

Commentary

Impact of ACA on the Dinner-for-Three Dynamic

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ABSTRACT

The Patient Protection and Affordable Care Act (ACA) aims to expand coverage to the previously uninsured, improve the quality of coverage, and help eliminate inefficiencies in the health care market. We evaluated the implications of ACA on the drug industry by examining the impact on the “Dinner-for-Three” dynamic in our health care system. We can think of our system as an odd dinner party in which one person pays (the insurer), one orders the meal (the physician), and yet another eats the meal (the patient). This dynamic requires us to examine each stakeholder and how they interact with one another to assess the impact of the ACA. Of the 6.7 million initial exchange enrollees, ~3.8 million subjects were previously uninsured. A higher percentage of these enrollees are using their pharmacy benefit, and they are disproportionately filling prescriptions for specialty drugs relative to those covered in employer-sponsored plans. Formulary designs in exchange plans are passing on higher cost-sharing for prescription drugs to the patient. ACA has also resulted in the development of accountable care organizations (ACOs); these organizations may play a role going forward in the management of drug spending and the development of formularies and protocols that impact drug prescribing. Payers are tightening control over drug spending and are finding physicians and physician groups increasingly less reluctant allies in doing so. Patients are faced by more complexity than ever in the health care system and are expected to take a more active role in responsibly managing the cost of their care. It is

increasingly critical that drug manufacturers develop robust value propositions and communicate that value to all stakeholders. They should re-evaluate trial investment decisions and consider changes in price setting, rebates (how much and to whom), copay programs, and physician and patient support programs in light of changing market needs. (*Clin Ther.* 2015;37:733–746) © 2015 The Authors. Published by Elsevier HS Journals, Inc.

Key words: ACA, Managed Care, payer, pricing, health policy, formulary.

INTRODUCTION

President Barack Obama’s Patient Protection and Affordable Care Act (ACA) have dominated the US political landscape for at least the last 5 years. Statements about success or failure of the law are often politically inspired and not necessarily founded in facts. Irrespective of political positions, what are the real implications of the various components of the ACA on the pharmaceutical industry?

The most important elements of the ACA that impact prescription drugs involve expansion of the insured population, improving quality of coverage, and eliminating inefficiencies. Some specific factors include the following:

- Introduction of health care exchanges, aimed to provide affordable coverage for the previously uninsured.
- Expansion of Medicaid coverage up to 133% of the federal poverty level for participating states.

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- Increased minimum Medicaid rebate, from 15.1% of the average manufacturer price to 23.1% of the average manufacturer price for most drugs.
- Expanded health care coverage for dependents up to age 26 years.
- Prohibition of annual and lifetime coverage limitations.
- Various initiatives to improve quality and efficiency of health care, including Medicare payment links to quality performance, accountable care organizations (ACOs), and various bundled payment initiatives and pilots.

Expanding health care coverage and improving health care quality are intuitively promising characteristics that should be beneficial to the drug industry. However, how will the new insurance offerings and ACO incentive structures affect formulary management practices, prescribing behaviors, and patient preferences? How will they affect the prescription drug business?

In evaluating the impact of changes in a health care system, we need to consider the complexities and the host of stakeholders and influencers involved. Third-party insurance of medical services and prescription drugs create a dynamic that makes the industry unique in that purchaser (insurance), decision maker (physician), and end customer (patient) form a much more complex decision-making platform than the usual buyer–seller relationship for consumer products. *The Price of Global Health (Second Edition)* describes this process as an odd “Dinner-for-Three.”¹ We used this framework to analyze and predict the impact of the trends resulting from ACA on the US prescription drug environment.

THE CHANGING US PRESCRIPTION DRUG MARKET

We cannot consider the impact of ACA on today’s prescription drug environment without looking at other market developments. Prescription drug costs have been an increasingly “hot topic” over the last few years, with heavy public criticism over Zaltrap[®] (ziv-aflibercept [Sanofi US, Bridgewater, New Jersey]) pricing voiced by Sloan Kettering,² a *Blood* article by US hematologists over prices of hematology drugs,³ and, most recently, public and payer concerns regarding the pricing of Sovaldi[®] (sofosbuvir [Gilead Sciences, Inc, Foster City, California]). Under leadership of the American Society of Clinical Oncology,

medical communities have started to explore how to take cost into consideration in clinical guideline decision making.

Although payers are often hesitant to take action on a cost-related issue (unless they have a solid medical rationale), payers have shown a willingness and confidence to be more vocal about drug cost issues, as evidenced by the public anger of Express Scripts (ESI) regarding the Sovaldi pricing. In December 2014, ESI announced their decision to exclude Gilead’s Sovaldi and combination therapy Harvoni[®] for hepatitis C treatment from their 2015 National Preferred Formulary, covering only the newly approved regimen of AbbVie, Inc. Soon after, Caremark announced their decision to list only Gilead’s therapies and exclude AbbVie’s therapies from their national formulary. Although these decisions do not apply to the entire membership of the pharmacy benefit managers (PBMs) (eg, self-insured employers can use a custom formulary), PBMs are demonstrating a willingness to manage high-cost drugs more tightly. Caremark and ESI also have, for some of their plans, removed nonpreferred anti-tumor necrosis factor drugs from formulary rather than placing them on a higher copay tier, allowing for only a few covered options. One can wonder whether this action is at least in part motivated by the extensive use of copay offset programs (coupons) by drug manufacturers with nonpreferred brands. Coupons have been troublesome for many payers, but they have been very selective in combating the use of these coupons, for example, by the introduction of step edits or prior authorizations for nonpreferred brands.

It remains to be seen whether the formulary exclusions for hepatitis C drugs are an exception or a harbinger of further exclusions for new high-cost specialty drugs. It also remains to be seen how willing commercial health plans, beyond PBMs, are to create exclusion lists. Although health plans have used exclusions on their Medicaid and Medicare formularies for many years, they have been less likely to do so thus far for their commercial formularies. An important element in this evolution is the acceptance of limitations in prescribing choices by physicians, employers, and patients.

