

TRENDS IN HEALTH CARE REPORT

Disruptors and Opportunities

AM
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Academy of
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Pharmacy

FOUNDATION



Acknowledgments

Development of this report was directed in its entirety by the **Academy of Managed Care Pharmacy (AMCP) Foundation**, and is made possible by the generous support of **Pfizer, Inc.** through the **Patient and Health Impact group**. This collaborative environmental monitoring is designed to identify current trends in health care, and assess potential disruptors that may impact patient care. On behalf and at the direction of the **AMCP Foundation**, research and report development was conducted by **Xcenda**, a unit of **AmerisourceBergen**. Appreciation is extended to the leaders serving on the project's Steering Committee and Advisory Panel (listed on final page of this report).

With growing recognition of the need to integrate medical and pharmaceutical patient care, the findings contained in *Trends in Health Care: Disruptors and Opportunities* are available to the public without charge. This report is intended to serve as a comprehensive resource for managed care organizations, providers, health care payers, policy makers and other stakeholders engaged in patient care and research. First published in Spring 2019, visit www.amcpfoundation.org for updated analysis and programs.

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Introduction

Among the certainties in health care is the constant pace of change and intensity.

With the release of *Trends in Health Care: Disruptors and Opportunities*, the AMCP Foundation examines the speed and extent of health care innovation and system redesign in the delivery of patient services. This report continues our legacy of facilitating the newest research about the evolving health care environment. The report and accompanying resources (Research Symposium, webinars, and more) further contextualize managed care pharmacy's role in advancing patient care, which has been our focus since our founding in 1990. Learn more at www.amcpfoundation.org.

Our objectives in this environmental monitoring centered on a comprehensive study of the factors forcing health system change and their impact on various stakeholders. A significant emphasis was on those factors that have the potential for disruption of health care services, and implications if stakeholders fail to address these trends.

A key priority of this research included reviewing best practices that stakeholder groups have implemented in addressing or reacting to the dominant trends. We also sought to assess environmental, customer, and infrastructure trends, to determine their potential impact, and to identify key variables for consideration. In our research, the AMCP Foundation utilized a hybrid approach that included gathering publicly available information regarding health care trends, as well as collecting insights from thought leaders to identify the challenges, opportunities, and impact to various stakeholders regarding these trends in health care.

The **AMCP Foundation** is proud to partner again with **Pfizer, Inc.** in developing and maintaining this body of knowledge, and pleased to have joined forces with **Xcenda**, our research partner.

METHODOLOGY

First, a targeted review of current academic and trade literature on subjects of interest was conducted to identify potential trends to study. Searches were conducted to obtain relevant sources from the past five years based on keywords related to health care trends and managed care pharmacy. Additionally, websites of key health care organizations, associations, and advocacy groups were reviewed to gather sources. A framework was developed to extract specific elements within the literature search, as shown in **Figure 1**.

FIGURE 1. SPECIFIC ELEMENTS CAPTURED IN THE LITERATURE SEARCH



Over 163 potential sources were identified to provide support to the insights gathered from the other components of this research. **Figure 2** shows the 30 potential trends and areas of interest resulting from the targeted literature review.

FIGURE 2. INITIAL LIST OF TRENDS INCLUDED OVER 30 TOPICS

Affordability and value	Government policy	Patient voice in drug development	Optimal health coverage	Aging population
Mobile health	Diagnostics	Biosimilars	Preventive medicine	Disruptive innovators
Adherence	Expedited drug approval	Plan design	Health crises	Industry consolidation
Transparency	Artificial intelligence (AI)	Gene therapy	Population health management	Health information technology (IT)
Big data	Value-based contracting	Opioid abuse	Pandemics	Delivery system
Care coordination	Privacy	Innovative and curative therapies	Social determinants	Consumerism

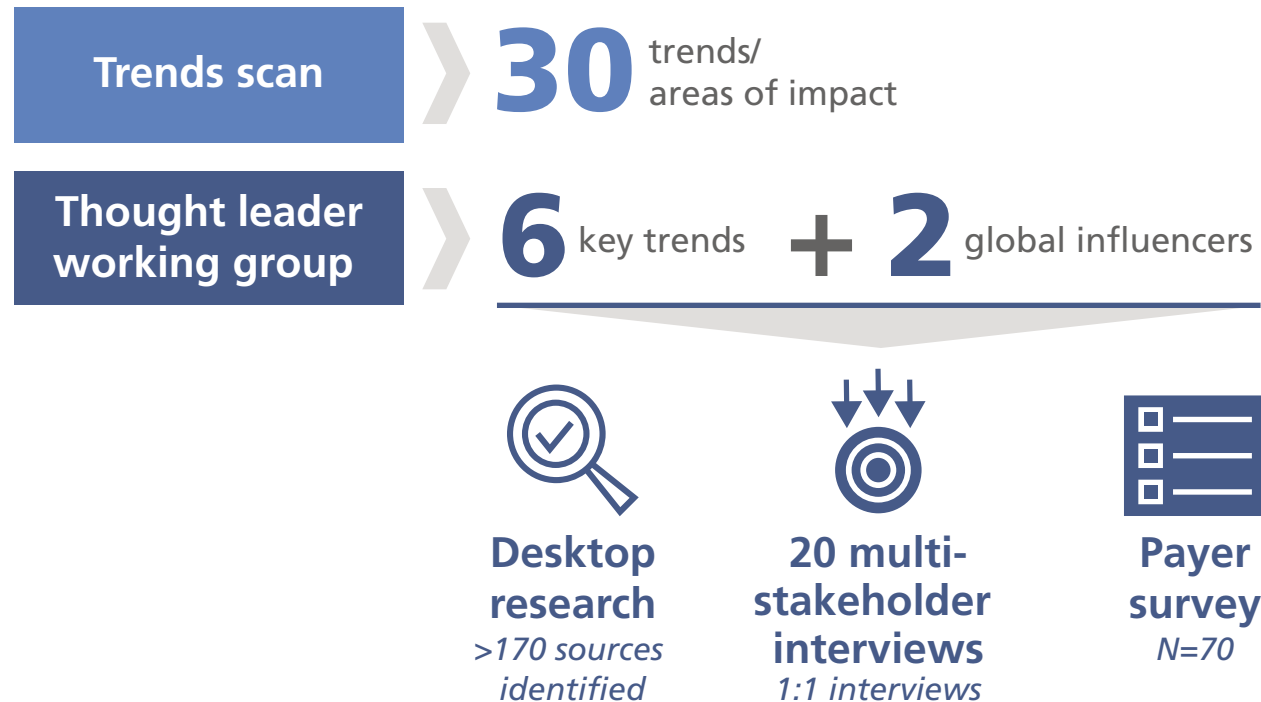
An advisory panel of health care thought leaders was subsequently convened to validate trends from the secondary research, prioritize key areas for focus, and provide insights. The panel consisted of 14 thought leaders with professional and research backgrounds spanning key stakeholder perspectives, as shown in **Figure 3**, including patients, managed care payer organizations, United States (US) government, and care providers. The panel composition ensured well-rounded insights from a variety of critical perspectives (see the final page of this report for a complete listing).

FIGURE 3. THOUGHT LEADER WORKING GROUP CONSISTED OF STAKEHOLDERS FROM A VARIETY OF PERSPECTIVES



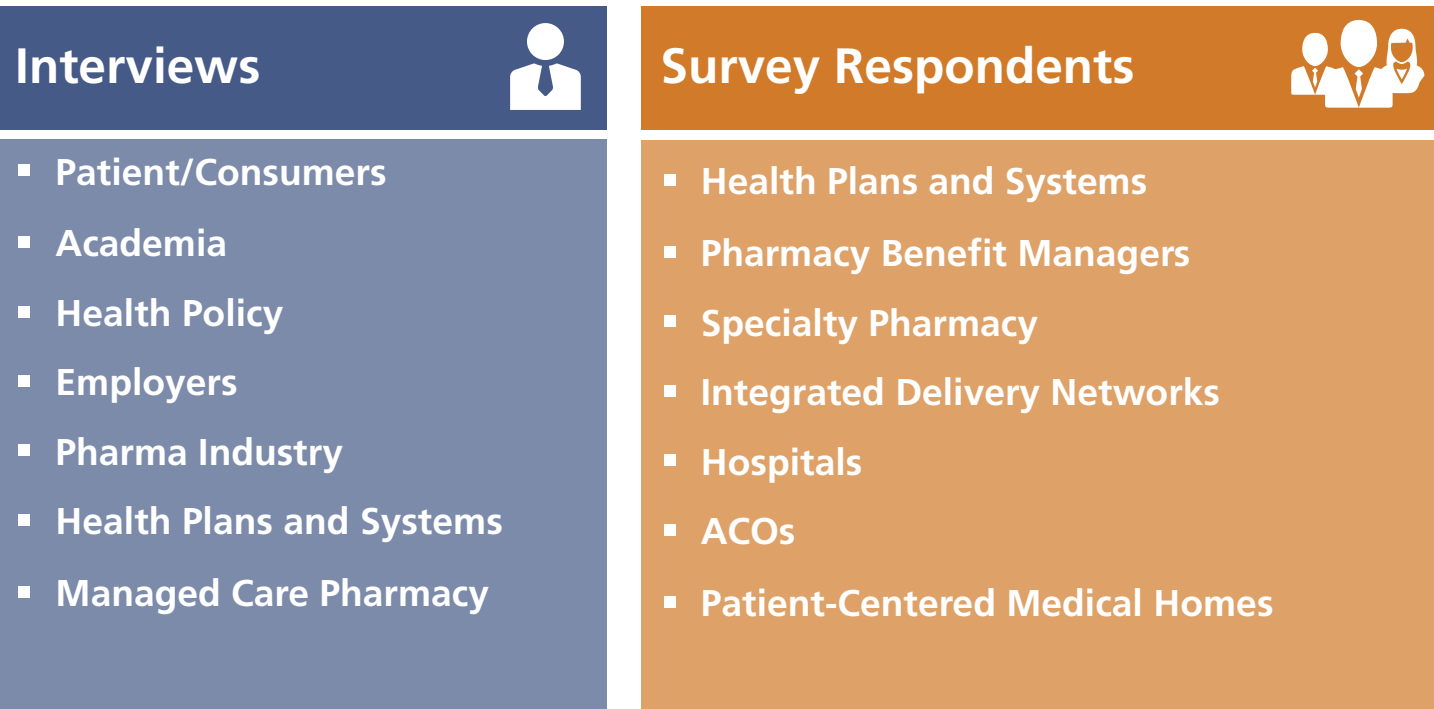
As depicted in **Figure 4**, the topics of focus were narrowed to six key trends along with two “global influencers” that impacted all key trends. Desktop research, 20 multi-stakeholder interviews, and a large payer survey were conducted for additional insights within the six key trends.

FIGURE 4. LIST OF 30 TRENDS NARROWED TO 6 KEY TRENDS PLUS 2 GLOBAL INFLUENCERS



Finally, each of the six key trends were researched in detail through a series of in-depth interviews and a payer survey. One-on-one multi-stakeholder interviews were conducted with 20 thought leaders that represented policy makers, employer groups, advocacy groups, pharmacy schools, health care professional organizations, and managed care pharmacists. To gather insights from a payer perspective and evaluate the motivations behind the trends and the likelihood of change, an online survey was conducted with 70 payer respondents including representatives from health plans, pharmacy benefit managers (PBM), integrated delivery networks, accountable care organizations (ACO), and hospital groups, as shown in **Figure 5**.

FIGURE 5. FURTHER INSIGHTS COLLECTED THROUGH INTERVIEWS AND SURVEYS FROM A VARIETY OF ORGANIZATIONS AND PERSPECTIVES





Trends and Global Influencers

Six trends were defined to capture the most impactful insights.

Innovative and Curative Therapies	<ul style="list-style-type: none">▪ Precision medicine▪ Gene therapy▪ Biosimilars	
Optimal Health Coverage	<ul style="list-style-type: none">▪ Design of health insurance to realize the best value while improving the quality of health care services and employee health	
Affordability and Value	<ul style="list-style-type: none">▪ Cost of health care, including prescription drugs▪ Aggregate spending throughout supply chain	
Industry Consolidation and Integration	<ul style="list-style-type: none">▪ Consolidation defined is simply bringing together two (or more) previously independent entities	
Population Health Management	<ul style="list-style-type: none">▪ Management of specific diseases in certain populations to improve outcomes	
Expedited Drug Approval	<ul style="list-style-type: none">▪ When the FDA deems a drug meets a particular unmet clinical need, it has the flexibility to expedite its review. Four programs offer this flexibility for drugs meeting different qualifying criteria: priority review, accelerated approval, breakthrough therapy, and fast track therapy	

We saw two global influencers acting as forcing factors, exerting pressure across all trends. We decided to analyze the ways each trend was influenced by:

Health IT, AI, big data

- Examples may include mining pharmacy and insurance data, using large data sets for treatment plans, and wearables that collect patient information

Social determinants of health

- Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks

These trends and influencers are discussed in detail in the following pages and online at www.amcpfoundation.org.

TREND #1: INNOVATIVE AND CURATIVE THERAPIES

Trend Overview

Innovative and curative therapies, such as precision medicine, gene therapy, and immunotherapy, have profound possibilities. Advances in science and medicine are enabling an understanding of how disease varies among subpopulations; in fact, many experts believe medicine is entering a period where genetic knowledge can be applied at an individual level.

This decade has already seen dramatic advances unthinkable just 20 years ago, as shown in **Figure 6**.

We will likely see additional breakthroughs in the future, and some may solve dreaded diseases that affect millions of people, such as Alzheimer's disease.

Payers acknowledge the importance of this topic; in our accompanying survey, 88% (N=70) felt innovative and curative therapies would be "extremely/very impactful."

