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TECHNICAL REPORT

Negotiation Strategies for Antiretroviral Drug Purchasers in the United States

Sebastian Linnemayr, Gery W. Ryan, Veena Karir, Jenny Liu, Kartika Palar

Sponsored by the AIDS Healthcare Foundation

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Preface

This report describes the market for antiretroviral (ARV) drugs in the United States and systematically lays out the characteristics influencing the bargaining power of buyers in negotiating prices with drug manufacturers. It also presents a case study of three countries to illustrate negotiation mechanisms that may present alternatives for the United States and discusses options that the U.S. government as well as other buyers could consider when trying to negotiate ARV prices, including alternatives to the current patent system. The analysis is based on publicly available data.

This study was sponsored by the AIDS Healthcare Foundation. The report should be of particular interest to scholars and policymakers in government institutions and other agencies, as well as individuals involved in the purchasing of ARVs.

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Summary

Antiretroviral (ARV) treatment has transformed HIV from a death sentence to a chronic condition, allowing people living with HIV (PLHIV) to live longer and healthier lives. However, PLHIV face significant barriers to accessing and affording life-saving—but expensive—ARV medications. These barriers are particularly severe for low-income PLHIV and disproportionately affect racial and ethnic minorities. High ARV prices create pressure for government payers to contain costs either by rationing care or by restricting eligibility for public programs. Limited funding, coupled with a growing demand for HIV care and treatment, is likely to make these hard programmatic decisions about who is covered more difficult over time. Therefore, it is important to identify options for reducing the cost of providing ARVs to allow more people to receive treatment.

This study focuses on options for negotiating lower procurement costs of ARVs. A case-study approach is used to assess the array of options that different stakeholders could deploy in negotiating ARV price discounts with drug manufacturers, given the regulatory and market constraints that exist in the United States.

The Economics of ARV Drug Pricing

Two characteristics of the market for ARVs are especially salient for understanding the alternatives for reducing costs. First, the prices for most ARVs are not determined in a free market but are typically negotiated between buyers and a single seller, the drug manufacturer, who enjoys considerable market power. Patent protection, which is intended to encourage drug manufacturers to invest in the development of new drugs, enables a single manufacturer to maintain a monopoly on selling a new ARV drug for 20 years. Thus, a key challenge for government payers is to balance the need to incentivize ARV drug manufacturers to undertake research and development (R&D) with the need to keep present drugs affordable.

Second, although drug manufacturers argue that high prices are needed to sustain the development of new drugs, the development costs appear to be overstated, for a number of reasons. In particular, there is a lack of credible data on manufacturers' costs, and without such data, it is impossible to determine the “fair” or “right” price for ARVs. Moreover, it is clear that development of ARVs has benefited from substantial federal and university contributions and that the fast-tracking Food and Drug Administration (FDA) process for many ARVs has substantially reduced their costs. However, it appears that drug companies may not be passing on these cost savings to consumers.

The Characteristics of the U.S. ARV Market

It is important to understand the mechanisms through which the three largest public ARV payers—the AIDS Drug Assistance Program (ADAP), Medicaid, and Medicare—currently attempt to lower ARV prices. The market power specific to drug sellers and purchasers (including available information about the market) determines the extent to which deviations from a competitive market price can be reduced through price negotiations. Government restrictions are also highly relevant for delineating payers’ scope of action.

For payers in the U.S. ARV market, government regulation sets a ceiling price and mandatory rebate levels for each drug to ensure lower prices to Medicaid and public health payers, including ADAP. State Medicaid and ADAP agencies may choose to capitalize on these price controls and mandatory rebates, with greater participation potentially leading to greater negotiation leverage with manufacturers. Meanwhile, the federal government also requires minimum formularies, which further constrains the ability of public payers to customize their formularies for greater discounts.

Information about the ARV market is limited. Manufacturers have complete information about their costs of production (R&D, marketing, etc.) and the different prices they offer to different payers, but such data are not publicly available, and purchasers of drugs often do not know the prices other buyers have negotiated. Further, many payers, such as state Medicaid agencies, do not negotiate directly with manufacturers. Pooling demand is one of the few tools wholesalers and retail pharmacies can use to negotiate for lower prices, and private buyers have minimal options within the market for ARV drugs other than attempting to put “moral pressure” on drug manufacturers.

Cross-National Comparisons of HIV Drug Financing

Case studies of three comparable developed countries with sizable drug markets—the United Kingdom, Canada, and Switzerland—indicated that although government drug-price regulations in these countries appear to result in lower prices for patented drugs, including ARVs, the impact of drug prices on health payers and patients is highly moderated by the health insurance systems. For example, PLHIV have nearly complete ARV coverage in the United Kingdom and Switzerland, but in the United States and Canada, many find themselves piecing together coverage from different programs to offset large out-of-pocket burdens. Some drug-price negotiation options used in other countries, including greater transparency in development costs and greater coordination among drug purchases, point to options that might be appropriate for use in the United States.

Policy Options for Reducing ARV Prices in the United States and the Implications of Health Reform

Systemic-Level Options

Systemic-level options for changing the way prices are set can be realized only by entities that have the power to use them—typically, the government. Five such options are

- **Reference pricing**, under which prices are tied to those paid in other markets (e.g., in other countries or for drugs with identical or similar therapeutic benefits).
- **Switching of dually eligible beneficiaries from Medicare Part D to Medicaid**, which pays lower prices, especially for drugs on the “protected list” maintained by the Centers for Medicare and Medicaid Services (CMS), including AIDS drugs.
- **National procurement of prescription drugs**, in which the government would be the single payer for AIDS drugs.
- **Increasing price transparency**, so that all players have a better understanding of drug manufacturer pricing information.
- **Easing minimum formularies (i.e., baseline levels of essential drug benefits)**, which restrict the negotiating power of payers by limiting the ability to exclude more-expensive drugs if an affordable price cannot be negotiated.

Such systemic changes are likely to affect ARV prices by bringing the market closer to a free-market situation in which the prices are equal to manufacturing and development costs. However, some options (such as easing minimum formularies) may not be viable strategies in the United States.

Changes to the Patent System

Changes to the patent system could address some of the shortcomings of the system as currently implemented in the United States. One alternative would be to pay rewards or subsidies for investors, such as prizes or commitments to pay a certain amount of money for delivering a drug that fulfills some technical specifications that were laid out in advance. Another option would be subsidies to support innovation. Such policies would de-couple prices charged for drugs from their development costs and would provide a one-time, lump-sum reward to drug innovators. These policies would affect the bargaining position of drug manufacturers and would decrease the need for regulations, since the drugs would be made by generic producers.

Two essential parameters of a patent also might be adjusted: patent length, or the duration during which a drug company benefits from exclusivity in the market, and patent breadth, which determines the reach of the market exclusivity granted. Such options might be worth considering, particularly for ARV developers that have received substantial federal funding for basic R&D and other cost-reducing factors such as fast-tracked FDA approval.

Negotiation Strategies

Negotiation strategies that could be pursued within the currently existing system in the United States include demand pooling (i.e., increasing negotiating power through combined purchasing power), formulary restrictions (i.e., easing baseline drug benefits provided by insurers), preferential contracts (contracts with fewer pharmacies or pharmacy networks in exchange for lower prices), and moral pressure/public relations.

The most promising of these mechanisms are demand pooling, particularly among Medicare Part D drug plans, and moral pressure (given the pharmaceutical industry’s concern with public relations, particularly for ADAP). While formulary restriction could theoretically be a powerful mechanism for all players, it has serious ethical and clinical drawbacks when applied to ARVs specifically.

The limited range of negotiation mechanisms available within the current ARV payer system means that health reform is unlikely to open new options for lowering ARV prices to

most payers. Only Medicaid is likely to see lower prices. Further, the ability to use moral pressure on the pharmaceutical industry will most likely be diminished under the Affordable Care Act (ACA) as the role of ADAP, which is HIV-specific and has traditionally had strong advocacy efforts attached to it, diminishes.

Winners and Losers from Policy Change

Decisionmakers who wish to change policy to lower ARV prices must consider who is likely to win and who is likely to lose from the changes. Such issues would be particularly important if U.S. policymakers decided to apply lessons from other countries, since the financial impact of regulating drug prices on both publicly funded programs and private out-of-pocket expenditures is highly dependent on features of the health insurance system. The benefits of regulation need to be evaluated in light of the equitable distribution of benefits and the prevailing health insurance system.

With the introduction of laws in the United States that mandate health insurance coverage, equity considerations may result in increasing the cost burden on public insurance programs. At the same time, with greater consolidation of public programs and increased demand for drugs through universal coverage, public programs might be in a better position to negotiate drug prices.

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Abbreviations

ABPI	Association of the British Pharmaceutical Industry
ACA	Affordable Care Act
ADAP	AIDS Drug Assistance Program
AHF	AIDS Healthcare Foundation
AMP	average manufacturer price
ARV	antiretroviral
AWP	average wholesale price
CMS	Centers for Medicare and Medicaid Services
CPI	Consumer Price Index
EBP	essential benefits package
EU	European Union
FDA	Food and Drug Administration
FPL	Federal Poverty Level
GDP	gross domestic product
HHS	Department of Health and Human Services
IT	information technology
LHC	London HIV Consortium
MAC	Medicare Administrator Contractor
NHS	National Health Service
NIH	National Institutes of Health
OECD	Organisation for Economic Cooperation and Development
OFSP	Federal Office of Public Health
OTC	over the counter
PBM	pharmacy benefit manager

PDPs	prescription drug plans
PLHIV	people living with HIV
PMPRB	Patented Medicine Prices Review Board
PPRS	Pharmaceutical Price Regulation Scheme
R&D	research and development
TrOOP	true out-of-pocket
VA	Department of Veterans Affairs

Introduction

Background

Antiretroviral treatment (ART) has transformed HIV from a death sentence to a chronic condition, allowing people living with HIV (PLHIV) to live longer and healthier lives. However, PLHIV face significant barriers to accessing and affording life-saving—but expensive—antiretroviral (ARV) medications. These barriers are particularly severe for low-income PLHIV and disproportionately affect racial and ethnic minorities. The chronic waiting lists to receive ARVs through the AIDS Drug Assistance Program (ADAP)—the government safety-net program that finances treatment for PLHIV who have no other or inadequate insurance—illustrate the unmet need for ARVs in the United States. At the end of January 2012, 4,118 people in need of ARV medications were on waiting lists across 12 states due to budget constraints, thus necessitating difficult decisions about how to provide treatment coverage to the greatest number of those in need (NASTAD, 2012).

Public payers, which are responsible for financing ARVs for the vast majority of PLHIV in the United States, face multiple challenges in covering all those in need. First, more and more people are living with HIV and will eventually depend on ARV drugs for their survival for the rest of their lives. The latest estimates indicate that well over a million individuals currently live with HIV in the United States (CDC, 2010; Kaiser Family Foundation, 2007).¹ However, roughly half of all PLHIV are not receiving care of any kind, despite public health and clinical recommendations that all PLHIV be in care and, when appropriate, initiate ART (KFF, 2007). Thus, while it is essential to get more people on treatment, identifying more PLHIV in need of assistance will put more pressure on a public system that is already confronting shortages.

The cost of HIV care is increasing, and expenditures on HIV drugs take up a large and growing fraction of government health-program budgets. ARV drugs have been identified as one of the factors highly correlated with increasing drug expenditures of public payers such as Medicaid (Guo et al., 2008). Medicaid spending on ARVs increased almost fourfold between 1996, when combination ART first became available, and 2005.² The primary drivers of the rising expenditures include newer, more-expensive drugs; rising per-prescription costs for existing medications; rising numbers of PLHIV overall; and a growing proportion of PLHIV receiving ART who are now living longer (Jing et al., 2007; KFF, 2009a). High ARV prices create

¹ Since the first HIV cases were identified in 1981, approximately 1.7 million people in the United States have been infected, 550,000 of whom have already died (KFF, 2007).

² Prior to 2006, prescription drug benefits for dually eligible Medicaid and Medicare beneficiaries were covered by Medicare; starting in 2006, the benefits were switched to Medicare Part D. To plausibly compare Medicaid's spending on ARVs across years, we consider only the years up to 2006.

pressure for government payers to contain costs by either rationing care or restricting eligibility for public programs, and as a result, PLHIV do not all receive the treatment they require. Limited funding, coupled with a growing demand for HIV care and treatment, means that difficult programmatic decisions about who is covered will likely become more pronounced and more frequent over time. It is therefore important to identify options for reducing the cost of providing ARVs to allow more people to receive treatment.

This report focuses on negotiating for lower procurement costs of ARVs. Lower costs could enable more PLHIV to access public treatment programs and life-saving ARVs and could allow resources to be directed toward other safety-net services. We employ a case-study approach to assess the array of options that different stakeholders could use to negotiate ARV price discounts with drug manufacturers, given the current regulatory and market constraints in the United States. Our analysis includes an in-depth examination of the strategies of each of the main public payers of ARVs in the United States and also compares the U.S. drug negotiation landscape with that of other selected countries to provide further insight into the structural factors that influence drug prices. We identify key intervention points that policymakers could consider in efforts to obtain more ARVs at lower cost from drug sellers. Although we recognize that other spending allocation decisions may also influence the ability to provide treatment to more PLHIV, these priorities often flow from program mission mandates and are not discussed in this report.

In the remainder of this introduction, we provide an overview of the report, including a brief discussion of the market for ARVs, our approach for analyzing price-negotiation options, and potential options for reducing procurement costs.

Organization of This Report

The Market for ARVs

Chapter Two describes our framework for understanding how prices for ARV drugs are set. Prices for most ARVs are not determined in a free market but are set by drug manufacturers. Patent protection provides this control over prices by allowing the manufacturer of a new drug to be the sole seller of that drug for a fixed period of 20 years.³ Patents for intellectual innovations were introduced in 1790 to remedy a “market failure”: Manufacturers would have difficulty recovering initial research and development (R&D) investments or reaping the benefits of bringing a new drug to market if potential competitors were allowed to immediately enter the market and drive prices down. The first patents for ARVs were granted in 1987 and are assigned for a uniform duration of 20 years, the same as for other drugs.

Government must thus balance two different objectives: incentivizing ARV drug manufacturers to innovate and keeping the drugs affordable. Given the public health insurance system in the United States and the specific public programs that provide PLHIV care and treatment, the U.S. government uses mandated rebates and other negotiation mechanisms to reduce the costs of drugs protected by patents. However, critics argue that the current system seems to largely benefit drug manufacturers; they point to the manufacturers’ consistently high profits and to the large number of people who need but cannot afford ARV drugs.

³ Only three single-entity drugs (didanosine, zidovudine, and stavudine) and one combination drug (lamivudine/zidovudine) are currently approved by the FDA for generic use in the United States. See FDA, undated.

To frame the key issues in this debate, our study focused largely on an examination of the efficiency of the current U.S. patent system for incentivizing and making ARV drugs available. A central discussion point concerns prices for ARVs, and in particular, what the “fair,” “efficient,” or “right” level is. We highlight the specific features of the drug market that differ from those of a freely competitive market and indicate how buyers and sellers are positioned to bargain over prices. Arguably the “right” price for a new drug should cover its cost (which in the case of drugs includes both manufacturing and development costs). However, development costs are private information held by drug manufacturers, so our discussion is limited to the publicly available evidence on the cost of drug development.