Outside the United States, the prescription drug market has also been undergoing extensive changes due to the economic recession and related budget crises. Particularly in Europe, the euro crisis and

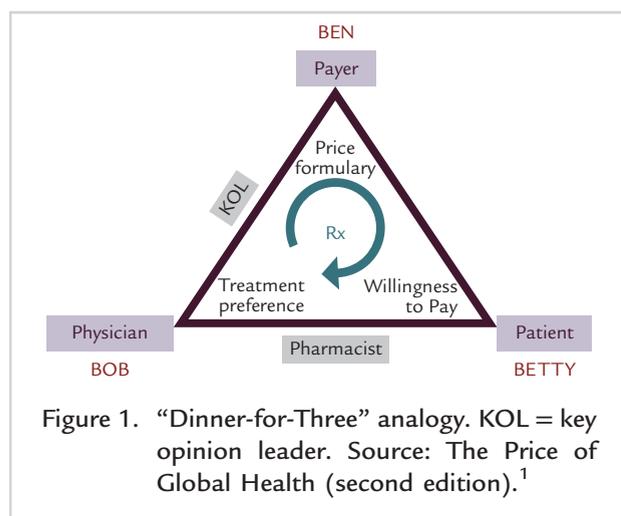
resulting fiscal austerity measures have had a strong impact on government decision making for reimbursement of prescription drugs. This includes some fundamental drug review system changes in Germany, France, and the United Kingdom.

In the United States, the cost of health care has been a central part of the discussion for many years and an important impetus for the ACA. The political discussions have since moved to the legality of the individual mandate and implementation challenges for the exchanges, but the underlying cost concerns remain a factor of consideration.

DINNER-FOR-THREE

Times are long gone that drug-prescribing decisions were unilaterally made by individual physicians. Because ~87% of US patients have insurance coverage that includes prescription drugs, most patients do not see the actual drug cost but are exposed to a fixed copay or percent coinsurance rate. A critique from payers worldwide has always been that due to the role of insurance, a natural market mechanism is lacking. Many ex-U.S. governments have argued that because of a lack of cost concerns by physicians and patients, there is not enough incentive to try less expensive options, and pharmaceutical companies can set relatively high prices.

*The Price of Global Health (Second Edition)*¹ describes this phenomenon as “Dinner-for-Three.” Imagine 3 people go to a restaurant (Figure 1). Decision maker (Bob) is ordering a meal from the menu, diner (Betty) is consuming the meal, and the



payer (Bob) is settling the bill. In this context it seems odd, but this scenario does describe the drug-prescribing process for patients with health care coverage. Payer Ben may argue that Betty does not really need that champagne and caviar, but Bob and Betty will be equally upset if Ben only allows for a hot dog 3 times a day.

Let us step away from the dinner context and transition to the “negotiating triangle” between payer, physician, and patient to analyze the impact of ACA and other recent market changes on each of the stakeholders and their influencers, as well as the implications for the pharmaceutical industry. We first analyze the details of ACA implementation as we know them to date.

CURRENT STATUS OF EXCHANGE ENROLLMENT

In the spring of 2014, the US Department of Health & Human Services (HHS) reported that 8.1 million individuals enrolled in the new exchanges, despite the many technical implementation issues. By November 2014, exchange enrollment was down to 6.7 million (Table I) as many exchange enrollees did not pay premiums, some lost coverage for not providing proof of citizenship,⁴ and initial HHS estimates included patients who only signed up for dental coverage.

There are no conclusive statistics on the proportion of exchange and Medicaid enrollees from the first enrollment period who were previously uninsured. Initial estimates indicated a drop in uninsured to 13.4%⁵ or 15%,⁶ but later estimates provide a different picture. The latest estimate from the Kaiser Family Foundation, dated June 2014, is that 57% of exchange enrollees were previously uninsured.⁷ The estimate is based on a survey of ~750 exchange enrollees. In October 2014, ESI released a report based on an actual analysis of their exchange membership.⁸ They found that 66% of their exchange enrollees were either previously uninsured or enrolled in a prescription drug plan administered by another carrier. However, they do not quantify the specific percentage of enrollees who were previously uninsured, and we can only be sure that it is <66%, which is consistent with the Kaiser data.

Assuming the Kaiser estimate is accurate, the exchanges have enrolled ~3.8 million Americans who were previously uninsured. This is a significant

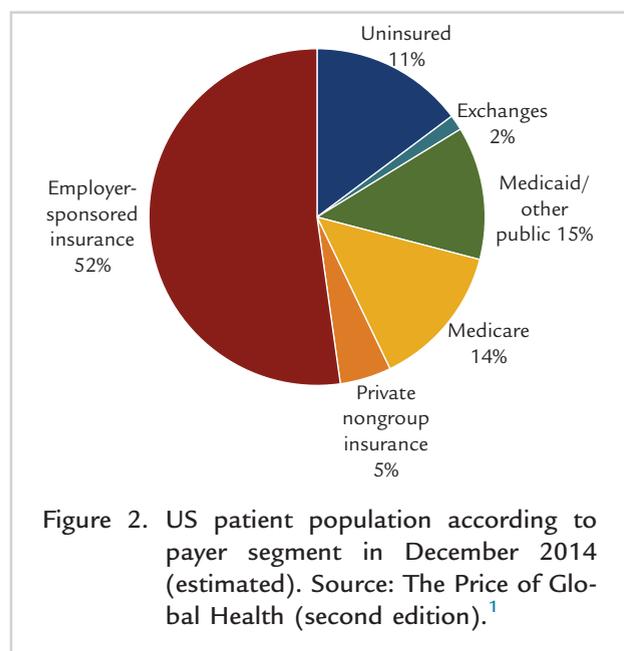
Table I. Exchange enrollment history according to the US Department of Health & Human Services (HHS).

