indirect impact; these will change the healthcare delivery system by changing how health insurance for virtually everyone is offered, funded, and managed. These changes will undoubtedly affect how payors and providers value, manage, and use pharmaceuticals. Therefore, research-based pharmaceutical companies should consider reassessing their discovery and commercialization strategies in the light of how the PPACA will be changing customer interests.

PPACA PROVISIONS THAT INDIRECTLY IMPACT THE PHARMACEUTICAL INDUSTRY

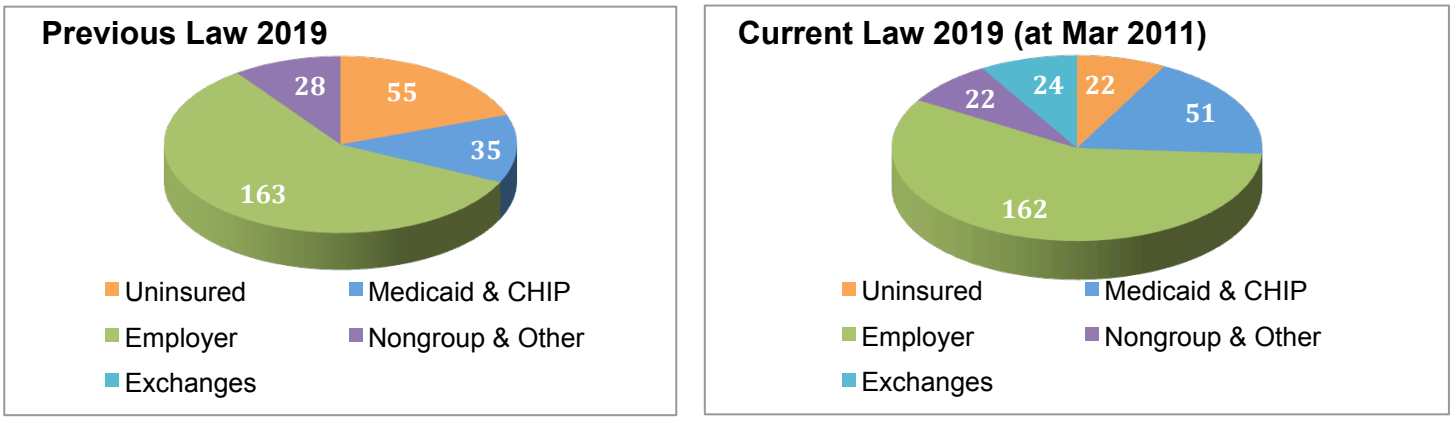
To make expansion of health insurance coverage accessible and affordable, the PPACA legislation includes significant changes to the way that Medicare, Medicaid, and commercial health insurance is offered, funded, and delivered. Although these reforms are not directed at pharmaceutical manufacturers, they will affect how pharmaceuticals are valued and utilized.

Coverage expansion

The PPACA requires that most commercial benefits cover prescription drugs because they are identified as an "essential benefit." This is not a huge change as almost all large employers with at least 200 employees offered their employees healthcare benefits (99%), and 69% of all employers offer benefits.[1] Although most benefit details have not yet been specified, the PPACA has directed the Secretary of Health and Human Services (HHS) to ensure coverage (including pharmaceutical benefit) equivalent to that under a "typical" employer plan. There is currently uncertainty as to how this pharmaceutical benefit will be managed, or which design elements will be allowed, including the use of formularies and coverage restrictions such as prior authorizations. In addition there is some uncertainty about how PPACA terms such as "medical necessity," "evidence-based medicine," and "medical management" will apply to pharmaceutical management.

According to the CBO, the PPACA will reduce the uninsured without prescription drug coverage by 33 million by 2019[2]. Of these, 16 million will be covered by Medicaid and the Child Health Insurance Program (CHIP). The other 17 million will be covered through the creation of state health exchanges. The CBO estimates that the exchanges will enroll 24 million in total, which includes enrollment shifted from other insurance such as by employers.

FIGURE 1: 2019 PROJECTIONS WITH AND WITHOUT PPACA



This increase in pharmaceutical coverage will increase demand for pharmaceuticals.

Managed Medicaid

Tight state budgets and the anticipated growth in the Medicaid population that is expected because of loosened eligibility requirements create incentives for states to shift the fee-for-service (FFS) Medicaid population to managed care (managed Medicaid). The PPACA gives states the ability to earn pharmaceutical rebates for prescription drug spending that is delegated to managed Medicaid care plans, which encourages states to shift that liability. It is likely that managed Medicaid will have lower brand utilization than traditional FFS Medicaid. Managed Medicaid plans seek to control utilization of "supply side" services to manage costs. The current, relatively low utilization of generic drugs by many state Medicaid programs is an inviting target. Pharmaceutical demand heightened by the PPACA-promoted growth in the Medicaid population could be more than offset by the lower utilization of services under managed Medicaid, greater utilization of generic drugs, and higher rebates.