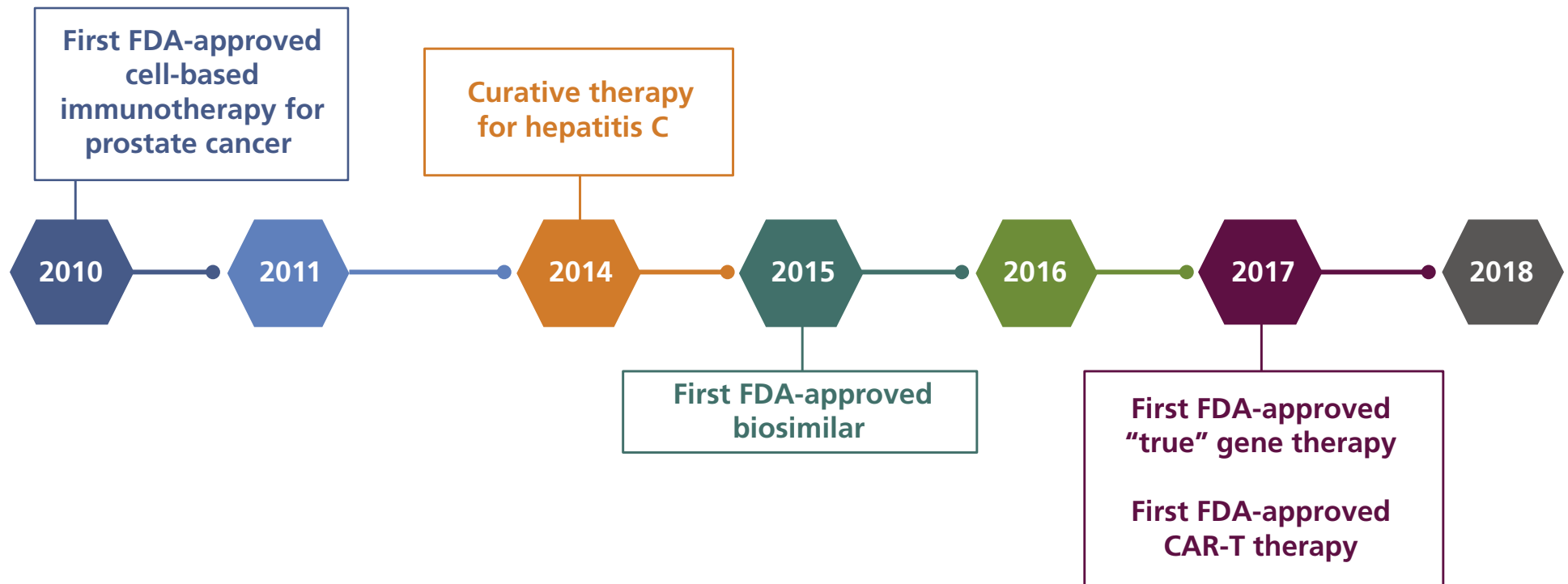
Finally we're entering a period of medicine where we move from the usual visual demographics of race and gender and we begin to understand individuals for who they are and for how their DNA contributes to their health and well-being.

Dean of pharmacy school

There is nothing more important for the future of our citizens and for mankind than to keep working and keep hunting for these elusive cures.

Federal policymaker

FIGURE 6. RECENT INNOVATIVE AND CURATIVE THERAPIES MILESTONES



Challenges

One challenge facing the advancement of innovative and curative therapies is understanding the appropriate populations. While these treatments represent promising advances in medicine, many are complex, only applicable to small patient populations, and have unproven long-term benefits. Additionally, their complexity often involves multiple sites of care and multiple entities within a health system. Ultimately, it will likely require clinicians to explain to patients why they may (or may not) be good candidates for an innovative treatment. Genetic- and algorithm-based decision making is complex, making education essential to help patients make informed health care decisions consistent with their needs.

An intimidating challenge for innovative therapies is their cost and how to potentially amortize the cost over multiple years. We are approaching the point where treatments costing a half-million dollars are not necessarily commonplace, but are being introduced on a regular basis. The potential cost impact to insurers and patients is obvious, and it may be unreasonable to finance these therapies immediately or even over a year particularly given that patients may not stay with the same payer year over year. The pressure that hepatitis C cures placed on state Medicaid programs shows how treating a small population with expensive therapies could pull resources from more common chronic conditions, such as diabetes or congestive heart failure, and drive up overall costs in the current year while saving money in the longer term.

Health system pharmacists are now not only looking at the clinical appropriateness of therapies but also making challenging financial decisions that engage the whole health system.

Opportunities

The enormous cost of these treatments will likely drive the conversation among all stakeholders to discuss how health care is paid for, what the coverage landscape looks like now, and how it should potentially change in the future. Many stakeholders are exploring a wide range of innovative payment mechanisms including outcomes-based contracts and paying for treatment over a long stretch of time—perhaps even over the course of a lifetime.

We can pay for our homes over 30 years, we can pay for a car with a 5-year loan, why can't my insurance company figure out how to spread the cost of this lifesaving or massively life-improving therapy over the course of my lifetime? We've got Star Wars science but Flintstones payment systems.

Federal policymaker

If the system as we know it changes—to discourage investment so that there is no payback for the risks that companies and individuals take [to bring innovation to market]—then [innovation] will potentially dry up, and that's a huge challenge and a huge concern.

Health policy representative

Innovative therapies are fundamentally changing what medicine is.

Health care attorney

Paying for innovative therapies as installments over time may cushion the impact of extremely high-cost therapies to payers and patients. A model in which curative therapies are billed over time—both to the current insurer at the time of treatment and to subsequent insurers—may help spread the burden.

While these innovative therapies are being considered and may require an evolution in current coverage and reimbursement systems, the fact remains that these therapies are still a new concept to the market. Decision making around who to cover, how to cover, and for how long is just starting, necessitating closer collaboration and ongoing conversations among all stakeholders. Payers, biopharmaceutical manufacturers, providers, and patients are having to consider either incremental or holistic changes to current access paradigms.

Innovative therapies are inherently a disruptor to the health care system, as they represent a fundamental shift in what medicine is. In some cases, we are shifting from product-based to service-based medicine. This novel approach will reconfigure our way of delivering medicine and, in some cases, may result in a change for health care stakeholders. For example, traditional retail pharmacies may not play a role in innovative therapies delivered in the inpatient or clinic settings. We are transitioning from an era of one size fits all to a much more personalized approach to health care delivery—with a recognition of the diversity of the disease's nature and response to therapy.

Global Influencers

Social Determinants of Health

As the World Health Organization notes, “Genetic inheritance plays a part in determining lifespan, healthiness, and the likelihood of developing certain illnesses.”¹ As researchers continue to develop amazing insights into our biology, we may eventually get to “personalized social determinants” at the genetic level to better understand underlying factors affecting health.

An example of how social determinants of health can be incorporated into innovative research is Kaiser Permanente’s Research Program on Genes, Environment, and Health (RPGEH). RPGEH is intended to advance research by creating a large databank of genetic and other medical information along with lifestyle, demographic, and environmental data that will be accessible to Kaiser Permanente researchers.² The long-term goal is to identify the genetic and environmental basis for common age-related diseases along with factors that influence healthy aging and longevity.

Health IT, AI, and Big Data

Given technological advances and a reduction in cost, even many low-income patients have access to the internet and smartphones and are able to use them to manage their health. For example, they can easily learn about diet and exercise, and download apps that can track and improve health. This access to information and tools will only improve.

Many clinical trials have longer-than-anticipated enrollment times and uneven data flow; these delays in research have significant time and cost implications. The use of claims data to assess feasibility of clinical-trial design can help predict trial enrollment, and can also screen for drug compliance. Payers own claim data that can immeasurably assist with clinical-trial planning. As health-informatics firm Optum observed:

Insurance claims can locate patients with these [capabilities]:

- 1. Geographical targeting on disease prevalence*
- 2. Investigator profiling with patient counts*
- 3. Physician profiling for referrals, with patient count and distance from sites³*

The pharmaceutical company Janssen has recognized the value of coordinating clinical-trial development with a health insurer. A September 2018 perspective article discussed how Janssen partnered with Aetna's outcomes-research and clinical-development subsidiary Healthagen to identify participants at risk for rheumatoid arthritis who were eligible to be invited to join its study.⁴

TREND #2: OPTIMAL HEALTH COVERAGE

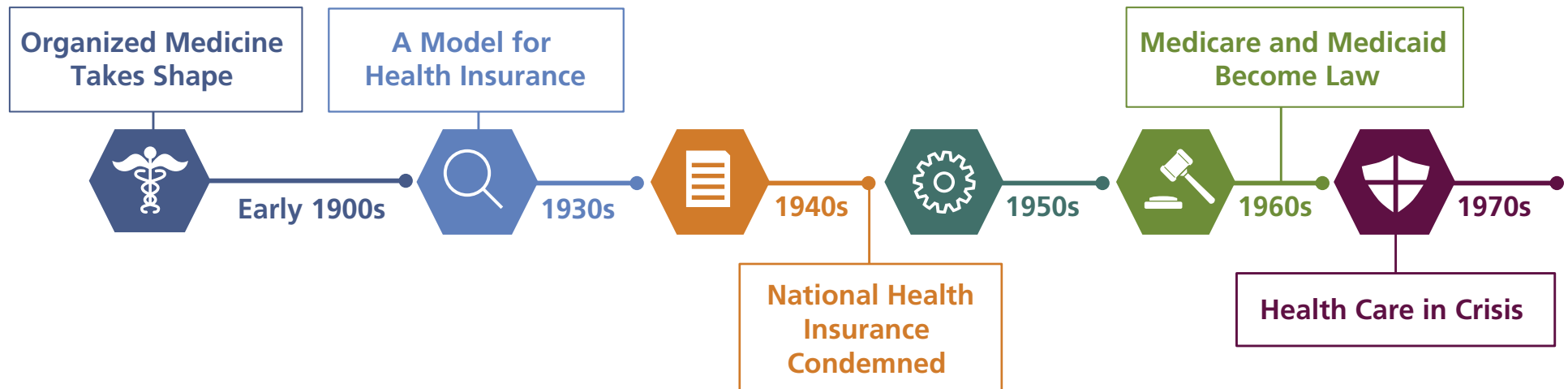
Trend Overview

Health insurance is essential for people of every health status. Costs for treatments and care make it unreasonable to expect people without insurance to build health care costs into their budgets so as to pay for everything out of pocket (OOP).

If a person is healthy, having coverage provides access to a wide range of preventive measures, which offers some protection against the risk of catastrophic illnesses and provides reminders to improve health. If a person is not healthy, coverage is absolutely necessary in order to access treatments and services.

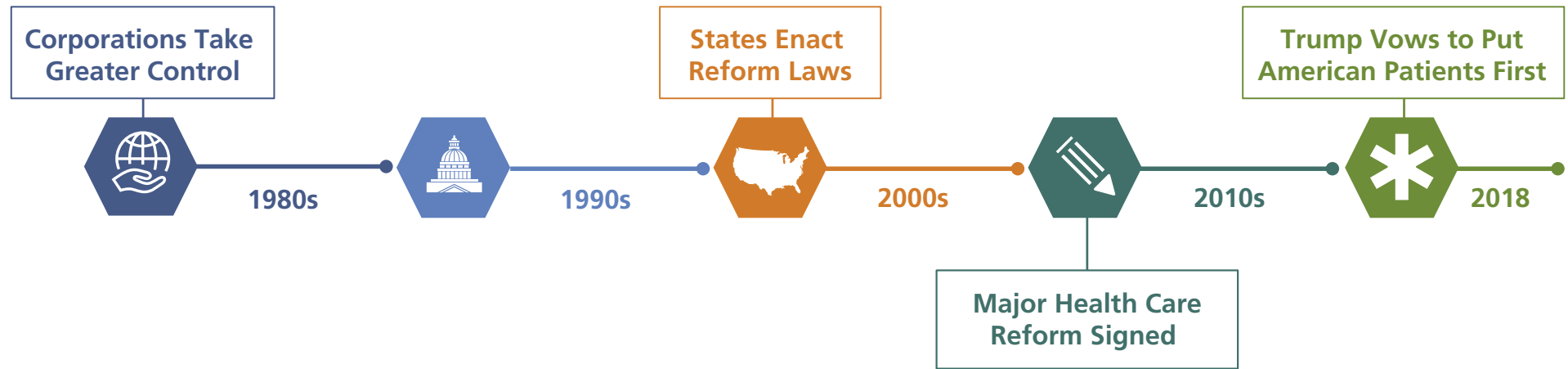
Figure 7 and **Figure 8** show the complicated history of the US health care landscape; it developed in fits and starts as emerging needs were bolted on to the existing structure. Coupled with the American belief in the private sector, it is unlike other health care systems around the world, many of which are more centrally planned and typically operated by the government.

FIGURE 7. THE COMPLICATED US HEALTH CARE EVOLUTION, 1900s TO 1970s



Starting in the 1980s, health care costs started to increase dramatically with the uptick in innovations coupled with an increase in costs, which triggered reform efforts that continue to this day.

FIGURE 8. THE COMPLICATED US HEALTH CARE EVOLUTION, 1980s TO PRESENT DAY



Despite several sweeping reforms and regularly tweaking health care, the system's costs are still on a trajectory without tangible progress made to restrain them. Steps to deal with rising costs are complicated by efforts to ensure as many people as possible have access to quality health care.

Challenges

The central challenge of accessing health coverage is affordability. According to the Kaiser Family Foundation's 2018 Employer Health Benefits Survey, the average annual premiums in 2018 are \$6,896 for single coverage and \$19,616 for family coverage.⁵ The average family premium has increased 55% since 2008 and 20% since 2013.

The high cost of health insurance is complicated by the variability among employer health plans, Medicare, Medicaid, Veterans Affairs, and other insurers.

Despite the gains in coverage due to the Affordable Care Act (ACA), the Commonwealth Fund has noted these gains are beginning to reverse due to 2 major factors⁶:

1. *Lack of federal legislative actions to improve specific weaknesses in the ACA*
2. *Actions by the current administration that have exacerbated those weaknesses*

Such actions “include the administration’s deep cuts in advertising and outreach during the marketplace open enrollment periods, a shorter open enrollment period, and other actions that collectively may have left people with a general sense of confusion about the status of the law.” Indeed, as shown in **Figure 9**, Kaiser Family Foundation data for enrollment in ACA exchange plans from 2014 to 2018 shows enrollment enjoying healthy growth from 2014 to 2016, and then drifting down in 2017 and 2018.⁷

In the accompanying survey of payers (N=70), three reasons dominated their challenges to optimal health coverage, as shown in **Figure 10**:

1. *Overarching lack of collective responsibility among stakeholders*
2. *Health care financing based on a 12-month cycle*
3. *Underlying fee-for-service system*

Another challenge for health care coverage is ideological. The debate over the role of government in health care is polarizing. Many Republican voters still retain hostility for “Obamacare,” while a growing portion of Americans believe health care is a right and insist major reform is needed to address inequities in access and treatments. Given such a stark divide, it will be difficult to agree on the balance of cost vs benefits.

