



U.S. Market Access

7 MARKET ACCESS TRENDS FOR 2027

Political, regulatory, and economic issues are transforming market access for the life sciences industry, increasing payer price sensitivity and challenging willingness to pay.

IQVIA examines how current trends and less predictable 'game changing' forces will shape the landscape in 2027 to help you navigate forward.

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INTRODUCTION

The U.S. healthcare market is in a state of continuous flux and uncertainty. Drug costs have generally grown at a slower rate than overall healthcare costs; however, as payers continue to look for ways to manage their overall spend, pharmaceuticals are a clear target. While scientific innovations are revolutionizing the treatment of multiple diseases in ways never before possible, the life sciences industry faces increasing market access pressure.

What will the 2027 U.S. market look like? Here's a snapshot:

- Overall spending on medicines in the U.S. (Wholesale Acquisition Cost) is expected to double from 2015 to 2027 (6.4% CAGR)
- Approximately 20% of the population will be over the age of 65 (compared to 15% today)
- Medicare spending as a percentage of federal budget will increase from 15% to over 18%
- Specialty medicines will exceed 50% of pharmaceutical spending

There are things we cannot predict. The Affordable Care Act currently remains a core part of the framework for U.S. healthcare. Will it eventually be replaced in whole or part by something else? Will the reimbursement and coverage approach for Medicare Part D and Part B change in 10 years? Likely - but crystal balling these changes will only get us so far. In the interim, there are core trends that will define how to engage in today and tomorrow's healthcare market. Industry leaders need to understand the long-term implications of the evolving landscape and take proactive steps to secure their companies' future. This means looking beyond the immediate landscape, and adapting to change in the years to come.

The more things change, the more they stay the same - some trends are merely incrementalism - "more of the same" pressures we have seen over the last 10 years. The old tactics we use today will have to be continually honed and refined. Others will more dramatically shift market engagement. New strategies and new approaches will be required to succeed. In our *7 Market Access Trends for 2027*, we combine internal expertise and IQVIA analytics with insights from industry thought leaders to shift the focus a decade forward.



IDENTIFIED TRENDS FELL INTO TWO CATEGORIES

More of the Same

Game Changers

**TO VIEW A TREND
CLICK ON THE
NUMBERED TILE.**

1

TIGHTER, MORE FRAGMENTED PAYER MANAGEMENT

Pharma will continue to feel the payer grip tighten as management across all brands increases; however, access position will be more mixed than ever.

Managed Care Organizations (MCOs) and Pharmacy Benefit Managers (PBMs) are increasingly utilizing strict management approaches such as NDC blocks, closed formularies, and formulary exclusion policies to manage drugs, including innovative and specialty medicines.

Formulary exclusions are among the most striking of these actions, and 2017 saw this tactic becoming more common. PBMs and health plans were excluding certain prostate cancer drugs from commercial formularies due to contracting and perceived clinical equivalence. Meanwhile, certain branded Chronic Myeloid Leukaemia agents were excluded from select commercial formularies due to the launch of a generic version of Gleevec (imatinib).

While payers will continue to be opportunistic across all therapeutic areas, the old rules will still apply - state mandates that support broader access for oncology

and protections for ongoing patients will hold, but the pressures will be higher. We have already seen “specialty products” become less “special” when it comes to access, and it is likely that “protected classes” will be less protected.

Over the coming decade this trend will result in a greater fragmentation of coverage across states and payer groups, as well as slower uptake of new products (*See Figure*). In order to minimize impact, industry will need to invest more in expert teams who engage earlier; negotiate directly with providers for access; and provide robust evidence of the clinical *and* cost-effectiveness of products.

HIGHER PATIENT OUT OF POCKET PAYMENTS

Solutions are needed as financial pressures on patients mount.

Today, payers are transferring a higher percentage of costs to patients through increased premium, deductibles, and out-of-pocket (OOP) payments. By 2027 the percentage of covered workers enrolled in an HDHP/HRA or HSA-Qualified HDHP could rise to 56% vs. 28% in 2016¹ (See Figure 1). Since 2014, co-pays have risen by more than 14% (See Figure 2) and are likely to continue to rise. Today, the average family has a coverage premium of approximately \$18,000, a figure that is expected to rise to approximately \$25,000 by 2027 (See Figure 3).