Timing	HHS Estimate	Reasons for Drop from Spring 2014 Estimate
Spring 2014	8.1 million	NA
August 2014	7.3 million	Many did not pay premiums
October 2014	7.1 million	Some lost coverage for failing to provide proof of citizenship or financial eligibility
November 2014	6.7 million	Previous estimate included ~400,000 individuals who only signed up for dental coverage

NA = not applicable.

number but represents only 8% of the estimated 47 million uninsured individuals in the United States before the implementation of the ACA.

In addition to exchanges, many Americans have benefited from the expansion of Medicaid coverage in participating states, as well as the expanded health care coverage for dependents up to age 26 years. Medicaid expansion is still evolving as several additional states have recently decided to participate. **Figure 2** shows an estimate of the US health insurance landscape according to coverage type on the basis of these preliminary numbers. The main observations are that: (1) the uninsured population has declined but is still a large population segment;



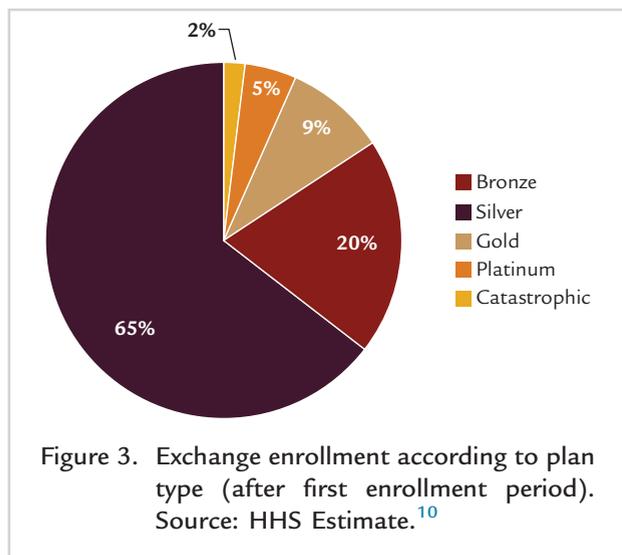
and (2) the exchange population is currently relatively small. During the second enrollment period, many states have implemented programs to provide enrollment support and raise awareness in target populations. As of the official deadline of the second enrollment period (February 15th, 2015), the Obama administration reported that 11.4 million people either re-enrolled in an exchange plan or enrolled for the first time.⁹ This number does not take in to account that in many cases the deadline has been extended. Final numbers will again have to be corrected for those who have not paid their premiums or not verified legal residency.

HHS still believes exchange enrollment will eventually reach 25 million but that this goal will take until 2019, as opposed to the 2017 estimate originally provided. Although no conclusive statistics are available, the shift from employer-based coverage or other private plans into the exchanges has been lower than HHS initially expected.

The ACA is likely here to stay, despite the continued legal challenges from opponents. The most recent challenge is that the federal government, due to specific language of the law, can provide tax subsidies to eligible residents only from the states running their own exchanges. Today, only 17 states operate exchanges on their own, but most legal scholars are skeptical that the challenge will be upheld in federal court.

STATUS OF EXCHANGE PRESCRIPTION DRUG COVERAGE

The ESI report states that 49% of ESI’s exchange enrollees who signed up for coverage during the first



enrollment period had already used their pharmacy benefit.⁸ This figure is nearly as high as the proportion for their commercially insured membership (55%). As one of the largest providers of prescription drug benefits in the country, ESI's data are likely a good proxy for the exchange population as a whole. The large majority of exchange enrollees are in a Silver or Bronze plan (Figure 3)¹⁰ with a 4-tier formulary design. Catastrophic and Platinum plans have attracted only a small share of patients.

Exchange enrollees thus far have been 59% more likely to fill a specialty medication than are commercial members; for ESI, this represents 38% of spending for exchanges compared with 28% for health plans.⁸ This finding is mainly due to a higher utilization for HIV and hepatitis drugs. The high utilization of specialty drugs may pose a significant cost challenge

for exchange plans. In this context, it is important to consider that the government offers financial assistance to low-income exchange enrollees in the form of premium credits or cost-sharing reductions. According to HHS, 85% of the current exchange population is enrolled in a plan with financial assistance. For the cost-sharing reduction plans, exchange carriers have wide discretion and flexibility about how to adjust that cost-sharing, and, so far, they have been much more likely to reduce the medical deductible than they are to reduce the coinsurance rate for specialty drugs.¹¹ This leaves even the lowest income exchange enrollees with a very high drug cost-sharing burden (Table II). Many plans have chosen to place a proportionally high burden on drug copayments for patients in favor of lower medical copays. This seems odd, given long-term cost savings of effective drugs, but it may be explained by the relatively short-term perspective of the plans in light of usual insurance turnover rates and the fact that spending on specialty drugs is one of the fastest growing categories in health care.

Given the pressure on insurance premiums, it is not surprising that most plans use multiple-tier formularies and relatively high copay and coinsurance rates. Avalere Health published an analysis of 603 exchange plan designs for 2014 across 60 major carriers in 19 states.¹² Their analysis included both federally operated and state-based exchanges. According to Avalere's analysis, coinsurance is more common than copays for specialty tier drugs in Bronze and Silver plans. Table III presents the Avalere study results, with average coinsurance rates of 37% for Bronze, 22% for Silver, and 28% for Gold plans. Coinsurance

Table II. Exchange cost-sharing reduction choices for subsidized offerings overwhelmingly favor medical deductible reduction.

Plan Type	% That Reduced Tier 4 Drug Cost-Sharing	% That Reduced Tier 3 Drug Cost-Sharing	% That Reduced Medical Benefit Deductible	% That Reduced Primary Care Copay
200%–250% FPL	5	13	74	31
150%–200% FPL	39	58	96	61
<150% of FPL	53	63	96	70

FPL = federal poverty level.
Source: Avalere.¹¹

Table III. Average coinsurance rate and use frequency of coinsurance tiers for exchange plans.

