

Deloitte.

2016 Global health
care outlook
Battling costs while
improving care



Overview and outlook

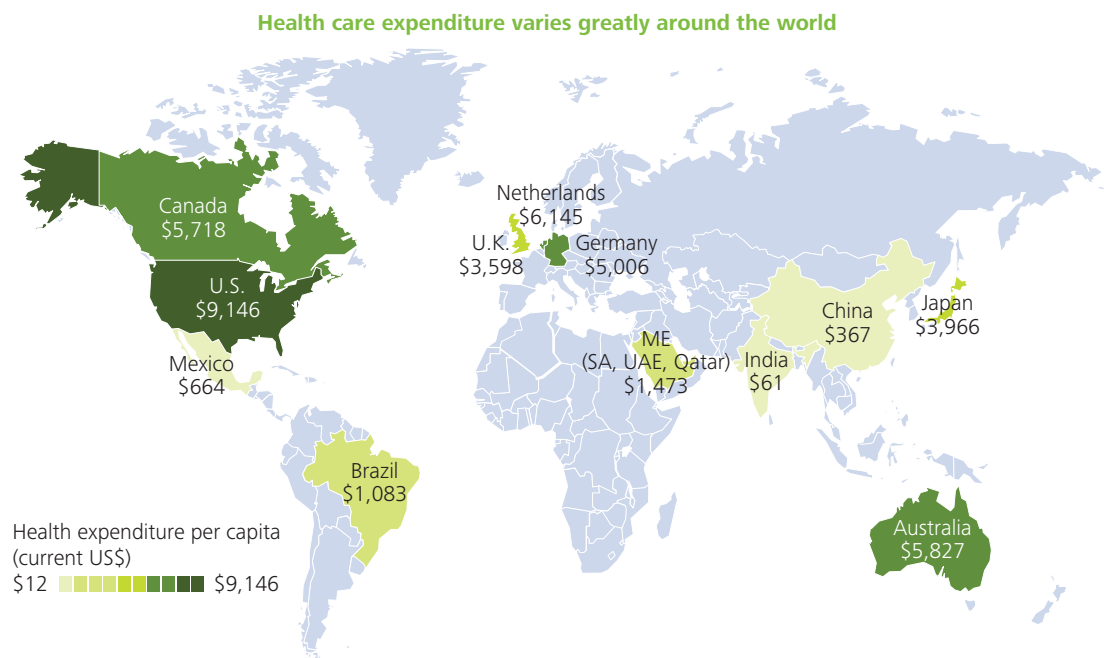
Change is the new normal for the global health care sector. As providers, payers, governments, and other stakeholders strive to deliver effective, efficient, and equitable care, they do so in an ecosystem that is undergoing a dramatic and fundamental shift in business, clinical, and operating models. This shift is being fueled by aging and growing populations; the proliferation of chronic diseases; heightened focus on care quality and value; evolving financial and quality regulations; informed and empowered consumers; and innovative treatments and technologies — all of which are leading to rising costs and an increase in spending levels for care provision, infrastructure improvements, and technology innovations.

The Economist Intelligence Unit (EIU) reports that health care spending in the 60 countries that it covers rose by 2.6 percent in nominal U.S. dollar terms in 2014 but that spending is forecasted to dip in 2015, reflecting the current weakness of the euro and other currencies against the U.S. dollar (USD)*.¹ On a Gross Domestic Product (GDP) and per-capita basis, the most recent figures available from the

World Health Organization (WHO) show that health care spending varies greatly among developed and developing countries (Figure 1).²

It's expected that the dip is just temporary, though. Spending growth is anticipated to accelerate in 2016, topping four percent, and rise to over six percent a year in 2017 and 2018.³ Growth in several markets — mostly in Asia and the Middle East — will be particularly rapid as public and private health care systems develop in some countries; in addition, the trend towards universal health care is likely to be a growth driver in numerous markets.⁴ However, the pressure to reduce costs, increase efficiency, and demonstrate value will continue to intensify. As a result of these contradictory trends, the EIU projects that global health care spending will increase by an average of 4.3 percent during 2015-2019, more slowly than it did before the 2009 recession. Average spending as a percentage of GDP is expected to decline from a forecasted 10.3 percent in 2015 to 10.1 percent in 2019.⁵

Figure 1: Countries' GDP and per-capita health care spending, 2013



Source: DTTL Global Life Sciences and Health Care (LSHC) Industry Group analysis of The World Health Organization Global Health Expenditure database (see <http://apps.who.int/nha/database> for most recent update)

* Unless otherwise identified, all monetary references are in U.S. dollars.

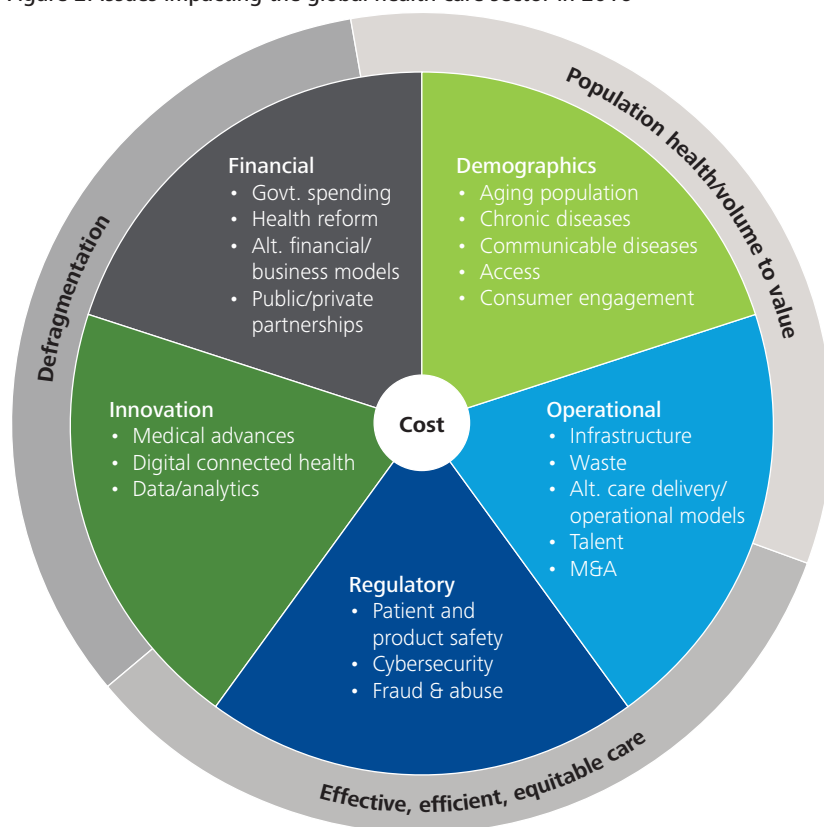
So pivotal is the role of cost on the global health care ecosystem that it is at the core of the many issues — demographic, financial, operational, innovation, and regulatory — impacting sector stakeholders in 2016 (Figure 2). Meanwhile, these issues are acting as levers to either increase or decrease costs.

While most people associate increasing health care costs with negative situations — such as administrative waste, rising insurance premiums, expensive care for chronic diseases — increasing costs can also signal positive developments such as amazing new medical treatments and innovative technologies that may one day cure diseases that were formerly incurable. The way forward is clear: sector stakeholders must look for ways to decrease costs, given the consensus that the current upward trajectory is unsustainable. In addition to demographic, financial, operational, innovation, and regulatory considerations, three macro issues are framing the cost discussion: sector defragmentation; the shifts from episodic care to population health management and from volume- to value-based care; and efforts to deliver effective, efficient, and equitable care.

Defragmentation

The health care sector is moving from its traditional, fragmented approach to clinical and financial operations to one focused on consolidation, convergence, and connectivity. In some countries, increasing competition and sharply climbing costs are fueling the trend of “bigger is better” — individual (fragmented) hospitals are merging with each other and with independent physician groups to form large health systems that can leverage economies of scale and broader service reach to withstand rising economic and regulatory pressures. Emerging reimbursement models are no longer requiring a provider organization to “go it alone” — risk-sharing schemes are increasing in availability. Government organizations are also looking beyond their traditional health care models for innovative ways to manage and deliver care. In countries including the United States, health plans are also “defragmenting” via mergers and acquisitions (M&A) and collaborative relationships with providers to create powerful data-sharing networks that help drive integration across the continuum of care.

Figure 2: Issues impacting the global health care sector in 2016



Increased transparency into care quality, outcomes, and pricing is improving due to mandatory and voluntary surveillance, and through metrics and tracking at department and enterprise levels. Purchasing decisions based on personal preference are being replaced by centralized guidelines and standards. Finally, as the ubiquity of communication technology enables the world to become more connected, peoples’ awareness and understanding of developments in health care are also increasing, raising expectations.

Population health

Health care providers and payers, both public and private, are seeking to address the cost curve with innovative approaches to managing the health of a population. Providers responsible for the full spectrum of health needs for a population (as opposed to those delivering episodic procedures or illness-focused care) realize they need to know about their population's risks and requirements even before they get sick. They also need to measure and improve care processes for their overall population. However, if stakeholders are going to be successful at managing population health, then health and social care systems will need to join forces, and the public and private sectors will have to transition financial incentives from the "break-fix" model of care to prevention, predictive maintenance, and outcome optimization. While a philosophical shift has occurred — in countries like the United Kingdom, Mexico, Japan, and Germany, for instance — balancing the potential benefits of population health management with the practicalities of implementing, funding, and delivering such models remains in the early stages.

Volume to value

Regulatory and market changes are disrupting business as usual and making the concept of "value" top-of-mind for the health care sector and consumers alike. The traditional fee-for-service (FFS)-based payment model incentivizes health care providers to increase the volume of services without much thought to cost. Although providers have professional goals of improving health outcomes, the FFS model does not reward them for this. Due to concerns about rising costs and wide variations in performance on quality indicators, employers, health plans, and governments are pushing for a transition to outcome- or value-based care (VBC) payment models. The premise of VBC payments is to align physician and hospital bonuses and penalties with cost, quality, and outcomes measures.⁶

A larger role for value in health care

The concept of value in health care is impacting the greater health care system. Shifting payment models, such as "pay for performance" and "value-based purchasing," reimburse physicians or pharmaceutical companies on results around value. These models aim to motivate providers to deliver better quality care.⁷

Some health care organizations are actively preparing for the transition to VBC while others are hesitating. Their reluctance is understandable: the level of financial investment is substantial and the current FFS payment structure is still highly profitable for some.⁸ In addition, stakeholders have yet to develop and align on definitions and measures of value. As uptake accelerates, there is little doubt that VBC models have the potential to up-end health care stakeholders' traditional patient care and business strategies.