Patients fear 'financial toxicity' - a term that has become part of the political dialogue and speaks to the distress patients experience as healthcare costs and OOPs soar. Under the Affordable Care Act (ACA), expanded eligibility for Medicaid, and certain insurance plans, some patients have enjoyed free prescription benefits. However, if the ACA is repealed or replaced with a more fiscally conservative plan, OOP cost growth for patients will be inevitable.

Manufacturers have been working actively to address this issue through co-pay card programs and foundation support - with co-pay card penetration across oral oncology drugs increasing from 2.2% in 2010 to 64.4% in 2016. Between 2014 and 2016, manufacturer co-pay offset across retail brands increased by 32%. But is this sustainable? Industry will not be able to unilaterally fix these system-wide problems or force politicians to legislate. As more co-pay card programs face increasing scrutiny, new approaches will need to be considered. Companies can take a stand on protecting patients by forging new multi-lateral agreements with payers to establish limits to OOP costs for patients, and working directly with patients to disrupt a flawed model.

¹Kaiser Family Foundation and IQVIA analysis

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INCREASE IN VALUE-BASED MODELS

Value moves from buzzword to business model.

We expect a continued increase in value-based payment models and innovative agreements as organizations work to remove regulatory hurdles and companies invest in lowering data and administrative barriers. At the same time, the concept of structured value “frameworks” that lay out rubrics to assess value will also proliferate, but it is unlikely that one model or framework will be preferred and dominate the pricing landscape.

Among the most notable value frameworks currently in use in the U.S. are the Institute for Clinical and Economic Review (ICER) value framework, American Society of Clinical Oncology (ASCO), and National Comprehensive Cancer Network (NCCN). Each of these frameworks has different approaches, criteria, outputs, and target therapeutic areas. Academic, policy group, and patient group value framework approaches have also entered the market.

We expect value frameworks to expand influence and add further complexity to the value landscape

by 2027 (*See Figure*). As an example, in November 2017 ICER received a three-year \$13.9 million grant to expand activities such as reviewing newly approved agents, identifying unjustified price increases, stakeholder engagement, and developing innovative benefit and reimbursement programs. It is still early and details on these initiatives are limited; what is clear, is that the organization will continue to be a player within the value debate.

In the coming years, the concept of value will become part of the fabric of U.S. healthcare. The next step is for “value” to enter clinical decision-making criteria – and we’re already seeing this with the NCCN Guidelines inclusion of Categories of Preference, where cost can be a factor, as well as ACC/AHA commitment to include “cost/value” in guidelines.

Value-based agreements and payment models are also expected to increase as companies, payers, and policy makers align on strategies to address current data and regulatory challenges such as tracking of utilization

by indication, ASP spiral, and Medicaid best price. The entry of cell and gene therapies across multiple disease areas will drive new structures of value based agreements and innovative payment models to capture their unique treatment dynamics and benefit.

As value is seen through the eyes of the stakeholder, even as far as 10 years out there will not be one sole path forward. Industry needs to engage early with the leading value-driven organizations to ensure these models are robust and ensure, not restrict, access to innovative medicines.

4

AMPLIFIED PUBLIC PRESSURE FOR STRICTER PRICING SCRUTINY

Expect the “Name and Shame” approach to continue for drugs perceived as having too high a price, without a clear value story and value communication strategy.

Public pressure on industry regarding U.S. pricing policies has reached a fever pitch, with the issue rooted firmly in the nation’s conversation on healthcare (*See Figure*).

President Trump continues to publicly attack pharma regarding its pricing policies, saying that, “prescription drug prices are out of control.” The actual impact on policy is yet to be determined; however, his administration’s approach to this issue will certainly influence the next four years, with a lasting impact into the next decade.

Companies seen as excessively increasing prices will face increased pressure across all media, particularly social media. New patient groups have formed with a focus on drug pricing and as OOP costs rise, patient advocates are likely to become more vocal and engaged in this discussion.

All new drugs will be pushed to communicate a clear rationale for their pricing and will face scrutiny and pushback from payers, providers, and policymakers. Manufacturers will need to show innovation and differentiation to make a case for higher prices.