Plan Type	Average Coinsurance on 4th Tier	Frequency of Coinsurance on Specialty Tier	Frequency of Copay on Specialty Tier	No. of Plans Assessed
Bronze	37%	75%	25%	144
Silver	22%	59%	41%	145
Gold	28%	56%	44%	111
Platinum	19%	38%	62%	49

Source: Avalere.¹²

rates for the Avalere study, based on the plans selected, may seem out of line for the Silver plans. HealthPocket, a consumer information website, found that the average coinsurance for a drug on a specialty tier in November 2014 was 37% for a Bronze plan and 34% for a Silver plan.¹³ Of the plans Avalere assessed, 39% require coinsurance of $\geq 40\%$ for all covered drugs in at least 1 specialty class, most frequently in multiple sclerosis (MS) and oncology.¹²

Exchange enrollees are also subject to cost-sharing through deductibles. For 2015, the average deductible for a Silver plan is expected to be approximately \$3000 for an individual and \$6000 for a family. Most plans will have combined medical and pharmacy deductibles.

It is important to consider that the ACA also has provisions for out-of-pocket (OOP) maximums, and many exchange enrollees could reach their maximum in their first or second specialty drug fill. The OOP limit is federally regulated and must conform to specific amounts. For 2015, the OOP amount can be no higher than \$6600 for an individual plan and \$13,200 for a family plan. This includes both medical and pharmacy claims. OOP maximums are adjusted based on income, and thus many enrollees will see lower limits. However, patients would still incur several thousands of dollars in OOP costs before hitting the limits, thus creating a “sticker shock” that discourages them from using their benefit. If enrollees do not have a full understanding of their benefits and how OOP limits work, they may believe they will have to pay the same high OOP expense for each prescription refill or medical encounter.

Critics of the ACA state that requiring cost-sharing as high as $\geq 40\%$ for all drugs in a class goes against the central “affordability” tenet of the law. Others

have criticized the exchange plans for their propensity to restrict network access. A recent McKinsey Center report concluded that about one half of the exchange plans offer “narrow network” plans, defined as plans that have 31% to 70% of hospitals in the area in-network.¹⁴ We should consider that there may be a significant group of Americans who cannot afford their coverage at work but earn too much to be eligible for exchange subsidies, and these individuals are very likely to be left without coverage.

In summary, analysis to date on the coverage characteristics for patients under the exchange plans found that:

1. A high proportion of exchange enrollees are already using their pharmacy benefit.
2. Specialty drug use and spending are significantly higher for exchange enrollees than for commercially insured patients.
3. For many plans, coinsurance rates for high-cost specialty drugs exceed cost-sharing for commercial and Medicare plans.
4. Although OOP limits (which are income adjusted) can alleviate consumer burden, sticker shock remains.
5. Exchange enrollees may face other restrictions on access above and beyond high specialty drug cost-sharing (eg, narrow physician/hospital networks).

IMPACT OF PATIENT COST-SHARING

Patient cost-sharing was not introduced by the ACA. It is important to consider the high cost-sharing for the new exchange plans in the context that patients have been subject to continuously increasing cost contributions and multiple copayment tiers in the years before the introduction of the ACA. Figure 4 illustrates the development of the private employer-sponsored plans from 2000 to

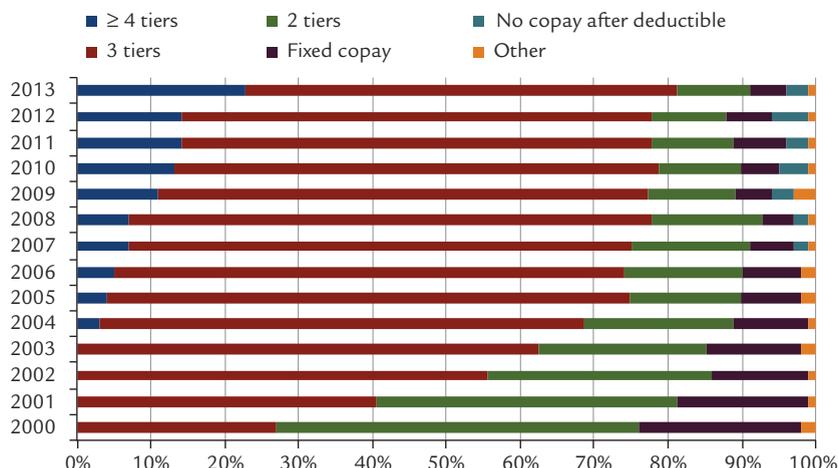


Figure 4. Private employer-sponsored plan evolution according to number of tiers, 2000 through 2013. Source: Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2013.¹⁵

2013.¹⁵ The majority of plans used a 2-tier structure in 2000. By 2013, >80% of plans had ≥3 tiers, with 4-tier plans growing rapidly. Interestingly, the emergence of 4-tier formularies started in 2004 at the implementation of Medicare Part D, which by design was requiring an average 25% coinsurance rate across its drug portfolio. Figure 5 displays the development of copay rates for private employer-sponsored health plans within each tier from 2000 to 2013. Copays have been rising steadily. In the same period, coinsurance rates have been more stable,

but coinsurance tiers (usually tiers 4 and 5) have been increasingly applied, as shown in Figure 4.

Increased cost-sharing through deductibles and copayments is intended to keep premiums low and encourage patients to make better decisions regarding health care utilization. What are the longer term cost implications, however? Can patients really make better decisions when faced with a disease that is only treated effectively by using high-cost drugs? Gleason et al¹⁶ presents an example of the impact of copayments

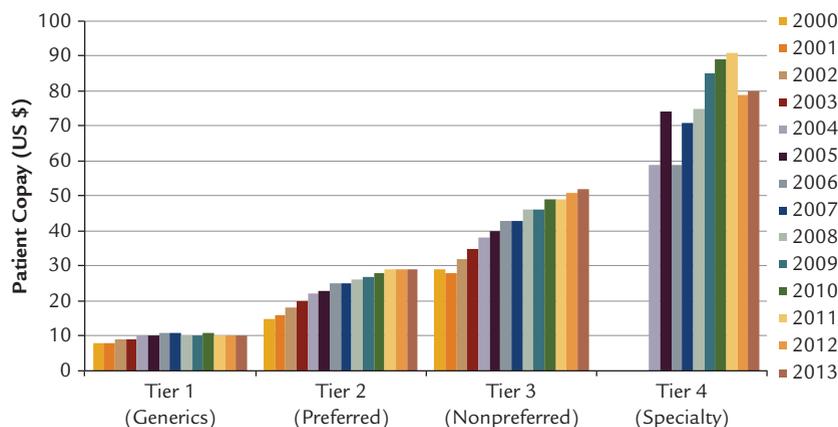


Figure 5. Private employer-sponsored plan copay development from 2000 through 2013 according to formulary tier. Source: Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2013.¹⁵