Price Negotiation Options

Chapter Two also includes a discussion of price negotiation options. Although the limited information about manufacturers’ costs precludes a definitive statement regarding what a “fair” price should be, we can identify the negotiation options that exist under the current regulatory and market structure for ARVs. To identify price negotiation alternatives for ARVs, we develop a framework that characterizes the market power held by drug sellers and purchasers (i.e., the “players”). The market power (and market limitations) specific to a player are important because they determine the extent to which deviations from a competitive market price can be reduced through price negotiations. Perfectly competitive markets are defined as having five key characteristics (Arrow, 1963): (1) price transparency on both sides of the market; (2) full understanding of the quality of all goods; (3) costless entry and exit of producers; (4) no increasing returns to production; and (5) many buyers and sellers.

The pharmaceutical market deviates from this ideal scenario on almost all points. Prices are typically not publicly available, and many consumers (patients) have only limited knowledge of the ingredients of drugs and their substitutability—information for which they rely on the advice of their health-care providers. Low production costs (in contrast to high R&D costs) encourage marketing strategies that sell greater quantities of goods and increase profits. Finally, market power is typically observed on the seller’s part, but it may be observed on the buyer’s part if there are few purchasers.

To facilitate an analysis of different players’ positions in the market for ARVs, we simplify these key market characteristics into two dimensions: (1) market power (i.e., the extent to which the player has the ability to influence prices) and (2) the information available to each player (in particular, about prices paid by other players and about the true cost of developing a particular ARV). We add a third dimension for government (legal) regulation (i.e., the regulatory framework that government has set up to remedy a market failure). Legal restrictions are highly salient for delineating the scope of action, as exemplified by a Medicare statute that precludes direct negotiations with drug manufacturers, restricting buyers’ market power (Outterson and Kesselheim, 2009). In the subsequent chapters, we use these three parameters to characterize the market systems in the United States and abroad, examine the situations under which certain negotiation strategies may be more or less successful, and present policy options players might employ to negotiate for lower ARV prices.

Chapter Three focuses on the characteristics, key players, and negotiating mechanisms in the U.S. ARV market. We first analyze the current landscape of public payers for HIV care and treatment to determine the size, scope, and depth of the ARV market in the United States. ADAP, Medicare, and Medicaid—the largest public payers for ARVs—each have unique programmatic features that facilitate some negotiation levers while limiting others. We present a

brief overview of each program and summarize the current strategies used by players in the public ARV market to negotiate lower drug prices. We then assess each program's market position in relation to the three key parameters to assess the breadth of negotiation levers that could be exercised.

Chapter Four compares HIV drug financing practices in different countries to elicit policy options aimed at structural changes that result in efficient prices of ARVs. We review past studies of international drug price comparisons, which generally show U.S. prices to be somewhat higher than those in other developed countries, depending on how the prices are adjusted for various confounding factors (e.g., income level, purchasing power parity, exchange rates). We then report three case studies of comparable developed countries with sizable drug markets—the United Kingdom, Canada, and Switzerland—to examine tactics other countries have employed to achieve price discounts and to assess how applicable these strategies would be in the United States. These countries were purposefully chosen on the basis of how similar or different their drug regulatory environments, health systems, and perceived drug prices are from those in the United States. While government price regulations in other countries appear to result in lower prices for patented drugs, including ARVs, the impact of drug prices on health providers and patients is highly moderated by the health insurance systems in those countries.

Lessons Learned and Potential Ways Forward

In Chapter Five, we summarize key observations about demand- and supply-side factors that influence drug pricing, identify policy options for reducing ARV prices in the United States, and discuss their implications for health reform. We find that systemic changes, such as alternatives to or changes in the patent system, would be most likely to affect ARV prices. For example, drug manufacturers might be required to reveal drug development costs or be incentivized to reveal them through rewards.⁴ Such mechanisms could bring the market closer to a free-market situation in which the price of a drug would be equal to the manufacturing and development cost.

We consider possible alternatives for achieving lower ARV prices for buyers, particularly in light of anticipated changes to the U.S. health-care system under the Affordable Care Act (ACA). The most promising mechanisms, not taking the ACA into account, include increased demand pooling, particularly among Medicare Part D drug plans, and leveraging moral pressure and the pharmaceutical industry's concern with public relations, particularly for ADAP.

⁴ For example, the government might award a prize to the manufacturer willing to produce a certain type of (new) drug at the lowest cost. This resembles contracts made for other government works such as building roads or providing other services.

Framework for Understanding How Prices for Antiretroviral Drugs Are Set

This chapter discusses the economics of the pharmaceutical market and how its particularities influence the way prices are set.¹ While many insights from general drug-market economics apply to the market for ARVs, there are some features specific to ARVs that uniquely influence their pricing and the resulting possible negotiation strategies.

The main characteristic of the market for ARVs is that patents protect manufacturers and allow them to set prices. A policymaker trying to arrive at a “correct” pricing of such drugs must trade off two objectives: (1) incentivizing drug manufacturers to provide new drugs in the future and (2) maximizing access to existing drugs (i.e., to keep them affordable for those in need). In a freely competitive market, the market price would equal the production cost, which in the case of drugs includes both manufacturing and development costs. To approximate this “right” price in a system in which drugs are under patent to allow drug producers to recoup their development costs, then, requires knowledge of both of these costs.

There is currently a heated debate about the level of development costs but, unfortunately, little data to inform it. Because of their desire to protect their proprietary rates, drug companies generally do not provide data on those costs. We reviewed the available literature on drug development costs and found widely varying estimates. Thus it is difficult to determine whether current prices paid for ARVs within the patent system are exaggerated—which would be one indicator of whether or not the patent system works (i.e., leads to prices that cover manufacturing and development costs while keeping profits at a low level, thereby maximizing access to the drugs.)

This chapter highlights data about ARV development costs that suggest that ARV prices result in drug manufacturers earning significant profits. The available evidence also suggests that prices are set according to how sensitive demand is to price (so-called monopoly pricing, as predicted by economic theory in situations where there are no competitors because of patent protection) rather than by a price-plus system (i.e., where prices are set to equal manufacturing and development costs *plus* a certain appropriate profit margin), as is often claimed by drug manufacturers. Thus, there is some rationale for the government striving to lower prices with-

¹ The focus of our discussion is on the *supply price* of drugs, that is, the price that drug manufacturers receive. This stands in contrast to much of the analysis in the literature—in particular, the literature on Medicare Part D drug pricing—which focuses on the *demand price*, i.e., the price consumers pay in the form of deductibles and coinsurance rates (Newhouse, 2004). Supply prices determine the profits of drug manufacturers as well as the cost to private and public buyers.

out compromising the future availability of ARVs. Negotiation strategies and policy options to attain this objective are discussed in Chapters Four and Five.

Characteristics of the Market for ARVs

The market for ARVs is very different from that for other goods, even that for other drugs. Unlike most other drugs, ARV drugs are largely shielded from competition due to patent protection, along with the absence of substitutes. Therefore, drug manufacturers possess considerable market power in setting their prices to maximize profits (Mas-Colell, Whinston, and Green, 1995). Some critics have contended that pharmaceutical companies have taken advantage of patent protection to achieve excessive profits, which has led the government to negotiate for lower drug prices. The critics argue that development costs for ARVs are significantly overstated because producers have benefited from federally funded research and fast-tracked Food and Drug Administration (FDA) approval. In the following section, we review the available evidence on this topic.

The Background to Setting Drug Prices

ARVs are typically monopoly goods. The development of drugs in general often gives monopoly power to manufacturers because of patents, first-mover advantages, and the lack of close substitutes for new therapeutics (Scherer, 2000). ARVs in particular almost always face limited or no close substitutes. This is partly a result of HIV being a relatively new disease for which relatively few drugs have been developed. However, monopoly power can also come about because of regulatory provisions; for example, Medicare mandates that new drugs for treating HIV/AIDS must be on the formulary of all their qualified prescription drug plans (PDPs). Because PDPs have to offer every drug, manufacturers are free to set high prices without fear that their drugs will not be purchased.

Drug manufacturers typically sell their drugs in several countries, and even within a single country such as the United States, there are numerous buyers of drugs, including consumers using PDPs and pharmacies. These markets are linked, and attempts to manipulate prices in one market may lead drug manufacturers to make changes in other markets. For example, when there are price differences across markets, drug purchasers may try to engage in “reference pricing,” altering the prices they charge in one market (the “referenced” market) when a buyer demands a discount based on the prevailing price in another market. Similarly, drug prices experienced pronounced hikes before major pieces of legislation took effect, such as when drugs were included as part of Medicare in 2006. These occurrences clearly indicate that drug manufacturers react to (anticipated) changes and that market dynamics must be taken into account when analyzing the market for drugs. Pharmaceutical markets have to be understood as global, dynamic systems. International considerations also affect drug pricing specifically for developing countries, an issue that is beyond the scope of this study.²

² For example, drug manufacturers often cite the higher profit margins in rich countries as necessary to subsidize prices in developing countries. Henry and Lexchin (2002) caution that this approach may lead to the delivery of out-of-date or inap-

How Prices for Drugs Are Determined

Drug manufacturers typically claim that their prices are dictated by high drug development costs, whereas economic theory would predict that prices be set according to how much clients in need are willing to pay for them.

However, for goods with no or limited competition, the drug manufacturers possess monopoly power, and economic theory predicts that they will charge a profit-maximizing monopoly price.³ The less responsive demand for a good is to price, the higher the price-cost margin the supplier can set. For life-saving drugs, demand is probably less responsive to prices than it is for goods such as watches or shoes, for example. Therefore, economists would predict that many drugs will be priced at high levels, largely independent of their costs of production.

Pharmaceutical companies have repeatedly stated that high prices are needed to recover the R&D costs incurred in inventing new drugs. However, Keyhani, Diener-West, and Powe (2005) concluded that drugs with lower development costs, such as those that benefited from government support, did not have lower prices, casting doubt on this assertion. Moreover, the sale of similar drugs at different prices in different markets runs counter to the claim that prices are set relative to costs incurred. The available evidence supports the view that prices are set according to profit maximization in a monopoly market. If this is the case, drug manufacturers have an incentive to charge a price that maximizes their shareholders' profit, which is likely to clash with the government's goal of maximizing the benefit for the population in need. The question, then, is what constitutes an "efficient" price that the government should try to negotiate that allows maximum access to drugs while ensuring sufficient innovation to maintain an appropriate future supply of new drugs.

Because of the limited availability of evidence on drug development costs (if these data were available, the government could simply reimburse the manufacturers for their costs and allow for a certain profit margin), the discussion has focused on indirect indicators of a divergence between drug prices and development costs, such as the profit levels of pharmaceutical companies and whether the high profits observed have led to increased innovation. A related question is whether the current one-size-fits-all approach to providing patents (i.e., all patents provide the same duration of protection, which is not linked to either development costs or the expected benefit of a drug relative to existing drugs) can be modified to maximize social welfare. Possible alternatives to the patent system that may be more apt to achieve the government's goal of providing new drugs at affordable prices are discussed in Chapter Five.

Fairness Considerations

Monopoly pricing for drugs results in those with the highest willingness to pay paying the highest price (because they value the drug most); willingness to pay increases with the client's need of the drug (since essentially all PLHIV have a need for ARVs to survive, their willingness to pay is very high). However, the fairness of prices of life-saving drugs that are out of reach for populations with limited means (whether in the United States or in developing countries)

appropriate drugs in these countries and that, in general, developing generic drugs may be a more sustainable and less costly method for supplying drugs to resource-poor countries.

³ Basic economic theory predicts that a monopolist will set a price to maximize profits in a way that the margin between price P and the marginal costs of producing another unit of a drug MC equals $(P - MC)/P = 1/\epsilon$, where ϵ equals the price elasticity of demand, i.e., how much demand decreases following a price increase.

is questionable, since many PLHIV are poor, marginalized populations for whom the cost of ARVs constitutes a major share of their income or even surpasses their income. An alternative that has been proposed to address this issue in the context of co-payments is the benefit-based model that makes drugs available at the lowest prices to those most benefiting from them (Sipkoff, 2004).

The Effect of Insurance on Price Sensitivity of Demand

A significant portion of the drug consumers in the United States and other developed countries are covered by insurance (see Chapter Three for a discussion of the insurance status of PLHIV in the United States). In cases where the consumer pays only a fraction of the price (e.g., the consumer provides a co-pay and the insurance pays the rest of the drug price), the consumer is shielded from the full price of the drug. The quantity demanded is less sensitive to the full price, and thus manufacturers can set higher prices than they could in the absence of insurance.⁴ In essence, insurance leads to a lower *observed* price by the consumer and further reduces his or her demand price elasticity. Insurance contributes to high drug prices that have led to the paradoxical situation in which the government has instituted the patent system allowing for monopoly power and at the same time is intervening in the drug market to negotiate for lower prices. For example, in the United States, Medicaid demands discounts on drug prices; in the United Kingdom, government intervention is more direct, such as when the National Health Service (NHS) puts a profit cap on drug manufacturers.

The Effect of Prices in Other, Linked Markets

Drugs are sold in different countries at different prices; even within a single country, drugs are sold to different clients at different prices. For example, drug manufacturers receive different prices for the same drug from Medicare, Medicaid, privately insured consumers, and consumers without insurance coverage. Because of these linked markets, both manufacturers and purchasers must take into account the actions of the other players when devising approaches to negotiating drug prices. From the point of view of the drug manufacturers, the existence of multiple, segmented markets—both domestic and international—implies that price discrimination, i.e. the selling of identical products to different buyers at different prices, can be practiced (Reinhardt, 2007).⁵ The (currently illegal) practice of reimporting drugs from Canada practiced by many U.S. citizens indicates that it is not always possible to completely separate markets and underscores the prevalence of price discrimination on the part of drug manufacturers.

Schweitzer and Comanor (2011) discuss options for drug pricing when there are multiple markets within a country or between different countries. One option is for firms to maximize profits by using price discrimination and charging different prices depending on the price sensitivity of demand in different markets. Another option is the public-utility pricing model, which allocates the fixed costs of R&D according to willingness to pay in the different markets. In this model, consumers in markets where demand is less sensitive to prices should pay

⁴ The manufacturer has an incentive to set the supply price as a multiple of the price paid by a privately paying individual bearing the full cost of the drug. For example, if the consumer pays 20 percent, the final price will be five times the private monopoly price (Newhouse, 2004).

⁵ *Segmented markets* means that drugs purchased in one market cannot be sold in other markets (or can be sold to only a limited extent).

higher prices. The application of this pricing model (like the price discrimination model) leads to consumers with the highest need (i.e., the most inelastic demand) paying the highest prices for a drug, as discussed above.

Prices Used in the Market for ARVs

The system of drug pricing is primarily defined by two prices: the average wholesale price (AWP) and the average manufacturer price (AMP). The AWP is the wholesaler list price, which is publicly available and serves as the basis for pricing (but not the actual selling price) for wholesalers, retail pharmacies, and retail customers (Leibowitz and Sood, 2007). The AMP is the average price wholesalers pay to manufacturers and reflects discounts and other negotiated concessions (Peters, 2009). The AMP is reported to the Centers for Medicare and Medicaid Services (CMS) but is not publicly available. It is also used as the basis for determining rebates from manufacturers.

Pharmaceutical Profits and Government Efforts to Limit Them

The call for controls on drug prices stems from the perception on the part of many policymakers that drugs are priced too high and the resulting profits in the pharmaceutical industry are excessive. Pharmaceutical industry profits have, indeed, been found to be significantly higher than profits in other industries (Scherer, 1996). For example, median profits in 2002 for the top ten drug companies were 17 percent, compared with about 3 percent for all Fortune 500 companies in that year (Public Citizen, 2003).