Medicare

The PPACA contains Medicare provisions intended to both reduce cost and incentivize quality. From a cost reduction perspective, government payments to Medicare Advantage (MA) plans will be cut by $132 billion over 10 years[3],with the cuts occurring primarily over three years beginning in 2011. About 25% of the Medicare population was enrolled in an MA plan in 2011[4]. Medicare Advantage plans will also be subject to coverage mandates and other reforms. Medicare Advantage Prescription Drug (MAPD) plans often reduce their medical cost and use the savings to expand prescription coverage, and this is one way MAPD plans attract members. The payment cuts will mean MAPD plans will need to reduce costs further to fund the extra benefits that attract members. In addition, the Centers for Medicare and Medicaid Services (CMS) will attempt to incentivize quality by providing bonus payments based on a plan's star quality rating. Plans are evaluating their benefits and costs in light of these changes.

The PPACA also contains other Medicare payment reform provisions. Medicare payments for home healthcare would be reduced by $40 billion and some payments to hospitals would be cut by $22 billion between now and 2019.[5] The PPACA includes creation of the CMS Center for Medicare & Medicaid Innovation, which is charged with testing new payment models—for instance, value-based purchasing—beginning in 2011. The PPACA includes payment reforms around shared savings programs[6] (e.g., accountable care organizations) and state grants for innovative delivery models (e.g., patient-centered medical home).

Very importantly, the PPACA creates the Independent Payment Advisory Board (IPAB), which will make proposals to save Medicare costs. IPAB will be required to recommend cost saving proposals based on explicit savings targets outlined in the legislation. However, unlike similar organizations such as MedPAC, IPAB's proposals have the force of law unless Congress specifically acts to forestall its recommendation by adopting other cost saving efforts that save similar amounts. IPAB's first recommendations are due in 2014 for the 2015 fiscal year. Hospitals are exempt from IPAB's recommendations until 2020, which means the focus will be on prescription drugs, physician services, and other healthcare products and services.

The PPACA also targets improving the quality of Medicare Advantage plans. Beginning in 2012, Medicare Advantage plans become eligible to earn significant bonus payments based on a five-star rating system. The quality rankings will be administered by CMS and criteria include members' use of preventive care, managing chronic conditions, member complaints and appeals, and customer service. The upside financial opportunity of improved quality combined with lower reimbursement will lead plans to reevaluate the operations, physician incentives, customer relations, and medical and pharmaceutical benefits to maximize star ratings. MAPD plans that achieve a five-star rating will have significant marketing advantages as they can enroll new membership year round, including members from lower-rated MAPD plans.

Individual and group insurance market

The PPACA phases in changes to insurance that may increase medical coverage (including prescription drug coverage) for some individuals, including:

* No lifetime or annual coverage insurance limits

* No exclusion for preexisting conditions or medical underwriting

* Coverage for children up to age 26

* Strict limitations on how rates can vary by age and sex

* First-dollar coverage for preventive services

While these are significant changes to insurance in some states, other states have imposed similar rules for years. The increase in coverage from these rules may not result in much increase in prescription drug spending.

Another change is the requirement that employers provide coverage—and individuals obtain coverage—or pay a financial penalty. It is unclear whether the size of the penalties will encourage currently uninsured to obtain insurance—or encourage currently insured to drop insurance.

The minimum medical loss ratio (MLR), which is 80% for individual/small group and 85% for large group, adds new business constraints to insurers. Insurers have, of course, always competed on cost, and those with lower cost have an advantage. Insurers that can significantly lower administrative and marketing costs, as well as those that are able to shift some risk to healthcare providers, may have an edge over those that cannot. Capitation or risk sharing may allow insurers to reduce administrative costs as medical costs, and this can help insurers meet MLR rules. Risk sharing can also create incentives for providers to manage costs more effectively, and providers may address costs on a population basis rather than trying to maximize their individual revenue. This is one way minimum MLR can affect providers.

Another PPACA change will be the exchanges, through which insurers will sell standardized individual and small group insurance. As with Medicare Part D, exchanges will create an environment that flips the industry adage, “Insurance is sold not bought.” Individuals and groups will choose insurance benefits from standard offerings through a menu of options. As with Part D, the exchanges create a more competitive and transparent environment for consumers. In addition, they may foster “private label products” through accountable care organizations (see below).

Accountable care organizations

The PPACA also includes funding to support a Medicare accountable care organization (ACO) program that starts in 2012. It allows providers organized as ACOs that meet quality and other thresholds to share in cost savings they achieve for the Medicare program. Medicare ACOs may have minimal impact on prescription drugs over the next few years as they will be at financial risk for managing the medical portion (Medicare Part A and B) of patient care and not the drug benefit portion (Part D). Medicare ACOs will have risk for drugs paid through Part B, such as infused drugs. CMS has offered to consider Part D as part of the Pioneer ACO pilot, which suggests that CMS is seeking ways to integrate Part D into its ACO efforts.