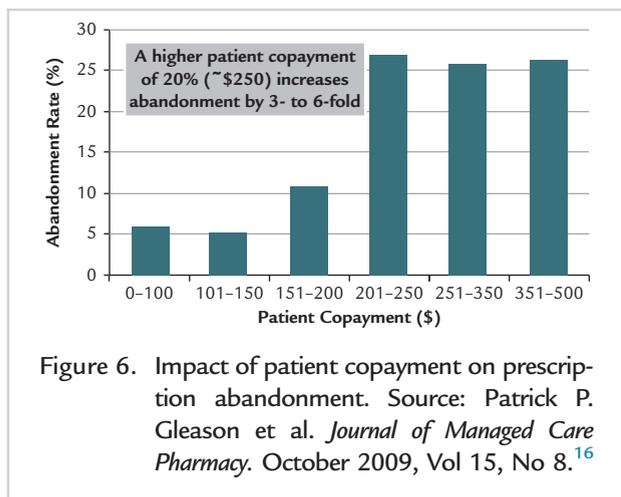


Figure 6. Impact of patient copayment on prescription abandonment. Source: Patrick P. Gleason et al. *Journal of Managed Care Pharmacy*. October 2009, Vol 15, No 8.¹⁶

for an MS treatment on patient adherence. Patient abandonment (i.e., not filling prescriptions) increased from 5% to >25% for higher copayments (Figure 6). Abandoning drugs that treat MS puts patients at higher risk for relapses, hospitalization, and, in the long term, disability.

A recent United Healthcare study found that increased spending on drugs decreased the overall cost of health care for patients with cancer.¹⁷ The study assessed 810 cancer patients with breast, colon, and lung cancer from 5 major oncology practices over a 3-year period, and the authors examined the difference in total treatment costs when practices were reimbursed under standard buy and bill or a fee-for-service versus a bundled, prospective reimbursement approach. Even though drug costs were approximately \$13.5 million higher for the bundled payment group, overall costs were 34% lower.

Similarly, the “Diabetes Ten City Challenge” study, with first-year results published in 2009, illustrated the impact of pharmacist intervention and increased drug spending on overall costs and quality.¹⁸ For the 573 patients studied, total costs were reduced by 7% versus projection. The net 7% reduction comprised a drug spending increase of 19% and a medical spending decrease of 19%. Numerous outcomes were improved as well, including reductions in glycosylated hemoglobin, cholesterol, blood pressure, and body mass index.

A health care system’s focus on costs, as well as patient exposure to health care costs, can be seen as disproportionately focused on drug spending, given that only 15% of total health care spending is on drugs. Many health care plans have a short-term focus or manage pharmacy

benefits only, and they therefore may not experience the long-term benefits of increasing drug spending or decreasing drug cost-sharing for their membership. This is also a byproduct of the fact that it is easier to monitor and control drug costs than it is to measure the impact of drugs on long-term patient outcomes and medical costs.

High copayments should also be considered in the context of the devastating impact that they can have on the finances of patients with diseases such as rheumatoid arthritis, MS, and cancer. Oncologists have recently started to use the term “financial toxicity” to express the trade-off between clinical performance and cost in decision making.

As exchange enrollments increase and the number of patients who are exposed to high cost-sharing for drugs is growing, we need to be concerned about higher-than-desired abandonment, with its potential negative impact on patient outcomes and long-term total costs. For drug manufacturers, the promise of increased enrollment may not yield increasing sales, and patients may associate “fault” for high costs with drug manufacturers rather than with insurance design.

PROGRESS WITH ACOs

Today, >300 ACOs provide coverage to ~5 million Medicare patients.¹⁹ Government records show that, within the first year of the ACO program, about one half of eligible ACOs earned bonuses for saving Medicare money and also meeting needed quality metrics, resulting in \$705 million in total Medicare savings.²⁰ Program advocates view these preliminary results as a good sign that the ACA could translate into substantial savings if the program expands. In reality, the program seems to mainly entice a quest for short-term savings opportunities; an open question is whether there will be any longer term cost and quality impact.

The actual savings generated are small in comparison to total Medicare costs, which amount to not millions or billions, but trillions of dollars each year. In addition, the risk for financial penalty has already caused many ACOs to drop out of the program. In fact, in the latest assessment, ~100 ACOs spent more than Medicare’s expectations.¹⁹ Dean Clinic and St. Mary’s Hospital ACO in Wisconsin is notable for having cost Medicare \$10 million more than expected. Most ACOs have a 3-year grace period in which they can only earn bonuses without incurring penalties, and due to the novelty of the ACO program,

financial loss to date has been limited. To incentivize continued, further participation, the federal government proposed in early December 2014 to extend the grace period by another 3 years. There are currently 4 different ACO programs with varying risk/savings profiles to further incentivize program growth.

It remains to be seen how effective the ACO program will be at saving money and improving quality of care. Indeed, the sustainability of the program as a whole is still very uncertain. We should not take as a given that the more integrated model will realize the promised benefits or that the benefits will exceed the administrative costs. However, the trend toward integration of provider systems and paying for value rather than volume is likely here to stay. Integrated systems need to be considered as a distinct customer that requires a targeted value proposition, with relevant quality and financial metrics as part of the offering. The program's incentives are expected to further drive the scale and integration of services.