These high profits have turned the pharmaceutical industry into the most profitable industry in the United States almost every year in the last quarter-century (Angell, 2004). However, a study by Newhouse (2004) argues that R&D expenditures, which represent a significant fraction of costs, should be included in the assets of a company (as they represent investments with expected future payoffs).⁶ When these R&D expenses are taken into account, pharmaceutical profit levels are still higher than those of other industries but by only about 2 to 3 percentage points (Newhouse, 2004). Nevertheless, it is unclear why pharmaceutical companies should be treated differently in the calculation of their profits than other industries that also rely on R&D for profits—i.e., virtually all companies, and in particular, R&D-heavy industries such as information technology (IT). Another argument made to support high prices by drug companies is that drug development is a high-risk activity. However, it is difficult to reconcile the steadiness of pharmaceutical profits with the riskiness of investment in drug innovation claimed by drug manufacturers; if drug innovation were risky, profits would show strong yearly fluctuations, which is not the case. While steadiness of profit could also come about through a portfolio of investments that spreads risk across a number of drugs, profits are high and steady even for companies focusing on a single class of drugs (such as Gilead, which reaps most of its benefit from ARVs and other HIV-related drugs).

Perceived excess returns have led some governments to put caps on allowable profits of the pharmaceutical industry to guide drug pricing. For example, the British NHS limits a manufacturer's return on its business with the NHS to 20 percent. This practice is similar to the rate-of-return regulation for utilities (see, e.g., Kirkpatrick and Parker, 2004). The under-

⁶ In contrast, the accounting view used in the calculation of the profit levels mentioned above treats these costs as outlays.

lying reasoning is that monopoly firms (and drug companies selling ARVs typically have government-granted monopolies through the patents they possess) should be required to charge the price that would prevail in a competitive market, which is equal to the efficient production costs and a rate of return on capital as would be determined in a competitive market. While this approach should be considered by policymakers, Newhouse (2004) discusses several problems with it. For example, it is difficult to determine a company's assets, particularly if the company is multinational and may merge with or acquire other companies. Also, the approach leads to market distortions by encouraging larger firm sizes, as smaller firms with successful drugs would have an incentive to acquire less successful companies to enlarge their asset base (which forms the basis for the rate cap). However, if a government feels that it wants to pursue the utility approach, evaluations should be undertaken to analyze the cost effectiveness of such action.

What Are Drug Manufacturers' Profits Used For?

While data limitations make it difficult to determine with much precision how profits are being spent, recent data indicate that the largest fraction is spent on marketing, followed by R&D; more specifically, pharmaceutical companies are reported to spend almost twice as much on marketing as they do on R&D (Gagnon and Lexchin, 2008).

Once a new drug has been approved and production has been scaled up, the marginal costs of producing an extra unit of the drug are low. Evidence of this phenomenon is provided by the fact that generics typically sell for as little as 15 percent of the price of a branded product (Scherer, 2000). This indicates that profits on an existing drug (particularly one that is on patent) tend to be high, as low marginal costs increase the price-cost margin. Moreover, it is in the interest of drug manufacturers to sell as many units of a drug as possible because of the low cost of producing extra units. This is very different from products, such as cars, that incur substantial production costs.

Are Marketing Expenditures of Pharmaceuticals Excessive?

The debate surrounding pharmaceutical marketing expenditures goes back to the 1950s, when Senator Estes Kefauver claimed that many drugs were not therapeutically innovative and that drug costs were significantly inflated due to marketing expenditures (Froud, 2006). Gagnon and Lexchin (2008) estimated that drug companies in the United States spend almost twice as much on marketing-related activities as they do on R&D. However, Newhouse (2004) argues that high marketing costs do not necessarily mean that less money is spent on R&D: Economic theory predicts that a company allocates resources to each activity to maximize returns (i.e., until the marginal dollar invested in each activity has the same return). From this perspective, a company investing less in marketing would reduce its profits and would potentially have less money available for developing new drugs. However, this relates to the private profits of a company, not necessarily the maximization of social welfare.

Scherer (2000) highlights some potential benefits of marketing expenditures, including making more information available to doctors and clients and increased uptake of necessary drugs that clients may not otherwise have been aware of. However, Scherer doubts whether such benefits are significant enough to justify the high levels of marketing expenditures observed in practice. As of 2008, only two countries allowed drug advertising directly to consumers:

the United States and New Zealand. There is also evidence that the incentive for marketing drugs has led to questionable and sometimes illegal activities, including paying physicians to prescribe drugs for off-label uses (Harris, 2009).

How Much Do Drug Companies Spend on New-Drug Development?

Drug manufacturers often cite the costs of developing new drugs as the primary justification for high drug prices. Within the health economics profession, there is a heated debate on the true cost of developing a new drug. If drug companies are held to using a “cost-plus” pricing strategy as they often claim (i.e., that they charge the development cost plus a reasonable profit margin for a drug), the actual costs of developing new drugs are a crucial element in setting prices. If drug development expenses are revealed to be significantly lower than claimed by pharmaceutical companies, governments could negotiate for lower prices without having to worry that they would necessarily translate into less innovation.

Pharmaceutical companies often cite DiMasi, Hansen, and Grabowski (2003) in defending the need for high prices to sustain drug development, as they report a cost per new drug of \$802 million. That figure has been widely criticized on the grounds of lack of data transparency and the methodological issues used to arrive at it. Critics have pointed out that the drug company in the study would have had an incentive to provide data on the drugs that are most costly to develop. Unfortunately, we cannot verify the study results, as the pharmaceutical company did not release the names of the drugs for which it provided costs.

A systematic review by Morgan et al. (2011) of the costs of drug development produced estimates ranging from \$92 million to \$883.6 million but cautioned that the “results are based on confidential surveys of unnamed companies about unnamed products and are impossible to assess for accuracy, representativeness, or sensitivity to outliers.” Reinhardt (2007) discusses the challenges in calculating R&D costs, the interest rate used to discount expenses to a point in time, and whether present- or terminal-value costs should be reported. Light and Lexchin (2004) cite potential bias in existing studies that focus on new drugs rather than on less costly “me-too” innovations. Finally, the consumer advocacy group Public Citizen suggests that a more realistic cost to develop a drug, based on data from 1994 to 2000, is less than \$100 million (Public Citizen, 2003).

Drug manufacturers (in particular, ARV manufacturers) have benefited from substantial public contributions. In 2000, \$18 billion in National Institutes of Health (NIH) and other public R&D funds went toward basic drug research, from which drug manufacturers benefited substantially, as well as toward about 5,000 clinical trials (Light and Lexchin, 2004). A Senate report in 2000 found that “the federal government, mainly through the NIH, funds about 36 percent of all U.S. medical research. . . . Of the 21 most important drugs introduced between 1965 and 1992, 15 were developed using knowledge and techniques from federally funded research. Of these, NIH research led to the development of 7 drugs used to treat patients with cancer, AIDS, hypertension, depression, herpes, and anemia” (United States Senate, 2000). In addition, ARVs have benefited from fast-tracking in the FDA approval process, which lowers research costs associated with clinical trials. For example, Atripla was approved in July 2006 after only three months, substantially less than the average approval time for other drugs (FDA, 2009).

Do High Profits Result in Innovation?

Despite the continued debate about the true costs of developing new drugs, there is general agreement that the process is uncertain and costly and that some form of incentive is needed to spur innovation. The U.S. patent system is not the only option, however, as other incentives such as rewards or subsidies for inventors have been suggested and implemented (Goldman and Lakdawalla, 2011).

The “correct” amount of profit needed to spur innovation is hotly debated. On one end of the spectrum is social-value pricing (Lakdawalla and Sood, 2012), which calls for the government as a “social welfare maximizer” to compensate drug companies for the full social value created. However, given the limited budgets available for HIV programs, for example, it is unlikely that this option is feasible or even necessary to achieve innovation: Manufacturers of ARVs obtain about 5 percent of the social value they create (Philipson and Jena, 2006), which implies either that incentives for drug innovation are too low and that consequently there is not a sufficient number of ARVs on the market or if we believe that there is a sufficient number of ARVs on the market, it is an argument against the theoretical prediction that all social value should accrue to drug companies.

The claim by drug companies that R&D costs need to be reimbursed is a pricing strategy and a view of innovation that is independent of the social value created by a drug; in economic terms, it would be an example of a cost-plus price strategy that emphasizes the “correct” evaluation of costs incurred. The prevailing pricing strategy, monopoly pricing, puts willingness to pay as the central determinant of price setting. The willingness of the government to buy drugs for persons who rely on federal insurance depends on the benefits it perceives from paying a certain price as it trades off high prices (which are unaffordable by many needy current clients) and lower prices (which are beneficial to current patients but possibly detrimental to future patients, who may have access to fewer drugs if lower prices lead to less innovation).

The empirical evidence for the profit-innovation link is not unambiguous: Some studies have found a positive link between expected market size and innovation (Acemoglu and Linn, 2004) or between larger markets for vaccinations and R&D in investments in vaccinations (Finkelstein, 2004). However, Keyhani et al. (2010) found that in countries with price regulations (i.e., all countries except the United States), the proportion of new drugs developed relative to total prescription drug spending and gross domestic product (GDP) is as high as that in the United States and in some countries is even higher.

Another issue that has been raised concerns whether the “wrong” kinds of drugs are potentially being developed because of the emphasis on profit maximization rather than social welfare. Critics argue that the way new drugs are currently being approved contributes to this problem: new drugs have to demonstrate that they are more effective than a placebo rather than being pitted against the currently most effective drug. Therefore, many drugs with characteristics similar to existing drugs enter the market and offer little additional benefit. Developing such “me-too” drugs is less risky than developing truly innovative drugs, as there is already an existing market for them. Recent statistics indicate that of the 487 drugs approved between 1998 and 2003, almost 80 percent were classified by the FDA as either having therapeutic qualities similar to those of an existing drug or were new formulations or combinations of existing drugs (Angell, 2004). Similarly, Light and Lexchin (2004) found that drug companies spend more than 80 percent of their R&D funds on derivative innovations for existing drugs, and only 18 percent is spent on basic research for breakthrough drugs. Another indicator of a slow rate of innovation despite high profits is that between 2001 and 2004, only five

drugs have come on the market that established a new drug class, compared with 43 between 1991 and 2000 (Newhouse, Seiguer, and Frank, 2007).

It is uncommon for drug manufacturers to do all the basic research on a new drug in-house and then develop and bring the drug to market. Pharmaceutical companies more often either buy start-ups or use inventions from the university sector to acquire promising drugs that they then bring to the market. They may even acquire drugs to treat one disease with profits from a drug for a different disease, as did one of the market leaders in ARVs, Gilead. At the end of 2011, Gilead acquired Pharmasset, a company with a promising hepatitis-C drug, for \$11 billion, with profits acquired from selling HIV-related drugs, in particular ARVs. This is an example of the way in which manufacturers are often little involved in providing basic research or in the (risky and costly) early stages of drug development. In the case of Gilead, the profits acquired from HIV-related drugs were not used to increase innovation in this drug category but were used to acquire a drug for a different disease that was seen as bringing in more profit in the future.

The University and Small Business Patent Procedures Act of 1980, commonly known as the Bayh-Dole Act, was targeted at correcting the perception that many patents generated in publically funded universities were not brought to market and hence did not benefit U.S. citizens. The Act essentially transferred the ownership of inventions from the government to the recipients of federal funds used to develop these inventions. The government kept the right to “march in” should an owner not take steps to commercialize an invention or use it to benefit citizens in need. However, critics contend that universities and other entities selling these ownerships receive little return from drug companies, i.e., that the Act essentially benefits the drug companies who buy federally funded research inventions at very low cost. Kesselheim and Rajkumar (2011) have asked the government and universities to step in in such situations to revamp licensing practices to protect the social benefit. For example, universities may include provisions stipulating that the products of their research be made available to the greatest number of people in need rather than to maximize their gain.

Once a drug is developed, the know-how incorporated in it could in theory be made available to all in need at no extra cost, i.e., to provide a global public good. Currently, however, drug price negotiations are undertaken by each country separately, which can lead some countries to “free-ride” on R&D spending. A 2004 study by the U.S. Department of Commerce analyzed the price-negotiation mechanisms for drugs in 11 Organisation for Economic Cooperation and Development (OECD) countries and found that price controls and other government actions have led to drug prices from 18 to 67 percent lower than those in the United States (U.S. Department of Commerce, 2004). Keyhani et al. (2010) did not find evidence that the higher prices in the United States translate into increased drug innovation.

Conclusion

This section has described the market for ARVs and argued that in the monopoly situation created by the U.S. patent system, prices are typically negotiated between buyers and a single seller who enjoys considerable market power.

Drug manufacturers contend that high prices are needed to sustain the development of new drugs; however, there are a number of indications that suggest that these R&D costs are overstated. Studies justifying high R&D costs have been criticized as having methodological

flaws and limited data transparency. Furthermore, it is clear that drug manufacturers have benefited from substantial federal and university contributions and also from the fast-tracking FDA process for many ARVs. Drug companies may not be passing on these cost reductions to clients in need of life-saving drugs as evidenced by the high ARV drug prices relative to many other drugs not benefiting from these cost reductions. Therefore, government efforts to alter the existing patent system or to negotiate for lower drug prices may not endanger the availability of new drugs in the future.

Drug companies are reluctant to provide the research community with data that would allow for more-precise R&D cost estimates. However, development cost data could be de-identified through a clearinghouse to protect proprietary information. Greater data transparency might provide an incentive by offering to enhance the image of drug manufacturers. Similarly, pharmaceutical companies might want to avoid being seen as denying life-saving drugs to marginalized populations, an argument that has been used by purchasers such as the AIDS Healthcare Foundation (AHF) or the ADAP Crisis Task Force in demanding lower prices. Such moral and ethical arguments represent another category of negotiation strategies, discussed in Chapter Five.

The ARV Market in the United States: Characteristics, Key Players, and Negotiating Mechanisms

In this chapter, we describe the landscape of public HIV-treatment financing and the purchase of ARV drugs in the United States. We analyze the mechanisms through which the three largest public ARV payers (ADAP, Medicaid, and Medicare) currently negotiate ARV prices, including the strategies of demand pooling, formulary restriction, contractual agreements, and ceiling prices.

Basic characteristics of each of the three major payers include overall program mandate, source of financing, populations served, and HIV-specific benefits offered.

We lay out the structure of each payer's "system," characterized by the relationship and flows of resources (money, ARVs) among them to highlight key differences in players and structure that determine the degree of each player's negotiation power. Price negotiations can take place at various places in the system, not only with the manufacturer but with intermediary players as well.

Finally, we characterize the gamut of negotiation levers used by public ARV payers, given the overarching structure of the ARV market and each payer's structural model, relating each of the levers back to market power, information, and regulation. We find four types of levers used by ADAP, Medicaid, and Medicare, all of which serve to either increase the market power of the payer or constrain the market power of the pharmaceutical company:

1. Demand pooling
2. Formulary restriction
3. Contractual agreements
4. Guaranteed discounts.

We find that the government (rather than private insurers) finances ART for the majority of PLHIV in care through a complex, patchwork system comprised of entitlement and discretionary programs, including ADAP, Medicare, and Medicaid. Each of the programs has a unique set of relationships between players and regulations constraining (or aiding) their bargaining power, resulting in different prices achieved across programs, and even within programs across states. However, from a systemic perspective, the range of negotiation levers available to ARV buyers is limited, as the market is defined by the monopolistic power of the manufacturers.