This is an extremely challenging pursuit considering all of the variables attributed to genetic profile, age, gender, race, financial status, education, access to health care delivery channels, and environmental influences. Can a model successfully address all of these variables to create an informed, affordable, and unbiased delivery mechanism?

PBM representative

I just don't think there is the political will to change the current model that much. I know that the system is frayed, but I don't think it's broken enough to where you're going to see some dramatic changes. I'm not optimistic that legislatively we'll come up with something that's completely different, but there could be some free-market solutions brought to bear that could disrupt enough to transform.

Patient advocate

Opportunities

In 2017, most people (91.2%) had health insurance coverage at some point during the calendar year. More people had private health insurance (67.2%) than government coverage (37.7%).⁸ As shown in **Figure 11**, employer-based insurance was the most common subtype of health insurance in the civilian, noninstitutionalized population (56.0%), followed by Medicaid (19.3%), Medicare (17.2%), direct-purchase insurance (16.0%), and military health care (4.8%).

FIGURE 9. AFFORDABLE CARE ACT EXCHANGE ENROLLMENT, 2014 TO 2018

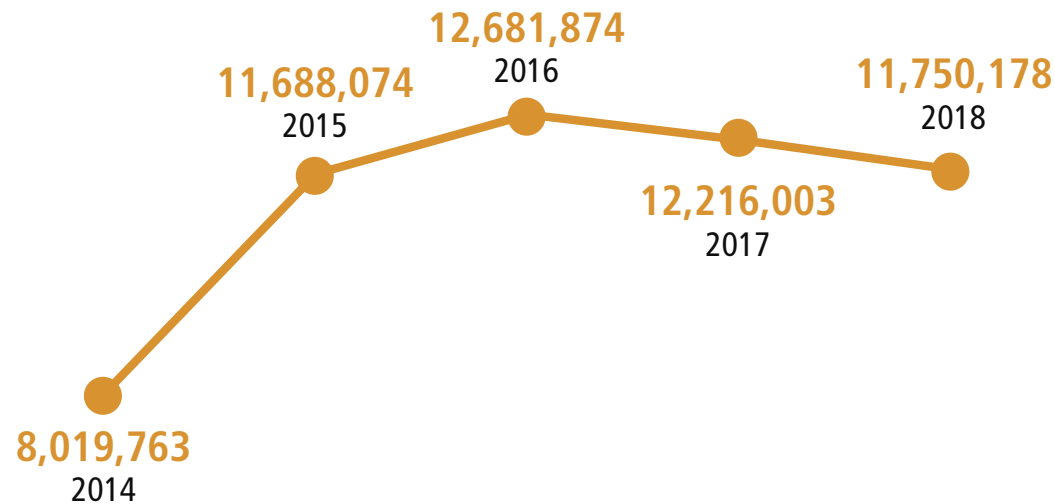


FIGURE 10. PAYERS IDENTIFY MAJOR CHALLENGES TO OPTIMAL HEALTH COVERAGE

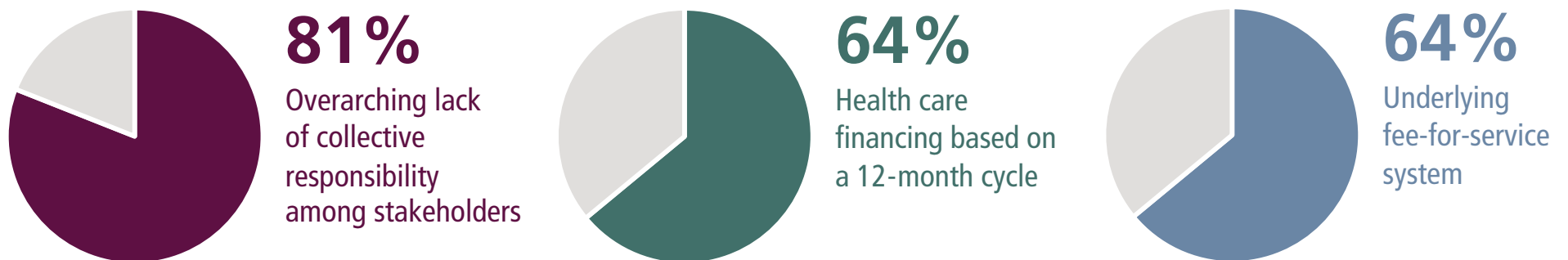
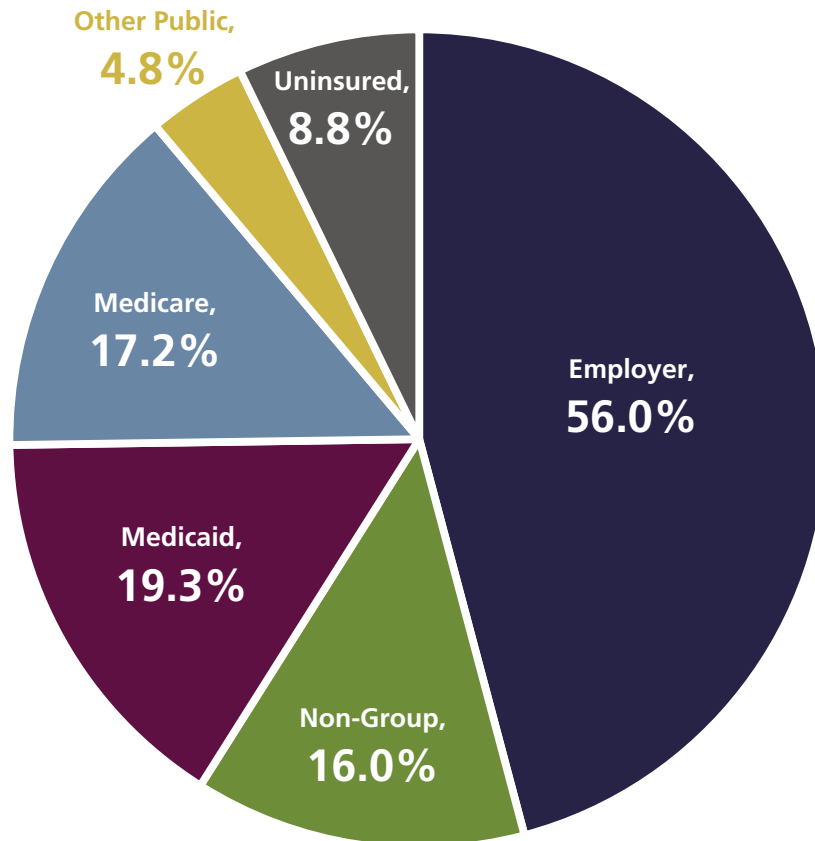


FIGURE 11. HEALTH INSURANCE COVERAGE OF THE UNITED STATES, 2017*



*Some people may have more than one coverage type during the calendar year.

Despite the successes of the ACA, which extended coverage to 20 million Americans, a Gallup-Sharecare study estimated 12.2% of US adults (approximately 27 million) remained uninsured as of the end of 2017,⁹ and many more were unhappy with their coverage. The percentage of uninsured increased 1.3% from 2016 to 2017, which was the largest single-year increase Gallup and Sharecare measured since beginning to track the rate in 2008, including the period before the ACA went into effect. The 1.3% increase represented an estimated 3.2 million Americans who entered the ranks of the uninsured in 2017.

There remains tremendous opportunity to extend coverage to millions of Americans. Adopting Medicaid expansion in the remaining 14 states would certainly put a dent in the uninsured rate, as would enacting legislative measures to ease the cost of exchange plans to those not qualifying for federal subsidies.

With the Democrats winning control of the House of Representatives in November 2018, there will be no efforts to repeal the ACA until 2021, at the earliest. That would require Republicans to win back control of the House, retain control of the Senate, and to have a Republican-elected President.

However, by 2021, the ACA will likely be too embedded in the country's health care infrastructure to be repealed. Conversely, should the Republicans regain control in 2020, they may make another effort to repeal or modify the ACA, especially through the reconciliation process, which only needs a simple majority to pass.

Should a Democrat be elected President in November 2020, the health policy agenda is likely to be focused on identifying and shrinking the gaps in coverage under the ACA. “Medicare for All” and single-payer models have captured a lot of attention among progressives and appear to be gaining favor. The Pew Research Center found in January 2017 that 60% of Americans felt the government should be responsible for ensuring health care coverage for all Americans, an increase from 51% in 2016 and the highest point in nearly a decade.¹⁰ However, opposition among Republicans, centrists, and moderates is stout enough that such transformation is unlikely.

An October 2018 survey of 3,412 physicians found more than half were planning to retire in the next five years, with electronic health records and regulations the leading causes of burnout.¹¹ Such an atmosphere is breeding grounds for change, such as more physicians pursuing concierge care. There are no registries of physicians practicing concierge care, but industry experts and observers indicate that growth is between 3% to 6% each year, with specialty physician participation on the rise.¹²

On the other hand, smaller-scale, market-based efforts may proliferate and become more mainstream, such as “direct-to-consumer” approaches by physicians and hospitals. Adventist Health began delivering health care services to Whole Foods’ employees in Southern California.¹³ The partnership, in which Whole Foods bypassed insurance companies and negotiated directly for services from Roseville, Calif.-based Adventist, gave the organic supermarket chain access to a tailor-made health plan that it couldn’t get from the traditional insurance market. The 19-hospital system used the experience to scale the care-navigation expertise it developed for its Medicare ACO. Additionally, the continuing growth of walk-in community clinics, like those offered in retail pharmacies, continue to be popular and in many cases are an acceptable care option vs insurance for millennials and others.

The National Business Group on Health reported in August 2018 that direct contracting with health systems and providers is expanding, from 3% in 2018 to 11% in 2019.¹⁴ Large, self-insured companies using this approach include Boeing, Walmart, Lowe’s,¹⁵ and General Motors (just announced in August 2018).¹⁶

Direct contracting could expand as health systems acquire more hospitals and practices, especially across geographic areas, creating closed-loop systems and ACOs that may aggregate sufficient patient volume to be able to absorb risk.

Given that the country is split almost evenly along partisan lines, it is doubtful Congress will legislate full-scale coverage reforms in the near- to medium-term future. Much more likely are experiments and changes on the margins, such as direct contracting, that may propagate through the country should they prove successful.

Global Influencers

Social Determinants of Health

According to the American Hospital Association, socioeconomic factors are responsible for approximately 40% of a patient's health, while just 20% is tied to access and quality of care.¹⁷ As a result, knowing nonmedical information about patients, such as where they live, their income, education level, job status, and other social determinants is crucial to improving their health and lowering health care costs. The negative impacts of social determinants become magnified for low-wage workers and those who do not receive benefits through their employer.

Improving social determinants of health offers twofold benefits for insurance companies:

- 1. Their members get healthier, and*
- 2. Their businesses become stronger with fewer claims to pay*

Granted, insurance companies that are separate from providers will have a harder time developing interventions to impact members' lives. Insurers, however, that share an ecosystem with providers, such as ACOs and integrated health systems, are able to invest more in prevention and in the constituents that comprise 40% of patients' health outside of medical care.

For example, within the last 18 months Kaiser Permanente, the country's largest integrated health system, announced a \$200 million investment to prevent displacement or homelessness of lower- and middle-income households in rapidly changing communities; reducing homelessness by ensuring access to supportive housing; and making affordable homes healthier and more environmentally sound.¹⁸

Also, in 2018, health insurer UnitedHealthcare announced a \$35 million investment in four new affordable-housing communities in Michigan to improve access to affordable housing for individuals and families with the greatest needs.¹⁹

Poor health care literacy also remains a problem, especially when a lack of understanding of the advantages and disadvantages of insurance types can lead to selecting a plan that runs counter to a patient's best interest. For example, a patient with several chronic conditions or one who is on expensive pharmacotherapy may not want to select a high-deductible health plan, as they may forego appropriate health care treatments due to their cost and, consequently, have an exacerbation of their disease. Other patients may select an exchange plan with low premiums, not realizing that high deductibles and copays usually accompany low premiums.

Health IT, AI, and Big Data

Payers are in a unique position in the health care continuum allowing them to identify, and then drive utilization of, high-value products. The usage of health IT, AI, and big data facilitates this natural advantage.

Health insurers possess robust claims databases that are of inestimable value to evaluate medical and pharmacy trends, assess and improve benefit design, and observe outcomes. Those insurers that are integrated with medical practices and/or hospital systems have the additional advantage of linking their claims data with health and medical records for additional insights.

The Office of the National Coordinator for Health Information Technology (ONC) is an enormously influential entity, and serves as a resource to the entire health system. Its primary purposes are to support the adoption of health IT and to promote nationwide health information exchange to improve health care.

The ONC is currently engaged in the following initiatives:

Improving the interoperability of health IT

Advancing the access, exchange, and use of health information

Challenging the health IT industry to facilitate consumers' abilities to determine when and how to share their health information

Leveraging health IT to combat the nation's opioid crisis

Communicating complex health IT concepts to the public

The ONC has already improved the flow of health information. For example, as a result of rules it promulgated regarding electronic health records, the majority of health care providers have created patient portals, allowing patients to easily see their data, as well as pay bills online.

Currently, there is great focus on the use of blockchain in health care. Blockchain enables participants in a group to securely share data with each other without a middleman and to track what was exchanged and when. Importantly, the transactions are recorded on multiple computers, shrinking the ability for tampering.

Blockchain could dramatically improve the ability of different providers to share patient information, which could improve outcomes and reduce adverse interactions. Additionally, providers and insurers could potentially track the progress of a claim through the system, allowing them to correct errors that would reduce delays and minimize incorrect payments. In addition to securing medical records, blockchain could help the pharmaceutical supply chain ensure the integrity of products and enable insurers to maintain current provider directories.