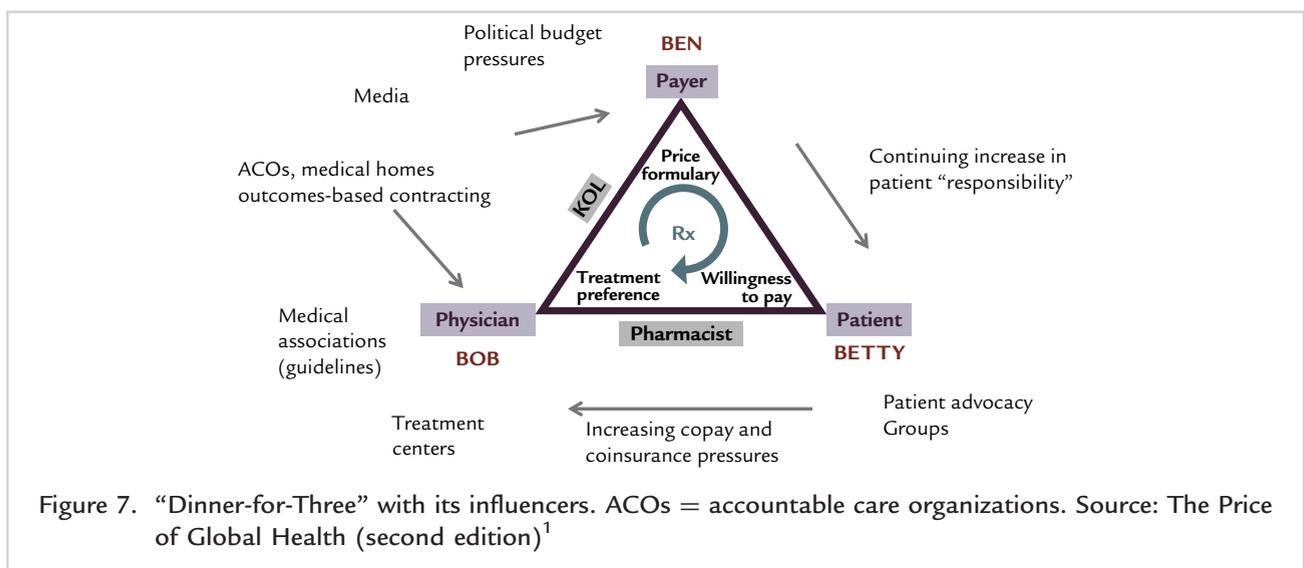
For drug manufacturers, ACOs present both risks and opportunities. From the risk side, if manufacturers are unable to link their drugs to overall cost-savings or meaningfully improved outcomes relative to comparators, risk-bearing provider groups will likely choose lower cost options. From an opportunity perspective, because ACOs tend to look at the overall picture of total spending and patient outcomes, they are likely to try and account for the complete value of drug interventions, not just the cost.

IMPACT ON THE DINNER-FOR-THREE DYNAMIC

Introduction of ACA, in combination with other gradual changes in the health care marketplace, has had an impact on the pharmaceutical market and its individual decision makers and users. In terms of the Dinner-for-Three phenomenon that was explained earlier, we examine here what the likely impact is on each of the players and then evaluate what the implications are for the pharmaceutical industry. Figure 7 shows the various changes in the environment that were identified in the previous sections in the context of the Dinner-for-Three situation.

Payers

Payers face unprecedented budget pressures, as employers and patients criticize the cost of private insurance plans, and political pressure is exerted with respect to government-funded plans. ACOs offer payers attractive opportunities to engage other stakeholders in reducing costs, but it is unclear if the ACO model will be fully supported by provider networks and individual providers. Managed care plans have continued to increase “patient responsibility” through copays and deductibles, particularly for Medicare Part D and exchanges, but employer-sponsored plans have also seen recent rapid increases in coinsurance tiers, perhaps building on the experience gained with Medicare Part D plans in past years. Some plans, particularly PBMs, have also been more willing to exclude drugs from coverage even on their commercial formularies in cases



with multiple similar high-cost options and drug companies willing to offer attractive contracting terms.

While facing strong budget pressures, many payers are seeing financial upside from an influx of new customers as a result of Medicaid expansion and the creation of exchanges. The revenue share from individual patient policies is growing rapidly. Payers are therefore beginning to focus increasingly on direct-to-consumer strategies (vs business-to-business strategies) and patient experience-related improvements, as they prepare for the likelihood of increased turnover at the individual level and a decrease in employer-sponsored coverage.

Physicians

Physicians are generally expected to prescribe the best available treatment option for each patient, irrespective of cost. Medical associations have historically provided general treatment guidelines to the physician community, but those have generally been sufficiently broad to give physicians latitude to address specific patient conditions and needs. Cost of treatment has, until recently, rarely been a determining factor in the guidelines.

Increasingly, medical associations are including cost considerations in their guidelines. For example, the American College of Cardiology and the American Heart Association will begin characterizing treatments with value ratings related to the cost per quality-adjusted life-year.²¹

In addition, individual physicians and provider groups have been forced to focus more on cost. Contracting with insurance companies continues to be a challenge, especially as some plans move to narrow their networks. Mandated and negotiated cuts in reimbursement for office-administered drugs require practices to carefully consider financials associated with drug administration. The emergence of ACOs, payment models based on episodes of care, and new requirements for electronic medical records have further increased the complexity of the financial trade-offs for providers and potentially expose them to the adverse selection paradigm that payers have long faced. For example, as physicians are held accountable for total spending and outcomes, will they consider screening out higher risk, sicker, or less compliant patients? Even if ACO payment schemes take into account case mix and adjust for risk, physicians may initially be concerned as to the appropriateness of such adjustments. Furthermore,

as their patients are exposed to higher cost-sharing, and the types of plan designs proliferate, physicians and staff will need to expend more time and energy making drug and treatment choices that are in the best clinical and financial interest of their patients.

As the burden associated with running the business has increased for providers, many have joined large groups and provider systems. Although this can free providers from administrative burdens associated with running their own practice, it tends to mean that they must more actively consider group policies and protocols, thus limiting their autonomy. For those that remain in private practice, maintaining the practice's financial health will require more attention than ever.