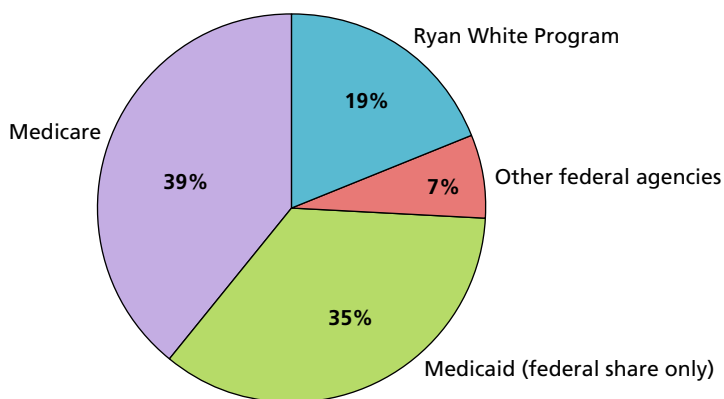
Public Payers of Antiretroviral Drugs

There are multiple domestic U.S. markets for ARVs, including both public and private payers. Medicare, Medicaid, and ADAP (funded through the Ryan White Program) receive full or partial federal funding. Of these three payers, only ADAP deals exclusively with HIV. Several other government agencies—most notably the Department of Veterans Affairs (VA)—also receive federal funding for HIV treatment and care. Figure 3.1 shows a breakdown of federal funding for HIV/AIDS treatment and care (KFF, 2004; KFF, 2009a).¹

The public payers are vital for covering care for low-income individuals. According to the Department of Health and Human Services (HHS), only about one-fifth of PLHIV have some form of private insurance (employer-based or privately purchased), while one-third do not have any health insurance coverage (HHS, 2010). The rest are either fully or partially covered under publicly funded government entitlement programs (Medicaid or Medicare). The PLHIV who lack full coverage for ARVs are uninsured or underinsured by employer-based insurance, earn too little to purchase private insurance, earn too much to qualify for Medicaid, or are not disabled or old enough to qualify for Medicare. ADAP is specifically designed to cover individuals who cannot afford or access medications from other sources (KFF, 2008).

Figure 3.2 shows that the vast majority of PLHIV rely on at least one of these publicly funded programs for their treatment and care, including ARV drugs. Medicare receives the largest portion of federal HIV funding, followed by Medicaid and the Ryan White Program, which are also funded partially by states via a system in which manufacturers rebate a portion of the purchase price of ARVs to the state program. The high cost of care, together with the growing numbers of PLHIV, puts further pressure on these systems to provide HIV treatment to all those who need it (Bassett et al., 2008).

Figure 3.1
Federal Funding for HIV/AIDS Care by Program, FY 2008



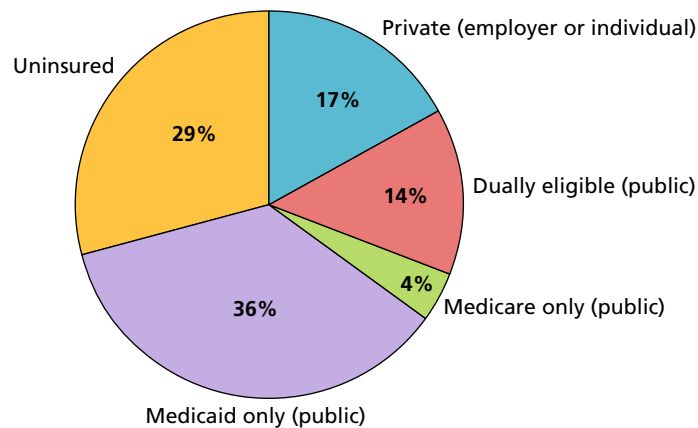
NOTE: Other federal agencies include the Department of Veterans Affairs, the Department of Health and Human Services, and the Departments of Defense and Justice.

SOURCE: KFF, 2009a, 2009b, 2009c.

RAND TR1273-3.1

¹ Some government-funded ARV programs, such as state pharmaceutical assistance programs, operate solely on state funds, but given their small size, we do not include them in this analysis.

Figure 3.2
Health Insurance Coverage of PLHIV in the United States
as of 2006



SOURCE: NASTAD, 2011.

RAND TR1273-3.2

ADAP

Overview. ADAPs are state-run, publicly financed HIV-drug purchasing programs. They purchase prescription medications for their clients at a discount, capped at a government-negotiated ceiling price (the 340B price).² ADAP is jointly financed by the federal government (via Part B of the Ryan White Program³) and state governments. The proportion of funding from each of these sources varies by state, partially determined by the financial need and HIV burden of the state, as well as whether the state uses a rebate or direct-purchasing system (KFF, 2008; NASTAD, 2011).

Under its Ryan White mandate, ADAP covers people who have no or inadequate coverage from other insurance sources, making it the payer of last resort. It generally has more-generous income eligibility criteria than Medicaid and does not require that recipients be con-

² The 340B Drug Pricing Program was established by the Veterans Health Care Act of 1992 in section 340B of the Public Health Service Act and is administered by the Office of Pharmacy Affairs in the Health and Resources and Services Administration. It requires all manufacturers that participate in Medicaid (and rebate programs) to provide discounted covered outpatient drugs to covered entities, which include eligible hospitals, family planning clinics, and federally qualified health centers. The 340B price can then be accessed by public payers by purchasing drugs through these covered entities. The 340B program sets a ceiling price, which is the maximum drug price manufacturers can charge for each 340B purchased drug. Purchasers can also negotiate prices lower than this ceiling price directly with drug manufacturers (GAO, 2006). The 340B ceiling price for most drugs is set according to a formula based on AMP less a discount: 13 percent for generic and over-the-counter (OTC) drugs and the lower of AMP less 23.1 percent or the best available price for brand-name drugs.

³ The Ryan White Program is the largest federal program designed specifically for people with HIV in the United States and the third largest source of public funding for HIV care (KFF, 2009c). The program specifically functions as the payer of last resort for those who have no other source of financing for their HIV care (GAO, 2006; KFF, 2009c). Funding for the program was established through the Ryan White Comprehensive Resources Emergency Act (CARE Act), enacted by Congress in 1990 as an emergency response program. Since then, it has shifted into a critical and ongoing source of care for low-income people with HIV. As part of the Ryan White CARE Act, ADAP was authorized to purchase and provide HIV/AIDS medications to eligible individuals at the state level. Congress must appropriate funds for the Ryan White Program each year.

sidered disabled to access it (KFF, 2008; NASTAD, 2011). However, ADAP is a discretionary program; unlike Medicare and Medicaid, which are entitlement programs, each state ADAP can set its own eligibility criteria.

ADAP may be the only source of ARVs for beneficiaries with no other source of insurance. It may provide “wraparound” coverage for lower-income Medicare patients who are not eligible to receive Medicare Part D’s low-income subsidy (KFF, 2008; KFF, 2009b).⁴ For example, ADAP pays for Medicare drug costs associated with being in the “donut hole” (costs for which the patient is 100 percent responsible incurred after the initial coverage limit and before the out-of-pocket threshold), co-pays, monthly premiums, and deductibles.⁵ ADAP may fill coverage gaps for Medicaid beneficiaries who are not dually eligible with Medicare Part D or whose Medicaid-only benefits are not sufficient to cover all needed drugs (KFF, 2008, 2009a). However, budget constraints have led some states to use eligibility restrictions or waiting lists as cost-containment strategies. As of February 2012, ADAP had 4,118 on waiting lists in 12 states, primarily in the South (NASTAD, 2012).

In 2007, ADAP instituted a minimum formulary requirement that requires all states to include at least one FDA-approved drug from each ARV class (e.g., at least one protease inhibitor). As of 2008, the majority of ADAPs (29) covered all approved ARVs in each class (KFF, 2008).

Structural Models. The majority of state ADAPs can be characterized by one of two structural models, the direct-purchase model and the rebate model, which affect the negotiation levers the ADAPs can use.⁶

In the direct-purchase model (Figure 3.3), the state ADAP purchases ARVs directly from wholesalers, brokered by an intermediary who then manages distribution of the drugs to patients (Leibowitz and Sood, 2007). Some ADAPs use a state-owned pharmacy to purchase ARVs, and the pharmacy distributes medications directly to patients. Other ADAPs contract with public agencies or hospitals to purchase ARVs; these agencies or hospitals either have in-house pharmacies to distribute the drugs to clients or arrange for distribution. ADAPs can also hire a pharmacy benefit manager (PBM) to purchase drugs and arrange their distribution. Although ADAPs using the direct purchase model are eligible for the 340B Prime Vendor program, not all accept the 340B Prime Vendor price, particularly if lower prices are negotiated.

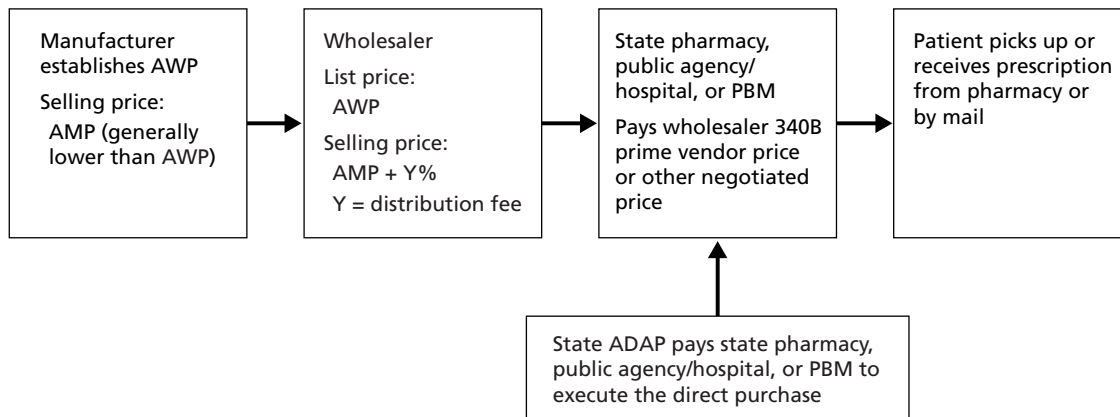
In the rebate model (Figure 3.4), the state reimburses retail pharmacies, which purchase drugs directly from the wholesaler, for dispensing ARVs to patients. The amount of this reimbursement is negotiated with retail pharmacies, often by a PBM (Leibowitz and Sood, 2007). The state ADAP receives rebates from the drug manufacturer to bring the total price down to the negotiated level. Rebate levels are set at the federal level for the Medicaid program (which operates entirely on rebates) but are extended to ADAPs; any state using the rebate model is

⁴ The Medicare Part D low-income subsidy program significantly reduces prescription drug costs for people who are either dually eligible with Medicaid or below 150 percent of the federal poverty line and have low assets (KFF, 2009b).

⁵ The out-of-pocket threshold is determined on the basis of true out-of-pocket (TrOOP) costs of beneficiaries, their family/friends on their behalf, or certain institutions on their behalf. Prior to 2011, ADAP expenditures did not count toward a beneficiary’s TrOOP costs; as a result, ADAP covered the costs of being in the donut hole, but it was hard for the recipient to ever get out of that hole. Under the ACA, starting in 2011, ADAP spending counted toward TrOOP costs, and in 2014, the donut hole will be eliminated (KFF, 2004, 2008; Health Law and Policy Clinic, 2010).

⁶ A few ADAPs use hybrid models combining direct purchasing and rebates; however, this is not common (NASTAD, 2011).

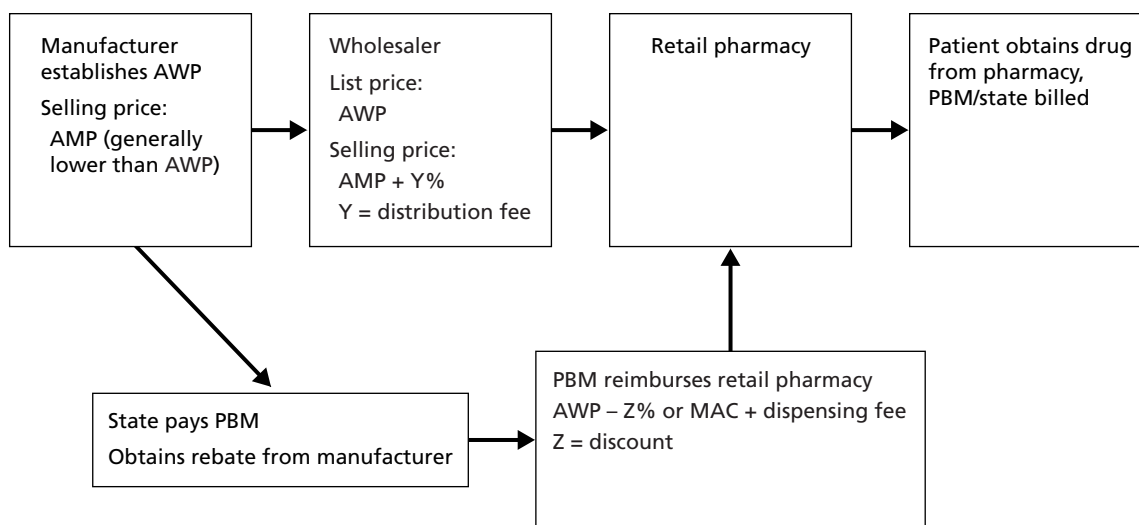
Figure 3.3
Structural Model: ADAP Direct-Purchase States



NOTES: If the state purchases through PBM or a public agency without a pharmacy, it must arrange for distribution. Participation in the 340B Prime Vendor program is voluntary for qualifying entities. It allows sub-340B prices for most drugs, according to a formula based on average manufacturer price (AMP) less a discount of 13 percent for generic and OTC drugs and the lower of AMP less 23.1 percent or best available price for brand-name drugs. AWP = average wholesale price.

RAND TR1273-3.3

Figure 3.4
Structural Model: ADAP Rebate States



SOURCE: Adapted from Figure 2 in Leibowitz and Sood (2007).

NOTE: MAC = maximum allowable cost.

RAND TR1273-3.4

entitled to the same rebates as Medicaid under law. In addition, ADAPs sometimes negotiate supplemental rebates in times of economic difficulty or shortage.

Each state decides which model to use. Using data from state ADAPs, Leibowitz and Sood (2007) found that the choice of model did not affect average ARV drug costs, but choices made within each system did (discussed below).

Negotiation Mechanisms. In the direct-purchase model, ADAPs derive a limited amount of market power from the following sources:

- **Guaranteed discounts.** If the ADAP chooses to participate in the 340B Prime Vendor program, it can take advantage of the discount provided by the Prime Vendor—a wholesaler contracted by the government—negotiated by aggregating the demand for drugs from all participating ADAPs.
- **Demand pooling.** The Prime Vendor wholesaler can use the larger pooled demand as leverage to negotiate volume discounts with manufacturers that can be passed onto ADAPs. However, whether they participate in the 340B Prime Vendor program or not, state ADAPs with larger HIV populations are able to leverage higher demand and attain lower prices than states with smaller HIV populations (Leibowitz and Sood, 2007).

In the rebate model, the state ADAP has a different (although still limited) set of options to leverage lower ARV prices:

- **Contractual agreements.** The state ADAPs' primary source of market power is the ability to contract with a smaller number of pharmacy retailers. The state can obtain larger drug discounts from pharmacies in exchange for ensuring business to them (Leibowitz and Sood, 2007). Although a PBM conducts the actual negotiations with the pharmacies, the ADAP must decide how many pharmacies to contract with, taking into consideration potential issues of patient access if fewer pharmacies are contracted. In some states, limiting the number of pharmacy outlets does not yield any leverage if ADAPs purchase medications through a fixed per-prescription payment to the PBM (usually AWP less 15 percent). Any additional discount the PBM may obtain from the pharmacy is not passed on to the ADAP (Leibowitz and Sood, 2007). Similarly, larger pharmacies or pharmacy networks may be able to obtain greater discounts from manufacturers, but such savings are not likely to be passed on to the ADAP.