Effective, efficient, equitable care

As expenses and patient numbers mount, health care stakeholders will need to operate more efficiently, lower their unit costs, raise their quality levels, and identify ways to optimize the value of their limited resources. If providers, payers, and patients work collaboratively and do everything right — control health care spending, reduce variations in care, deploy technology cost-effectively, and engage consumers in self-care — the result should be effective, efficient, and equitable health care for all. Unfortunately, many obstacles stand in the way of achieving this goal. Read on to learn how cost and other issues are impacting the global health care sector in 2016.

Global health care sector issues in 2016

Demographics

Aging population

Population aging is accelerating rapidly worldwide. Increased life expectancy — up from an estimated 72.3 years in 2014 to 73.3 years in 2019 — will bring the number of people aged 65+ worldwide to over 604 million, or 10.8 percent of the total global population. That number is anticipated to be even higher in Western Europe (nearly 21 percent) and Japan (28 percent).⁹ Among factors contributing to increased life expectancy in low- and middle-income countries are declining infant mortality, enhanced living conditions, improved sanitation, better prevention of communicable diseases, and growing access to medicine. In higher-income countries, increasing life expectancy is mainly due to declining mortality among those who are older.¹⁰ Unfortunately, health quality is not keeping pace with longevity, nor is the development of age-appropriate health policies and services.

The potential impacts of an expanding, aging population on countries' health care systems, workforce, and budgets are profound. Yet, existing systems are poorly aligned to the care that older populations require.¹¹ In addition, many common misperceptions and assumptions about older people exist — the “inevitable” deterioration of mental and physical abilities, for instance — that hinder progress. Although many older people will experience health problems at some point, older age does not imply dependence.¹² Rather, increasing numbers of informed, active, and affluent seniors are willing to pay for new health care services and technologies. Undoubtedly, changes will be required in the way health policies for aging populations are formulated and services are provided to encompass the great diversity of older populations and address the inequities that lie beneath it.¹³

“Contrary to common assumptions, aging has far less influence on health care expenditures than other factors, including the high costs of new medical technologies.”
World report on aging and health, World Health Organization, 2015

Chronic and communicable diseases

The proliferation of chronic diseases — in part, a consequence of increased life expectancy — is having serious repercussions in both developed and emerging countries. Obesity, cardiovascular diseases, hypertension, and dementia are becoming persistent, widespread health problems and appear to be challenging public health systems to meet increasing demand for drugs and treatments. Mexico's health reform program will be strongly focused on this issue: public providers may partner with the private sector to treat these diseases and promote a culture of prevention and risk mitigation, which also contributes to cost containment.

The current number of people with diabetes globally is 387 million and that number is expected to increase to 592 million by 2035, according to the International Diabetes Federation. China and India have the largest number of diabetes sufferers in the world, at more than 96 million and 66 million, respectively.¹⁴

Fortunately, research into treatments is generating promising results. The Pharmaceutical Research and Manufacturers of America (PhRMA) estimates that 180 new diabetes drugs are in late-stage development, and seven new treatments have won U.S. Food and Drug Administration (FDA) approval in the past two years.¹⁵ New immune-oncology drugs are showing great promise against cancer. Efforts to reverse the rise in obesity are also intensifying, particularly initiatives to influence consumer behavior. As part of its national goal to “consolidate the actions of protection, health promotion and disease prevention,”¹⁶ Mexico is strengthening the first level of care — the health system is changing from a curative approach to one focusing on prevention and adoption of good health habits that can help improve quality of life.

Meanwhile, the fight against communicable diseases continues, especially in developing countries. In July 2015, the world's first malaria vaccine, Mosquirix, gained approval from the EU, and a new dengue vaccine marks a similar breakthrough against that disease. Better sanitation, improved living conditions, improved access to health care, and more widespread vaccination are also supporting the fight.¹⁷ Yet communicable diseases are far from beaten. HIV-AIDS continues to affect 36.9 million people worldwide, with around 70 percent of those living in Sub-Saharan Africa.¹⁸ Adding to the challenge is the issue of growing and serious antibiotic resistance, which can hinder efforts to control and eradicate disease.

Access

Population access to health care clinicians, facilities and treatments varies widely around the globe, from poor countries – many in Africa and Southeast Asia – seeking infrastructure basics such as clean water, sanitation, and treatments for communicable diseases; to developing economies such as India and China that have an opportunity to leapfrog the break-fix model but are fighting both third- and first-world diseases; to mature markets such as the United States, Japan, and Europe that have plenty of hospitals but issues with cost containment.

Population expansion and rising wealth are becoming strong drivers of health spending in developing markets, particularly Asia and the Middle East. By 2019, the number of high-income households (those earning over \$25,000 a year) will rise to over 540 million globally; Asia is projected to generate more than half of that growth.¹⁹ The expansion in personal wealth should help to drive up private spending on health care and prompt governments in many developing markets to implement public health care services to meet rising expectations.²⁰

While some governments are rolling out more and improved public health care services,²¹ other countries' public health systems continue to struggle with poor access, funding shortfalls, and subpar infrastructure and services. These deficiencies are driving an increase in private insurance plans and private hospitals for those who can afford them, resulting in two-tier systems of care delivery and funding mechanisms in an increasing number of countries:

- Public hospitals are still positioned as the main pillar of China's health care system; however, the government is promoting private investment and competition to improve care quality and access, and to address the health-related demands of the country's growing middle class. And while China's public medical insurance has achieved an amazing coverage of over 95 percent,²² the government, under the pressure of rapidly increasing medical expenses, is encouraging private health insurance as a supplement to the public scheme. In 2013, private pre-paid insurance plans accounted for only eight percent of private health care expenditure²³ but the market has been growing. Local large insurance companies stand to benefit, and while foreign insurance providers are active, their market share is likely to remain marginal.
- The Japanese government's Welfare and Medical Service Agency (or WAM) historically has taken care of health care funding in Japan. However, the importance of private sector funding has been increasing in recent years, given the government's financial reform initiatives. One of the measures to promote private funding is a health care real estate investment trust (REIT), for which the government issued guidelines in 2014. Hospitals' management is also shifting from public to private. The government is recommending privatization of public hospitals to increase business efficiency, given that private entities are more likely to pursue a profit and are good at cost optimization. Also, the government allows private hospitals to affiliate with public hospitals under certain conditions.
- The growing prosperity of many Indian households is prompting demand for high-quality medical care and increasing private sector participation.²⁴ Private entities have contributed 70 percent of the country's hospital beds added over the past decade.²⁵ India's established private hospital chains, such as Apollo Hospitals, are embarking on ambitious growth campaigns, while newcomers, including foreign entities, have boosted investment.²⁶ The growing presence of the private sector has led to "corporatization" in health care, with the eight to 10 large chains counting ~200-250 hospitals among them.²⁷ The market is also witnessing an increasing presence of private equity (PE) players which are focusing on super-specialized care and emerging delivery formats such as asset-light, single-specialty, and hub-and-spoke models.

- The current state of health care service in Brazil’s public sector is driving the use of private care by wealthier citizens. In 2014, private health insurance programs covered 50.8 million people — a quarter of the population — making Brazil the world’s second-largest insurance market by population, after the U.S.²⁸ The most popular form of health insurance is provided by U.S.-style health maintenance organizations (HMOs), usually subsidized by employers, and covers 40.2 million enrollees.²⁹

Finally, the trend towards adoption of universal health care continues, with more countries expanding public and/or private health care system coverage or deepening it in order to reduce out-of-pocket spending.³⁰ In perhaps the most visible example of expanding health care coverage, U.S. federal and state governments continue to implement health insurance exchanges under the Patient Protection and Affordable Care Act of 2010 (ACA).³¹ As of June 2015, 9.9 million U.S. customers have bought plans through the federal HealthCare.gov portal and a handful of state-run exchanges, according to the Department of Health and Human Services (HHS).³² The proportion of the U.S. population lacking health insurance, meanwhile, has declined from 16.2 percent in 2009 to 11.1 percent (as of April 2015), and is likely to drop still further by 2019 as measures to enforce company-based enrollment are implemented.³³

Consumer engagement

Today’s consumers are more informed, involved in, and financially responsible for their health care decisions. They also have higher expectations for the services and products they receive. Increasingly, consumers are defining their ideal health care experience beyond traditional clinical elements to include convenience, amenities, and service. Providers, health plans, and governments are adapting to these new expectations by focusing on consumer engagement strategies, cost transparency, and service/product quality.

Several trends driving consumers’ new health care behaviors have significant implications for providers and health plans:

- Employer-sponsored health plans in countries including the United States are shifting most of the cost of premiums to employees and offering high-deductible plans. This increased cost-sharing is expected to result in more economically rational consumers.

- Relationships between consumers and companies in the new technology-driven economy are becoming less transactional and more interdependent.
- Consumers increasingly value online and mobile information exchange with their provider and health plan. Sixty-two percent of respondents to Deloitte’s *2015 Survey of U.S. Health Care Consumers* feel comfortable consulting with a provider via email or phone; 52 percent of consumers would like access to technology that enables review of quality and satisfaction rankings; and 36 percent of consumers have no concerns about using mobile technology to pay their medical bills (23 percent have done so in the past year).³⁴

Changing consumer attitudes and behaviors are prompting sector stakeholders to invest more in new and expanded customer engagement capabilities. For example, if providers wish to retain existing patients and engage new ones, then they should invest in electronic health records (EHRs) that provide a fully featured patient portal system. Patient portals are projected to develop from being reactive regulatory compliance tools to being key patient engagement channels. Implementing access functionalities that patients find beneficial, such as billing and online scheduling, has been found to be important ways to boost patient portal adoption. Health plans, meanwhile, are developing unique offerings and prioritizing the consumer experience by training employees to be more customer-focused and utilizing technology to make services and information more accessible.