Patients

Over the last few decades, patients have become more empowered to at least participate in health care decisions. Medical websites gain high traffic, and patients with chronic diseases can be well informed about the disease and its treatment choices. New digital health software and data analytics technologies are generating more transparency and insight to patients about the delivery and costs of their care. As a consequence, physicians continue to evolve from being an autocratic decision maker toward becoming a health consultant. At the same time, employers are increasingly leveraging financial penalties for workers who do not participate in wellness programs, and payers are giving more "responsibility" to patients in terms of higher financial contributions through premiums, deductibles, and copayments. In response to nonpreferred copay and coinsurance rates, drug companies have introduced copay offset programs (coupons).

How well will patients be able to play an active role in the decision-making process with increasingly restrictive provider networks and multiple treatment choices with differences in copays and availability of coupons? Although medical information is available in abundance through the Internet, understanding and deciphering how insurance plans work (and with which providers and for which drugs) can be intimidating even for the most educated of health care consumers. Add into the mix the emotional turmoil that comes with diagnosis of a serious disease, and it can be overwhelming for patients to be at the center of treatment decisions.

PAYER–PHYSICIAN–PATIENT INTERACTIONS

Prescription drug companies have learned to assess the influence that payers have on physician prescribing and patient fulfillment by considering them as an integrated system. Figure 8 illustrates the Dinner-for-Three relationships with an example of attributes and decisions that payers, patients, and physicians make.¹

It might immediately be apparent from this illustration that physicians have to deal with coverage decisions as imposed by a complex group of commercial payers, Medicaid, Medicare, and now the health care exchanges. The commercial model includes many employer-sponsored plans. Similarly, there are many options for exchanges and Medicare Advantage or Part D plans in most states. The payer environment is highly fragmented and complex, and physicians are unlikely to know the specific insurance plan offerings for each patient and thus will only learn of any problems after a pharmacist calls or a patient complains.

Patients can influence physician prescribing, either through a direct request for a brand or through a perceived or direct request for a drug with a lower copayment. In the office, a physician may be hesitant to prescribe a higher cost drug option to a patient after receiving multiple patient complaints and relatively good results with a less expensive drug. In the absence of good information, physician prescribing will be guided by his or her judgment on patient willingness to copay and general experience regarding copay levels to inform a decision.

In summary, the introduction of ACA is further building on and accelerating ongoing trends in the Dinner-for-Three dynamic of the US prescription drug marketplace:

1. Payers continue to shift cost responsibilities to patients and their treating physicians by increasing coverage hurdles, deductibles, and copayments.
2. Physicians and their provider organizations have to find a balance between new financial risks and incentives, increasing cost considerations in medical

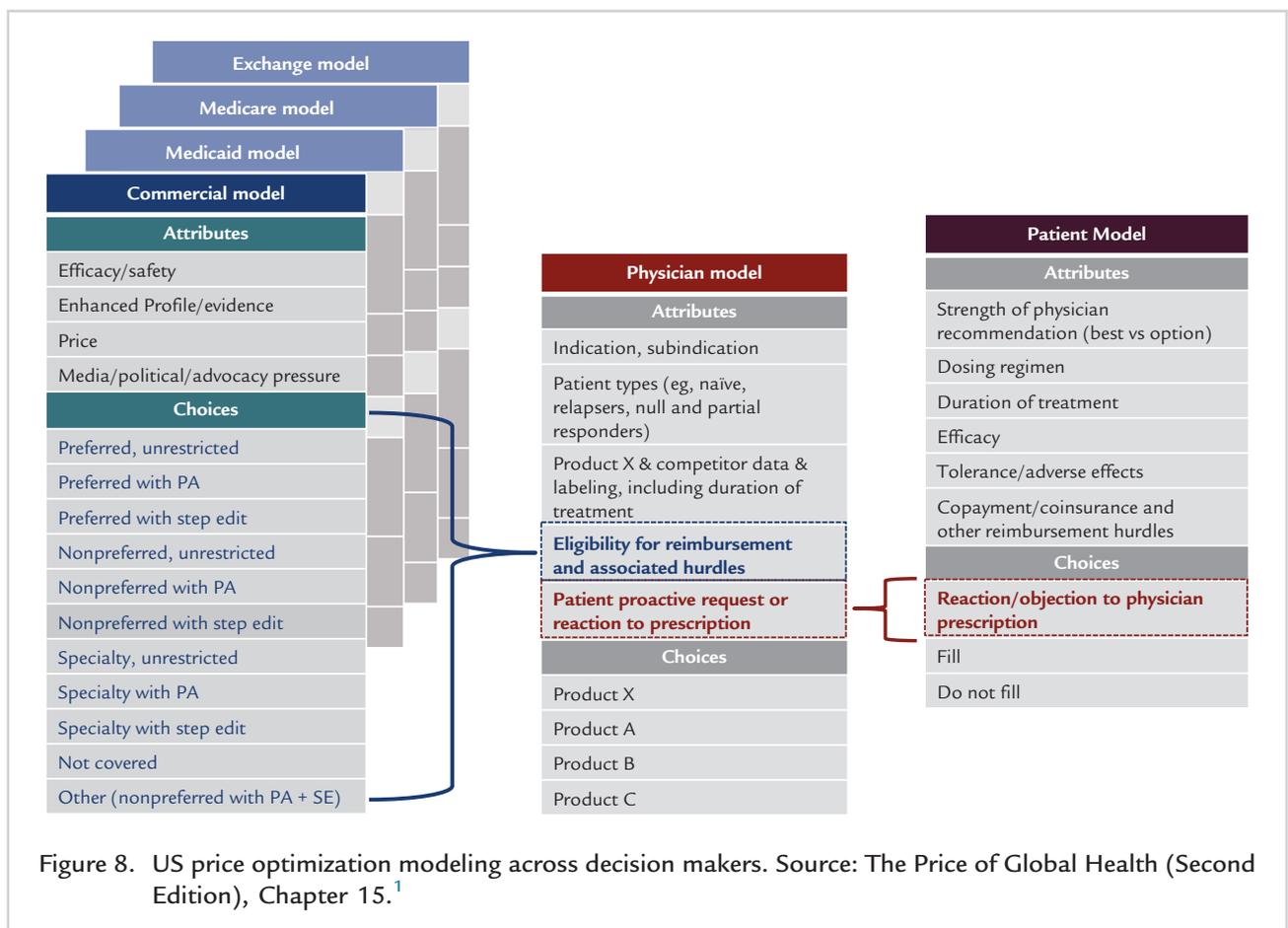


Figure 8. US price optimization modeling across decision makers. Source: The Price of Global Health (Second Edition), Chapter 15.¹

guidelines, and growing individual patient concerns regarding high deductibles and copayments.