5

GREATER PRICE TRANSPARENCY

Regulators are demanding clarity from complexity – and pharma must find a way to adapt.

Currently numerous pieces of legislation are being developed at the state and federal levels to provide drug price transparency and help governments tackle rising healthcare costs. Most notable is the state of California, which passed a drug price transparency law in October, compelling pharma companies to provide 60 days' notice to the state if prices are raised more than 16% over a two-year period – as well as provide reports on how pricing affects healthcare premiums in the state. On the individual state level, the impact of these legislation efforts is minor; however, collectively they signal a swing in the market perspective.

Several other states have either passed legislation or are looking to introduce new legislation. And the calls for transparency are echoed by multiple stakeholders: media, shareholder groups, patient advocacy groups, and consumers (*See Figure 1 and 2*). While industry opposition will be effective in

containing the impact of these measures in the near term, action by state legislatures across the country will continue to accumulate.

There is also growing pressure for greater transparency in relations between pharmaceutical companies, Pharmacy Benefit Managers (PBMs), and health insurers, which will likely reshape not only the payer market, but the entire value chain.

Pharma leaders need to model how this could impact their businesses – and find ways to sustain performance for shareholders.

6

SHIFT AWAY FROM THE DEEP REBATE MODEL

The age of deep rebates will end – requiring a step change in pharma-PBM relations.

The current rebate system provides a platform for payers and manufacturers to differentiate products. However, the system has been broken as value of access is eroding, and manufacturers have been paying more for less. Deep rebates may soon become a volume tactic of the past.

We're already seeing a decrease in the growth of branded product list prices and estimate that while Wholesale Acquisition Cost (WAC) will continue to grow at approximately 8-11% (*See Figure*), net price will grow much slower at only 2-5%². We are already beginning to see brand price increases at 7% YTD compared to 15% two years ago². The average rebate sits around the 33% mark² ranging from 42% for traditional primary care brands to 22% for specialty brands. If list price continues to slow as predicted, we will see this percentage shrink significantly, placing greater strain on negotiation efforts between payers and manufacturers.

A reduced delta between rebate and list price will present a significant challenge for manufacturers in differentiating their products, and limit the ability for negotiations between manufacturers and payers.

To strike a balance moving forward, the industry must find a 'win-win' scenario to both protect margins and the interests of patients.

²IQVIA Institute for Human Data Science

MORE STRINGENT MEDICAL BENEFIT MANAGEMENT

Shifting market forces suggest that Medical Benefit Management – the “Final Frontier” of payer management – will finally be conquered.

Historically, management of the medical benefit has been limited. Driven primarily by physicians, Prior Authorization and PreCert represented the extent of payer management. However, with commercial medical benefit spend increasing 55% since 2011 (compared to Medicare’s 5%)³, as well as the integration of medical and pharmacy benefits, we expect a significant shift in the next 10 years.

Our forecasts predict that by 2020, more than half of all specialty medication spending will be under the medical benefit, and this trend will continue to 2027 and beyond. Payers are taking note and investing heavily in new programs and partnerships: MagellenRX and OptumRX are working on plans to bring more management to medical benefits; Express Scripts acquired eviCore, a company skilled in medical benefit management; and Aetna recently

announced plans to build its own PBM. As these shifts begin to take root in the broader marketplace, we can expect further disruption of Medical Benefit Management.

The implications for the pharma industry are clear: generating outcomes-based data across speciality therapy areas will become critical to minimize downward pressure on prices and commoditization products.

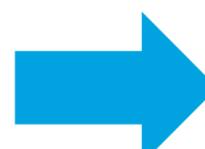
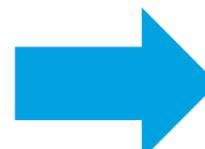
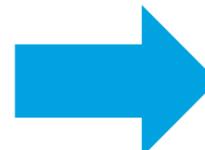
³<http://www.ajpb.com/news/survey-commercial-medical-benefit-spend-jumped-55-in-last-5-years>

SO WHAT NOW? PRACTICE MINDFULNESS AND ADAPT TO CHANGE

While it remains impossible to predict exactly how events and trends will shape the market by 2027, corporate level awareness and preparation will be key to staying competitive over the coming decade. Manufacturers will have to “do more with less.”