TREND #3: AFFORDABILITY AND VALUE

Trend Overview

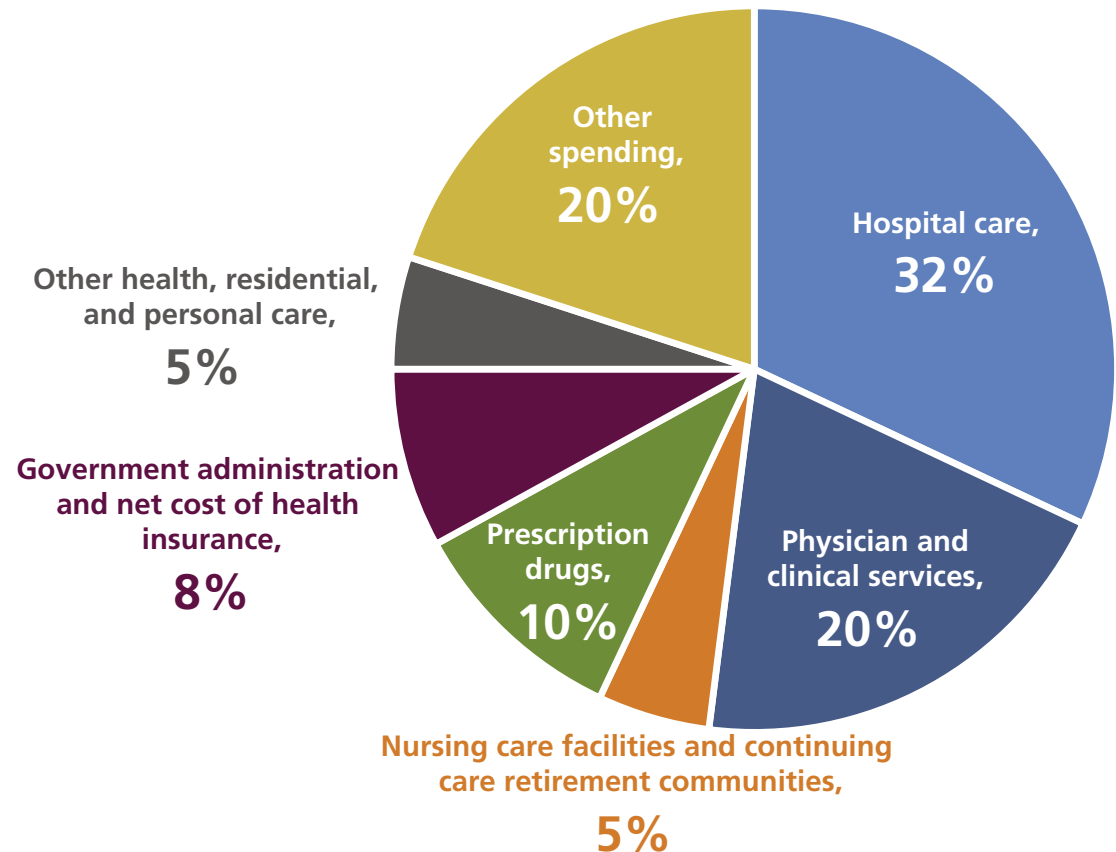
Drug spending and OOP costs are top of mind for many Americans. People who live in the US spend more on prescriptions than any other high-income country.²⁰ A May 2018 study reported that total US spending on prescription drugs—including those administered in retail and non-retail settings—in 2016 was \$471 billion, or almost \$1,500 per person.²¹ Total spending on prescription drugs as a share of national health expenditures (NHE) in 2016 was 14.1% and is expected to grow to 15.4% by 2026. The media has focused a great deal of attention around rising costs, with state and federal elected officials also proposing laws to rein in drug prices.

Drug Spend Remains a Small Component While Providing Significant Value

While drug spending is increasing, retail prescription spending still represents only a small fraction of NHE, as illustrated in **Figure 12**.²² Prescription drugs, however, serve as a highly visible component of health care spending, especially with more innovative and curative therapies entering the market, and some stakeholders argue that it is easier to implement policies to reduce drug prices than to radically adjust other benefit categories.

A fact sheet by the Pew Charitable Trusts shows prescription-drug spending holding steady as a percentage of health expenditures during the 2010 to 2020 time frame, as shown in **Figure 13**.²³ Prescription drugs remain an excellent value for the health care system. In fact, a couple of advisors to this study commented that an increase in drug spend (for the right reasons) is not a bad investment.

FIGURE 12. HEALTH SPENDING BY SERVICE OR PRODUCT, 2017*



* "Other spending" includes dental services, other professional services, home health care, durable medical equipment, other non-durable medical products, government public health activities, and investment.

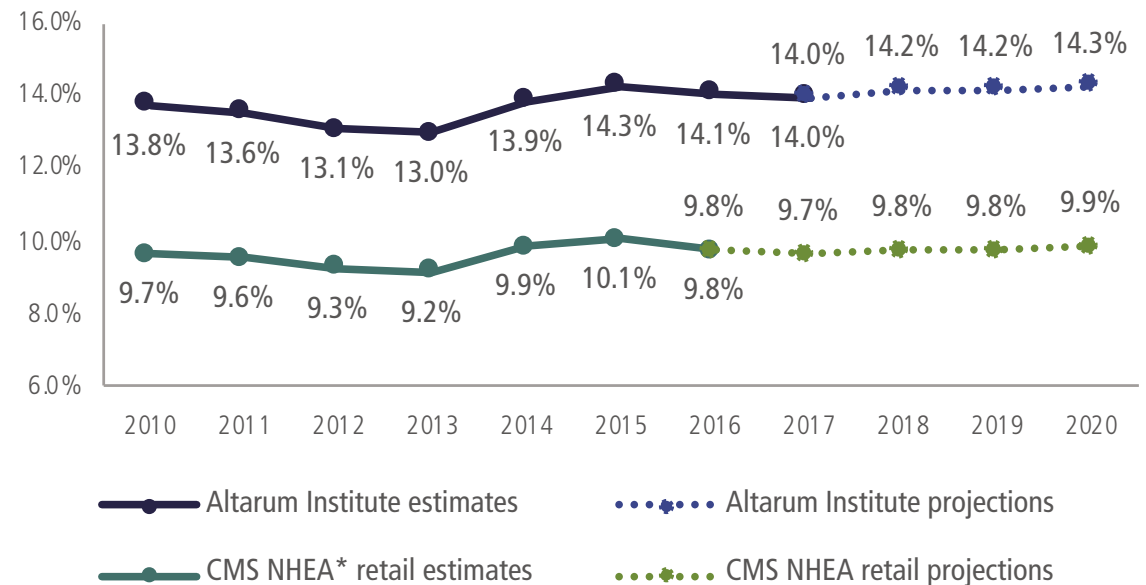
A more holistic discussion of the health care system may lead to broader discussions of the difficult choices to be made regarding the affordability of health care and the tradeoffs around costs and benefits. As US health care continues its transition to a value-based system, there will be greater insistence that biopharmaceutical manufacturers demonstrate the value their products bring.

It is difficult to see potential paths forward in the short term, given historical rising costs. President Trump's American Patients First blueprint is an attempt to "bring down the high price of drugs and reduce OOP costs for the American consumer."²⁴ The Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services have proposed an "International Pricing Index" model that would tie the prices of certain Medicare Part B prescription drugs in the US to prices paid by a basket of foreign countries, in addition to other reimbursement adjustments for those drugs in the Medicare Part B program.²⁵ The President and HHS Secretary Alex Azar have made clear that more substantial changes are on the way, although legislative and public-opinion hurdles may thwart them. The next couple of years may see large-scale reforms in the drug-pricing system...or the established system may prove too intractable, potentially forcing even more radical changes down the road.

“Even at a high list price, [hepatitis C drugs] are still a better deal than paying for liver surgery, advanced care, and medications that weren’t working. If you’re making it harder for patients to get access in the short term, you’re robbing Peter to pay Paul. And you’re paying Paul a lot more over time as a result.”

Patient advocate

FIGURE 13. PRESCRIPTION DRUGS AS A SHARE OF NHE, 2010–2020



*National Health Expenditure Accounts

Challenges

The evolution of insurance benefit design, where more financial burden is being shifted to patients, has meant that many consumers are more aware (and sensitive) to the price of drugs. When a patient pays for prescriptions under the copayment model, the drug's list price matters less. For patients obtaining prescriptions under a **coinsurance** model, however, a drug's price has immediate, direct impact on the OOP costs for patients. These are not isolated incidents, either. The Kaiser Family Foundation reported that, in 2018, among covered workers in a plan with a separate tier for specialty drugs, 59% have a coinsurance, and the average coinsurance rate is 26%.²⁶

59%

of workers in a plan with a separate tier for specialty drugs have coinsurance

26%

average coinsurance rate

Drug spending has a disproportionately large impact on patients taking expensive medications on a regular basis to manage chronic conditions. If they have difficulty affording their drugs, the likelihood they will forego filling one or more prescriptions skyrockets, leading to the negative consequences that noncompliance and nonadherence bring.

“

We can't afford to pay for all the innovation that's about to come down the pike. We just don't have the money to do it. And that means there are some very difficult choices and tradeoffs that have to be made. And those tradeoffs get to really deep and challenging issues. One reason drug pricing and spending is so important is because it forces America to finally confront the fact that everybody cannot have everything all the time.

”

Health policy consultant

“

I'm cynical because...for example, as a drug patent nears expiration, the price increases because the manufacturer has got to squeeze as much profit out of that product as possible. On the specialty side, biosimilars are not going to be priced like generics are in the small-molecule market. There's no cost-reduction calming.

”

Employer benefits consultant

Another challenge is the lack of transparency and awareness around drug pricing. Unlike many other countries, the US does not regulate drug prices, and companies have more flexibility in setting prices than elsewhere. With patients paying about 14% of prescription costs OOP,²⁷ they are directly affected by the list price of the product, but often have no line of sight to the original list price or advance awareness of OOP costs. This complexity, along with discounts and rebates, may be misaligning incentives—such as deciding which drug offers the most value—that contribute to pharmaceutical and health care spending growth.

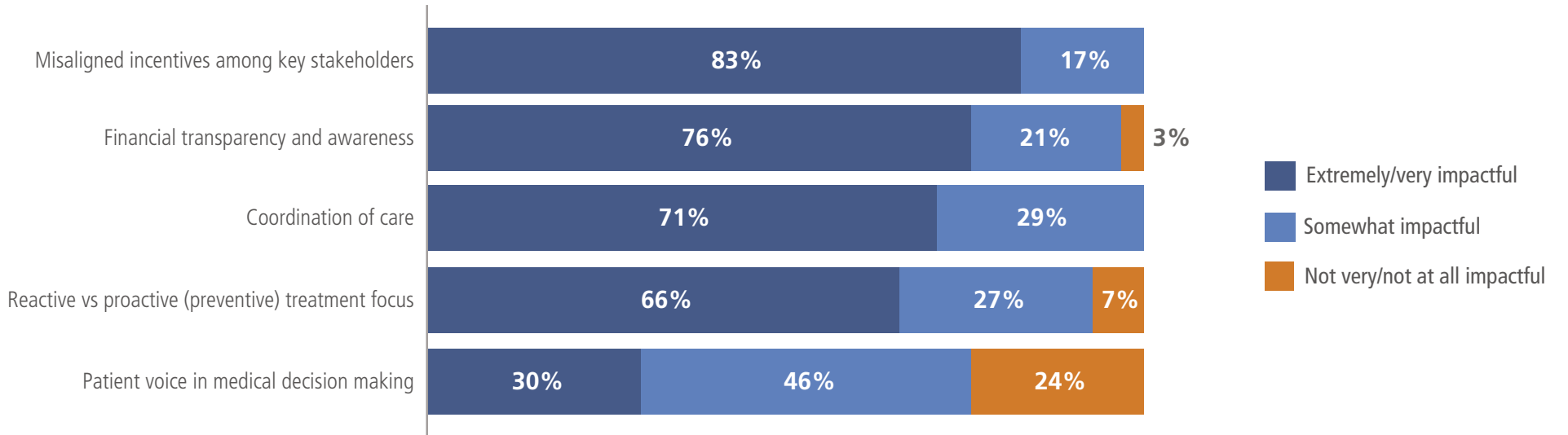
Reining in Drug Spend

Our multi-stakeholder thought leaders described a few main categories impacting our ability to rein in drug spending; therefore, we solicited managed care’s perspective on which of these factors are most impactful, the results of which are shown in **Figure 14**.

In the survey accompanying this issue brief, 83% of respondents felt misaligned incentives among key stakeholders were highly or extremely impactful to drug spending. The chain of health care delivery and payment is so fragmented that incentives can be skewed across the stakeholders.

The lack of pricing transparency was ranked highly as a barrier to addressing drug spending and pricing. Helping patients identify and understand the costs associated with different treatment options (not just via the payer but throughout the health care system) would allow them to make more informed, cost-conscious decisions.

FIGURE 14. IMPACT RANKING OF KEY FACTORS DRIVING DRUG SPEND (PAYER PERSPECTIVE)*



* Question: How impactful are each of the following elements of drug spending? (N=70)

Several thought leaders commented on preventive care potentially having the most impact—not only on drug costs, but also on overall health care costs. The literature indicates the cost-saving relationship of prevention is not so clear-cut; rather, it is quite nuanced.²⁸

Opportunities

Scott Gottlieb, the Commissioner of the Food and Drug Administration (FDA) from 2017 to 2019, introduced a Drug Competition Action Plan to encourage generic drug development and speed them to market.²⁹ His efforts are bearing fruit: in July 2018, the FDA approved or tentatively approved a record 126 generic drugs.³⁰

As highlighted in President Trump's *American Patients First* 2018 blueprint, insurers do not pay list prices for drugs when they negotiate with manufacturers for discounts and rebates.²⁴ However, coinsurance amounts have historically been based on list prices, so patients do not benefit from the mass purchasing power held by their insurers or PBMs. A few insurers have announced changes to that practice since the blueprint was released. The consequential impact to premiums to offset the direct rebate/discount applied at the point of sale could be sizable.

In addition, several organizations are experimenting with the value-based insurance design model which, by aligning OOP costs with the drug's clinical value, offers an opportunity to lower drug spending for patients. Instead of linking a patient's OOP cost to the cost of the drug or health care service under the current system, the patient's OOP cost is linked to the clinical value of the item or service. High-value interventions—those that significantly increase health—would have low patient cost-sharing.

Another opportunity rests with large retail companies possessing a strong infrastructure that could evolve our disconnected, opaque system to be more transparent and nimbler. A retailer like Amazon could compete on both cost and convenience, offering challenges to local pharmacies and even large chain pharmacies. Some large retailers are particularly adept at optimal consumer engagement, which would play well in the health care sector. However, there is still healthy skepticism about how non-health care companies will be able to navigate the highly regulated and complex industry of pharmaceuticals to lower costs.