3. Patients are generally better informed about treatment options, but they are also faced with tougher choices as complexity of the health insurance market and level of copayments and deductibles keep increasing.
4. The dynamic between payers, physicians, and patients is increasingly influenced by other stakeholders, such as media, medical organizations, and government incentive programs.

IMPLICATIONS FOR DRUG COMPANIES

Although drug manufacturers can model payer–physician–patient dynamics to help make the right pricing, rebating, and copay card decisions, what else must they consider? [Figure 7](#) presents the US environmental changes discussed in the context of the Dinner-for-Three dynamic. Influencers of the dynamic between payers, physicians, and patients (eg, medical associations, treatment centers, patient advocacy groups, ACOs, media) will require emphasis of a drug’s value proposition and benefits provided that are of importance from their particular perspectives.

Value Proposition

We have previously discussed how the Dinner-for-Three relationship historically has contributed to a lack of natural market mechanism, with limited incentives for patients and physicians to try less expensive options. However, we can think of the growth of technology, patient empowerment, and physician financial incentives as continuing to “shift the balance” in decision-making roles and responsibilities for our Dinner-for-Three participants. A drug manufacturer’s ability to charge premium pricing for innovative drugs has become increasingly dependent on value as perceived by patients and physicians rather than just payers.

Drug manufacturers need to ensure that their value proposition is compelling to all key stakeholders, including not just payers, prescribers, and patients but also their representing organizations. Depending on the specific situation, additional stakeholders such as media, provider groups, ACOs, and others need to be considered.

Specific aspects of the value proposition requirements include several prescriber, patient, and payer propositions. Prescriber and patient value propositions will need to articulate why the drug is “worth” paying for (ie, copays). For providers, this means continuing to provide a strong

clinical rationale but also helping them articulate to patients why the drug is “worth it.” Providers will need resources to help patients address cost burdens (including coupons and patient support services). For patients, this means describing clinical benefits in patient-relevant ways, including patient-relevant endpoints in trials and by providing potentially customizable resources that help address cost burden or manage treatment, and perhaps even resources that help patients understand their insurance coverage. Payers, including provider organizations, require clinical and health outcomes trial data that help justify costs relative to other options. It is important to consider the perspective of each payer (ie, PBMs will be more focused on drug cost-savings than medical cost offsets). A good understanding of financial perspectives and incentives (ie, “follow the money”) is essential.

Value Communication

As the role of a broader group of influencers is making the coverage and prescribing process more complex, drug companies need to take a broader view on value communication needs. Particularly for high-cost specialty drugs, drug companies need to address general value proposition in the context of price, as well as the appropriate patient population to facilitate medical community consensus on appropriate use:

- For highly “visible” disease areas, it is important to develop value messaging for the broader public and media that help avoid pricing controversies at launch.
- For drugs with a potential for broad application, it is important to clearly formulate intended positioning. This must be based on the value proposition provided and must be credible to the medical community on the basis of the evidence provided. The latter can only be successfully achieved through early and implicit consideration of the payer’s value proposition and evidence needs during early stages of drug development.

Given the high stakes of acceptance of drug price and intended use, it is critical to carefully design a communication strategy that is customized to the individual therapy area and drug under consideration.

INVESTMENT DECISIONS

US and international market changes have implications for drug development decisions. Evidence requirements, price potential, and payer coverage

decisions will change the relative attractiveness of individual investment opportunities and will require changes in the marketing investment mix.

- How will the increased emphasis on value demonstration affect choice of new drug development candidates, indication selection, and development program design?
- How will these strategies and considerations affect the revenue and profit contribution forecasts for a drug?
- What prelaunch medical and marketing activities are essential to demonstrate the need for new treatment solutions?

CAREFULLY MONITOR MARKET EVOLUTION

The US prescription drug market is still under rapid development, as ACA implementation is evolving in an emotionally charged political landscape. Therefore, it is critical to carefully monitor the continued evolution of the market:

- Evolution of exchange enrollment statistics and quality of drug coverage for those enrollees.
- Further shift from more drug-friendly employer-sponsored plans to exchanges over time, as employers opt out of employer-sponsored plan offerings.
- Willingness of other commercial plans beyond PBMs to create exclusion lists for new high-cost specialty drugs. Is Sovaldi an exception or a harbinger?
- Data systems that enable improved measurement of outcomes and costs associated with different interventions. These could be helpful, if a drug is delivering good value, or unhelpful, if a drug is shown not to provide much incremental value.
- Technology (eg, apps, websites, tools) that help physicians and patients quickly understand coverage and copay implications for available treatment options.

Conceptually, it is hard to argue that the expansion of coverage to uninsured populations will be a negative for drug manufacturers. However, it is possible that the quality of drug coverage and high OOP costs for newly covered individuals will lead to a relatively lower utilization of branded drugs compared with employer-sponsored plans, and perhaps even relative to Medicare.

Thus, manufacturers will be well served to develop good models that evaluate the payer–provider–patient decision-making dynamic, build stronger value propositions, make well-informed access investment decisions,

communicate more effectively about price and value, and continue to monitor the roll-out of the ACA. Companies that are adjusting to the new realities are likely to be best positioned to take advantage of them.

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