Financial

Government spending

Health care is one of the largest industries in the world, at close to 10 percent of global GDP,³⁵ and governments fund much of its operations. However, challenging economic conditions are making it difficult for governments in many of the world’s regions to devote the necessary financial resources to handle expanding health care demands, especially when they are coupled with ever-rising costs. Although the U.S. economy has improved, other countries are not faring as well: there are sanctions and falling oil prices in Russia; a stagnating economy in Japan; significant growth slow-down, rising debt levels, and currency devaluation in China; and recession and inflation in some Latin American countries, to name just a few examples.

The trend towards universal health care illustrates governments' efforts to meet the needs of their growing and aging populations. However, health system expansion typically is accompanied by public and private sector initiatives to control costs and encourage more efficient use of resources.

Health care reform

Many countries are taking a broad approach to cost containment by implementing comprehensive health care reform. In the United States, many elements of the Affordable Care Act are now in place, including the establishment of individual health insurance marketplaces. One major provision that remains to be implemented is the "Cadillac" tax, an excise tax on high-end, employer-sponsored health coverage. As proposed, the Internal Revenue Service (IRS), beginning in 2018,* would assess a 40 percent tax on the value of certain health benefits above the threshold amounts of \$10,200 for individual coverage and \$27,500 for family coverage. Health insurance issuers and self-funded group health plan sponsors must pay the tax on any dollar amount beyond the caps that is considered "excess" health spending.³⁶ Employers across all industries may need to consider whether and how the tax will affect their health benefit offerings; their ability to attract, retain, and motivate employees; and their regulatory compliance. Health insurance plans and other sector players may need to consider the implications and options for product offerings and other impacted aspects of their business.³⁷

China is shifting its focus from increasing health care service volume to enhancing provision efficiency, and is making strides in providing higher-quality care. Current government reform efforts are centered on reducing unnecessary drug usage, upgrading public hospitals, and channeling private capital into health care provision and health insurance. The government is also strongly supporting new digital health technologies as a way to improve efficiency. Additionally, public hospital reform is moving to the forefront. Public hospitals are the dominant care purveyor, providing 90 percent of health care services in China. Two issues are most prominent: One is to establish a tiered health care system so that patients can be diverted from Class III to Class I or II hospitals to enhance overall system efficiency. Another is to restructure hospital revenue models so that public hospitals no longer rely on medicine markups for funding.

In Mexico, implementing health care reform may produce major changes for several key sector players. Three institutions are responsible for providing public sector health services for more than 90 percent of the population (Instituto Mexicano del Seguro Social, at 41 percent; Ministry of Health, at 38 percent; and Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado, at 4.1 percent).³⁸ A primary goal of reform in Mexico is to bridge gaps and enhance communication among these institutions and other stakeholders in the fragmented public health system. Doing so is expected to help reduce duplicated functions and costs, and contribute to greater efficiency in the use of allocated resources. One example is consolidating drug purchases, which, to date, has generated \$225 million in public sector savings³⁹ and contributed to a better supply of medicines. Consolidation also positively impacts consumers' out-of-pocket expenditures, which comprised 91.5 percent of private health spending in 2013.⁴⁰

Recent restructuring of India's government health care budget could impact efforts to improve basic health indicators and the quality of public sector health care services. It also could derail an ambitious universal health care program launched in April 2015. The plan aims to provide all citizens with free drugs and diagnostic treatment, as well as insurance benefits. The cost of that program over the next five years is estimated at \$18.5 billion.⁴¹ As a result, talks are now in progress to revamp the program.

* In a December 2015 budget deal, the U.S. Congress delayed implementation of the tax for two years. (Source: "Cadillac tax delay gives employers relief," *Business Insurance*, December 21, 2015, <http://www.businessinsurance.com/article/20151220/NEWS03/151219784/cadillac-excise-tax-delay-included-in-1-1-trillion-budget-deal-gives>)

Drug price controls

Amid the reform-driven shift to outcomes-focused, value-based payment and reimbursement systems, numerous countries are instituting reform-driven drug price controls. Drug manufacturers will continue to be pressured to justify the cost of their products⁴² based on, among other things, the product's comparative effectiveness against similar offerings. In addition, there exists the perception of predatory pricing by some drug companies, which recently are increasing prices of older yet essential generic drugs by orders of magnitude. Such practices may accelerate governmental regulation of the pharmaceutical industry.

U.S. health plans try to control pharma costs through reference pricing, formularies, and co-payments. Germany moved to a highly regulated pricing regime from a free pricing market in 2011. Value dossiers are used that evaluate treatments as a summary of clinical, economic and patient-relevant therapeutic value.⁴³ The U.K.'s National Institute for Health and Care Excellence (NICE) uses quality-adjusted life years (QALYs) to evaluate the cost-effectiveness of treatments.⁴⁴ In China, the government mandates that all public hospitals procure pharmaceuticals through a provincial, centralized bidding system. The next round of provincial pricing tenders is in 2016, and additional cuts of five to 20 percent are expected for branded drugs.

In December 2014, India's National Pharmaceutical Pricing Authority (NPPA) extended its pricing policies to cover 52 additional medicines, including commonly used painkillers and antibiotics and drugs for cancer and skin disease treatment. More than 450 drug formulations are now on the NPPA's price cap list.⁴⁵

Generic drugs will continue to gain market share as both public payers and health plans seek to reduce costs. Already, generics account for the majority of prescription drugs supplied in China and around two-thirds of total sales value.⁴⁶ In the United States, generic drugs already comprise about 70 percent of the pharma market by volume.⁴⁷ Generics' share is even higher in the United Kingdom; it accounted for around 84 percent of the pharma market in

2012.⁴⁸ Generics sales in Brazil are increasing at a rate of 11 percent year on year.⁴⁹ Japan's government recently raised the target for generic use from 60 percent by the end of April 2018 to 80 percent by April 2021, given a faster pace of generic penetration than expected. Indonesia's shift to universal health coverage in 2014 through its social security provider Badan Penyelenggara Jaminan Sosial (PBJS)⁵⁰ is increasing generics consumption.

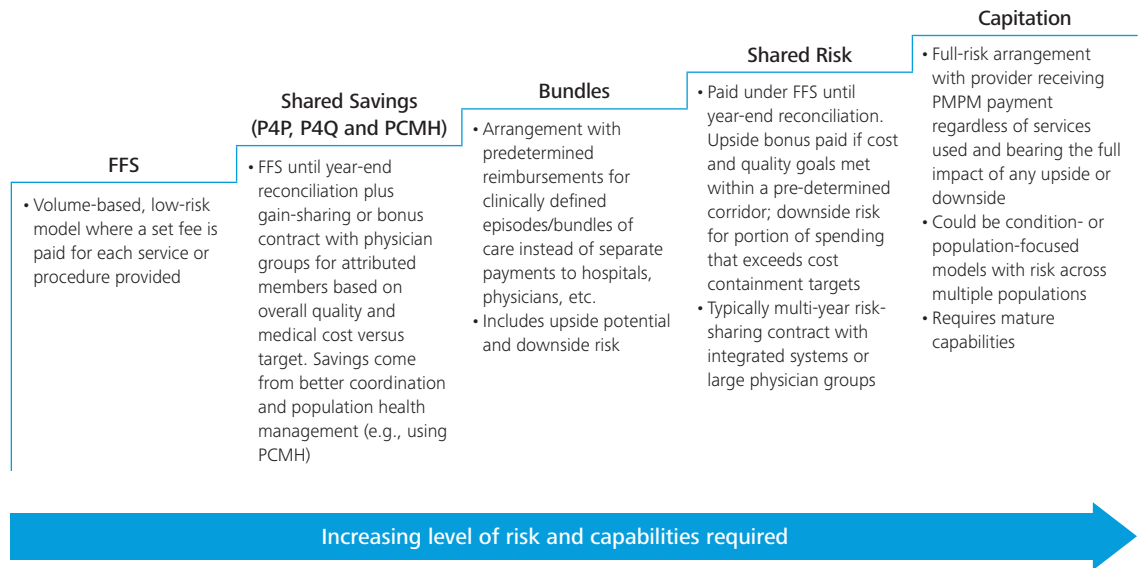
Development and sales of biosimilars, biologic products which are similar but not identical to reference biologic products — and less expensive — are accelerating, as well. Analysts expect the worldwide biosimilars market to reach \$25 billion to \$35 billion by 2020.⁵¹ The European Union (EU) first approved a biologic in 2006; now there are more than 700 biosimilars approved or in the pipeline globally.⁵² In the United States, the Biologics Price Competition and Innovation (BPCI) Act, passed in 2010 as part of the ACA, created an abbreviated licensure pathway for biosimilar products.⁵³ In March 2015, the FDA approved the country's first biosimilar product.⁵⁴

Alternative financial and business models

Value-based payment models

Health systems traditionally have addressed cost management issues by optimizing their supply chain and revenue cycle, using bulk purchasing, improving records management, reducing labor expenditures, and improving clinical efficiency. These approaches can be effective at improving short-term margins but they are not truly transformational. Forward-looking health systems are taking a more critical look at their existing financial/business model to determine how best to shift from volume- to value-based payment methods that emphasize improved outcomes per dollar spent.⁵⁵ Government and commercial payers are accelerating the transition through a range of alternative models designed to align with specific markets and populations, and increase provider risk-sharing across the ecosystem (Figure 3):