Both direct-purchase and rebate model ADAPs can use formulary restriction as a negotiation lever for better ARV prices. Each state ADAP can adjust its formulary within each ARV drug class, enabling it to concentrate demand on fewer drugs as a means of attaining price discounts and threatening not to purchase ARVs that are too high-priced. In this way, ADAPs have some ability to counter the market power of pharmaceutical companies, at least in theory. However, these options are limited, since there is a mandatory minimum formulary, and any restrictions may be clinically and ethically undesirable. Since 2009, ADAPs in some states (including states with large ADAP clienteles such as Florida, Georgia, and Illinois) have reduced (or are considering reducing) their formularies as a cost-containment strategy.

Medicare

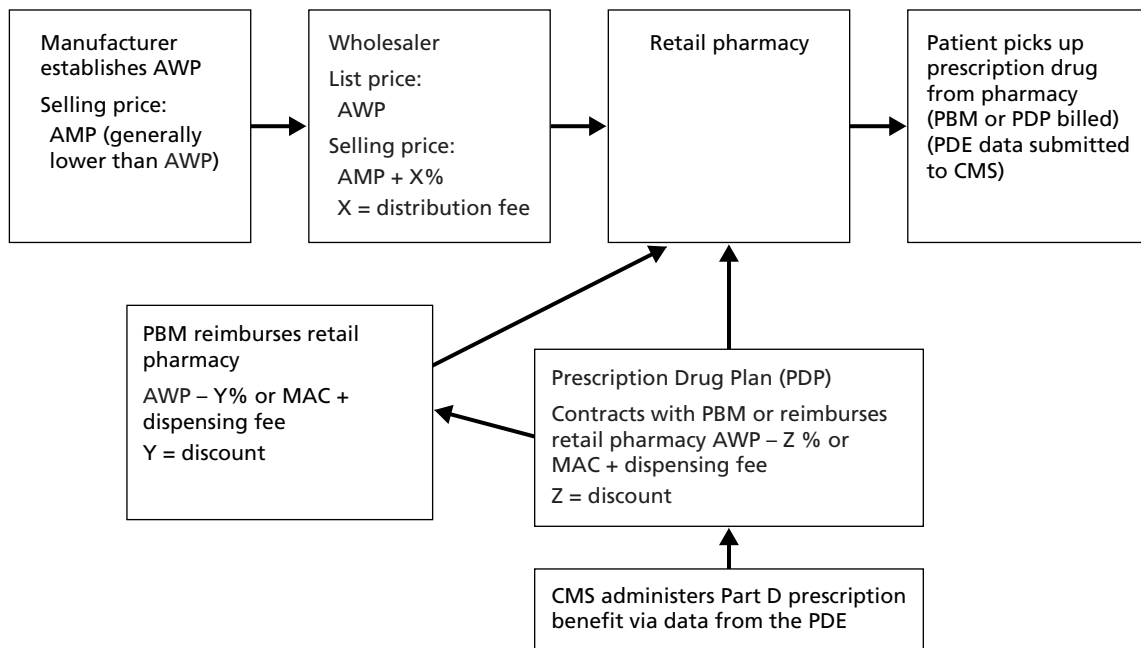
Overview. Medicare is the federal health insurance program covering individuals 65 years of age and older who have sufficient work credits to qualify for Social Security payments and adults under 65 who are permanently disabled (HIV does not automatically qualify as a permanent disability). To qualify under Medicare's disability criteria, a person must have sufficient work credits to qualify for Social Security Disability Income payments. Implemented in 2006, Medicare Part D (the prescription drug benefit) turned Medicare into the largest single source of HIV-care financing, a position previously held by Medicaid. As Medicare started to pay for prescription medicines for beneficiaries with HIV, the dually eligibles who were also covered by Medicaid (see Figure 3.1) had their drug costs shifted from Medicaid to Medicare.

The Part D benefit relies on private insurers to provide drug coverage, offered through Medicare Advantage prescription drug plans that cover all Medicare benefits including drugs or stand-alone PDPs. Approximately 60 percent of the Medicare Part D beneficiaries (29.5 million people) are enrolled in PDPs.

On average, Medicare Part D pays 30 percent more for drugs than does Medicaid, and this discrepancy resulted in a \$3.7 billion windfall gain for drug manufacturers in the first two years of the program, when financial responsibility for dually eligibles was transferred to Medicare (U.S. House of Representatives, 2008).

Structural Model. There are six players in the Medicare Part D model (Figure 3.5) and thus multiple points where prices may be influenced. The manufacturer-wholesaler-pharmacy-patient relationship reflects a one-way distribution of drugs, and the pricing flows with the initial price set by the manufacturer. While manufacturers interact only with wholesalers, and wholesalers in turn engage only with retail pharmacies, multiple players come into the purchasing market further down the supply chain. PDPs and PBMs attain reimbursements with varying discounts from retail pharmacies. PDPs may also choose to engage the services of PBMs, which are typically private firms that focus on insuring and managing prescription drug use and spending (Frank, 2001). Overall, PDPs are relied on to administer the Part D benefits, even though the financing comes from CMS.

Figure 3.5
Structural Model: Medicare



NOTE: PDE = prescription drug event.

Negotiation Mechanisms. The Medicare model includes the following negotiation mechanisms:

- **Formulary restriction.** PDPs and PBMs have some leeway to determine formulary composition and the terms of other contracts that may yield additional concessions. They can use their market share as leverage with manufacturers by steering purchasing volumes toward better deals or concentrating demand via formulary restrictions (Frank, 2011; Leibowitz and Sood, 2007). However, there is limited scope for such action with ARVs, since they are “all or substantially all” required to be covered by Medicare Part D plans (KFF, 2006). Alternatively, PDPs can vary the formulary tier placement of ARVs, which may have some impact on manufacturers’ concessions, but this is likely to be minimal, as most ARVs are brand-name drugs and are placed on higher or specialty tiers. As a result, beneficiaries may be left with potentially significant out-of-pocket costs.
- **Contractual agreements.** PDPs may use contractual agreements to negotiate reimbursement levels with retail pharmacies. PBMs can negotiate exclusive contracts with retail pharmacies to leverage price discounts in return for greater retailer volume (Leibowitz and Sood, 2007). The market power of both PDPs and PBMs is limited by competition, since they must compete with others for market share and contracts.

Wholesalers and retail pharmacies hold little market power, as they are subject to more regulation.⁷ However, many of the larger wholesalers offer other services and tools (e.g., supply-chain management) to retail pharmacies to increase profit-sharing and market share. In sum, private buyers have limited latitude—in both market share and pricing transparency—to negotiate for price discounts.

Medicaid

Overview. Medicaid is the principal health insurance program for low-income Americans (KFF, 2009a). State and federal government contributions—about \$7.5 billion in FY 2008—make Medicaid the largest source of public financing for HIV in the United States. However, HIV accounts for less than 2 percent of total Medicaid spending.

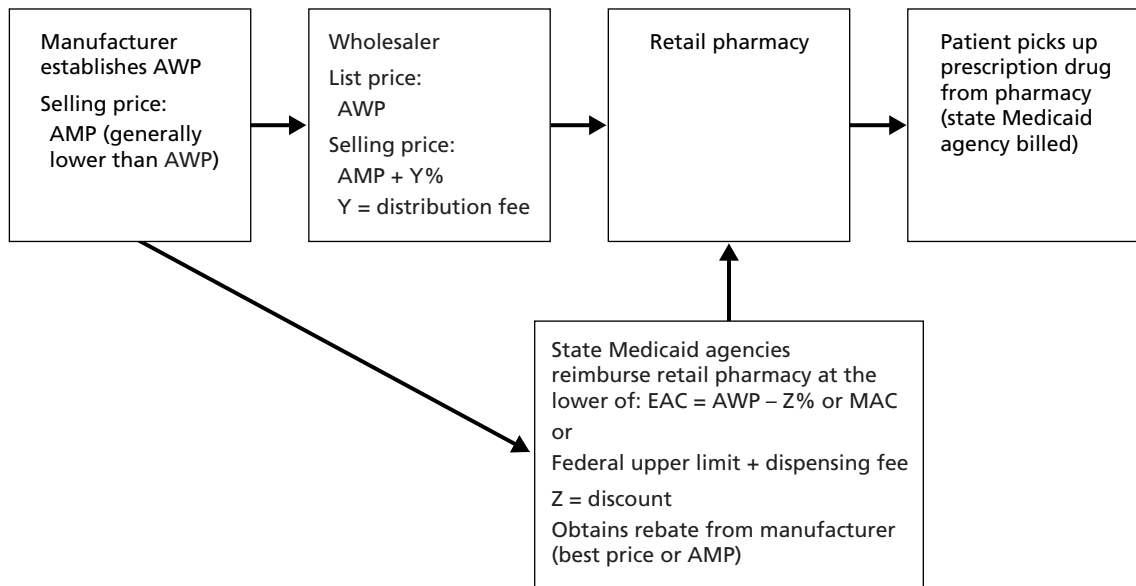
Medicaid is administered by states and financed with matching federal contributions of 50 to 76 percent of total Medicaid funds, depending on the income level of the state (KFF, 2009a). Medicaid is also financed in part by rebate revenue for fee-for-service drugs.⁸ The mode of Medicaid reimbursement for drugs is chosen by the state: The benefit amount can be included in the capitated payment to Medicaid managed-care plans or reimbursed on a fee-for-service basis (KFF, 2011).

Structural Model. The Medicaid model has fewer players than Medicare and ADAP (Figure 3.6). The manufacturers interact with both the wholesalers and the state Medicaid agencies and thus must give rebates directly to the Medicaid agencies in addition to negotiating prices with wholesalers. The dynamics of the other players are similar to those in the Medicare

⁷ The Prescription Drug Marketing Act of 1987 established rules for the reselling of prescription drugs and set standards that define wholesalers of prescription drugs (Frank, 2001).

⁸ Under an agreement between manufacturers and the Secretary of HHS, manufacturers are required to rebate a specified portion of the Medicaid payment to states. In turn, Medicaid must cover all FDA-approved drugs that these companies manufacture.

Figure 3.6
Structural Model: Medicaid



NOTE: EAC = estimated acquisition cost.

RAND TR1273-3.6

model, i.e., the flow of drugs is one way—from manufacturers to wholesalers to pharmacies and, finally, patients, and the prices are set by the manufacturers.

Negotiation Mechanisms. The following negotiation mechanisms are included in the Medicaid model:

- **Guaranteed discounts.** A unique feature of the Medicaid system is the state Medicaid agency. Under contract with HHS, manufacturers must pay rebates to state Medicaid agencies or be held to 340B ceiling prices. Both strategies allow state Medicaid agencies to access drugs at the same discounts that are available to private purchasers. Rebate amounts are computed and paid quarterly and are based on the AMP or the best price (i.e., the lowest manufacturer price paid by any purchaser) (Peters, 2009). However, in 2008, more than half of the manufacturers failed to fully comply with the quarterly requirements for AMP reporting, and more than 75 percent of them did not fully comply with the monthly stipulation (Levinson, 2010).
- **Demand pooling.** State Medicaid agencies can pool their purchases with other state agencies or with other states to increase their purchasing power (KFF, 2011).
- **Formulary restriction.** While most states maintain formularies, the extent to which formulary restrictions may benefit state Medicaid agencies and their fee-for-service transactions is unclear in light of the rebate program.

The main market-power limitation of state Medicaid agencies, however, is that they do not negotiate prices up front with manufacturers. With the lifting of the injunction that pro-

hibited CMS from disclosing AMP data to state Medicaid agencies, more information to help establish reimbursement rates is now available.⁹

Summary

At the system level, the ARV market structure is constrained by regulations. The patent system is the primary source of manufacturers' ability to set prices, particularly for drugs such as ARVs for which there are few substitutes. Government regulation implements price controls through the 340B ceiling price and sets mandatory rebate levels to ensure lower prices for Medicaid and public health providers, including ADAP. State Medicaid and ADAP agencies may choose to capitalize on these price controls (e.g., 340B pricing, MAC) and mandatory rebates, with greater participation potentially leading to greater market power and negotiation leverage with manufacturers. The federal government also requires minimum formularies, which vary by public payer system. The requirement further constrains the ability of public payers to customize their formularies for greater discounts.

Limited information is available in the ARV market. Manufacturers have complete information on their costs of production and the different prices they offer to different payers, but these data are not publicly available, and purchasers of drugs often do not know what prices other buyers have negotiated. The only public payer that releases data on its drug expenditures is Medicaid.

The ability of players to negotiate directly with drug manufacturers is a potentially powerful mechanism for gaining competitive pricing. However, not all players are able to exercise this option. State Medicaid agencies do not negotiate directly with manufacturers, nor does Medicare (at the system level). Negotiations are handled by the insurance contractors that provide PDPs.

Pooling demand can be used to achieve some degree of purchasing power. It is one of few negotiation tools available to wholesalers and retail pharmacies. However, state ADAPs that participate in the 340 Prime Vendor program use the program's purchasing pool to achieve lower prices.

The VA has been more successful at negotiating lower drug prices than other government agencies through the use of demand pooling—of the veterans they serve—and the ability to negotiate directly with manufacturers, including for ARVs. Compared with Medicare, Medicaid, and ADAP, the VA finances a relatively small portion of treatment and care for PLHIV; however, its success at achieving low drug prices suggests that demand pooling and direct negotiation with manufacturers could be powerful tools if they were more widely available to other government programs (KFF, 2004).

The private buyer has very limited negotiation options within the market for ARV drugs. Along with state ADAP agencies, private buyers may engage advocacy groups to lobby for lower prices, using a moral argument. For example, a recent budget crisis in Florida's ADAP resulted in long waiting lists for clients to receive their medications. The problem was temporarily solved when a public advocacy group, the Fair Price Coalition, brokered a deal between

⁹ CMS makes available Medicaid prescription reimbursement information, including ingredient cost, dispensing fee, co-payment, and whether it sets Medicare Administrator Contractor (MAC) rates by state (CMS, 2011). Legislation requires manufacturers to disclose to CMS the AMPs that are used to calculate rebate amounts to states (Federal Register, 2010).

an online pharmacy (Welvista), ARV manufacturers, and the Florida ADAP that covered a large portion of ADAP clients.

Health reform under the ACA will cause the landscape for public ARV financing to change in important ways. Most important, the number of PLHIV who are covered under entitlement programs or private insurance will increase dramatically, and ARV coverage will be guaranteed by the federal government. These changes and their potential implications are discussed in Chapter Five.

Cross-National Comparisons of HIV Drug Financing

Critics of the pharmaceutical industry often claim that consumers in the United States pay disproportionately higher prices for drugs than consumers in other developed countries where governments more actively regulate pharmaceutical prices. However, there is little comparable information on the actual prices paid by public programs in different markets. Thus, it is difficult to evaluate the strength of the link between regulatory restrictions and prices across countries. The picture is further clouded by differences in countries' health systems, which provide varying degrees of coverage for out-of-pocket expenditures related to HIV care and treatment. Although the level of coverage does not change the price of drugs, it influences how much of the ARV financing burden is placed on public payers.

This chapter presents a brief review of how drug prices in the United States compare with prices in other developed countries, based on data in published studies. It also takes a more in-depth look at the regulatory environment through case studies of three countries—the United Kingdom, Canada, and Switzerland. Finally, it discusses the negotiation strategies used in these countries that could be options for the United States. These countries were chosen on the basis of how similar or different their drug regulatory environments, health systems, and perceived drug prices are from those in the United States. The United Kingdom exercises extensive price regulation and provides full coverage for PLHIV care, so patients have very little out-of-pocket expense. Canada also exercises price regulations, but it does not provide universal drug coverage. Some PLHIV in other countries face large out-of-pocket expenses for ARVs, while individual drug insurers may separately negotiate prices with manufacturers. Although Switzerland has some price regulations, Swiss PLHIV do not bear any out-of-pocket costs because the government provides universal health coverage.