Medicare is perhaps not the main story for ACOs.[7] As commercial and Medicare managed care plans seek ways to control costs, risk sharing to ACOs competent in managing care becomes attractive. The launch of exchanges in 2014 is an opportunity for insurers to offer lower-cost, "private label" products in collaboration with ACOs. Such products could be limited network products, but ones where the local provider system, not the "big city" insurer, controls patient referrals and sets patient expectations.

ACO physicians will likely be at risk for quality and financial results. Using generic drugs when brand-name drug alternatives are not superior will be an inviting opportunity and will be less politically challenging within an ACO than changing either hospital or physician practice patterns. Price elasticity for drugs may now include physician considerations as well as the usual patient and payor reactions.

The ACO movement is consistent with the provider consolidation trend. Consolidation builds local market clout and may include hospitals buying physician practices or creating ACOs. Providers consolidate to protect margins from commercial reimbursement in light of downward reimbursement pressures from government sources. Consolidation will certainly affect the marketing of pharmaceuticals, as the physician employers will have the opportunity to set or influence prescribing policy. This consolidation has been seen by payors as potentially inflationary, although it is also seen as creating organizations with which an insurer can share risk.

Conclusion and considerations

By changing the way that Medicare, Medicaid, and commercial health insurance is offered, funded, and delivered, the PPACA will affect how pharmaceuticals are valued, managed, and used by payors and providers. Research-based pharmaceutical companies should make it a priority to understand and assimilate the effects on discovery and commercialization strategies. To do this, pharmaceutical companies should develop studies, services, and communications that enable payors and providers to derive value from in-line and pipeline drugs in the PPACA environment. Some questions to consider are:

* Does your organization possess sufficient PPACA and customer insight, including the ability to evaluate PPACA implications on product revenues and strategies?

* Do discovery and/or commercialization opportunities exist that could meet payor and provider needs, including tactics that could improve their quality and operational efficiency?

* Are efforts underway to provide payors and providers with product information in a context of new payor reimbursement and delivery systems, including accountable care organizations, exchanges, managed Medicaid plans, and medical homes?

* Is the organization positioned to create value in a PPACA environment, including structural and incentive alignment with meeting the new needs of customers?

APPENDIX 1

SUMMARY OF PPACA PROVISIONS DIRECTLY AFFECTING THE PHARMACEUTICAL INDUSTRY

The PPACA includes many provisions focused directly on the branded pharmaceutical and biotechnology industries. A summary of some of these provisions follows.

Medicaid rebate and pricing

Since the passage of the Omnibus Budget Reconciliation Act of 1990, branded pharmaceutical manufacturers provided a 15.1% minimum "best price" rebate to state Medicaid programs, with additional rebates for price increases above inflation. The PPACA keeps the best price and inflation rules in place and increases the minimum rebate from 15.1% to 23.1%,[8] with most of the difference accruing to the federal government. In addition, it extends Medicaid prices to managed Medicaid plans. The increased rebate is retroactive to January 1, 2010, for the fee-for-service Medicaid drug benefit and became effective in managed Medicaid on March 23, 2010. The law also makes changes to the definition of average manufacturer price (AMP) and to the formulas and methodologies used to calculate Medicaid rebates. This could further increase rebate exposure for many manufacturers.[9]

Expansion of 340B program

In 1992, Congress established the 340B Drug Discount program to limit the costs of outpatient drugs paid by safety net hospitals, community health centers, and other healthcare providers that serve a high proportion of indigent individuals.[10] Once admitted into the program, facilities are entitled to receive Medicaid level discounts on all covered outpatient drugs that they purchase, regardless of the patient's payor status. On average, these discounts equate to 49% of the average wholesale price for a branded prescription drug, according to a report released by the Congressional Budget Office.[11] The PPACA changed the eligibility requirements for participating in the 340B program, appreciably expanding the number of eligible facilities to include, among others, additional children's hospitals, freestanding cancer hospitals, and critical care hospitals. Depending on the manufacturer's portfolio and market exposure, this provision will serve to further reduce revenue.