The average number of patients per launch brand in the first year has gone from 180,000 in 2007 to 42,000 in 2016. Projecting the same rates, this number will drop to 28,000 by 2027. How will companies succeed in this environment?

Move from “Patient Centric” to “Patient Driven”



MARKETING

- Leverage technology in new ways
- Personalize medicine through digital health

MARKET ACCESS

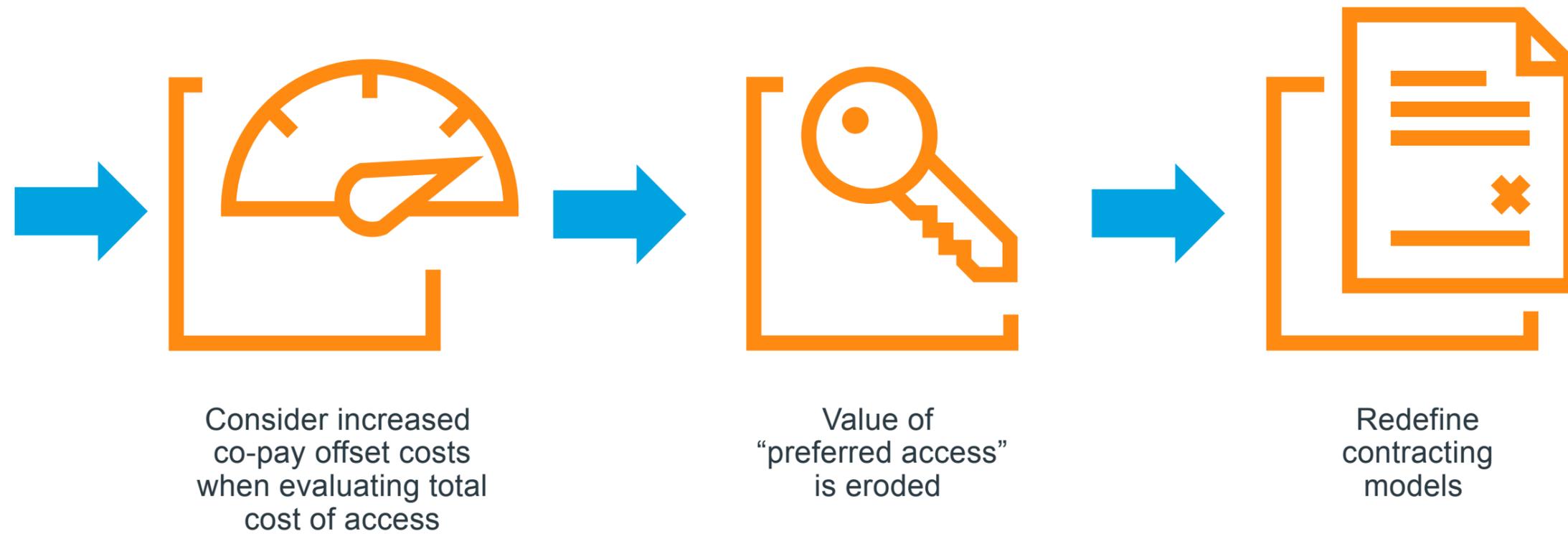
- Treat patients as shoppers
- Engage with payers and influencers
- Gather patient-relevant outcomes

MEDICAL

- FDA considering Patient Affairs office
- Leverage real-world evidence to support value frameworks and shared decision making in the clinical development process