Overall, government drug price regulations appear to result in lower prices for patented drugs but higher prices for generics. This generally means higher prices for ARVs in the United States than in other countries. However, the impact of drug prices on health providers and patients is greatly moderated by the specific features of the health insurance systems in different countries, i.e., PLHIV have nearly complete ARV coverage in the United Kingdom and Switzerland, but in the United States and Canada, they may have to piece together coverage from different programs to offset larger out-of-pocket burdens. The drug purchasing arrangement of a country's health-care system influences the proportion of drug expenditures that are paid by public programs.

The drug price negotiation mechanisms employed in other countries point to some options that might be used in the United States:

- Process-oriented policies could help spur competition in the pharmaceutical market and preserve incentives for innovation; these include greater transparency in R&D costs and an independent body to review manufacturers' recommended prices.
- Greater coordination among drug purchasers, even within a health system that relies on private sector competition among providers (like that in Switzerland), may improve buyers' bargaining position vis-à-vis drug manufacturers.

Drug Price Differentials Across Countries

Studies conducted by U.S. government agencies have found that U.S. drug prices are typically 32 to 70 percent higher than prices in Canada and double the price observed in Mexico (GAO, 1992; GAO, 1994; United States House of Representatives, 1998; United States Department of Commerce, 2004).¹ However, some academic researchers dispute the methods typically employed in such cross-country comparisons (see Table 4.1), arguing that U.S. drug price differentials are smaller than purported and are mainly explained by income differentials (Danzon and Furukawa, 2003).² Nonetheless, Danzon and Furukawa (2003) found prices in Canada to be 33 to 40 percent lower than prices in the United States, and 28 to 42 percent lower in other countries, on average, after adjusting for a number of factors. Only generics were found to be somewhat cheaper in the United States than in Canada (which has led to instances of reimportation from Canada [Nelson, 2004]).

It is generally agreed that the relatively unregulated, more competitive structure of the U.S. market seems to result in relatively high prices for on-patent products and relatively high use of new products, as well as strong generic competition, high generic shares, and low generic prices once patents expire. All of the studies cited suffer from limited information on drug prices overall, however (see Table 4.1). Even less is known about the true amount of R&D spending by manufacturers and publicly sponsored research funders (e.g., NIH). There is also little evidence regarding the linkages between pharmaceutical profits and subsequent reinvestment in R&D (as discussed in Chapter Two).

The UK Market

Drug prices in the United Kingdom are generally lower than U.S. prices and among the lowest in the European Union (EU). In a recent comparison of prices across several EU countries,³ average prices in the United Kingdom were found to be consistently the lowest, and margins on patented drugs were also lower (Brekke, Holmås, and Straume, 2010). Average UK prices for patented drugs were found to be 30 percent lower than those in the United States, but generic

¹ The GAO concluded that U.S. drug prices were 32 percent and 60 percent higher than prices in Canada and the United Kingdom, respectively (GAO, 1992, 1994). U.S. drug prices were 70 percent higher than prices in Canada and 102 percent higher than prices in Mexico (United States House of Representatives, 1998).

² These researchers compared average prices for pharmaceuticals in nine countries (Canada, Chile, France, Germany, Italy, Japan, Mexico, the United Kingdom, and the United States) and found that after adjusting for manufacturer discounts, Japan's prices are typically higher than U.S. prices, and other countries' prices are from 6 percent to 33 percent lower than U.S. prices. Canadian prices are the lowest. Exchange rates and adjustments for purchasing power parity significantly influence the observed price differentials. U.S.-foreign price differentials are roughly in line with income and are smaller for drugs than for other medical services.

³ Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Norway, Sweden, and the United Kingdom.

Table 4.1
Reasons for the Difficulty of Comparing Prices Across Countries

Reason	Examples
Limited information on prices is available to the public.	<ul style="list-style-type: none"> • IMS, a market research company based in Plymouth Meeting, Pennsylvania, is a leading provider of pharmaceutical and health-care information. The IMS Midas database reports pharmaceutical sales in more than 70 countries, based on audits of retail pharmacies and other channels. These data are privately owned and very expensive for third parties to purchase. Moreover, the prices reported are not adjusted for any discounts that may be given to individual buyers. • Few countries make drug prices publicly available. One notable exception is Switzerland, which publishes its approved list of drugs and prices online.^a
Comparing prices is not straightforward.	<ul style="list-style-type: none"> • Each country's pharmaceutical cache is different, based on epidemiology, structure of the health-care system, and patterns of health-care utilization. Few products are sold in the same form, strength, and package size, even by the same manufacturer. • Standardization of comparable units (e.g., dose, form, packaging) must be balanced with how representative the unit is across contexts. Comparisons that are restricted to identical products in all countries may be unrepresentative. There are price markups and discounts throughout the supply chain. Prices at the retail-pharmacy level include wholesale, retail, and possibly various tax markups. Manufacturer prices do not include all of these markups and may provide a better comparison. However, since bulk discounts can be obtained directly from manufacturers in negotiations (for example, by managed-care companies^b), these discounts should be factored in (reducing the real U.S. price). These types of discounts are also common in the United Kingdom. • Prices need to be adjusted for exchange rates (purchasing power parity) and possibly the depth of the health-care market (health-care-specific purchasing power parity). In general, countries with higher incomes have higher drug prices (Danzon, 1997).

^a See <http://www.bag.admin.ch/themen/krankenversicherung/00263/00264/06700/index.html?lang=en>

^b Originator manufacturers compete by giving off-invoice discounts to pharmacy benefit managers and health maintenance organizations in return for preferred formulary status, which increases market share.

drugs were slightly more expensive (Danzon and Furukawa, 2003). These studies take a variety of approaches to adjust prices to facilitate cross-country comparisons.⁴

Government Price Controls. Pharmaceutical regulation in the United Kingdom is implemented primarily through price controls. This is in contrast to reference pricing (which is used in Canada, for example), where price levels are determined relative to the prices other countries pay. The Pharmaceutical Price Regulation Scheme (PPRS) is used by the UK Department of Health to negotiate prices for branded drugs with the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI). Negotiations are conducted every few years; the latest agreement for five years was concluded in 2009. Spending on branded drugs by the NHS, which is the main purchaser of drugs, is around 10 percent of total NHS expenditures, or about £9 billion a year.⁵

⁴ Brekke, Holmås, and Straume (2010) and Danzon and Furukawa (2003) used drug price data obtained from IMS (a market research company). Brekke, Holmås, and Straume (2010) calculated a number of price indexes—bilateral and global—in which various products were assigned weights to reflect consumption patterns in the benchmark country. Danzon and Furukawa (2003) similarly adjusted prices according to a variety of factors—consumer price indexes, income levels, currency exchange valuation, manufacturer discounts—and drug price differentials can be summarized when looking across all types of adjustments.

⁵ For more information, see the official PPRS website: <http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/index.htm>.

Prices of branded drugs are regulated through two mechanisms in the PPRS:

1. **Flexible pricing**, which allows the price of newly entering drugs to increase by up to 30 percent relative to the original list price upon new clinical evidence or the development of a different indication (there is no limit to the price increase for new indications, while original indications and prices are preserved).
2. **Patient access schemes**, which facilitate access to drugs that are not initially found to be cost effective but that are valued by consumers.

In addition, for large pharmaceutical sellers,⁶ two price cuts were included in the first two years of the agreement (3.9 percent in 2009 and 1.9 percent in 2010), with preset price increases each year thereafter (0.1 percent in 2011 and 0.2 percent in 2012 and 2013). In conjunction with substitution of generic brands, these price cuts are aimed at reducing NHS expenditures on brand-name drugs by 5 percent per year. With these controls in place, the PPRS aims to ensure that pharmaceutical companies still make a reasonable profit. For example, it allows for a return of 21 percent over the historical value of average capital expenditures. Other provisions include set targeted rates of return for R&D and information and marketing expenses (ABPI, 2008). For generic drugs, which account for about four-fifths of prescriptions by volume but only around one-fifth of the overall cost of medicines, the Department of Health reimburses pharmacists for dispensing costs.⁷

Although the PPRS regulates prices for patented drugs, NHS bodies, ranging from individual trusts to large consortia, are free to negotiate their own deals with drug suppliers. For example, the London HIV Consortium (LHC), which treats nearly 50 percent of the HIV+ patients accessing care in the United Kingdom, pays about 25 percent less than the list price for ARVs (Cairns, 2011). In addition, in an effort to save costs, the LHC has issued new treatment guidelines, swapping certain drugs for cheaper alternatives, while being conscious of efficacy (London HIV Consortium, 2011). Thus, ARVs represent a special case where providers negotiate directly with suppliers for discounts on top of PPRS regulated prices, and the volume of LHC purchases may determine the size of the discount.

Since 2004, free HIV treatment has been available through the NHS to those legally residing in the United Kingdom. The cost of treatment in 2006 was estimated to be around £18,000–£32,000 per year, depending on the stage of infection and the drug regimen used (Mandalia et al., 2010). There has been some controversy about the NHS failing to provide treatment for failed asylum seekers, migrants, and others who are unofficial residents (Parliamentary Office of Science and Technology, 2007), but with a few special exceptions, PLHIV do not bear the costs of treatment, which was estimated at around £400 million in 2005.

Applicability of UK-Style Price Negotiations to the United States. The number of health insurers in the United States limits the ability of buyers to negotiate directly with pharmaceutical manufacturers. However, some observers argue that the largest public programs—Medicare and Medicaid—should be able to engage in direct negotiations with drug manufacturers because of their considerable market share. These programs are designed to use competition, with some default price controls on sellers, such as the 340B program, to exact price reduc-

⁶ Defined as companies with NHS home sales greater than £5 million in 2007.

⁷ All of these prices are available online at http://www.ppa.org.uk/ppa/edt_intro.htm (as of October 18, 2011).

tions. To implement bulk purchasing power, however, these programs would have to relinquish considerable local autonomy.

Direct negotiation would be possible if U.S. buyers could be represented by a limited number of bodies, including both public and private programs, and would be willing to accept the outcomes. Because of the considerable monopoly power held by manufacturers of ARVs, such a mechanism could help lower drug spending for all purchasers of ARVs if negotiations for them could be decoupled from the current market-based mechanisms in place for all other drugs.

The Canadian Market

Most studies comparing U.S. and Canadian drug prices show that Canadian prices for patented drugs are lower because of the regulatory regime practiced by Canada but that prices for generics can be higher than their U.S. equivalents (Danzon and Furukawa, 2003), depending on the method of calculation used.

Government Regulation. Canada regulates the prices of newly patented drugs and the price increases of extant patented drugs through the Patented Medicine Prices Review Board (PMPRB⁸). The government does not purchase drugs; it determines the maximum prices that manufacturers can charge for patented drugs, thereby preventing market participants from negotiating a price among themselves.⁹ One key provision of this regulation is that the price of a patented drug cannot exceed the highest price of the same medicine sold in the United States, the United Kingdom, Switzerland, Sweden, France, Germany, or Italy, and price increases cannot exceed the Consumer Price Index (CPI). One drawback of this mechanism is that because the PMPRB bases the ceiling prices of many new drugs on those of existing older drugs, there is no incentive to reduce the prices of older drugs or generic drugs, which remain artificially high.

Differentials in standards of living and legal practices are also key drivers of price differences between Canada and the United States. When the gap between real incomes across the border increases, price differentials also increase (Danzon and Furukawa, 2003). However, higher legal-liability costs in the United States may account for a significant portion of the price differential, along with regulations imposed by the PMPRB (Graham and Robson, 2000).

Unlike most members of OECD, Canada does not have a national catastrophic drug coverage system (Phillips, 2009). All Canadians enjoy universal access to all medically necessary services through the Canada Health Act of 1984, which is funded by the federal government

⁸ See <http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1> (as of May 29, 2012).

⁹ The PMPRB classifies patented drugs into three categories:

- Category 1 (“line extension”) usually comprises drugs that are a new strength of an existing drug. The introductory price is judged to be excessive if it does not bear a “reasonable relationship” to the average price of the same medicine in the same or comparable dosage forms.
- Category 2 (“breakthrough”) includes drugs that produce a substantial improvement over predecessors. The introductory price is judged to be excessive if it exceeds the higher of the cost of therapy with medicines in the same therapeutic class or the median of prices of the same drug in the United States, the United Kingdom, Switzerland, Sweden, France, Germany, and Italy.
- Category 3 (“me-too”) comprises drugs that provide moderate, little, or no improvement over existing medicines. The introductory price is judged to be excessive if the cost of therapy with the new drug is higher than the cost of therapy with existing comparable drug products in the same therapeutic class.

in the form of a cash transfer to provinces. Physician and hospital services and inpatient pharmaceuticals are covered, but not outpatient pharmaceuticals. Features of health-care programs, including drug coverage, are designed and implemented by individual provinces.

Coverage for drug spending is provided by a patchwork of programs—19 publicly funded drug plans complemented by more than 1,000 private drug insurance programs offered by employers, unions, and professional associations across the country (Phillips, 2009). An estimated 60 percent to 75 percent of Canadians have private insurance coverage for prescription drugs (Health Council of Canada, 2009). Even though the federal government has provided funding for catastrophic drug coverage since 2003 (under the Federal/Provincial Fiscal Arrangements Act), it transfers funds to provincial programs to improve drug coverage but falls short of setting up a single unifying national system. Hence, each provincial program can choose which diseases and drugs are covered for which people at which income levels. While this type of system provides greater flexibility for provincial governments to tailor their drug coverage programs to the health needs of their populations, it can lead to inequitable coverage for HIV/AIDS patients.

Inequities in Drug Expenditures. There are substantial inequities in drug expenditures among Canadians, and HIV/AIDS drugs are not covered to the same extent in all provinces. Only a minority of provincial/territorial programs carve out specific provisions for the treatment of HIV/AIDS; coverage ranges from complete or nearly complete in Alberta, Ontario, the Yukon Territory, and New Brunswick to coverage only for specific ethnic groups in the Northwest Territory and a means-tested program on Prince Edward Island. Anecdotal evidence suggests that HIV/AIDS patients may pay up to \$36,000 CAN out of pocket per year for drugs (Carlyle-Gordge, 2010).

The Canadian government does not engage in bulk-purchase price discount negotiations for pharmaceuticals. Insurers negotiate with drug suppliers on their own, taking into account the health needs of their covered populations, formulary coverage, and other cost-sharing mechanisms.

The hodgepodge network of insurers covering drug expenditures in Canada lends little added purchasing power beyond the national price controls in negotiating with pharmaceutical manufacturers and results in widely varying (i.e., less equitable) coverage for ARVs, for which many patients still face high out-of-pocket expenditures.

The Swiss Market

Prices for drugs in Switzerland are among the highest in the EU. Swiss pharmacies purchase medicines at factor prices 22 percent above the EU average, despite a duty-free regime on them (Mbitha-Schmid, as cited in U.S. Department of Commerce, 2004). Patented drugs have the greatest price differences relative to prices in neighboring countries. The pharmaceutical industry is the second largest sector in Switzerland, and Switzerland is the largest exporter of pharmaceutical products worldwide.¹⁰

Between 1997 and 2003, prices of Swiss drugs increased rapidly, mainly due to the replacement of old drugs by more-expensive preparations. Expenditure on medical drugs as a share of household expenditures increased from 1.37 percent in 1993 to 2.74 percent in 2004,

¹⁰ More than 90 percent of the drugs produced in Switzerland are destined for export, mainly to Europe, the United States, and Asia. Patent-protected original brand-name drugs accounted for 59.8 percent of the export market in 2004 (United States Department of Commerce, 2004).

mainly because of price increases. However, these proportions were among the lowest for out-of-pocket payments in the EU, because of generous insurance coverage for drugs (discussed further below). A drive is now under way to reduce overall drug expenditures by increasing the use of generics (Paris and Docteur, 2007).