Figure 3: Range of VBC payment models



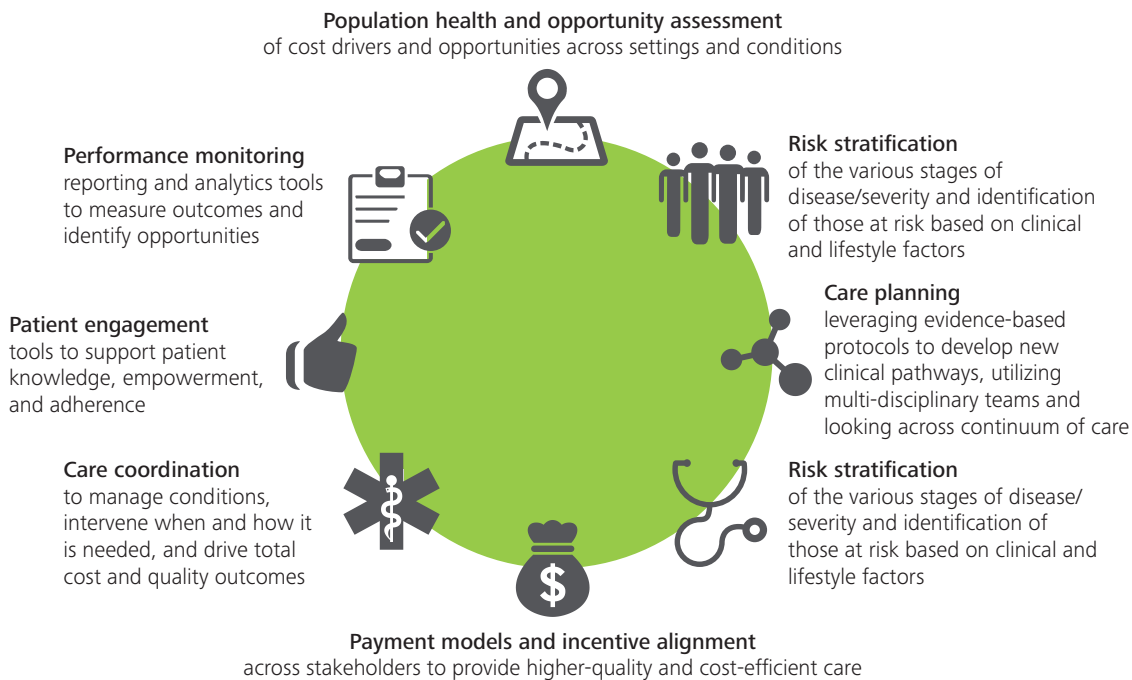
Some governments, in their role of health care payer, are setting goals and timelines for the adoption of alternative payment models. In the United States, for example, Medicare spending accounts for 14 percent of the federal budget and 20 percent of all U.S. health care expenditures.⁵⁶ In early 2015, the U.S. Department of Health and Human Services (HHS) set a goal to tie 50 percent of traditional FFS Medicare payments to alternative models, such as ACOs, by 2018.⁵⁷

Many providers have been hesitant to move to value-based payment models but are now accelerating their build-out of the risk-management capabilities they need to function in a VBC-based ecosystem (Figure 4). Payers are aiding the transition by increasing the level of VBC payment innovation and partnering to help providers successfully assume higher levels of risk.

“At every legislative and regulatory turn, the pressure to shift towards more complex and financially risky payment models will likely only get stronger. The devil will be in the details of balancing investment in new capabilities, speed of transition to VBC, and managing financial risk. Organizations can start now by understanding their market position, assessing their capabilities, conducting a financial analysis and aligning around opportunities.”⁵⁸
 — Mitch Morris, MD, DTTL Global Life Sciences and Health Care Industry Leader and Global Health Care Sector Leader

Not all countries are on board with the shift to VBC payment models. For example, the South African health care system is still structured on the FFS principle. There is considerable talk about shifting to an outcomes-based system but nothing tangible has been put into place yet to help realize this. In the United Kingdom, some of the new models of care being developed under the National Health Service’s (NHS) Five Year Forward View (5YFV) will trial alternative financial models, but substantive change is not expected for several years.

Figure 4: Providers are investing in new capabilities as they reconfigure around VBC models



Public/private partnerships

Opportunity, entrepreneurship, and favorable government policies are prompting increased use of public-private partnerships (PPPs) to fund infrastructure, technology, and other operational improvements. PPPs can concurrently help governments provide more health services to more people and address cost challenges. Some PPP models may include risk-sharing arrangements, similar to VBC, where compensation to the private entity has a component dependent on some result.

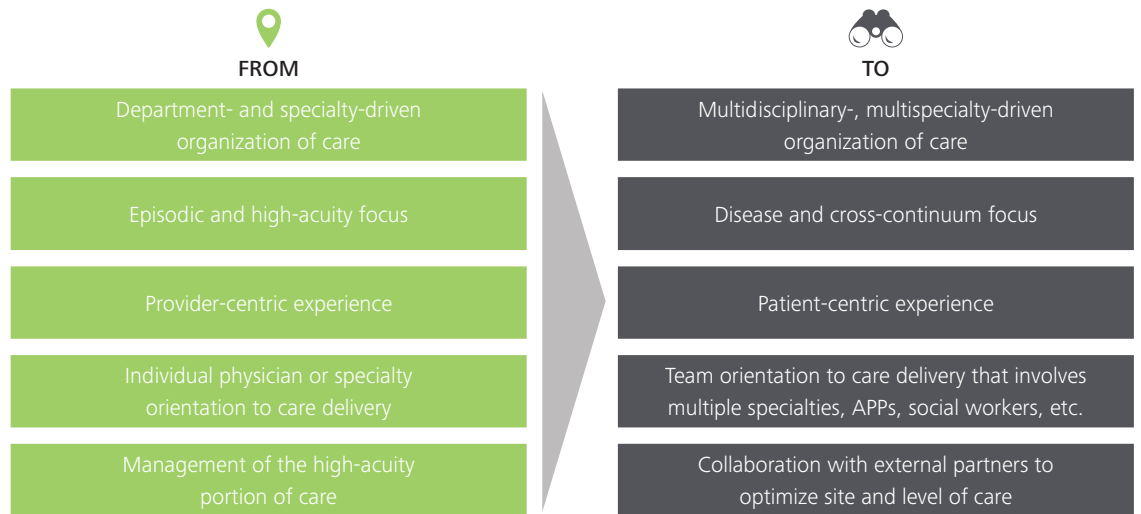
The Brazilian government has been involved in partnership with the pharmaceutical sector and has supported the development of 103 drugs by forming PPPs.⁵⁹ In recent years, Mexico’s debate on private sector participation in the country’s health care system has been focused on adjusting the regulatory framework to enable infrastructure construction projects using PPPs. The National Infrastructure Program for 2014-2018 indicates that, under the current

government, 1.45 percent of resources for health care infrastructure improvements will come from the private sector.⁶⁰ Private-public partnerships are of growing importance in the Philippines, where public need has outstripped government spending.

Operational

As they shift their financial/business model to support outcome- and value-based care, providers also may need to shift their operating model to one that addresses variations in care and that aligns clinicians around consumer/patient-centered care (Figure 5). Many public health systems are grappling with how to reduce variations in care that can lead to health inequalities at the national, regional, and local levels. In London, United Kingdom, for example, the difference between the highest and lowest life expectancy for women is 3.8 years; for men, the difference is 5.1 years. The difference between women and men is 4.1 years.⁶¹

Figure 5: Patient-centered health care provider operating model



Source: HBR, “The Strategy that Will Fix Healthcare”

Moving to a patient-centered health system, meanwhile, can empower patients and engage them in their own health management; open the door to more collaborative provider-patient relationships; enable formal involvement of informal caregivers; create longitudinal relationships which facilitate population management; and advance medical technology adoption by patients and providers.

Patient-centered care extends well beyond the confines of inpatient hospital stays or physician office visits. Providers may need to re-evaluate their role in the care continuum and consider diversifying the care settings and types of services they offer to solidify control over patients as they move through the health system. Developing a service line or integrated practice unit (IPU) that supports strategies centered on value may help drive the overall transformation to patient-centered care. Other potential offerings include preventative care and disease management, wellness programs,⁶² outpatient surgical centers, and provider-sponsored health plans. To support new service offerings, investments in enabling technology will be critical as providers attempt to manage patients across different sites of care.

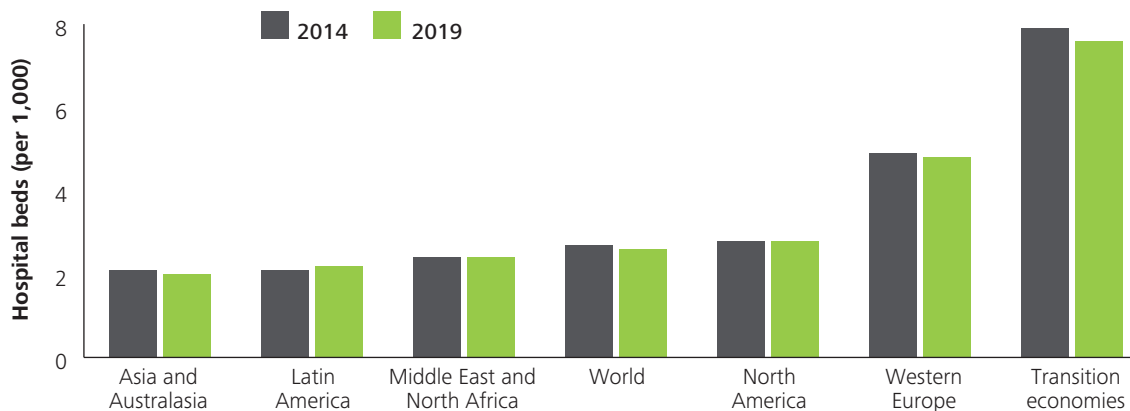
A focus on consumer-/patient-centered care also applies to health insurance. Many companies in the United States are opting out of providing employer-sponsored health plan

coverage. Instead, they are giving employees the money and empowering them to select an insurance plan (using one of the new federal or state insurance exchanges, for example) that meets their needs.

Infrastructure

Numerous developing countries are hampered in their efforts to deliver health care services, especially in rural areas, by an acute lack of resources and infrastructure. Sixty-two percent of Africa’s entire population resides in rural areas, where there is poor access to medical facilities.⁶³ A persistent power crisis in South Africa is making it difficult for hospitals to maintain continuous services, especially in their critical care units. India, with an average 0.7 hospital beds per 1,000 of its population, has a patchy public health care system with underfunded hospitals and clinics, and ineffective health-related schemes.⁶⁴ The country’s limited health care resources are heavily skewed towards urban areas (65-70 percent of infrastructure and manpower), while ~70 percent of the population resides in rural areas.⁶⁵ There is continued need for improved health care infrastructure in China’s tier II and III cities, even though the government has spent a huge amount of money on hospitals and facilities. These cities still need trained doctors, clinicians who know how to run diagnostics, and other medical capabilities to maximize the investments already made in the physical infrastructure and digital health technology.