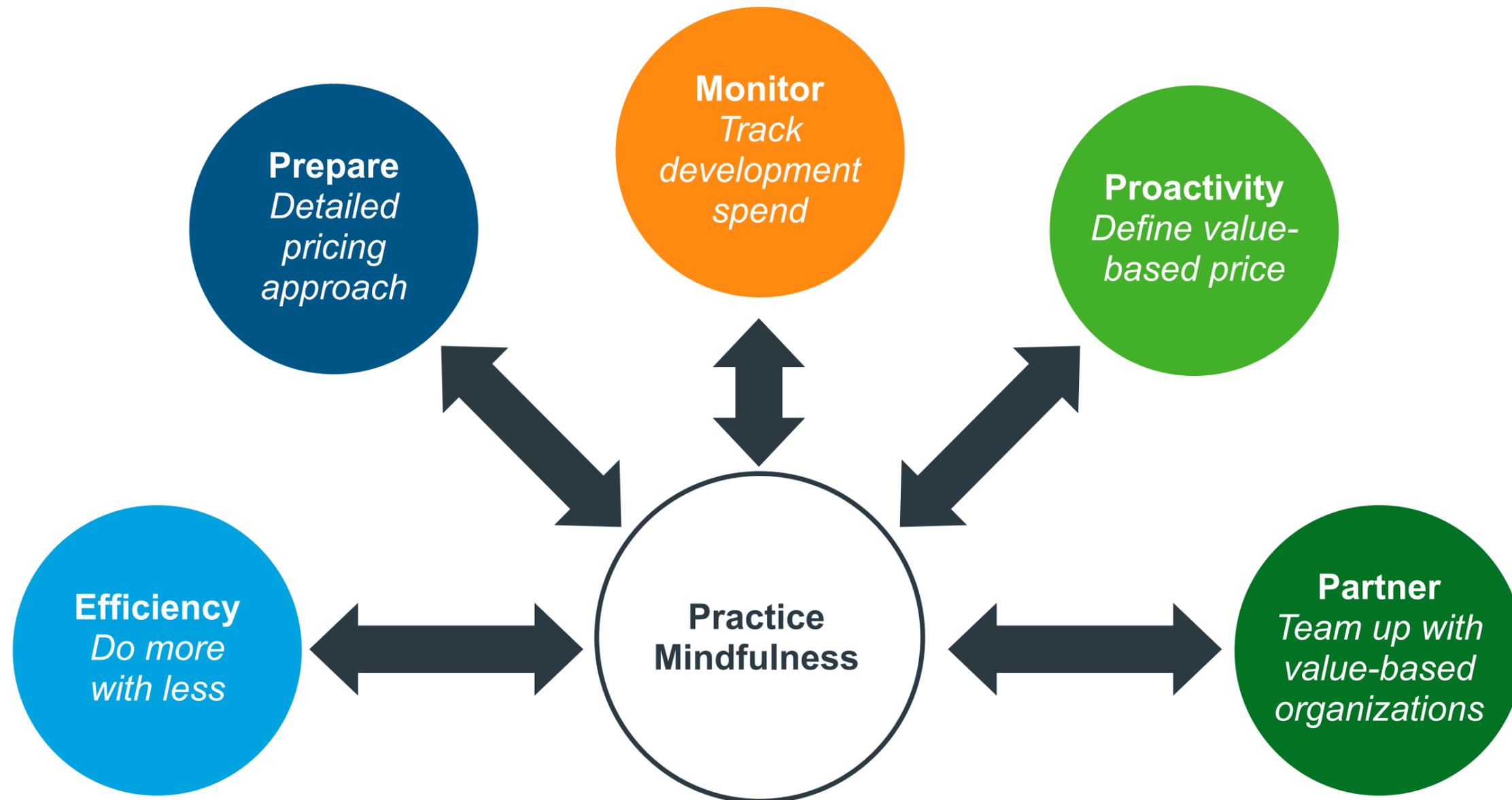
NEXT
IMPLICATION

ACKNOWLEDGE THE NEW (PAYER) DEAL



NEXT
IMPLICATION

WINNING BEHAVIORS FOR 2027



CONCLUSION

The U.S. healthcare market of 2027 will retain many dynamics familiar to us today, but emergent trends such as the shift away from deep rebate models, greater price transparency, and increased management within the medical benefit could all be 'game changers'.

There will also be important technological advances: artificial intelligence (AI) has the potential to streamline drug discovery and disease diagnosis and treatment, while the maturing of genomic profiling will allow the era of precision medicine to truly arrive. In addition, the evolving field of human data science, a combination of deep healthcare expertise and innovative thinking, will empower patients to make more informed decisions and enable improved health outcomes.

All these factors will create a very different relationship between the biopharmaceutical industry, payers, physicians, and patients. The often conflicting challenges facing stakeholders will remain, but new approaches to co-operation and risk-sharing will be vital. In practical terms, this will increasingly depend on mutually beneficial contracts to bring innovative products to patients at reasonable costs and with minimal administrative delays.

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