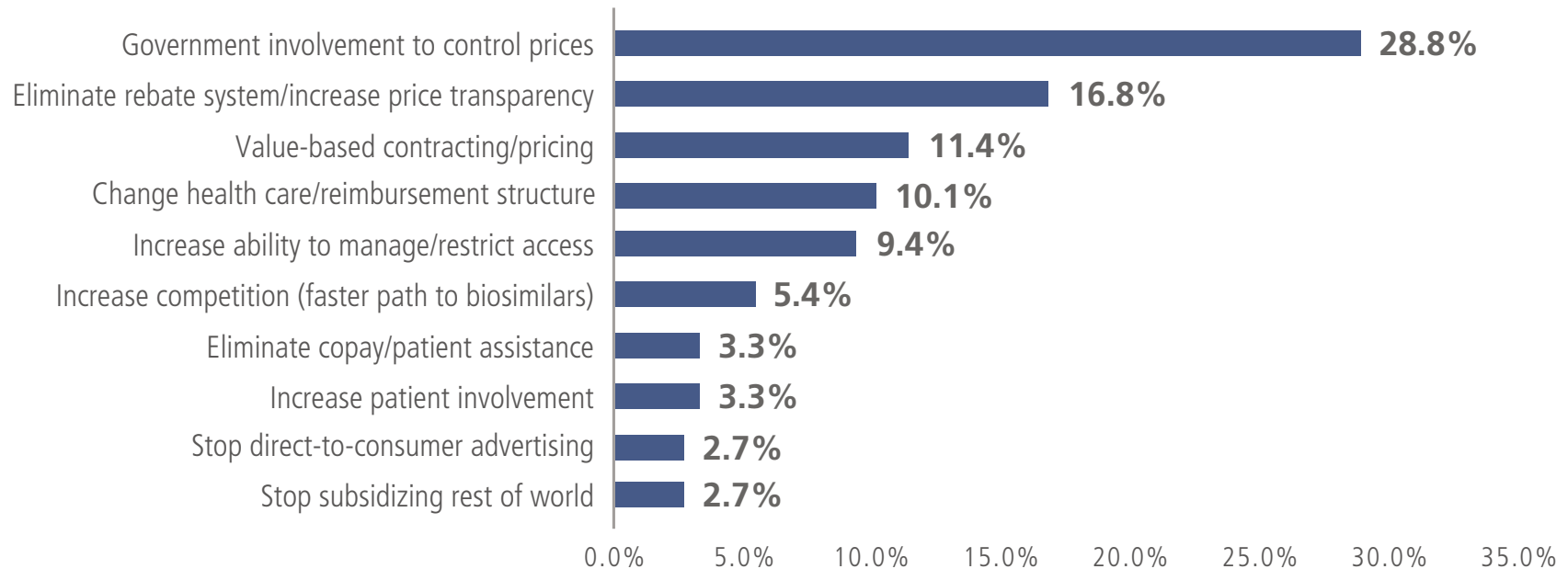
It is true there is a lack of transparency in drug pricing, but the entire system is guilty. Patients have the opportunity to see the price of a retail prescription before they purchase it. Patients can, and sometimes do, refuse prescriptions at pharmacies; this opportunity differs from the consumption of medical services, where most patients do not know the actual cost until they receive a bill. Transparency, not just in drugs, but the entire system, needs to be a priority to help patients make informed health care decisions.

Pressure to Address Drug Pricing

There is an overwhelming sense of urgency to address aspects of drug pricing, according to our survey of 70 payer decision makers. Eighty-seven percent of respondents stated it was an issue that need to be addressed in the near term.

We asked our payer decision makers to provide potential solutions; their responses are in **Figure 15**. Almost one-third suggested some form of government intervention, including having the government negotiate prices for the system and evaluating drug pricing in a similar fashion as the United Kingdom (UK) and German systems. Another sizable group favored increasing price transparency by eliminating the rebate system.

FIGURE 15. PROPOSED SOLUTIONS TO HIGH DRUG PRICING (OPEN-ENDED RESPONSES, PAYER PERSPECTIVE)*



* 6.1% of responses were categorized as "other" because they didn't have $\geq 2\%$ of mentions. N=149 responses collated.
Question: Please list any other possible solutions to addressing drug pricing and spending issues.

Incorporating measures such as quality-adjusted life-years (QALY) to establish a value threshold, as with the UK and German systems, may be gaining a foothold. CVS Caremark, the country's largest PBM, announced in August 2018 it is initiating a program that will allow their clients to exclude any drug launched at a price of greater than \$100,000 per QALY from their plan.³¹ CVS Caremark will rely on the Institute for Clinical and Economic Review to determine the QALY ratio.

The Trump Administration blueprint placed a spotlight on the rebate system—not only obfuscating drug pricing via a lack of transparency, but also increasing patient costs, as patient's coinsurance amounts are based on pre-negotiated list prices.

Paying for Expensive Drugs

Reflecting the shift of stakeholders to move health care away from a volume-based to a value-based system, several respondents also emphasized value-based contracting and pricing and value-based insurance design as efforts that would align incentives better and increase plans' abilities to manage or restrict access to low-value interventions.

The tremendous advances in treatment that change a death sentence to a chronic condition or a cure puts great pressure on the system to pay for the value of the innovation in a short period of time. Several advisors and survey respondents observed that paying for extremely expensive drugs over a long period of time—possibly even a lifetime—is one alternative to help ease the burden. This payment concept is a paradigm shift in the way we have paid for and thought about pharmaceuticals. Survey respondents acknowledged they are willing to pay for value, when they deem it significant and proven. However, difficulty arises when paying for a high-cost drug that provides minimal marginal benefit. Historically, our society has been unwilling to deny providing those treatments, but it also has not often explained the potential outcome and cost to patients to help them make informed decisions.

In addition, the move to high-deductible health plans, benefit designs shifting to place more financial burden on patients, and the growing spread between list price and net cost that incurs a higher cost burden on patients have a large impact on adherence; thereby, increasing overall health care costs.

“Why don't we just agree on a good price on the front end and pass that onto the patient? ...Just get rid of the rebate, reduce the administrative burden [and avoid having everyone] jump through hoops.”

Pharma industry representative

“Hepatitis C was a bump in the road. But there are others—gene therapies, immunotherapies—in the future, that will be more like a mountain in the road.”

Health plan advisor

“Generate competition more aggressively. My organization has advocated for legislation that allows the federal government to license out a product if they pay off the patent holder.”

National political advocacy organization representative

More Invasive Actions May Come

We are seeing how governments are imposing top-down actions in increasingly draconian fashion to lower drug prices, should the markets and moderate governmental actions not be sufficient.

For example, the American Patients First blueprint highlighted a number of potential actions to lower drug prices, and the administration has carried out a few, including a proposed rule to require drug-pricing transparency,³² issuing guidance to allow Medicare Advantage plans to allow prior authorization and step therapy for Part B drugs,³³ and allowing indication-based formulary design in Part D.³⁴

However, more disruptive solutions are being proposed by various stakeholders. One advisor to this study stated his organization has advocated for so-called “march in” rights,³⁵ in which the federal government could march in and license a drug patent to a third party that would then manufacture the drug at a, presumably, lower price. In addition, the Trump Administration announced its intent to base Medicare payment rates for Part B drugs on the International Pricing Index model for half of the country for five years; this demonstration would impose international price controls on drugs.³⁶

Global Influencers

Social Determinants of Health

Socioeconomic status greatly affects access and adherence to therapy. One 2017 survey reported that the most cited reason by respondents who did not fill their prescription was cost (67%), and 12% of all respondents said that cost drove them to purchase prescription medication outside the US. And few people are immune from the rising cost of health care. Using a conservative definition, researchers found that 62.1% of all bankruptcies in 2007 were medical.³⁷

To complicate matters, addressing the cost of therapy will not necessarily fix the issue, as social determinants of health are at play that are beyond finances. The lack of access to transportation to medical appointments, lack of child care, poor health literacy, the inability to travel to and from pharmacies, as well as not recognizing the importance of staying adherent to pharmaceutical regimens, all contribute to the difficulty of accessing medical care.

Health IT, AI, and Big Data

Managed care has been doing big data before “big data” existed; payers have been collecting information on covered populations and development data-informed interventions for quite some time. The challenge now is to convert that information to better identify and prevent disease, highlight personal risk factors, and personalize care plans to maximum benefit.

To best develop those solutions, health insurers will need to focus on integrating disparate and varied datasets, and to make better use of that data via predictive analytics and value-based evaluation, among other techniques.

Of course, insurers must be sensitive to privacy concerns and ensure patients such information will be used beneficially. A July 2018 *ProPublica* story detailed how some insurers were partnering with data brokers to predict members’ health care costs based on “things like race, marital status, how much TV you watch, whether you pay your bills on time or even buy plus-size clothing.”³⁸

TREND #4: INDUSTRY CONSOLIDATION AND INTEGRATION

Trend Overview

Industry consolidation has been increasing, as separate companies form one new company either through a merger or on equal terms to wield more influence in the health care industry, or through integration, defined as the merger of companies at different stages of production or distribution in the health care industry. We have seen numerous mergers and acquisitions occurring across a myriad of health care stakeholders, including insurers, PBMs, pharmacies, manufacturers, and even nontraditional health care entities. Some view the move to a more consolidated health care system as a path to efficiency, but others are skeptical about whether the move will help or harm patients. As a Brookings Institution report stated: “A firm that dominates a market and faces little competition doesn’t have to lower prices or costs, push for better quality, or focus on innovation.”³⁹

Health services deals continue to occur at a high rate. Looking back to 2016, consolidation volume has stayed pretty steady, as shown in **Figure 16**; however, the value or size of the deals has increased with some particularly large mergers (eg, CVS/Aetna, ESI/Cigna).^{40,41}

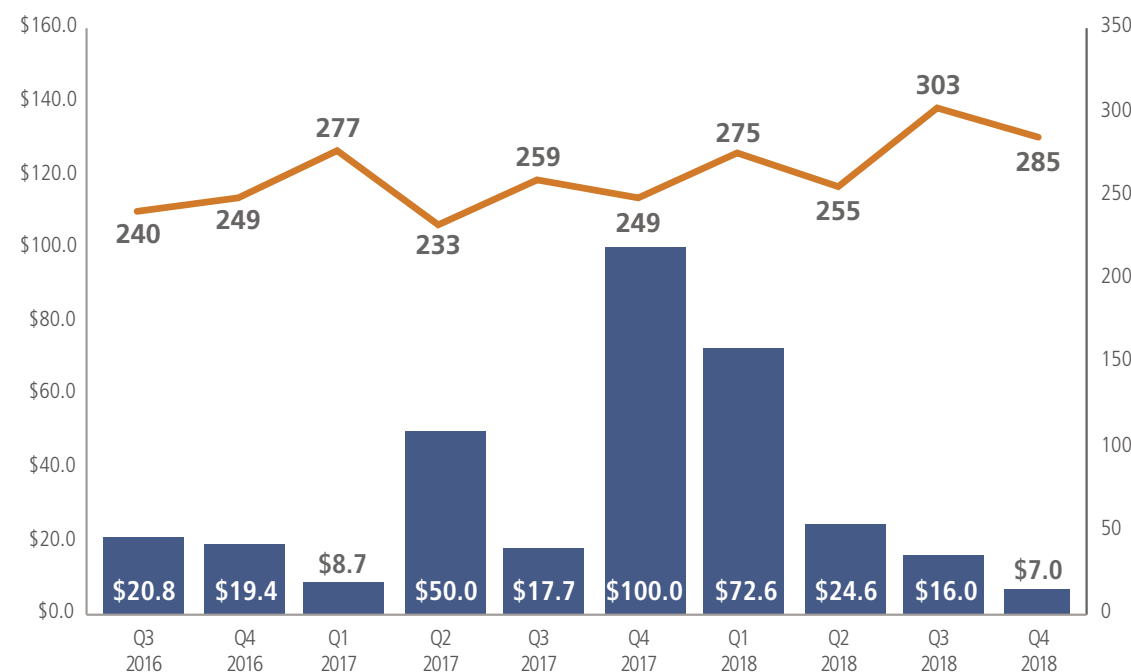
Consolidation is occurring in all sectors of health care.

Hospitals continue to consolidate, with 78 hospital mergers and acquisitions annually from 1998 to 2015,⁴² despite 90% of metropolitan statistical areas considered highly concentrated⁴³ (for example, two health systems in Massachusetts—Partners HealthCare System and Beth Israel Lahey Health—would control approximately 50% of inpatient services in the commonwealth⁴⁴ once Beth Israel and Lahey Health complete the merger).

“It is inevitable that consolidation will continue as long as medical costs remain way too high. This is the only defense mechanism the insurance and provider systems have to counter the escalating costs of health care and drugs.”

Health plan representative

FIGURE 16. HEALTH SERVICES DEAL VOLUME AND VALUE, Q3 2016–Q4 2018



Physicians continue to join larger practices and/or become employees of hospitals/health systems. In fact, 2016 marked the first time in history that more physicians were employed rather than owning their own practice; only 47% of physicians owned their practices, down from 53% in 2012.⁴⁵ This trend is expected to continue as younger physicians (under the age of 40) are three times as likely to be employed by a hospital. Moreover, the percentage of physicians being employed by a hospital or health system increased more than 50% between 2012 and 2016 (from 26% to 42%).

Meanwhile, an American Medical Association study of 2017 **health insurer** enrollment data found that in 91% of 380 measured metropolitan statistical areas (MSA), one health insurer had a market share of at least 30%.⁴⁶ Furthermore, in almost half of MSAs (46%), a single insurer had at least half of the market share. In 12% of the MSAs measured, one insurer had a market share of 70% or more.

And this concentration has been building for years. A 2012 study published in the *American Economics Review* found that the share of US communities in which health insurance markets had become “highly concentrated” (using the standard deployed by federal anti-trust regulators) increased from 68% in 1998 to 99% in 2006.⁴⁷

While the possibility of price/fee increases and reduced competition may fuel trepidation about consolidation, the health care system has evolved to a point of being too complex for single-silo solutions. The explosion of medical and pharmaceutical advancements, the ability to perform population health management, and the increasing specialization of care, all create an argument for reimagining health care through integration to coordinate care. Consolidation becomes a more common goal to increase access to capital and allow successful companies to increase their influence.