Government Regulation. To be included in the list of government-approved (and funded) medicines in Switzerland, a drug must meet standards of quality, safety, effectiveness, and “value for money.” The latter can involve comparing the manufacturer’s proposed price against the price abroad. The Swiss Federal Office of Public Health (OFSP) regulates an approved list of pharmaceuticals for which the compulsory health insurance system will pay; the list contains about 57 percent of all available drugs (Paris and Docteur, 2007). The OFSP retains the right to unilaterally include a drug that is particularly important and to set the price at its discretion. However, it is not clear how often this right is exercised, and the default price is set according to the manufacturer’s recommended price in the absence of other information. According to an OECD review of pharmaceutical pricing, a decision by the OFSP not to list a drug is rare, the main issue being the reimbursement price rather than inclusion (Paris and Docteur, 2007).

For all approved drugs, including on-patent drugs and generics, the OFSP sets maximum prices using reference pricing¹¹ and comparative cost effectiveness against older products in the same therapeutic group. If neither of the two criteria applies, the manufacturer’s suggested price is considered to be the maximum price. The Price Council, a monitoring agency, also publishes an annual comparison of prices of non-listed patented drugs against those in Germany to prevent abuse of market power (Paris and Docteur, 2007). Parallel imports of off-patent drugs—buying the lowest-priced drug from another country—are allowed, but parallel imports of medicinal products protected by a patent are not (Federal Authorities of the Swiss Confederation, 2000). All drugs not listed by the OFSP are priced at the manufacturer’s discretion.

Access to Drugs and Treatment. For the roughly 18,000 PLHIV in Switzerland (HIV InSite, 2007),¹² the Swiss health-care system provides unrestricted access to all necessary medications and medical procedures (Sendi et al., 1999; UNAIDS, 2006). Health insurance in Switzerland is not government-run; Swiss law mandates that all residents purchase and be covered by a “basic” health insurance package, including both medical and pharmaceutical care (Federal Authorities of the Swiss Confederation, 1994). The mandated benefit levels are akin to luxury packages offered in other countries (Civitas, 2002). Furthermore, insurers cannot deny enrollment for basic insurance coverage (unlike health insurers in the United States, which may exclude some preexisting conditions from coverage). About 80 percent of the Swiss population also elects to purchase supplemental insurance coverage (Paris and Docteur, 2007).

HIV patients are insulated from the high cost of ARVs, since they often pay only up to the maximum out-of-pocket expenditure per year. Compulsory health insurance generally protects patients from large catastrophic medical expenditures, as they are responsible only for insurance premiums and any co-insurance and deductible amounts. The Federal Council is also entitled to exempt people from cost-sharing for serious or long illnesses. However, a list of qualifying illnesses does not yet exist (Paris and Docteur, 2007). Government subsidies are

¹¹ Prices are compared with those in Germany, the United Kingdom, Denmark, and the Netherlands.

¹² Adult prevalence = 0.4 percent; total population = 7.8 million.

available for elderly, disabled, and low-income people when their insurance premium amount is more than 8 to 10 percent of their income (Herzingler and Parsa-Parsi, 2004). For approved drugs, patients are responsible for a 10 percent co-payment on the public price (20 percent for brand-name drugs that have available generic substitutes) up to a plan-specified maximum.¹³ Although low-income persons are not exempted (this might create the potential for problems in getting or using insurance), there is no documented evidence of accessibility or affordability problems (Paris and Docteur, 2007).

Applicability of Swiss Regulatory Measures to the United States. The Swiss pharmaceutical and health-care markets share many features with the U.S. market—large drug manufacturers, relatively high health expenditures, and commitment to competition among a multitude of health providers for increased efficiency. But differences need to be taken into account when comparing the systems and investigating the Swiss approach to drug price determination as an alternative to the current U.S. system. Restrictions of the sort used in Switzerland would require deviations from market-based mechanisms that are characteristic of the U.S. economy. The Swiss government sets uniform prices for a fairly comprehensive list of patented drugs; all private providers are bound by these prices, which limits the scope of price competition among them. There are also limits on pharmaceutical marketing and information campaigns.

Moreover, Switzerland's reference-pricing practices may be of limited effectiveness in stopping drug price increases over time. Experts speculate that manufacturers may choose Switzerland as a country for the first or early world launch of drugs, in part because of the pricing leeway granted to new market entrants when comparable products are not available (Paris and Docteur, 2007). This phenomenon may partially explain why even though pharmaceutical consumption in Switzerland is generally low, prices are among the highest in Europe. The Swiss tend to be early adopters of new pharmaceutical products, and new medicines are generally promptly available on the market. The rapid take-up of new and often more-expensive drugs or therapeutics fuels faster growth in the cost of health care.

Conclusion

While comparing prices of drugs across international markets is fraught with difficulties, the few studies that have adjusted prices for a myriad of factors to facilitate comparability generally indicate that U.S. consumers pay lower prices for generics but higher prices for patented drugs, which include most ARVs. These pricing differentials can be associated with government price controls in other developed countries that target patented drugs for regulation. However, the impact of drug prices on health providers and patients is highly dependent on the government's share of responsibility in providing drug coverage. While PLHIV have nearly complete ARV coverage in the United Kingdom and Switzerland, those in the United States and Canada may have to piece together coverage from different programs to offset large out-of-pocket burdens. Although the level of coverage does not change the price of drugs, it influences how much of the ARV financing burden is placed on public payers. Thus, before adopting further drug price regulations, policymakers will need to consider the objectives of the health insurance system

¹³ Cost-sharing is capped annually, with the level determined by the insurance plan. For the basic mandated benefits level, the maximum amount is 700 CHF per year. All drugs not on the OFSP approved list are either paid for in full by patients or paid by supplementary insurers at prices set by the manufacturer (Civitas, 2002; Paris and Docteur, 2007).

in the United States and balance the objectives of equitable coverage and access for consumers, achieving fair prices for both patented and generic drugs, and reaching an acceptable financial-responsibility level for public provision of drug coverage.

Policy Options for Negotiating ARV Prices in the United States and Implications of Health Reform

In this chapter, we discuss alternatives and changes to the patent system that have been presented in the literature and their likely consequences for ARV drug prices. We highlight how they influence the parameters of the system, along with who would benefit and who would lose out from each policy option, based on our theoretical framework. We focus on describing strategies rather than discussing in detail their (political) feasibility.¹

We first look at *options at the systemic level* that change the way prices are set. These can be realized only by players that have the power to use such options—in particular, the government. Systemic-level options might be useful as general alternatives in certain situations; for example, prize rewards were offered in the context of the Orphan Drug Act of 1983. The main point of the discussion is to present *alternatives* to the patent system.

We next discuss potential *changes* to the patent system (while keeping the system itself in place) that address some of its shortcomings as currently implemented in the United States. Changes to the patent system have been made before; for example, as part of the America Invents Act signed into law by President Obama in 2011, patent lengths for biologic drugs will be shortened.

Finally, we present *negotiation strategies* that could be pursued within the current system in the United States. These may be of interest to players who do not have the power to change the system yet strive to obtain ARVs for their constituents at lower prices. The chapter ends with an overview of the available strategies.

Policy Options Involving the Patent System

A fundamental system-level decision for U.S. policymakers concerns whether the patent system represents the best way to encourage innovation while delivering drugs at affordable prices to people currently in need of them. The trade-off involved in changing the system is that lower prices benefit people living with a disease (and in need of drugs) today but may have a negative impact on the availability of drugs in the future. We would expect politicians to demand low drug prices to satisfy the demand of current voters rather than those of future generations, who may suffer from a lack of available drugs potentially brought about by low prices. Running

¹ Any change to the current system will face resistance from those not benefiting from it; for example, switching back dually eligibles from Medicare would probably face strong opposition from states that would have to pay for a share of those covered by Medicaid.

counter to this strategy are the substantial lobbying efforts of the pharmaceutical industry: Between 1998 and 2005, pharmaceutical companies spent about \$900 million on lobbying (iWatch News, 2005). Given the discrepancy between the incentives of people currently living with a disease (who want low prices) and drug manufacturers (who benefit from high prices), the government has to try to design a system that provides incentives for drug manufacturers to develop new drugs while keeping prices low to maximize access to current drugs.

Alternatives to the U.S. Patent System. Patents are the most widely used mechanism for spurring innovation, though not the only one. The basic idea underlying patents is that they provide a manufacturer with a period during which no other manufacturer is allowed to offer the same product, allowing the developer to reap monopoly profits. Some researchers and advocates have argued that this system does not lead to the right amount of innovation but, rather, provides drug companies with excessive profits.

Some of the main alternatives to patents are rewards for investors, subsidies for investors, and two-part pricing and health insurance designs (see, for example, Kremer and Williams, 2010).

Rewards for investors include prizes and commitments to pay a certain amount of money for delivering a drug fulfilling some predetermined technical specifications. Similar mechanisms to increase the profit incentive of pharmaceutical companies to develop drugs for otherwise small, low-profit markets are advance market and purchase commitments. Advance market commitments are agreements to pay a guaranteed maximum prize for a specific number of treatments. Another type of prize, suggested in the Medical Innovation Prize Fund Proposal, would reward innovators of drugs for certain diseases, using a fund (sponsored through a payment proportional to the GDP) to license the innovation knowledge to generic companies. Such rewards could provide a viable alternative for diseases for which a certain type of drug is clearly needed but the market does not have enough purchasing power (e.g., diseases in developing countries), but these rewards are less likely to spur innovation for as-yet-unknown diseases. For this reason, they are probably not a general remedy for innovation, although they may be useful in certain clearly specified situations.

Reward policies in essence decouple prices charged for drugs from their development costs and provide a one-time, lump-sum payment to drug innovators (as opposed to the per-drug development reimbursement and profit that is currently making up most of a drug's price). These policies would reduce the market power and therefore the bargaining position of drug manufacturers to influence prices. Drug manufacturers would receive the reward, which also constitutes the highest level of development costs they could incur to still make a profit (this would increase information about their drug development costs, as they would agree to supply a certain drug only if the reward was higher than the development costs). With the one-time payment for the drug innovation, the manufacturers would have no further bargaining power, as drug prices would then simply reflect the relatively low manufacturing costs. These policies would also clearly influence regulations—there would be no need to regulate drug prices, since the drugs would be produced by generic producers in a competitive market. Information transparency would be improved, because the level of the reward would be known. Consumers would probably pay a low price for the drug itself but might pay an additional tax, depending on how the reward is being financed.

Such systemic changes would need to be enacted at the highest level and therefore are not likely to occur easily, but they have been employed in other contexts, usually to achieve a narrowly defined goal in a particular situation. A recent example in American history is the afore-

mentioned Orphan Drug Act of 1983, which used both push mechanisms (tax credits) and pull mechanisms (a seven-year market exclusivity provision) to spur innovation on drugs for rare diseases. Lichtenberg and Waldfogel (2003) found that the Orphan Drug Act was highly successful in increasing the number of orphan drugs. One could think about reward mechanisms for developing ARVs if there were, e.g., a clear undersupply of a certain type of drug.

Alternatives to patents could provide viable means to address existing or potential shortcomings of ARV drugs. For example, if some PLHIV develop resistance to existing ARVs, a prize for developing new ARVs could be instituted. Since the unfettered patent system in the United States may not result in increased innovation, as concluded by Keyhani et al. (2010), alternatives would not necessarily result in less drug innovation. In addition, R&D subsidies have been found to induce innovation.

Changes to the U.S. Patent System. The current patent system assigns patents for a fixed duration of 20 years, irrespective of R&D time and costs or government contribution to those costs. Patents have two essential parameters that could be adjusted to a particular situation: *patent length* (the duration during which a manufacturer benefits from exclusivity in the market) and *patent breadth* (which determines the reach of the market exclusivity granted). In theory, it would be desirable to adjust the patent to the characteristics of a new drug, such as the costs of bringing it to market.² This possibility was considered but ultimately not adopted in the legislation of the Bayh-Dole Act of 1980 (Sampat and Lichtenberg, 2011).

Adapting this option for ARVs would likely bring about significant changes for patents that have received substantial federal funding for basic R&D and that benefit from other cost-reducing factors such as fast-tracked FDA approval. Sampat and Lichtenberg (2011) studied 19 HIV/AIDS drugs and found that one-third of them had a public-sector patent; almost all of them had benefited from government-funded research. The counterargument to drug-specific patents is that there are also costs associated with designing and enforcing them. A rigorous, independent evaluation would shed light on whether the increased costs would justify the approach. Another option for adapting patents to the characteristics of a new drug would be to explicitly link the marginal therapeutic benefit of the drug to that of existing drugs. As noted earlier, current FDA approval requires a drug's effectiveness to be demonstrated against a placebo, rather than against existing drugs; the option discussed here would determine comparative effectiveness, which would be more meaningful and would allow calculating a drug's relative cost effectiveness. This issue should be a high-agenda item in policy discussions about system-level changes.

An argument against shorter patent length would be that drug manufacturers might react by raising their prices to make up part of the lost profit. The likelihood of this depends on the pricing strategy employed by the manufacturers. When the manufacturers have monopoly power, the profit-maximizing price is set as a function of the price sensitivity of consumers. If the manufacturers employed a cost-plus strategy, which we found to be unlikely, price increases could result if the price with the current patent length is lower than the profit-maximizing monopoly price. Under the more likely scenario of monopoly pricing, the price is unlikely to be revised upward when the patent length is reduced, since it would move away from a profit-maximizing point.

² For a thorough review of the design of a patent system for pharmaceuticals, see Goldman and Lakdawalla (2011).

In contrast to the alternatives discussed above, the main change in the regulatory framework would be a change in the parameters of the system. The potentially higher price of drugs while on a shorter patent would probably be outweighed by lower prices once the shorter patent is over. There would be no changes to the bargaining position of the players or to information availability unless the patent were linked to therapeutic benefits or development costs, in which case the manufacturers would have an incentive to provide more information on these variables.

System-Level Policy Options Not Related to the Patent System

There are other strategies that government could adopt, including changes that are not related to the patent system, such as laws regarding price- or information-sharing. The implications of five such strategies for reducing prices for different players in the U.S. context are considered here: reference pricing, switching dually eligible beneficiaries from Medicare Part D to Medicaid, national procurement of prescription drugs, increased price transparency, and easing of minimum formularies. They can be grouped by our framework parameters, according to the lever(s) they relate to. For system-level policy options, the regulation parameter is especially salient, as shown in Table 5.1.

Approaches the U.S. government could use to negotiate prices for pharmaceutical drugs for its publicly funded programs have been considered primarily in the context of Medicare Part D, which pays higher prices for prescription drugs than other government programs. Newhouse (2004) proposed potential approaches to negotiating prices, including paying prices comparable to those paid by other payers or countries (i.e., reference pricing), price controls, and capping returns on assets. Outterson and Kesselheim (2009) presented a comprehensive list of strategies to negotiate lower drug prices from manufacturers. Among those relevant to systemic change that could affect the price of ARVs are formulary design and returning responsibility for prescription drug payment to Medicaid for those dually eligible for both Medicaid and Medicare. Finally, Chalkidou, Anderson, and Faden (2011) put forward a national procurement approach whereby the government would purchase drugs at a single rate for all public programs.