Figure 6: Hospital beds per 1,000 as compared with regional population, 2011-2019E



Source: DTL LSHC Industry Group analysis of EIU database (accessed July 6, 2015).

*Transition economies include Russia, Ukraine, and East-Central European countries.

Even advanced countries are facing infrastructure issues, such as the need for ubiquitous broadband and mobile communications, technology infrastructure to enable transfer of medical records and imaging such as MRIs, and sharing case management across health and social care populations. Unfortunately, persistent budget constraints are likely to exacerbate infrastructure challenges in many countries. The OECD *Health at a Glance 2015* report⁶⁶ shows wide variation in the number of hospital beds among European countries; in addition, the EIU projects that the number of hospital beds per 1,000 population is likely to decrease between 2014 and 2019, despite growing demand from expanding and aging populations (Figure 6).⁶⁷ There is also a pressing need for community- and home-care beds.

Waste

The need to deliver health care to more patients for less money requires that stakeholders continually identify ways to drive waste out of the system. However, given today's challenging health economy and the fact that organizations have largely picked all the low-hanging fruit, they will have to look towards more complex, fundamental changes to drive down operational expenses. Options include analyzing cost structures to be most efficient in the transition from FFS to VBC contracts; restructuring back office functions; executing shared services; reducing variations in and duplication of tests and other services; embracing and increasing adoption of digital technology to reduce reliance on face-to-face care; providing more care at or closer to home; and supporting patient self-management.

Many public sector health care systems (e.g., Canada, the United Kingdom, and Australia) have different, autonomous, health-related organizations consisting of primary, community, mental, secondary, tertiary, commissioning, clinical training, leadership development, standards, quality, inspection, regulation and policy-making entities. There can be considerable redundancy, overlap, duplication, waste, and delay between, across, and within organizations. For example, an independent review highlighted how England's local NHS hospitals could become safer, more efficient, and save £5 billion by tackling variations in clinical costs, infection and readmission rates, litigation payments, and device and procedure selection.⁶⁸ It's expected that in 2016 many of these health entities will address waste and inefficiency by reducing unit costs and implementing shared services.

One of the main challenges of Mexico's health care sector is the duplication of functions among provider institutions, a politically sensitive issue because it involves union negotiations. As part of its 2016 budget planning process, the government analyzed the country's main health sector programs for ways to reduce administrative costs. Based on its findings, the government is reducing or merging administrative-related programs. In the Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE, for public sector workers) the number of administrative programs was reduced by 52.2 percent; in the Ministry of Health by 15 percent, and in the Instituto

Mexicano del Seguro Social (IMSS) five programs were merged into three.^{69,70}

Population health management is viewed by some as a macro-level approach to making health economies more viable — health must be managed in new ways to ensure that patients are seen in the right place at the right time, and unnecessary treatments/hospital visits no longer take place. According to a RAND study, inpatient care represents around 31 percent of the health care costs in the United States. The general understanding is that improved care coordination and waste-reduction efforts in the inpatient care setting could favorably impact overall health care spending.⁷¹

Alternative care delivery and operational models

Cost pressures, changing staffing models, technology advancements, and consumer preferences are creating a business case for “everywhere care.” In response, numerous health care systems are introducing alternative care delivery and operational models, such as decentralizing or “devolving” from national to local control, and shifting the spectrum of care from hospitals to lower-cost settings. Such approaches can help to improve care efficiency and cost-effectiveness, and create new revenue opportunities for traditional health care providers and new market entrants.⁷²

The United Kingdom operates a universal, publicly funded, devolved health care system with different policies and approaches to delivery in Scotland, Wales and Northern Ireland. In 2015, the English NHS, which provides care free at the point of need for some 68 million people, introduced a new, five-year plan, known as the Five Year Forward View (FYFV). The plan is aimed at evolving the NHS to create a more equitable care landscape; to better enable the NHS to cope with surging demand and, at the same time, tackling an identified £30 billion funding gap that will develop by 2020-2021 if change doesn’t happen. One of the key elements in delivering this plan is the development of new models of care to deliver more local flexibility aided by investment in new workforce models and adoption of technology. Five alternative delivery models are being piloted: integrated primary and acute care systems; enhanced health in care homes; multi-specialty community providers; urgent and emergency care; and acute care collaborations. Each involves new partnerships among local provider organizations and a key role for digital technologies and data analytics aimed at

delivering care in radically different ways.^{73,74} Furthermore, following the establishment of devolved health care administrations in Scotland, Wales, and Northern Ireland in 1997, England in 2015 introduced a new program of public sector decentralization, with a £6 billion contract for the devolution of public services, including health care, in the Manchester health economy.

In the United States, hospital inpatient care and the hospital emergency department (ED) are considered to be the most expensive treatment locations. However, around 30 percent of patients that seek treatment in the ED could potentially receive care in a less acute setting⁷⁵ such as an urgent care center. Treatment costs for minor ailments such as sinusitis and allergies in urgent care centers are approximately 82 percent and 72 percent less, respectively, than ED costs.⁷⁶ In recognition of their cost-savings potential, the number of U.S. urgent care clinics is projected to grow from about 10,000 in 2014 (handling around 160 million visits annually) to more than 12,000 by 2019.⁷⁷

Among other alternative care options growing in popularity:

- **Retail clinics:** Staffed by nurse practitioners and physician assistants, retail clinics are gaining traction in the market, in part due to their convenient locations, hours, and lower cost of care. These clinics are evolving into providers of primary care and chronic disease management. It’s estimated that \$2.2 billion a year could be saved if patients used retail clinics instead of physician offices, urgent care centers, and emergency departments.⁷⁸
- **Home care:** With the appropriate use of technology and monitoring, home health care may reach hospital-level care. It also provides treatment with reduced costs and improved patient satisfaction.⁷⁹ The U.S. home health care market alone was valued at \$77.8 billion in 2012 and is projected to grow to \$157 billion by 2022.⁸⁰ India’s home health care market is worth \$2 billion and is growing at the rate of 20 percent annually, while in Europe, home health care is expected to be worth \$57.2 billion by 2017.⁸¹
- **Telehealth:** Patients in India, Africa, and other remote areas with limited access to health care services can use telehealth (e.g., video chats, patient support lines) to undergo screenings, consult physicians, and receive referrals and follow-up treatment if required. Telehealth is one example of connected health (cHealth), digital and technology-enabled integrated care delivery.

- Medical tourism:** Political actions such as the renewal of diplomatic relations between Cuba and the United States could substantially increase demand for medical tourism in the Americas region. Mexico is already the world's second-biggest medical tourism destination (behind Thailand), generating \$3 billion in 2014.⁸² Mexican agencies expect that with increased investment, the country could grow medical tourism revenues to \$10 billion-\$12 billion in the next seven to eight years.⁸³ Oil-rich countries in the Middle East, notably the UAE and Saudi Arabia, view better health care provision – including medical tourism – as a way to diversify their economies.⁸⁴

The U.S. home health care market was valued at \$77.8 billion in 2012 and is projected to grow to \$157 billion by 2022.⁸⁵

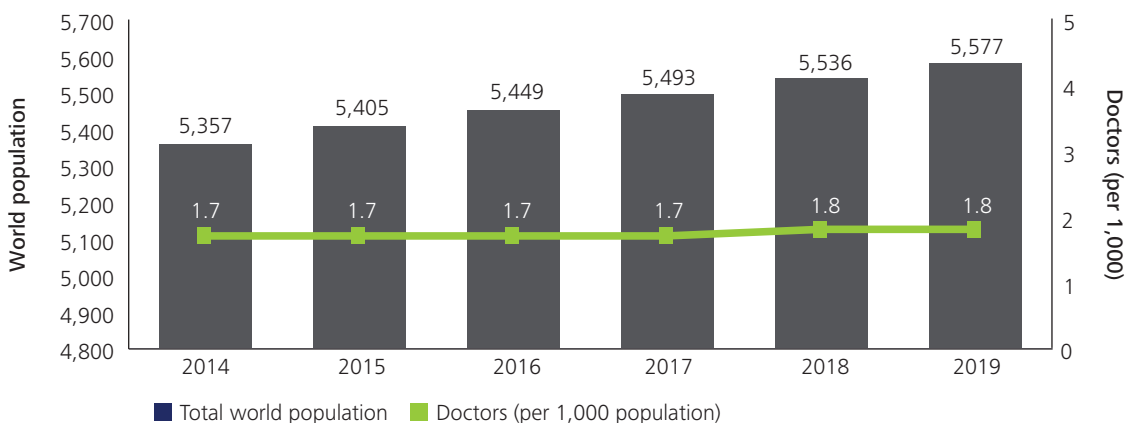
Talent

As their populations and health care needs grow, countries all over the world struggle to match the demand for trained medical professionals, mainly physicians and nurses. Workforce shortages are a major contributor to health care access problems in developing countries and increasing health care costs in developed countries. The problem is anticipated to persist well beyond 2016, as the number of doctors per 1,000 population is projected to remain almost the same globally between 2014 and 2019 (Figure 7).

India is desperately short of doctors, with just 0.6 per 1,000 inhabitants, and lacks specialists in many medical disciplines. The problem is particularly acute in rural areas.⁸⁶ Talent recruitment also is a critical issue for China's health care sector. Big hospitals often discourage their doctors from practicing in multiple facilities, either officially or unofficially, one factor which has held back the development of private hospitals. Although pilot projects are underway to allow physicians to practice at multiple sites, they are still tied to public hospitals and focus on maintaining their professional ranking within the public system. Private and foreign hospitals still face the obstacle of recruiting reputable physicians.

The United Kingdom's FYFV health initiative depends on access to sufficient appropriately qualified talent, however, shortages and "critical pressures" in the NHS workforce, including major disconnects between strategic goals and workforce trends, need to be addressed. Solutions include developing new types of health care professionals, such as nurse consultants and clinician assistants.