Challenges

Consolidation in an industry disrupts existing market dynamics. A health system that purchases many hospitals in a county, for example, has fewer concerns about matching or lowering competitor hospitals' contracting rates to insurers. Insurers have less negotiating ability with hospitals that have a dominant market position; in fact, if the health system decides to close an "unprofitable" hospital, consumer choice is lessened. Innovation can even be hampered if new hospitals cannot be built in the market.

In the survey of payer decision makers that accompanies this issue brief, 80% of respondents felt industry consolidation would be very or extremely impactful to them ... but only 10% felt it was very or extremely beneficial to health care. The fear of consolidated entities becoming "price makers" was prevalent, especially against patients, who are viewed as having little influence over their choice of insurer (under the US employer-sponsored model), and limited ability to negotiate prices with hospitals, doctors, and pharmaceutical manufacturers. Only 9% of the survey respondents felt consolidation was very or extremely beneficial to patient choice.

Payer respondents in the accompanying survey demonstrated pessimism about consolidation, as demonstrated in **Figure 17**. While they viewed it as very impactful along a number of health care dimensions (eg, competition, market/buying power, pricing, patient choice, etc), they did not view it as a beneficial activity, with many viewing it as not extremely/very beneficial to patient choice (9%), competition (19%), access to therapy (24%), or health care pricing (34%).



Consolidation often occurs under the guise of greater purchasing and negotiating power for lower prices, but I have severe concerns—based on historical trends—that a lack of competition will result in higher prices.

PBM representative



Rarely does consolidation lead to lower costs for consumers, so that is a concern for the overall effort for price pressure. Consolidation tends to be bad about bringing price down over time.

Patient advocate



Opportunities

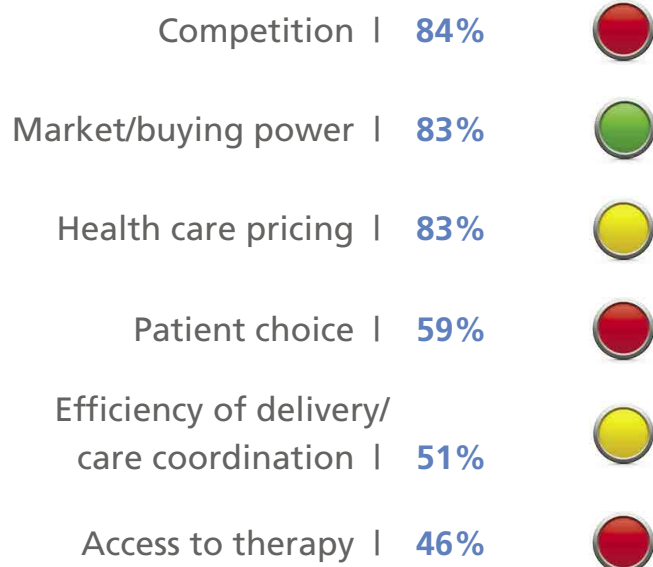
Despite the challenges, industry integration and consolidation have the ability to potentially join disparate entities together, combine skill sets, minimize waste, and augment the overall health care experience. Integration offers the promise of combining capital investment and consumer expertise to drive change and improve quality—with the recent JPMorgan, Berkshire Hathaway, and Amazon health venture as an example. The new approach may enhance efficiency across all segments, streamline work streams, and offer strength in numbers.

Integrated models, such as Kaiser Permanente and Geisinger, have historically led the charge on the delivery side while new entrants such as Uber Health may push the envelope of partnership and integration in the digital age.

FIGURE 17. PERCEIVED IMPACT OF CONSOLIDATION [PAYER PERSPECTIVE]*

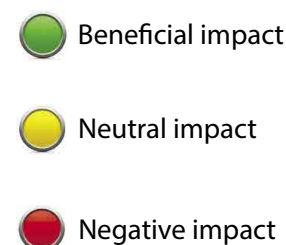
Impact of Consolidation

% rating as extremely/very impactful



View as Beneficial

% rating as extremely/very beneficial



* Question 1: How impactful is industry consolidation/integration on each of the following? (N=70)

Question 2: Thinking about it another way, how beneficial is industry consolidation/integration to each of the following? (N=70)

The recent spate of insurer and PBM consolidations could offer a unique opportunity to integrate an entity almost exclusively interested in pharmacy expenditures (PBM) with an entity that is also interested in medical expenditures (insurer). The CVS Health/Aetna merger would possess the additional advantage of having a CVS pharmacy in almost every neighborhood, elevating the possibility of taking even better care of patients.

Most organizations are challenged with internal silos that should be re-examined as their customer needs change. With current consolidation in the health care space, the opportunity is even greater. Consolidating organizations should not only look at redundancies but also take the opportunity to reimagine how they can deliver health care to patients.

Global Influencers

Social Determinants of Health

To the extent consolidation or integration results in expanded services, patients should benefit. Since “all coverage is local,” the potential benefit increases if the consolidation or integration is able to introduce more skilled personnel and expanded more advanced services to that population. Some of the recent vertical mergers and partnerships (CVS/Aetna, Humana/Walmart) may provide those expanded opportunities. Additionally, when larger hospitals/health systems acquire a small or rural hospital, they may be able to rotate more experienced health care professionals through that location to provide services to that community.

Consolidation, especially, has a potential downside. As hospitals, physician practices, or retail pharmacy chains expand via merger or acquisition, they may close low-traffic or low-performing locations. Unfortunately, such closures result in those patients served by them needing to travel further for necessary services. This additional travel often results in worse health, as patients may have difficulty seeing their physicians or filling prescriptions.

Health IT, AI, and Big Data

A clear benefit of the consolidation and integration of health care entities is the aggregation of larger, more diverse, and integrated datasets. The ability to integrate datasets for various sites of care across the patient journey would enable the system to better identify and predict patients at risk of an event or hospitalization.

Organizations also need sophisticated IT infrastructure to incorporate the more complex nature of a value-based system. A fee-for-service system is comparatively straightforward, as it is rooted in paying claims. However, as health care moves toward value, organizations need large datasets and the necessary computing tools to evaluate how to best extract value, how to coordinate patient care, and whether contracts with partner organizations are financially viable.

The most cited examples of disruptors were vertically integrated mergers, such as CVS/Aetna, Walmart/Humana, and Express Scripts/Cigna, as experts felt there were great opportunities to improve patient health by integrating the PBM and pharmacy silos with organizations that had greater vision into the overall medical and pharmacy history and treatment of patients.

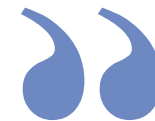
TREND #5: POPULATION HEALTH MANAGEMENT

Trend Overview

The shift in how health care is delivered and paid for has enabled a change in the management of disease from an individual basis to a population level. In 2003, David Kindig and Greg Stoddart proposed the definition of population health to be “the health outcomes of a group of individuals, including the distribution of such outcomes within the group,” and they argued that the field of population health includes health outcomes, patterns of health determinants, and policies and interventions that link these two.⁴⁸



The more you think about the population, the better the individual patient care will be.

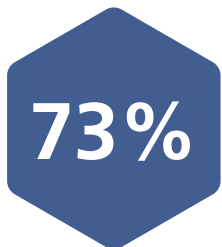


Federal policymaker

Performed correctly, population health management is a patient-centric approach and requires tight interconnection among providers, employers, insurers, and patients.

Population health management is not a new concept; payers have been engaging in basic population health management activities, such as identifying and enrolling members with chronic conditions in disease-management programs, for some time. However, the vastly increased computing power achieved in the last decade allows health plans to collect and analyze large data sets using AI and advanced analytics. This ability, when coupled with the ACA’s “birth” of ACOs, provides the breeding ground for a rich expansion of robust early detection, prevention, and disease-management programs.

In the accompanying survey for this report, 73% of respondents indicated that population health management will be very or extremely impactful to the future of health care, and only 3% felt it would not be impactful to the future of health care.



of respondents indicated that population health management will be very or extremely impactful to the future of health care

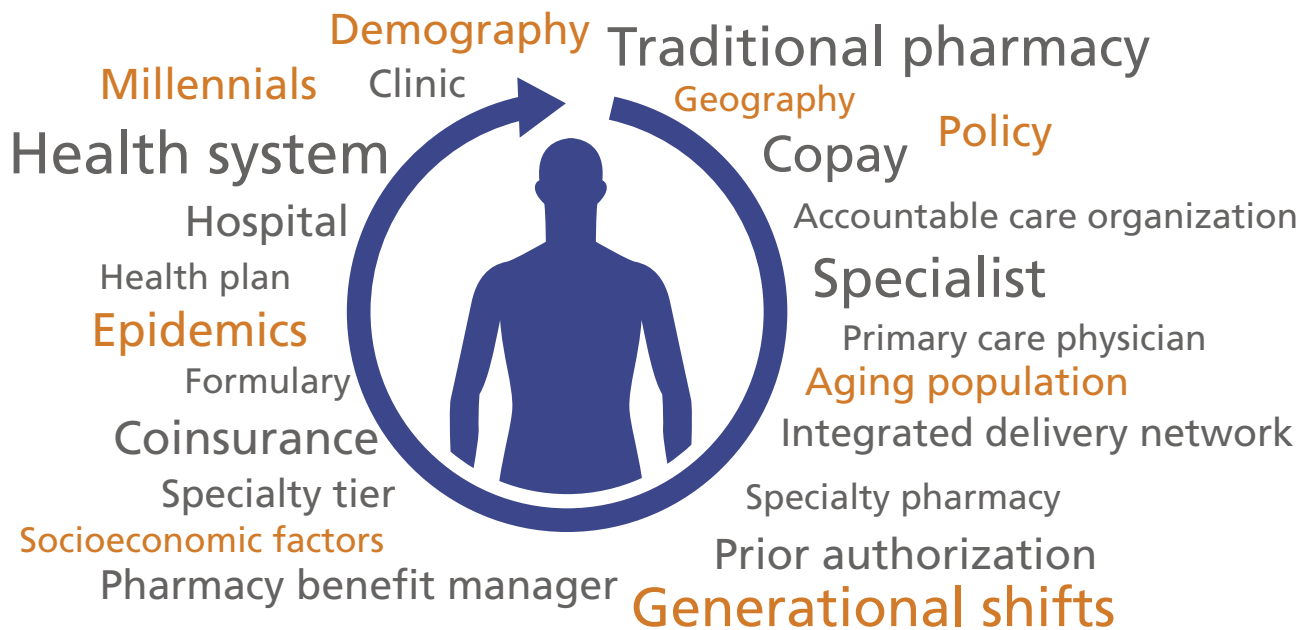


felt it would not be impactful to the future of health care

Challenges

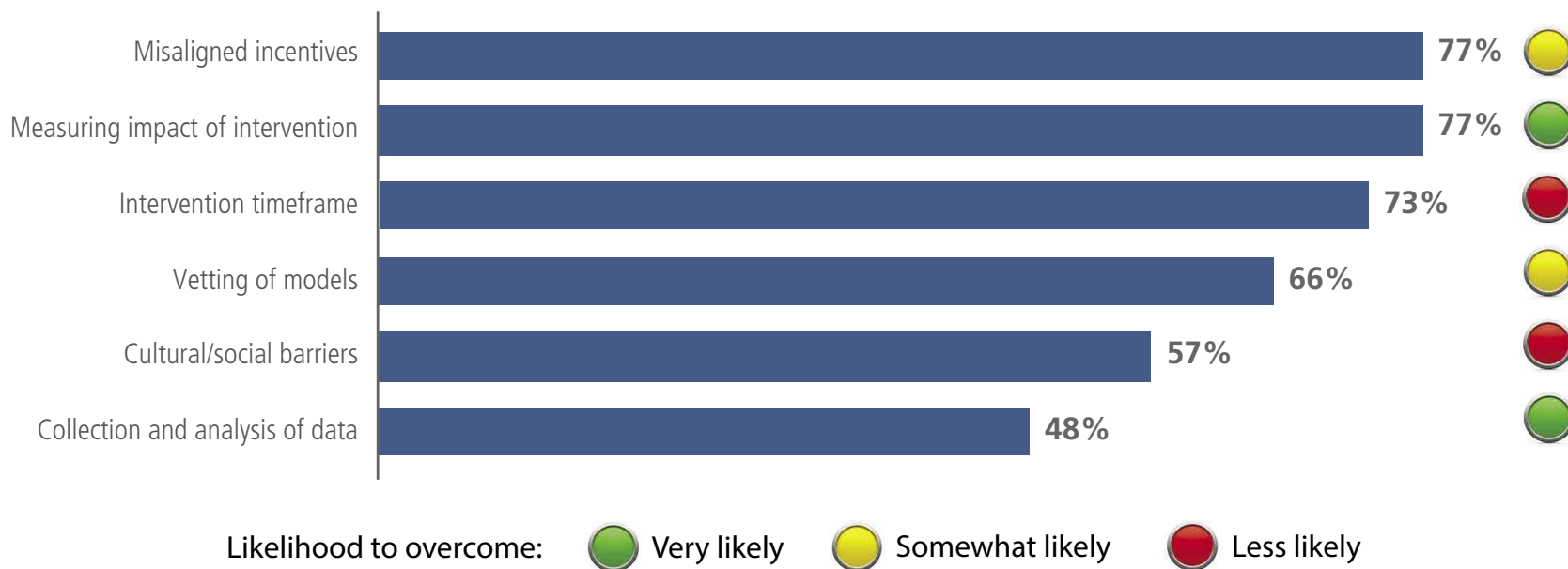
The evolution of population health management may be a piece of the puzzle to improving outcomes and reducing costs, but several barriers may slow down implementing consistently effective population health management. As shown in **Figure 18**, as our understanding of health care grows, more factors are seen as influencers. And population health management plays a role in many of those factors.

FIGURE 18. POPULATION HEALTH MANAGEMENT IMPACTS MANY ELEMENTS IN BEWILDERING HEALTH CARE LANDSCAPE



A chief challenge with population health management rests with the financial structure of our health care system and the lack of incentives to invest in less acute beneficiary needs. As shown in **Figure 19**, 77% of survey respondents stated misaligned incentives were very or extremely challenging. Given the relatively short member retention rate for commercial health insurance, any return on investment for a population health management program must be quick, while the many programs that are aimed to ameliorate chronic conditions take a longer period of time to generate results.