Reference Pricing. Some critics of the current U.S. system of prescription drug pricing have proposed reference pricing, i.e., tying prices to those paid in other markets, as a possible alternative. This option is already practiced in other countries, including Canada. “Other markets” can refer either to prices paid in other countries (international reference pricing) or to

Table 5.1
Framework Parameters of System-Level Policy Options

System-Level Strategy	Relevant Framework Parameter
Reference pricing	Regulation
Switching dually eligible beneficiaries of Medicare Part D to Medicaid	Regulation
National procurement of prescription drugs	Market power
Increased price transparency	Information
Minimum formularies	Regulation

prices paid by other domestic payers. In the United States, adopting international reference pricing would probably lead to dynamic responses by drug companies. For example, drug companies might increase prices in the reference countries, since revenues and profits there are likely lower than those in the United States, making such a strategy profitable. Since the United States is the largest drug market in the world, any country or group of countries that it uses as a price reference would likely be subject to such price increases. Reference pricing among domestic publicly funded programs (e.g., Medicaid and Medicare) would probably face a similar issue, with the reference program seeing higher prices in response. Such dynamic consequences make clear that the U.S. government must take into account how its policies affect other markets, both domestic and international.

A form of reference pricing that is already used in the United States ties the price of a new drug to that of existing drugs with identical or similar therapeutic benefits; an example is the tiered pricing system used by many drug insurers. Insured clients under such a system typically pay a higher fee for brand-name drugs than for generics with similar benefits. For ARVs, this approach might yield lower prices for consumers once more generics are on the market, but most ARVs are currently still under patent protection.

Switching Dually Eligible Beneficiaries from Medicare Part D to Medicaid. Another option that has been discussed in the literature is to switch dually eligible beneficiaries from Medicare Part D back to Medicaid. Medicare Part D insurers pay almost 40 percent more for drugs on the “protected list” maintained by CMS, including AIDS drugs, than Medicaid (United States House of Representatives, 2008). In addition to the potential cost savings from lower drug prices under Medicaid, there would be a reduction in administrative expenses associated with Medicare Part D. These expenses, sales costs, and the profits of Part D insurers account for nearly 10 percent of total program and beneficiary costs, or about six times the administrative costs of traditional Medicare (United States House of Representatives, 2007). However, such a change in policy would further increase Medicaid expenses, which will be greatly expanding in 2014 under the ACA.

National Procurement of Prescription Drugs. Drug price differentials across government programs could be eliminated by instituting a national procurement strategy in which the government is the single buyer (Chalkidou et al., 2011). Under such a policy, the government would purchase drugs at a single rate, enabling it to be a more effective purchaser for its beneficiaries and increasing its market power. Similar to issues involved in changes to the patent system, one issue for such a system would be the need to balance encouraging R&D with controlling health-care expenditures.

A national procurement system has precedents elsewhere in the world. Many developed countries in the OECD have one main payer, i.e., the government.³ In negotiations with pharmaceutical manufacturers, governments may be better able to dictate the terms of purchases, including lower prices. Exercising such power in response to the monopoly power accrued to drug manufacturers appears to result in relatively lower prices for patented drugs but higher prices for generics. In general, a strategy of demand pooling organized at a lower level may hold promise for players within the system. As noted above, greater coordination among buyers of ARVs could result in lower average prices for public payers.

³ When there are relatively few buyers and many sellers, the purchaser can be considered a monopsonist and has considerable market power to dictate the terms of sales to its suppliers.

Increasing Price Transparency. Drug manufacturers in the United States not only set prices but also do not disclose pricing information. State Medicaid agencies recently gained disclosure of pricing information to establish reimbursement rates, but other players are essentially in the dark with regard to pricing. Increasing price transparency among players or even within player levels (i.e., among PDPs) could allow these players to leverage the information to lower costs. However, this information remains essentially unattainable—only one study has been able to obtain manufacturer pricing information (United States House of Representatives, 2008).

Easing Minimum Formularies. Minimum formulary regulations ensure that public programs offer a baseline level of essential drug benefits to their beneficiaries. This is especially important for ARVs, since they are life-saving drugs. However, the minimum formularies also restrict the negotiating power of payers by limiting the ability to exclude expensive drugs if an affordable price cannot be negotiated. Medicare Part D has the strictest minimum formulary and pays the highest prescription drug prices among public programs. ARVs are included in one of the six classes of Medicare prescription drug plans that are required to offer “all” or “substantially all” drugs in a therapeutic class on their formularies (Newhouse, Seiguer, and Frank, 2007). The looser regulation of the VA minimum formulary allows the VA to negotiate lower prices for drugs in general. Some critics of Medicare’s system have questioned whether easing the minimum formulary requirements could bring prices down (Frakt, Pizer, and Feldman, 2011). Given that there is relatively limited substitutability among ARV drugs, this strategy may yield little leverage as a negotiating mechanism.

Player-Level Policy Options

Given the current structure of the ARV market and assuming no system-level changes, there are several potential options for negotiating lower ARV prices, including demand pooling, formulary restrictions, contracting with fewer pharmacies or pharmacy networks, and leveraging the manufacturers’ public image by making a moral argument for lower prices. Whereas regulation was the most relevant framework parameter for system-level policy options, at the player level, the most salient strategies involve increasing players’ market power relative to pharmaceutical companies. Framework parameters of player-level options are shown in Table 5.2.

Demand Pooling. There is some indication that Medicare Part D private insurers may not have enough purchasing power to negotiate effectively with manufacturers. Even for generics, for which economic theory predicts lower prices as a result of competition, these insurers pay a higher price than Medicaid does. This is consistent with the possibility that the demand

Table 5.2
Framework Parameters of Player-Level Policy Options

Player-Level Strategy	Relevant Framework Parameter
Demand pooling	Market power
Formulary restrictions	Market power
Contracting with fewer pharmacies or pharmacy networks	Market power
Leveraging pharmaceutical concerns about public image	Information

side of the market is too fragmented. If this is the case, pooling purchases by a number of insurers could improve their bargaining position.

Formulary Restrictions. Despite minimum formularies to which each payer is subjected by regulation, certain payers (e.g., ADAP, Medicaid) may still be able to employ formulary restriction as a negotiation mechanism (e.g., if minimum formularies do not require all drugs in a specific ARV class to be covered). However, low substitutability between ARVs reduces the value of this option, which could be ethically problematic given the life-saving nature of ARVs. The threat of formulary restrictions may become a more viable tool for price negotiations when more drugs in each class become available and when generic ARVs are more readily available in the United States. Formulary restrictions clearly point out the trade-off involved in many negotiations: While they may reduce the prices paid by those benefiting from a particular drug, they may increase (or make unavailable) other drugs that other people may benefit from. For all negotiation strategies, the effects on other players in the system need to be explicitly considered.

Preferential Contracts. As seen in the ADAP direct-purchase model, contracting with fewer pharmacies or pharmacy networks can help lower costs for the public payer by guaranteeing the pharmacy network a greater number of customers. However, it is unclear whether ADAP's lower costs are a result of reduced prices negotiated by the pharmacy based on a volume discount or simply a reduced markup by the pharmacy in exchange for the bulk business.

Moral Pressure/Public Relations. Arguing for lower prices based on the moral imperative of providing life-saving ARVs to those in critical need can be a potentially powerful negotiation tool when targeted at drug companies that are concerned with their public image. However, it is likely to be successful only in certain situations, and it is less likely to work for large government programs such as Medicaid and Medicare. Much like the case of small countries, which may receive lower prices because they do not have enough market power to disturb the overall price of drugs, it may be easier for smaller groups to use moral pressure to achieve lower prices, especially in situations where people are in immediate danger of not receiving their medications. For example, the AIDS Crisis Task Force negotiates sub-340B prices on behalf of ADAP, based on the recognition that it is the payer of last resort and that, while important, ADAPs serve a relatively small group of people. The lower prices do not significantly cut into the profits of drug companies, yet they provide positive public images.

Changes to the system under the ACA may change the utility of these options. In the next section, we explore whether and how the ACA will affect the negotiating strategies available to public payers of ARVs, recognizing that the law itself is currently under debate and its standing is uncertain.

Evaluating Player-Level Policy Options in Light of Health Reforms

The ACA has important implications for the financing of HIV treatment and care, including ARVs.⁴ The most salient change is that responsibility for many uninsured PLHIV will be shifted from the Ryan White Program and ADAP to Medicaid and private insurance sources. While ADAP will take an increasingly smaller role in financing ARVs, the numbers of

⁴ An overview of the ACA is available on the White House website, <http://www.whitehouse.gov/healthreform/healthcare-overview>. The whole law is online at <http://housedocs.house.gov/energycommerce/ppacacon.pdf>.

people on Medicaid will increase when the new eligibility requirements go into effect in 2014. Changes to Medicare Part D also have implications for PLHIV, reducing their out-of-pocket costs during the coverage gap in prescription drug coverage known as the donut hole. Major changes under the ACA that may affect ARV drug costs are listed in Appendix A.

Because of the limited range of negotiation mechanisms available to players within the current ARV system, health reform is unlikely to open new options for lowering ARV prices to most payers. Only Medicaid is likely to see lower prices—indeed, these have already been negotiated as part of the transition to health reform (KFF, 2011a). The major changes under the ACA that will affect public financing of ARVs are summarized below (KFF, 2011b).

- **Flexibility in the minimum essential benefits package.** The package of minimum essential benefits required for Medicaid and individual insurance plans under the ACA is currently under development, but it includes “prescription drugs.” Under the broader (and less specific) minimum formulary, Medicaid is more likely to be able to leverage formulary decisions for lower prices. However, the risk is that critical life-saving drugs will be left off the list for cost-cutting purposes, particularly if they are relatively high-priced. The tension between quality of care, ethical standards, and achieving low prices complicates this negotiation mechanism. Furthermore, the essential benefits package applies only to newly enrolled Medicaid beneficiaries; the patient population would be split between those held to a minimum formulary and those held to a potentially different standard. This split poses further problems for the use of formulary restriction as a negotiation mechanism.
- **Demand pooling.** The option of leveraging demand among PDPs will not change under the ACA, as Medicare will not be impacted in this regard. Although Medicaid will absorb many current ADAP clients and potentially the bulk of the newly diagnosed PLHIV, demand pooling is unlikely to gain any further ground there either. Under the ACA, drug rebates from manufacturers are already increased (to 23.1 percent for brand-name drugs), and rebates are extended to drugs purchased by managed-care plans with capitated payments (KFF, 2011a).
- **Contractual agreements.** ADAP’s role will diminish under the health reform law, so its preferential contracts with pharmacy networks will most likely also be limited. Within Medicare, the negotiating strategies and market power of PBMs are unlikely to be affected.
- **The moral argument.** Some players use moral pressure in certain situations to achieve lower prices; however, this is an unreliable negotiation tool, largely dependent on the public relations strategy of the manufacturer. The movement of many current ADAP clients into Medicaid under the ACA will reduce the ability of states to negotiate large rebates based on the moral argument, because each state will be negotiating on its own and because Medicaid is likely to negotiate less intensively and with a less credible threat of shaming than the HIV-specific ADAP program that is currently negotiating for many states.

Winners and Losers from Policy Changes

Decisions to change policy to negotiate ARV prices must take into account who is likely to win and who is likely to lose from these changes. If U.S. policymakers decide to apply lessons from

other countries, such issues are particularly important, since the financial impact of regulating drug prices on both publicly funded programs and private out-of-pocket expenditures is highly dependent on features of the health system. For example, although drug prices in Canada may be lower on average, inadequate coverage for catastrophic drug expenditures associated with ARV in the Canadian health system leaves some patients having to pay large sums out of pocket, transferring more drug costs from the government to individuals and resulting in greater inequality in access to ART. In contrast, more comprehensive and catastrophic drug coverage is available to residents in the United Kingdom and Switzerland, limiting out-of-pocket payments but increasing the government's share of drug costs, thereby providing more equitable access to ARV. The benefits of regulation need to be evaluated in light of the equitable distribution of benefits in the prevailing health insurance system.

With the introduction of new health reform laws in the United States that mandate health insurance coverage, equity considerations may be alleviated at the price of increasing the drug cost burden on public insurance programs. At the same time, with greater consolidation of public programs and increased demand for drugs through universal coverage, public programs may be in a better position to negotiate drug prices.

Major Changes Under the ACA That May Affect ARV Drug Costs

Medicaid

Expands eligibility. Starting in 2014, the ACA eliminates all categorical eligibility requirements for Medicaid (e.g., disability status) and bases eligibility solely on an income requirement, covering all uninsured individuals and families with incomes below 133 percent of the Federal Poverty Level (FPL). Some sources claim that as many as 70 percent of uninsured PLHIV currently served by ADAP will qualify for Medicaid under health reform.¹

Starting in 2014, the ACA will require Medicaid to provide a federally determined essential benefits package (EBP) that includes prescription drugs, along with many other services (e.g., hospitalization, outpatient services, mental health). Under the ACA, only newly eligible Medicaid recipients will be subject to the EBP, while Medicaid clients under the pre-reform law will not. While all state Medicaid programs currently offer some degree of prescription drug benefits, these are considered optional rather than mandatory in order to receive federal funding.² The House bill sets a broad mandate for categories of services to be included in the EBP; however, the exact benefits provided, including drug benefits, will be determined by a benefits committee convened by the Surgeon General. Furthermore, states may have room to reduce or expand the scope of coverage under each category of mandated benefits, so they may be able to determine which specific ARVs to cover.³

Medicare Part D

Reduces out-of-pocket spending in the “donut hole.” The ACA mandates that the coverage gap in Medicare (the donut hole) be completely eliminated by 2020. Before then, a series of reforms are in place to reduce the burden of the donut hole on clients, including a \$250 rebate for costs while in the coverage gap, starting in 2010, and the ability to count ADAP contributions toward the “true out-of-pocket spending limit” for Medicare Part D (which determines length of time in the donut hole) in 2011.

Requires pharmaceuticals to provide a donut-hole discount. Starting in 2011, the ACA requires pharmaceutical companies to provide a 50-percent discount on brand-name

¹ http://www.projectinform.org/pdf/hcr_faq.pdf (as of June 6, 2012).

² <http://www.taepusa.org/LinkClick.aspx?fileticket=NIFVBy-uvTk%3D&tabid=41> (as of June 6, 2012).

³ <http://www.familiesusa.org/assets/pdfs/health-reform/benefits-package.pdf> (as of June 6, 2012).

drugs for patients in the donut hole. Given that almost all ARVs used in the United States are not generic, this provision is highly relevant to people with HIV.

Private Health Insurance

Individual insurance mandate. Starting in 2014, the ACA mandates that all uninsured individuals must purchase individual health insurance and creates state-level Health Benefit Exchanges to assist people in purchasing affordable insurance. For people who still experience financial difficulty, subsidies will be provided to those with incomes up to 400 percent of the FPL. Some sources claim that many of the remaining 30 percent of uninsured PLHIV currently served by ADAP who will not qualify under expanded Medicaid coverage will qualify for individual coverage with federal subsidies.⁴

Starting in 2014, the ACA will require all private insurance plans offered through state Health Benefit Exchanges to provide the same federally determined EBP as Medicaid. The House bill sets a broad mandate for categories of services to be included in the EBP; however, the exact benefits provided, including drug benefits, will be determined by a benefits committee convened by the Surgeon General. Furthermore, insurance providers may be able to reduce or expand the scope of coverage under each category of mandated benefits, so insurers may have room to determine which ARVs they cover.⁵

⁴ http://www.projectinform.org/pdf/hcr_faq.pdf (as of June 6, 2012).

⁵ <http://www.familiesusa.org/assets/pdfs/health-reform/benefits-package.pdf> (as of June 6, 2012).

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