Figure 7: Doctors per 1,000 as compared with world population



Source: DITL LSHC Industry Group analysis of EIU database (accessed July 6, 2015)

Persistent talent challenges are prompting some health care providers to change their delivery structures. Certain services currently provided in hospitals are instead being provided in the community, either as outreach or by primary care clinicians, nurses, and other health care professionals. Consolidating or federating GP practices and better use of e-visits, online triage before appointments, and group clinics are options being deployed to address primary care demand. Recruiting adequate numbers of employees is just one part of the problem; health care organizations need to retain and develop employees with the clinical and leadership skills required to deliver care in a new quality-focused, value-based, consumer-centric environment. Deloitte's 2015 *Global Human Capital Trends* report⁸⁷ identifies 10 human resources (HR) trends that are likely to present talent-related challenges for health care organizations in the coming year. These include culture and engagement; leadership; learning and development; reinventing HR; workforce on demand; performance management; HR and people analytics; simplification of work; machines as talent; and people data everywhere. The report also calculates a "capability gap" for each challenge, measuring the difference between an issue's importance and an organization's readiness to address it. Unfortunately, comparing 2015's results to 2014 data, the capability gap in many of these areas has increased in magnitude. This suggests that the accelerating economy and rapid changes in the workforce have created even more urgency in the need to adapt HR and people practices around the world.⁸⁸

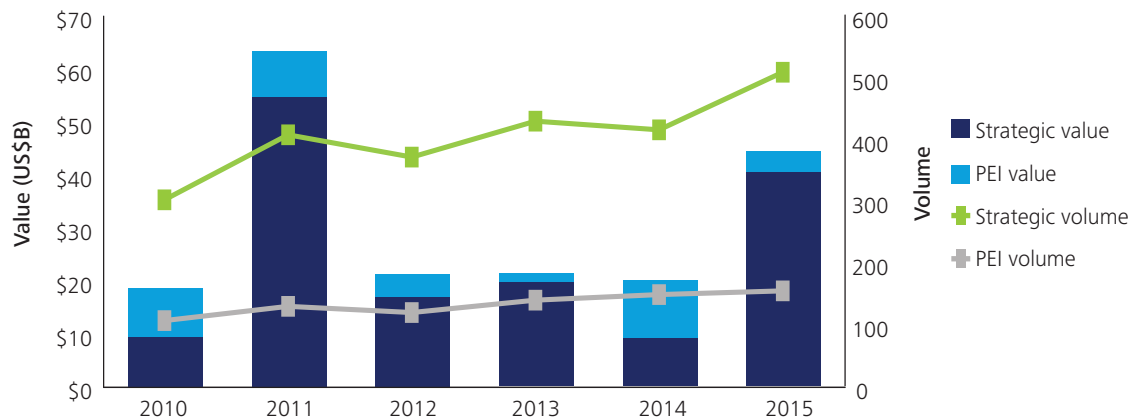
M&A

Spurred by market competition, reform-driven financial challenges, and persistent regulatory pressures, increasing numbers of health care providers, particularly in the United States, are using M&A to consolidate hospitals and form large health systems that offer economies of scale and broader service reach. Health systems are also acquiring independent physician groups and/or directly employing physicians to plug gaps in service offerings and support new models of care delivery. Organizations are leveraging their acquisitions by implementing integrated technology platforms which give the newly expanded entity the capabilities to run population health initiatives, assume greater levels of risk, and — for some — launch their own health plans. In fact, one in five U.S. health systems anticipates offering health plans by 2018.⁸⁹

M&A among global health care providers increased dramatically in both volume and value between mid-2014 and mid-2015 (Figure 8). U.S. health care providers generated the majority of top deals during the first half of 2015. These included UnitedHealth Group Inc.'s (UHC) acquisition of Catamaran Corp. for \$13.2 billion and CVS Health Corp.'s purchase of Omnicare Inc. for \$12.6 billion. In other global regions, AMP Capital Investors Ltd. of Australia acquired Royal North Shore Hospital for \$.9 billion and Remgro Jersey Ltd. bought a 29.9 percent stake in Spire Healthcare Group Plc. for \$.7 billion.⁹⁰

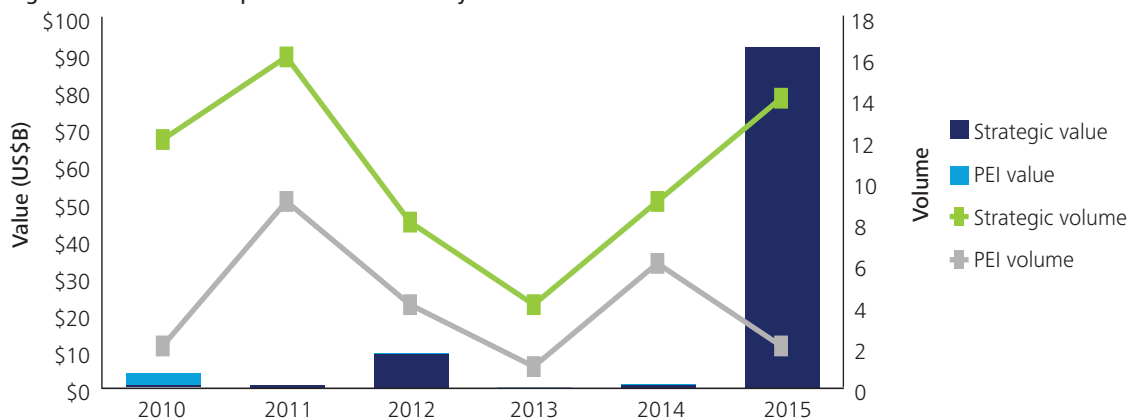
Health plan M&A deal volume and value rocketed in 2015 versus 2014 (Figure 9) due, in large measure, to

Figure 8: Global health care providers M&A — YTD July*



YTD comparison of the same period across prior years
Source: DTTL LSHC Industry Group analysis of Thomson Reuters

Figure 9: Global health plans M&A — YTD July*



YTD comparison of the same period across prior years
 Source: DITL LSHC Industry Group analysis of Thomson Reuters

two mega-deals by large U.S. health plans: Anthem Inc.'s announced acquisition of Cigna Corp. for \$49.4 billion and Aetna Inc.'s announced purchase of Humana Inc. for \$34.6 billion. There was also non-U.S. M&A activity, albeit on a much smaller scale. In China, health plan Jiangsu Sanyou Group Co. Ltd announced its intent to purchase Meinian Onehealth Healthcare (Group) Co. Ltd. for \$1.3 billion and in the UAE, NMC Health PLC agreed to purchase ProVita International Medical Center LLC for \$.2 billion.⁹¹

In addition to M&A, providers and health plans have been using partnering strategies as a way to expand their footprint and participate in selected aspects of the care continuum. Through partnering and alliance arrangements, organizations can build or expand much-needed capabilities — shared services, facilities, community outreach programs, pre-/post-acute services, wellness programs, clinical integration, population health, and risk sharing, to name a few — more quickly and cost-effectively than building solutions in-house.

Partnership models span increasing levels of integration, and include collaboration/network affiliations, joint operating agreements, capital partner joint ventures (JVs), and full JVs. For example, joint ventures with for-profit, post-acute providers are growing in popularity because they provide management expertise and require less up-front capital. In the United Kingdom, the NHS has entered into a five-year, £5 million partnership agreement with Virginia Mason Institute in the United States to help improve

hospital efficiency and improve patient safety. 2015 also saw the emergence of NHS partnerships with private sector IT companies to implement large-scale EHR systems, which are likely to increase in 2016.

Innovation
Medical advances

Innovation has been a core aspect of advancing medical care for decades. Unraveling the human genome and the emergence of precision medicine is opening new avenues of targeted therapies for the most challenging diseases. However, medical innovation comes with a high price tag.⁹² In all markets, advances in health technologies will continue to drive up costs.⁹³

Case in point: Four new drugs approved in the United States to treat hepatitis C can essentially cure the disease. Plus, the new treatments offer long-term cost savings by decreasing the risk of liver failure, cancer, and the need for possible transplant.⁹⁴ Yet, the costs of these drugs are substantial and some state Medicaid programs and other insurers have placed stringent restrictions on drug availability.⁹⁵ But comparing the lifelong treatment costs per patient for these conditions on existing treatment regimens is resulting in market competition and hard bargaining by public and private insurers to help to drive down the costs of these innovative and much-needed medicines.⁹⁶ Governments may begin to weigh the costs of a therapy to determine the overall value delivered by such new treatments against the resources saved by avoiding disease progression.

Personalized care

Widespread adoption of personalized/precision care, shifting clinical offerings from mass generalization to mass customization, will likely be made possible through public and private investments in offerings that integrate drugs and devices with low-cost diagnostics, disease management programs, and clinical decision support. In the United States, for example, the proposed FY2016 budget includes \$215 million for the Precision Medicine initiative, which is focused on building a large research cohort for longitudinal studies, and ensuring regulations are appropriate to facilitate sharing of patient data across institutions and agencies. Ultimately, the goal is to get more targeted treatments for a variety of diseases to patients faster.⁹⁷

Personalizing care based on genetics and individuals' health information has the potential to generate new therapies that may radically improve outcomes. For example, approximately 30-40 percent of patients take drugs for which the adverse effects outweigh the benefits.⁹⁸ This is neither cost-effective nor therapeutic. Targeted therapies paired with genetic diagnostic tests help physicians to select an optimal treatment the first time, avoiding the costly and risky practice of trial-and-error prescribing. Other innovations in personalized care include specialty drugs, which show potential to improve life expectancy and quality of life.⁹⁹ When used with biomarkers to target subpopulations, these drugs could improve outcomes, lower treatment cost, and even prevent disease.^{100,101} Although personalized medicine discoveries are increasing, payer reimbursement currently is "limited and highly variable." Additional research is needed to demonstrate a return on investment to payers.¹⁰² It's likely these treatment approaches will be slow to evolve in the next two-to-three years.

Digital connected health

The demand for value and an increasingly competitive environment are prompting health care organizations to find new and more effective ways to improve care delivery. This includes making services more accessible and potentially less expensive by enabling patient-provider connectivity "anytime and anywhere." Specifically, health care organizations are exploring ways to facilitate communication between providers and consumers; engage consumers; and support prevention and management of chronic care outside traditional settings.

Connected health (cHealth) is digital and technology-enabled integrated care delivery that allows for remote communication, diagnosis, treatment, and monitoring. An important goal of an effective, patient-centered approach is to improve digital connectivity between providers and patients to allow individuals to access the care they need, anytime and anywhere.