FIGURE 19. EXTREME CHALLENGES TO ACHIEVING POPULATION HEALTH (PERCENTAGE OF RESPONDENTS, PAYER PERSPECTIVE)*



* Respondents ranked as very or extremely challenging with respect to population health.

Question: How likely do you think it is that your organization will address the following population health management challenges within the next five years? (N=70)

Two-thirds of respondents felt the cost, resources, and time to vet different models would be challenging, and approximately one-half of respondents thought properly addressing cultural/social barriers, and collecting and analyzing data to effectively implement programs would be a challenge.

Given the evolving reimbursement of provider groups and a focus on practices bearing financial risk, providers—specifically primary care practitioners (PCP)—may be the drivers of population health moving forward. However, while physician practices have greater stability for patient retention than health plans; many practices are not equipped with sufficient infrastructure to support a lengthy or large population health management program.

Plans and providers have several weaknesses with administering population health management programs, such as the limited nature of the data they collect, some physicians not having electronic health records (EHR), and the lack of interoperability of some EHR systems. Some of these entities can analyze medical claims data, but they do not have access to other information that may shed insights, such as if a caregiver is overburdened with assisting a loved one. Some PCPs, of course, have developed close relationships with their patients and, therefore, understand nonmedical stressors, but far too many situations will not be identified.

Opportunities

Understanding the social determinants of health and aligning incentives for all stakeholders (eg, health plan, hospital, pharmacy, manufacturer, patient) are critical to improving population health. Data infrastructure to evaluate the entire continuum of care, coupled with lifestyle and behavior changes—the earlier, the better—were cited by many survey respondents as keys to improving population health management.

The spate of insurer and PBM consolidations offers a unique opportunity to manage population health by utilizing the strengths of each. PBMs have traditionally focused solely on pharmacy spend, with medical costs much less of a priority. Their mergers with insurers—who care greatly about medical costs and broader population concerns—could orient the thinking of the post-merger organization toward promoting better population health. The CVS Health/Aetna merger would possess the additional advantage of having a CVS pharmacy in nearly 10,000 locations, elevating the possibility of taking even better care of patients.

According to survey respondents, as shown in **Table 1**, the three most popular keys to success for population health management were: integration/data access (28.6%), patient engagement (21.7%), and change in structure of health care system (15.3%).

A potential innovation to realigning incentives to improve population health management and overall health care is to change the risk structure of the insurance contract to be outcome oriented. One example could be lengthening the contract to five years with a thorough health-risk assessment performed at the beginning and end of the contract period, with the insurer benefiting if the member's health remained the same or better at the end of the five years. Insurers would have the ability to perform robust population health management programs with a longer, and therefore greater, return on investment.



An acknowledgment of the intimate relatedness of physical medicine, behavioral health, and the social determinants of health is an absolute to the success of adequately assessing the health of a population.



Federal policymaker

TABLE 1. KEYS TO SUCCESS FOR POPULATION HEALTH MANAGEMENT (PAYER PERSPECTIVE)*

POPULATION HEALTH ATTRIBUTE	% OF RESPONDENTS	DETAILS	DISRUPTORS
Integration/data access	28.6%	Data interoperability and aggregation Ability to share/view information	Incorporation of nontraditional data Predictive analytics
Patient engagement	21.7%	Incentives Behavioral science Wearables	Fitbit partnerships Apple Watch from Aetna Health advocates
Change in structure of health care system	15.3%	ACO-type model Further consolidation Government/single payer system	CVS/Aetna ESI/Humana ACO model
Multi-stakeholder collaboration/engagement	13.7%	Align incentive Facilitate communication Develop team chemistry	CVS/Aetna merger
Ability to show return on investment	8.6%	Requires longer-term follow-up Investment to study models	Big data
Incorporation of social determinants	7.1%	Goals, incentives, and communication vary by social determinants	Personalization of population health
Awareness/education on prevention programs and tools	5.0%	Programs available, but constituents are unaware that they exist	Awareness campaigns to drive utilization Amazon/Google

* Question: What do you think is the key to improving population health management? (N=70)

Global Influencers

Social Determinants of Health

With few exceptions, health care delivery systems have not had to address the socioeconomic and social determinants of health to the degree that public health systems have. However, as our health care system moves from fee-for-service to value-based care, hospitals and other health care providers are becoming responsible for outcomes whether or not their population comes to their facilities.

And, since medical care is estimated to account for only 10% to 20% of the modifiable contributors to healthy outcomes for a population,⁴⁹ organizations are integrating social determinants of health into their population health programs to influence the other 80% to 90%.

As a result, many forward-looking organizations are striving to increase their involvement with social influences inside their geographical purview. A timely survey of payers and other health care stakeholders released in 2019 showed how social determinants of health initiatives are disrupting health care delivery and reimbursement, with many health care leaders planning to offer programs addressing care coordination, transportation, food insecurity, and other factors for members over the next 12 months.⁵⁰ The three leading initiatives were the following:



Efforts to address social determinants of health within population health may ignite the drive to improve outcomes and lower health care costs. As eloquently stated by David B. Nash, MD, MBA, Dean of Jefferson School of Population Health at Thomas Jefferson University,

“There is significant and as yet unrealized opportunity to advance the population health agenda and to improve health through efforts that focus on personal behavior and health promotion within each of these interactions.”⁵¹

Health IT, AI, and Big Data

Table 1 shows a number of population health attributes that were presented to payer decision makers in the accompanying survey. In addition to respondents being invited to share their opinions about whether the attributes were keys to success for population health management, they were asked to identify disruptors in this area. We describe a few here.

Respondents pointed to the pending mergers of CVS/Aetna and Express Scripts/Humana as potential disruptors, due to their abilities to merge and analyze different datasets that were siloed, to some extent, to create a more complete profile of the patients. The abilities of merging medical and pharmacy claims databases to explore interventions across many patients were viewed as being particularly valuable.

Another disruptor is the wearable device manufacturer Fitbit. The company has been expanding its enterprise business; its strength lies in the data its research team is accumulating to demonstrate the long-term results of wearing a tracker—both in increased engagement in wellness programs and improved health outcomes. The staff of the National Basketball Association team Minnesota Timberwolves saw a 43% decrease in medical claims in the first year of partnership with Fitbit, due in part to their increased focus on wellness.⁵² As Fitbit works with more employers, their wealth of data about the value of incentives (ie, more steps due to “challenges”) will accumulate. Employers and Fitbit will be able to correlate and/or demonstrate causation among the benefits of different levels and amounts of exercise and employers’ medical costs, employee productivity, etc.

Although many people have mentioned Amazon as a disruptor to health care, that may be more of a future trend than current reality. In June 2018, the retail giant announced its decision to purchase PillPack, a company that packages, organizes, and delivers drugs to patients with the specific number of medications they are supposed to take at specific times.⁵³ It also made a big splash with its announcement that they are partnering with Berkshire Hathaway and JPMorgan Chase on ways to address health care for their US employees, with the aim of improving employee satisfaction and reducing costs.⁵⁴ Both of those agreements centered on Amazon’s supply-chain expertise and high health care costs. However, Amazon has not yet (at press time) made waves in deploying AI for the purposes of improving population health management.

TREND #6: EXPEDITED DRUG APPROVALS

Trend Overview

While the pace of innovation and available treatment options is increasing, finding the right drug for the right patient can be a challenge. There are four FDA expedited drug approval programs (priority review, accelerated approval, breakthrough therapy, and fast track therapy) intended to facilitate and speed the development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition.⁵⁵ This option becomes particularly important for patients with rare diseases who face a host of challenges, such as misdiagnosis of condition and a lack of available treatment options.⁵⁶

Priority review designation

Drugs where late evidence suggests substantial improvement over currently available therapies



Accelerated approval designation

Drugs with strong early surrogate or intermediate endpoints



Breakthrough therapy designation

Drugs where *early* evidence suggests substantial improvement over currently available therapies



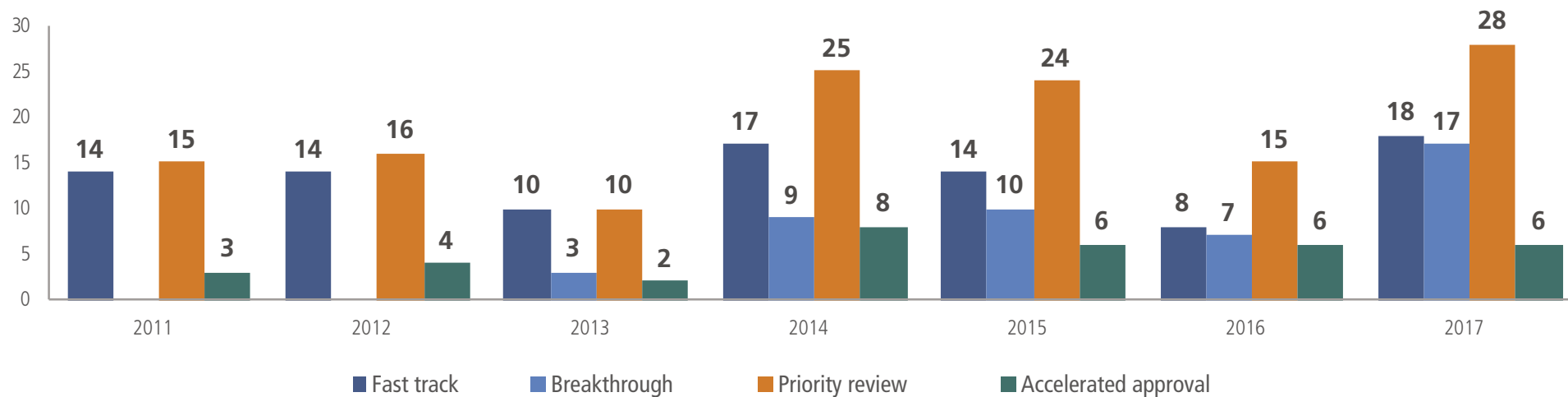
Fast track therapy designation

Quicker access to life-saving therapies



Since 2011, the number of drugs being reviewed under expedited approval programs has gradually increased, as shown on **Figure 20**.

FIGURE 20. FDA DRUG APPROVALS UNDER EXPEDITED-REVIEW PROGRAMS (2011–2017)



* NOTE: A drug development program may qualify for more than 1 expedited program.

Despite their obviously beneficial intent, expedited drug approval programs face several challenges and barriers. However, the almost limitless potential for innovative therapies on the horizon means those patients most underserved stand to benefit immensely.

Challenges

There was conflicting feedback among the multi-panel stakeholders and the payer survey respondents about the necessity of expedited drug approvals. While some felt the programs were important for bringing needed drugs to market quicker, others felt the FDA had excellent intentions behind the programs, but that the products being approved under the expedited approval programs did not offer transformative enhancements over existing therapies.

One of the biggest concerns with expedited drug approval programs is if they are not conducted properly. Unexpected poor outcomes can follow the treatment when it is released to the general population. The risk already exists that rare adverse events will not surface during the traditional development process using large-scale clinical trials, and so the likelihood can be even greater with an expedited approval program. In the survey related to this report, 79% of respondents were very or extremely concerned about having less efficacy data compared to therapies approved via nonexpedited pathways, and 72% were very or extremely concerned with having less safety data.

Another challenge for expedited approvals is that overly strict exclusion criteria can make it difficult to extrapolate findings for different patient populations. Additionally, the simple fact that the population for rare diseases is so small that identifying heterogeneous trial candidates can be extremely difficult.

I don't believe the majority of medications coming to market on this pathway are significant improvements. Most have a limited efficacy benefit and many unanswered safety issues.

Health plan representative

Expedited drug approvals [have offered]... false hope to patients with rare diseases. EXONDYS 51™ (eteplirsen) and GALAFOLD™ (migalastat) are clear examples.

Survey respondent

[Expedited approval programs] may be significantly impactful if addressing a significant unmet need, but this can be a subjective call, and not all drugs with accelerated approvals are necessarily impactful.

PBM representative

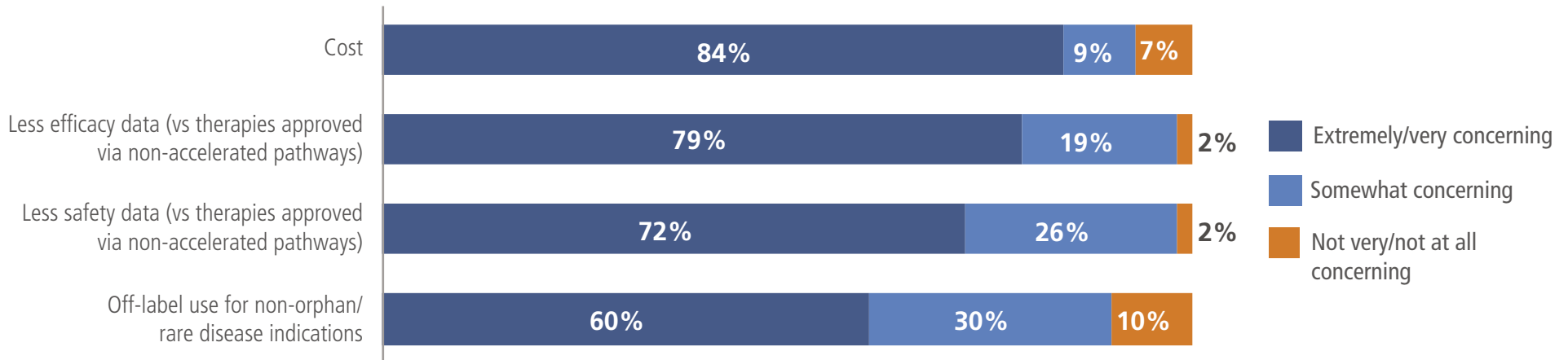
Thus, while a homogenous population may confer more consistent data, it shrinks the pool of candidates and also fails to advance learning about how races and ethnicities respond differently to drug therapies; this is not a trivial concern. A 2014 study showed about 20% of the new molecular entities approved between 2008 and 2013 reported some inter-racial/ethnic variability with respect to pharmacodynamics, safety, efficacy, dosing, or pharmacogenetics.⁵⁷

Many treatments for rare diseases are expensive. A 2017 Harvard Business Review article reported that the average drug approved under the Orphan Drug Act of 1983 (ODA) costs \$118,820 per year.⁵⁸

Assuming a similar cost, if a single drug were approved under the ODA for 10% of rare diseases, the total would exceed \$350 billion annually—more than 10% of the total amount that America spends on health care. Given such high costs while health care funding is a scarce resource, the discussion about the value such treatments bring inevitably arises and will continue.