Closing the coverage gap in Medicare Part D

Since 2006, Medicare Part D standard basic and actuarial equivalent plans have included a coverage gap with no coverage for non-low-income individuals between the initial coverage limit and the catastrophic coverage level.[12] In 2011, this gap began when the beneficiary received $2,840 of drugs and ended when spending reaches $6,483.72. In 2011, the brand-name pharmaceutical industry will subsidize 50% of beneficiary cost-sharing for brand-name pharmaceuticals in the coverage gap. In addition, the government will provide additional coverage in this so-called donut hole, which will be phased in and eliminate the donut hole by 2019. The industry subsidy will cost manufacturers as much as $32 billion over 10 years according to one estimate.[13] While filling the gap may lead to increased adherence and less switching to generic alternatives in the coverage gap, the effect on net revenue is expected to be negative for most brand-name pharmaceutical manufacturers.[14]

Annual fee for companies that sell pharmaceuticals to federal health programs

The PPACA establishes an annual fee from branded pharmaceutical manufacturers beginning in 2011. For 2011 these fees total approximately $2.5 billion and will total $28 billion from 2011 to 2020.[15] An individual manufacturer's share of the fee will depend on its market share of sales to federal health programs, including Medicare, Medicaid, VA, and others. Sales of orphan drugs that benefited from the orphan drug tax credit will be excluded.

Establishing protected drug classes in Medicare Part D

Medicare Part D plans must include in their formularies all covered Part D drugs in a category or class identified as protected by the Secretary of Health and Human Services (HHS). The PPACA gives the Secretary the responsibility for developing the criteria by which categories and classes of drugs must be covered by Part D sponsors. In addition, the Secretary can develop an exceptions process that would allow Part D sponsors to limit a drug in a protected class. Six drug classes (i.e., anticonvulsants; antidepressants; antineoplastics; antipsychotics; antiretrovirals; and immunosuppressants for the treatment of transplant rejection) are already treated this way. Detailed criteria will be set through a standard regulatory process. Plans will be allowed to apply formulary management tools for drugs in these classes.

Follow-on biologics pathway

For most pharmaceuticals, as is the case with some other products, patent expiration coincides with the introduction of imitation products from other manufacturers. Drugs sold in the United States require FDA approval, and there are well-established rules for generic drug approval. For a generic product to be approved by the FDA, it must prove that it is chemically equivalent to the patented pharmaceutical and it is exempt from clinical trials. In the case of biologic drugs with complex molecular structures, it is virtually impossible for a generic manufacturer to meet the current chemical equivalence requirements. The uncertainty and expense of conducting other studies has resulted in few generic alternatives to biologic drugs and, effectively, a patent in perpetuity for the original developer.

In section 7002 of the PPACA, new requirements were established for licensure of biologics as a biosimilar. The PPACA envisions an easier pathway for generic biologics. Along with this new pathway, the Secretary is given latitude to determine if a specific requirement is unnecessary in a given application. The details need to be worked out, but the PPACA calls for user fees and exclusivity periods for reference drugs and biosimilars, and grants the FDA discretion in creating regulations.

Physician payments "sunshine" provisions

Pharmaceutical company payments to physicians (including speaker's fees and research grants) are controversial, as some consider these payments an inducement. Prior to the PPACA, many states mandated the reporting of pharmaceutical company payments to physicians. In section 6002, the PPACA federalizes this requirement, and provides a list of payments to physicians that will need to be reported in the future.[16] The specific elements of the federal reporting requirements are complex and subject to additions through regulations; these regulations are expected to be promulgated by October 1, 2011. Manufacturers then will issue their first reports to HHS in early 2013, based on data from all of 2012.

ENDNOTES

1 Kaiser Family Foundation (2010). Employer Health Benefits 2010 Annual Survey, p. 38. This paper does not address the role of pharmaceutical companies as employer sponsors of health benefits. One of the coauthors, Bruce Pyenson, is a Member of the American Academy of Actuaries and meets its qualification standards for issuing this report.

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8 Anderson, B. & Filipek, T. (May 2010). Healthcare reform and pharmacy benefits. Milliman Healthcare Reform Briefing Paper. Retrieved Aug. 22, 2011, from http://publications.milliman.com/publications/healthreform/pdfs/healthcare-reform-pharmacy-benefits.pdf. The rebate for generic products will rise from 11% to 13%.

9 Anderson & Filipek, ibid.

10 U.S. Department of Health and Human Services. Introduction to 340B Drug Pricing Program. Health Resources Services Administration. Retrieved Aug. 22, 2011, from http://www.hrsa.gov/opa/introduction.htm.

11 Congressional Budget Office (June 2005). Prices for brand-name drugs under selected federal programs.

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13 Favole, Jared A. (March 25, 2010). For drug makers, closing doughnut hole promises silver lining. Wall Street Journal.

14 To learn more about the impact of closing the coverage gap on patients, Part D plans, and the government, see Filipek, T. & Anderson, B. (May 2010). Healthcare reform and Medicare Part D. Milliman Healthcare Reform Briefing Paper. Retrieved Aug. 22, 2010, from http://insight.milliman.com/article.php?cntid=6069&utm_medium=web&utm_content=6069&utm_campaign=Milliman%20On%20Healthcare.

15 Patient Protection and Affordability Care Act, Section 9008(a)(2).

16 Patient Protection and Affordability Care Act, Section 6002.