Advancements in digital health technology are leading to advancements in connected health. Data captured by wearable devices, mobile health apps (mHealth), and social media are being used to transform aspects of health care that earlier seemed beyond the purview of such technologies. For example, developing nations facing a critical lack of health care resources and infrastructure, especially in rural areas, are exploring the use of digital-based care delivery models to help bridge the gaps. Digital health is also becoming an important platform for providers and health plans to strengthen patient engagement programs and collaborate with other stakeholders in the health care system.

Use of digital technology is likely to be a key area of development within the U.K. health care system, although the speed of adoption will be variable. National and local governments are championing eHealth and digital health strategies — the NHS in England is expected to be paperless by 2020 and to have interoperable electronic health records accessible by patients by 2018. Health IT is the fastest-growing segment in India,¹⁰⁴ where digital health's potential benefits are particularly powerful in a country which has a large proportion of its population living in rural areas, with poor affordability and limited access to health care services. The innovative use of technology can help to maximize India's limited health care resources at a lower cost.

In the world of connected health, the combination of sensors, networks, standards, augmented intelligence, and consumer behavior is creating opportunities to impact and improve the patient journey. The key objectives of cHealth include:

- Improve digital connectivity among consumers, providers, health plans, and life sciences companies.
- Facilitate self-managed care, with the help of technology-enabled solutions, in a secure environment that protects consumer privacy.
- Deliver care outside the traditional clinical setting, potentially providing better access to care at a lower cost.
- Assist chronic care management and improve population health outcomes.¹⁰⁵

The size of the global digital health market comprising wireless health, EHRs, Electronic Medical Records (EMR), mHealth, and telehealth, among others, was \$60.8 billion in 2013 and expected to increase to \$233.3 billion in 2020, growing at a CAGR of 21.2 percent. Moreover, these offerings are leading to developments in related markets such as wireless network tools, sensors, and devices.¹⁰⁶ Digital health venture funding exceeded \$4 billion in 2014; telemedicine was the fastest-growing segment with 315 percent year-over-year growth from 2013-2014.¹⁰⁷

Five areas in digital and connected health — telehealth, mHealth, electronic patient records, wearables, and social media — are growing rapidly in use and influence and, thus, hold considerable implications for the health care sector.

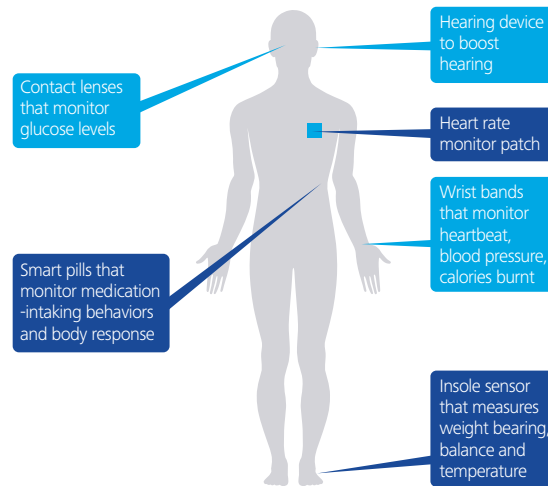
Telehealth: For patients with congestive heart failure, diabetes, depression, and other chronic conditions, telehealth technologies such as home telemonitoring can reduce hospital readmissions and increase the ability of individuals to live independently¹⁰⁸ and adhere to their prescription drug schedule. It also can defer the need for and/or improve assisted living and nursing home care. According to the Deloitte *2015 Survey of U.S. Health Care Consumers*, respondents view telehealth as an acceptable care alternative.¹⁰⁹

mHealth: Mobile health (mHealth) applies the power and reach of mobile communication to health care services. It plays a key role in transforming health care into a more efficient, patient-centered system of care in which individuals (and providers) have real-time access to information to support engagement.¹¹⁰ A report estimates that by 2015, over 500 million of a total 1.4 billion smartphone users worldwide will be using mHealth apps. And by 2018, 50 percent of the 3.4 billion mobile device users will have downloaded mHealth apps.¹¹¹ mHealth applications can range from basic (e.g., an app compiles reports on daily calorie, sodium, fat, and carbohydrate intake from manually entered user data) to intermediate (e.g., an inhaler with a built-in asthma sensor to measure air quality) to advanced (e.g., a portable device that measures temperature, heart rate, blood oxygen levels, respiratory rate, ECG, and blood pressure and transmits the data to a mobile device).¹¹²

Electronic patient records: Population health is anticipated to drive the need for integrated records across many different health and social care systems and, by extension, the use of electronic patient records. A trend may emerge (more quickly than many expect) for people to own and manage their own electronic health and social care record. This trend will be partially driven by the fact that (especially public sector) health care systems will lag behind technology available to patients and citizens, who will want to create, buy, and manage access and control before their health care systems are able to provide it.

Wearables: Many health-related wearable innovations leverage the power of biosensors, which can be placed in a watch, a patch on the skin, implanted under the skin, or swallowed like a pill (Figure 10). In addition to motion, light, pressure, temperature, moisture, and gas, biosensors soon may be able to monitor chemicals and biomarkers. For example, doctors may be able to use biosensors to determine how well a drug is metabolized and adjust the dosage and frequency accordingly.¹¹³ Illustrating the market interest in this digital health trend, venture capital funding for bio-sensing wearables increased five times from 2011 to 2013, reaching \$282 million in 2013.¹¹⁴

Figure 10: Examples of how wearables might transform information and understanding of people's health status



Source: *Healthcare and Life Sciences Predictions 2020: A bold future?*
U.K. Deloitte Centre for Health Solutions, 2014

Across the spectrum of care, digital and cHealth strategies may help to reduce costs and improve health outcomes, patient satisfaction, and long-term consumer engagement. For example, Deloitte analysis shows that a well-planned cHealth strategy that uses remote monitoring and telehealth for a targeted, high-cost patient population has the potential to increase health care cost-effectiveness under value-based payment models such as ACOs or global capitation.¹¹⁶

Yet, data integration challenges, privacy and security concerns, and provider resistance to adopt new business models have slowed cHealth adoption. Consumer demand and expectations, and the public and private sectors' rapid uptake of value-based care initiatives are changing the landscape for cHealth. In response, technology developers and health care organizations should consider the potential of cHealth savings, the investment costs for new digital technologies, and targeted strategies for the patients who may benefit most.¹¹⁷

Data & analytics

As health systems continue to face shrinking margins, tightening budgets, and evolving payment models, the combination of data and analytics is being touted as the

missing key to unlock new sources of value. Indeed, data and analytics are expected to be among key investment areas for health systems looking to update their IT infrastructure in 2016. However, the market for analytics remains complex and confusing, with too many solutions providers to count. Buyers are beginning to focus more on the value added by analytics, and we expect market consolidation in the space in the next year or two.

Health care analytics' growing importance is being fueled by industry stakeholders' thirst for information; the need to manage large, diverse data sets; increased competition; growing regulatory complexity; and innovation ranging from medicine to value-based care to population health management. Many look at health care analytics as "the next big thing" — health systems are undergoing a major transformation in how they are paid and how they are expected to deliver care, and analytics can assist with the transition. Real-time analytics will be useful to assess the efficacy of different interventions in disease pathways; to provide personalized patient care; to inform performance management of commissioned services; and to flex payments up and down (including incentives) according to provider performance.

Also, as more data becomes available from sources like electronic health records, claims, medical devices, and patients, analytics can help detect hidden patterns in information, delivering actionable insights and enabling self-learning systems to sense, predict, infer, and conceive alternatives that might not otherwise be obvious. In the future, such insights are likely to play a major role in helping health systems improve costs and quality, identify at-risk populations, connect with consumers, and better understand performance.¹¹⁸

Case in point: Outcome-based contracts (aka risk-sharing agreements) have been leveraged frequently in Europe, and offer the potential for earlier provider access to new products by linking coverage and reimbursement levels to real-world performance or utilization of the product. As more payers seek value-based contracts, coupled with the high cost of personalized/precision medicine, it is expected that life sciences manufacturers will need to deploy sophisticated analytical systems to determine, track, and provide outcomes evidence to demonstrate comparative effectiveness and justify desired levels of reimbursement.¹¹⁹

Analysts' estimates vary, but widely publicized numbers for today's global health care analytics market range between \$4 billion and \$5 billion, with the United States accounting for about half.¹²⁰ Investments in analytics technologies that improve operational insights and efficiencies are expected to contribute substantially to health care IT spending in 2016. However, barriers to widespread adoption remain; among them, data complexity, security issues, and privacy restrictions. In addition, much work will be needed to educate health care providers, payers, and the general public about the benefits of sharing health-care-related data to accelerate R&D outcomes and monitor patient benefits.¹²¹

Regulatory compliance

Patient and product safety

Much of health care's regulatory focus is on patient and drug safety. Regulatory agencies continue to exert pressure on pharma, biotech, and medtech companies, with increasing emphasis on off-label marketing, failures to disclose safety risks, and concerns about the clinical trial process.

Among recent developments with implications for 2016 and subsequent years is an upward trend in health authority findings, 483s, and Warning Letters related to unreported adverse events (AEs) found within third parties and non-safety departments at pharma companies. In response, companies are implementing ongoing AE reporting assurance and monitoring programs, leveraging technologies with natural language processing capabilities, to continuously identify AEs in non-traditional sources and confirm that those AEs were properly reported to health authorities.

Product serialization requirements are in various stages of development in the EU and its member nations, as well as Turkey, India, China, Brazil, Argentina, and Korea.¹²² Meanwhile, U.S. pharma companies are dealing with time-critical elements of the federal Drug Quality and Security Act, which mandated that, by January 2015, manufacturers had to incorporate product transaction data into a single document that is available, either electronically or on paper, each time ownership is transferred. By November 2017,

that information must be available electronically, and the product identifier must be affixed or imprinted on the label at the product and case level.¹²³ In a similar fashion, EU legislation is mandating the implementation of new data standards called Identification of Medicinal Products (IDMP), which allow for the unique identification of such products on an international level by developing a method and process for generating global product identifiers that can be used for product reconciliation and linkage across the entire product supply chain.¹²⁴ Compliance for IDMP is expected to begin in the EU in July 2016 and continue to evolve throughout 2017 and 2018 via iterative rollouts addressing additional scope.