Payer decision makers in the accompanying survey expressed concern about the high costs of many drugs approved under expedited programs, in addition to worries about efficacy and safety data, as shown in **Figure 21**.

FIGURE 21. CONCERNS ABOUT FDA EXPEDITED APPROVAL PROGRAMS (PAYER PERSPECTIVE)*



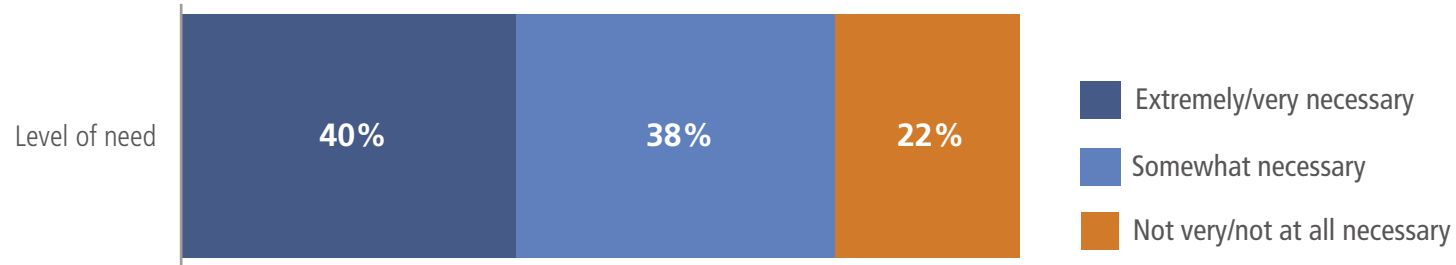
* Question: How concerning are each of the following with respect to accelerated drug approval? (N=68)

Another challenge for these programs is that post-launch, real-world evidence takes time to be generated, and it is still unclear how much data payers need. And, because post-launch trials are not controlled, patient-safety data traceable to the compound is also more difficult to recognize.

Opportunities

Despite the aforementioned concerns about expedited approval programs bringing needed drugs to market on an accelerated timeline, stakeholders still think they offer value. **Figure 22** shows that how the payer decision makers in the accompanying survey felt a plurality (40%) of the programs were extremely or very necessary, while only 22% felt they were not very or not at all necessary.

FIGURE 22. MOST PAYER RESPONDENTS FELT EXPEDITED REVIEWS AT LEAST SOMEWHAT NECESSARY*



* Question: How would you rate the need for accelerated drug approval? (N=68)

Beyond the opportunity to bring drugs to patients more quickly, expedited approvals can help evolve science at a faster pace. The possibilities offered by our advancing understanding of genomics and cellular mechanisms, unique clinical-trial designs, and vastly expanded computing power are allowing researchers to fine-tune clinical development and may make expedited approval programs almost unnecessary. In other words, expedited approvals may work themselves out of a job. Researchers will be able to use our growing knowledge of biology and physiology to incorporate genomic data, biomarkers, and other cellular mechanisms to develop small and large molecules that offer greater efficacy and improved safety.

Advancements in genomics present another opportunity. As articulated in an Institute of Medicine workshop, genomics could lead to even more precise—and effective—medications.

Biomarkers are also promising. As researchers develop a greater ability to use them for inclusion or exclusion criteria, especially in expedited drug approval programs, they will become more successful at identifying promising drug candidates. A 2016 BIO Industry Analysis showed how the use of biomarkers in trials drastically increases the likelihood of approval (from 8.4% to 25.9%).⁵⁹ The flip side of earlier identification of drug candidates also holds true: Biomarker presence and use in clinical trials will enable manufacturers to “fail faster.”

“Accelerated approvals are needed because there are rare, orphans, etc; there clearly is a need for new products where there are gaps for patients.”

Advisory panel member

“We are just at the beginning of understanding cellular mechanisms and signal pathways, which goes beyond genomics.”

Dean of pharmacy school

More radically, the explosion of computing power, big data, and AI have us at the cusp of tremendous progress. Researchers can incorporate genomic data that, quite simply, were not available 10 or even five years ago. As our knowledge and capabilities increase, a greater percentage of drugs developed will be curative or significantly disease modifying. The long-term benefits for patients, payers, and society are huge. Patients will be able to overcome formerly life-threatening conditions to become active, productive members of the community who will be working, taxpaying citizens, while payers will not be saddled with funding chronic treatments that do little to alter the course of the disease.

Despite the undeniable potential benefit offered by expedited drug approval programs to provide lifesaving medications to needy patients, we may soon enter a period of pharmaceutical development where expedited approval programs would not be necessary because most, if not all, development will proceed along those timelines.

Global Influencers

Social Determinants of Health

Social determinants of health have a direct impact on access to drug development in general, and even more acutely for expedited approval programs. Physicians in poorer communities may not be practicing cutting-edge, research-oriented medicine due to resource constraints and the health needs of their patients, which may be more rooted in chronic conditions, such as asthma, diabetes, and hypertension. If these scenarios are viewed through the lens of the Maslow hierarchy of needs in health care terms, many basic needs are not being met, so rare conditions receive even less attention.

Additionally, socioeconomic factors and other social determinants may limit patient awareness of clinical trials for drugs undergoing expedited review. Patients living in rural areas may not have geographic access to physicians and facilities conducting expedited-review clinical trials.

One study suggested that social-media platforms have enormous potential for balancing out unfair sampling within clinical trials.⁶⁰ As the authors explained,

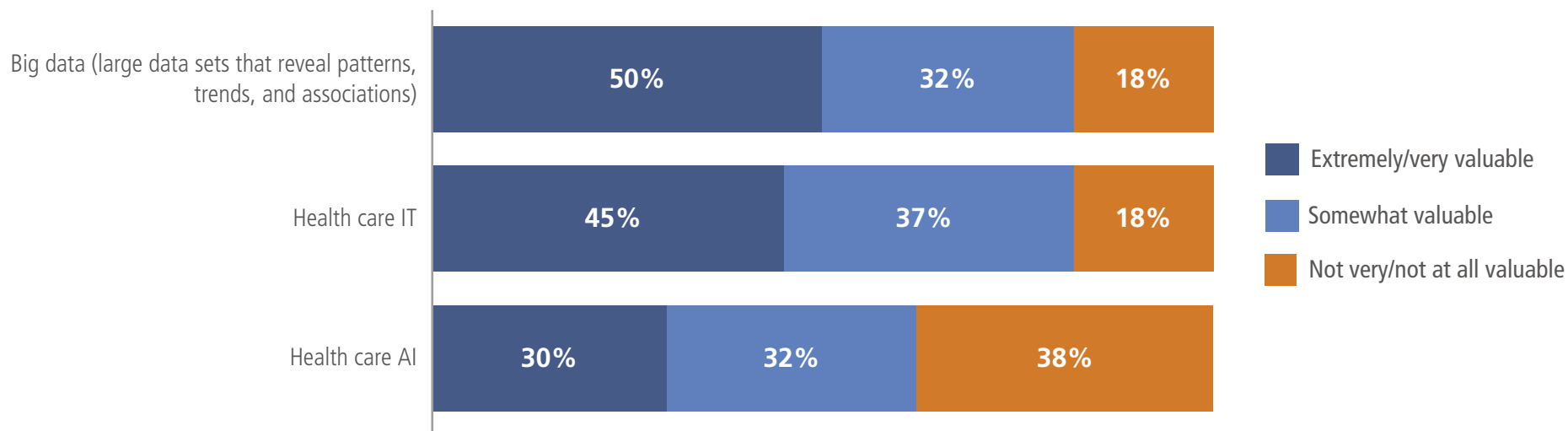
The potential for targeted messages and advertisements grants those tasked with recruitment for clinical trials an incredible amount of control over how recruitment materials are presented, to whom and when, making the task of recruiting a more diverse sample easier.

Health IT, AI, and Big Data

AI can speed up drug discovery, cut research and development costs, decrease failure rates in drug trials, and eventually create better medicines—and the pharmaceutical industry is not blind to AI's potential in drug development. According to a 2017 market study report, the health care AI segment is projected to see a staggering 40% compound annual growth rate between 2017 and 2024, resulting in a \$10 billion market focused on medical imaging, diagnostics, personal AI assistants, drug discovery, and genomics.⁶¹

Advanced technology, obviously, is critical to drug development; its use in expedited drug approvals is even more critical. When responding to the accompanying survey, payer decision makers felt big data and health care IT were more valuable than AI with respect to expedited drug approvals, as shown in **Figure 23**. Only 30% felt AI would be extremely or very valuable to the expedited drug approvals, while 38% felt AI was not very or not at all valuable.

FIGURE 23. PAYERS BELIEVE BIG DATA AND HEALTH CARE IT OFFER MORE PROMISE FOR EXPEDITED DRUG APPROVALS THAN HEALTH CARE AI



* Question: How valuable are each of the following with regard to accelerated drug approvals? (N=68)

Members of the multi-stakeholder panel observed that one use of advanced technology would be to analyze genetic data to better identify the subpopulations who would best respond to a particular drug candidate. That approach would streamline recruitment, thus saving time and reducing development costs.






The possibilities offered by our advancing understanding of genomics and cellular mechanisms, unique clinical-trial designs, and vastly expanded computing power are allowing researchers to fine-tune clinical development. As a result, in the near future, expedited approval programs may become almost unnecessary, as almost every drug-development program would be “expedited” due to increasing knowledge and capabilities.











Conclusion and Impact to Different Stakeholders

The impact of these six key trends will be felt by health care stakeholders in the coming three to five years. **Table 2** illustrates how this impact may manifest—for more information and updated analysis, visit us online at www.amcpfoundation.org.

TABLE 2. IMPACT OF KEY TRENDS ON HEALTH CARE STAKEHOLDERS

TREND 	PROVIDERS 	PHARMACY 	PATIENTS 
#1 Innovative and Curative Therapies 	<ul style="list-style-type: none">• Able to extend lives and improve quality of life for patients	<ul style="list-style-type: none">• Increased business due to wider array of treatment options for patients• Opportunity to enhance relationship with patient due to new treatments being more complex	<ul style="list-style-type: none">• Access to curative therapies for diseases and conditions, instead of chronic treatments to keep illness at bay• More treatments that can improve quality of life• Higher costs, as most newer therapies are more expensive than previous options
#2 Optimal Health Coverage 	<ul style="list-style-type: none">• Able to offer wider array of treatment options to patients• Increased business due to patients' enhanced ability to afford regular visits and treatments• May require providers to change their business practices toward more "whole patient" care (eg, more coordinated care, more risk-sharing)• Need for more providers to provide care for increased utilization• Growing demands from patients for medical practices to provide more financial information and counseling	<ul style="list-style-type: none">• Increased business due to patients' greater prescription-drug coverage• Increased ability to provide preventive and holistic care to patients	<ul style="list-style-type: none">• Improved ability to make health care decisions regardless of availability or type of health insurance• Better short-term health due to access to wider range of treatments• Better long-term health due to better access to preventive care• Ability to seek care at more efficient sites of care (rather than the emergency department)—with potentially better cost-sharing• Less concern and stress over financial impact

TREND 	PROVIDERS 	PHARMACY 	PATIENTS 
#3 Affordability and Value 	<ul style="list-style-type: none"> • Healthier patients due to their increased ability to stay adherent to medications • Greater revenue with value-based programs due to adherent patients having better outcomes • Decreased administrative costs due to fewer patient interactions regarding medication costs 	<ul style="list-style-type: none"> • More opportunity for inclusion of pharmacy services in provision of care • More revenue from insured patients filling more prescriptions 	<ul style="list-style-type: none"> • Better health, due to being able to see physicians regularly, obtain needed tests, fill prescriptions routinely • Opportunity to focus on improving social determinants of health
#4 Industry Consolidation and Integration 	<ul style="list-style-type: none"> • Ability to increase volume of procedures • Access to EHRs that are integrated across sites of care • Better ability to coordinate care with other providers • Ability to check drugs/safety more regularly • Potential layoffs, especially if practices and/or integrated health system consolidates locations or shrinks provider pool • Less autonomy if integrated delivery network or hospital purchases physician practice 	<ul style="list-style-type: none"> • Potentially lower costs if consolidation creates greater buying power • Access to integrated datasets that provide more holistic picture of patients' health • Reduced job security if chains force independent pharmacies to close or chain locations close • Potentially expanded opportunities via different roles in integrated delivery networks 	<ul style="list-style-type: none"> • Potentially lower costs and/or better access to care if consolidation/integration leads to improved system • Potentially higher costs and/or worse access to care if consolidation/integration leads to reduced care location or higher prices • May be able to better coordinate care/ appointments between providers
#5 Population Health Management 	<ul style="list-style-type: none"> • Will require practice changes currently based on fee-for-service influence • Application of predictive models will enable detection of patients at risk for chronic conditions • Potential financial challenges, as economics are different for fee-for-service and population-based (value-based) care • Will require providers to take on financial risk, which will work better with larger practices while small practices might close/consolidate • Require greater reliance on EHR • Require analytic capabilities/staffing to work through data and implement changes (case managers, nurses, etc) 	<ul style="list-style-type: none"> • Increased revenue, due to medication therapy management to ensure appropriate medication use for chronic conditions • More information will provide greater opportunity to interact with and counsel patients about management of their health, and to be reimbursed for those efforts • Health system pharmacists can play key role in educating patients about medication adherence and behavior modifications 	<ul style="list-style-type: none"> • More data will be available to patients to empower them, thus lowering costs and improving their health • Health care system is embracing and adopting patient centricity, allowing patients greater role in their care • Population health management will lead to multiple available points of contact between patients and providers (eg, office visits, telehealth, digital health) • Patients may be confused about why extra services are being offered
#6 Expedited Drug Approvals 	<ul style="list-style-type: none"> • Opportunity to offer more patients to enroll in clinical trials for previously undertreated or untreated conditions • Greater need to stay informed about additional educational opportunities 	<ul style="list-style-type: none"> • Opportunity for pharmacists to become more involved with patients by staying abreast of expedited drug approval programs for conditions undertreated or untreated 	<ul style="list-style-type: none"> • Opportunity to enroll in potentially lifesaving trials for undertreated or untreated conditions • Opportunity to expand the research knowledge base for the community suffering from the same condition • Quicker access to innovation (and hope)

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