In other regulatory developments, U.K. and European regulators are trying to control off-label use of medicines. The European Association of Euro-Pharmaceutical Companies (EAEPC), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Generic and Biosimilar medicines Association (EGA), European Association of Pharmaceutical Full-line Wholesalers (GIRP) and Pharmaceutical Group of the European Union (PGEU) announced in February 2015 the establishment of the European Medicines Verification Organization (EMVO). EMVO is a not-for-profit organization that serves as a tool to combat the emergence of falsified medicines in the EU legitimate supply chain and improve patient safety by allowing end-to-end verification of medicine packs from the point of manufacture through to wholesale distributors. It will carry out risk-based verification to the dispensing point for patients, with the intent of securing the entire supply chain. Germany will be the first member state to contribute fully to the improved Europe-wide verification system under the auspices of EMVO, through its securPharm system.

Developing countries also are addressing safety issues, with varying degrees of success. India's government has implemented new rules for clinical trials, which aim to protect patients from exploitation.¹²⁵ Additionally, the government is compiling an extensive database on domestic pharmaceutical manufacturers and is granting access to drug regulators and retailers around the world following concerns about counterfeit drugs emanating from the country.¹²⁶

“Clinicians and patients have exacting expectations of regulators and are unforgiving when regulators are perceived to impede the adoption of promising new technologies or treatment but also when they fail to protect patients from quality or safety issues. Regulators must invest in new capability to meet new expectations, such as assessing information governance and cyber security, which will gain increasing prominence in the light of increasing amounts of data.” (David Hodgson, DCTL Global LSHC Enterprise Risk Services Leader)¹²⁷

Cybersecurity

Although the digitization of health care data and advancements in enabling technologies are improving patient care and operational efficiency, these improvements are being accompanied by pervasive, persistent cyber risks that can leave organizations vulnerable to debilitating business losses and reputational damage. Provider and payer organizations handling personally identifiable information (PII) and protected health information (PHI) must continually guard against malicious cyber events that are increasing in frequency and severity. Among emerging threats that should prompt sector stakeholders to implement enterprise-wide cybersecurity programs are:

- **Cloud-based computing attacks:** With the broad migration of software to the cloud (public/hybrid) as a main backup storage platform, the health care sector has been exposed to new security challenges from distributed denial of service (DDoS) and related types of cyber attacks. Business losses from DDoS and other threats can range from \$10,000 to \$100,000 per hour,¹²⁸ and such security breaches may lie undetected for several hours or even days, driving damages and costs into the millions of dollars. This threat also holds regulatory implications, as health authorities appear to be focusing attention on risks related to unauthorized changes made to public cloud platforms that could inadvertently impact functionality that touches patient safety or product quality.

- **Medical device security concerns:** While medical devices are playing a transformative and beneficial role in health care, they also pose risks to patient safety and health information security. As innovation continues and the threat landscape evolves, securing medical devices becomes more crucial. The quantity and types of potential threats increase as awareness of cybersecurity vulnerabilities grows, potentially risking patient confidentiality and the integrity and availability of device and patient data. When a medical device itself, or the integrity and availability of its data, is compromised due to a security breach, the loss of integrity may lead to faulty data which, in turn, may cause the device to malfunction or result in incorrect care decisions by medical practitioners.
- **Privileged access:** Privileged accounts with access to the most sensitive information have been around for years, and protecting them has never been more important. Privileged access management has evolved into a framework that improves cohesion among business processes, user management and various tools. This framework enables improved operational effectiveness and reduces the risk of insider attacks, while also complying with organizational security policies and offering auditing capabilities to meet various regulatory obligations.

Fraud and abuse

Relationships can be complex in the business of health care: Tracking and analyzing them is an important part of minimizing fraud and abuse that may result from questionable relationships and improper influence. Increasingly, regulators are emphasizing relationship scrutiny in their fraud and abuse enforcement efforts. Health care organizations can follow their lead by using analytics to identify which improper relationships may present fraud and abuse risks. An effective program will likely enable organizations to identify risks in real time, adjust to mitigate them, and avoid the potential burdens of government investigations and enforcement actions.¹²⁹

Stakeholder considerations

The global health care sector is undergoing a dramatic and fundamental shift in business, clinical, and operating models. Rising costs are a primary driver — and outcome — and stakeholders are responding in various ways, with varying degrees of success. Governments are implementing measures such as direct contracts with hospitals, readmission penalties, and discharge planning to bring down expenses. Providers are developing expertise in population health management, outsourcing non-core activities and collaborating with payers, life sciences companies, and other organizations to fund infrastructure improvements and share information and expertise. Some of these collaborations are expected to advance new, cost-effective care delivery models and targeted treatments required for delivering personalized care. The following are among important considerations for health care stakeholders as they look to address marketplace and organizational issues in 2016 and beyond:

Demographics: Managing the health care impacts of population aging will be a major imperative in 2016 and the foreseeable future. Most of the elderly's health problems are the result of chronic diseases, many of which can be prevented or delayed by engaging consumers of all ages in healthier behaviors.¹³⁰ The World Health Organization's 2015 *World report on ageing and health* outlines an action framework based on the new concept of functional ability. Implementation will require health systems to shift from today's disease-based, acute-care, curative models towards integrated care that is centered on the needs of older people. It will also require global policies to align health systems to the needs of the older populations they serve; introduce better ways to measure and monitor the health and functioning of older populations; develop systems for providing long-term care; and create age-friendly environments.¹³¹ Community-enabled, self-directed elder care approaches should include modular, self-directed solution sets that encompass seamless expansion of support through the end of life, and enhanced non-medical caregiver skills training to expand much-needed capacity to care for the elderly outside institutions.¹³²

Financial: Health care payers, employers, and consumers are demanding more value for fewer dollars. Delivering on this directive will be essential to health care providers' future financial success;¹³³ as a result, historical payment schemes are being upended as new, value-based models incentivize providers to improve quality, transparency, and service, and to reduce waste and inefficiencies.¹³⁴

To boost physicians' participation in value-based payments, health care partners (health systems, hospitals, health plans, and other stakeholders) should provide fairly structured payment models and support to manage risk and protect financial interests. In addition, they should build physician-centered strategies around the clinical and business resources, capabilities, and skills needed for VBC success. These include expanded clinical support capabilities, enabling technology, health information technology (HIT), access to non-physician staff to coordinate patient care, and managerial expertise and business knowledge.¹³⁵

There is no single, "right" way to transition to value-based payments. Starting the process of getting to an equitable, risk-mitigated, aligned incentive model is what's important. This process requires a strong market, target population, and clinical data to determine what price point will result in a competitive rate and an appropriate share/target for each involved party. The process also requires informed physician and hospital leadership armed with data that can show what is needed to get to this price point, financial scenarios that illustrate a feasible path forward, and an opportunity analysis that demonstrates how savings can be generated.¹³⁶

Operational: The pace of change in health care operations needs to accelerate. Sector participants don't have the runway to slowly identify and adopt changes in clinical practices, policies, and processes — already, demand pressures are outstripping public and private organizations' abilities to respond to patient needs using existing care settings, operating funds, and workforce.

Efficiency is the watchword, and there are numerous ways for providers, health plans, governments, employers, and technology vendors to add it to their vocabulary. Among game-changing developments, large regional and global organizations are centralizing corporate services under a structure that uses shared services and centers of excellence to increase efficiency and innovation throughout the value chain. Hospitals are using predictive analytics to plan long-term patient health care management by identifying individuals at risk of repeat hospitalization. Payers and providers are using data analytics to aid physicians in clinical decision making (i.e., evidence-based medicine). Digitalized medical practices are generating vast amounts of data which can be employed for mapping and monitoring diseases and attaining greater precision in diagnostics.

Innovation: The convergence of powerful marketplace trends is generating growth opportunities for health care organizations and driving the need to innovate. Finding a way to pull through the value of innovation in an accelerated, scalable fashion, however, is an ongoing challenge. Executing tailored and integrated “innovation plays” that capitalize on new technologies, delivery options, patient experiences, and partnering across the value chain can help organizations reduce costs and propel them past their competition. As the health care ecosystem grows to include an increasing number of varied organizations, technology, and data sources, traditional stakeholders should consider looking both internally and externally for new innovation opportunities.¹³⁷

In developing countries, health innovations likely will need to come from the private sector, as most public resources are focused on providing quality health services through proven mechanisms, devoting little of their resources to developing innovations. However, given the amount of health information that is generated daily, analytics may help to guide public sector innovation efforts.

Finally, to support development and implementation of medical and technological innovations, regulatory agencies will need to employ greater speed in issuing and approving quality, safety, and effectiveness regulations.

Regulatory compliance: Taking a risk-based approach to regulatory compliance planning, execution, and monitoring makes good clinical and business sense in the risk-intensive and highly regulated health care environment. Health care organizations should promptly assess potential capability gaps, define their vision and needs,¹³⁸ establish a forum and governance process for risk-related decision making, secure adequate funding and trained staff, and develop appropriate implementation and remediation programs.

Cyber security should be a major focus of enterprise risk planning. New care and insurance models, electronic information transmission, and permeable boundaries among industry participants increase the complexity of managing sensitive and confidential information. Organizations can avoid or mitigate cyber breaches with a centralized security program that contains authoritative, uniform, and efficient policies and decisions;¹³⁹ encourages employees to recognize and report potential threats; and verifies the cyber security and privacy practices of third-party business partners that handle PII and PHI.¹⁴⁰

Finally, information-sharing and partnering can help to reduce operational and regulatory risks. Some countries are working across governments and agencies to promote a more systematic approach to regulatory rule-making, monitoring, and enforcement. For example, in the Southeast Asia/Asia Pacific region, which is generally regarded as having a fragmented regulatory framework with patchy enforcement, governments have been moving independently and collectively towards establishing more structured, collaborative regulatory oversight.¹⁴¹

For regional and country perspectives, please visit www.deloitte.com/healthcareoutlook. Please visit www.deloitte.com/healthcareoutlook/sources for a complete listing of sources referenced in this report.

Appendix

Explore the latest health care sector research from Deloitte members or visit:

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Are employers prepared for the “Cadillac” tax?

Although much of the Affordable Care Act has been implemented, some major provisions are not yet in effect, including the “Cadillac” tax — an excise tax on high-cost, employer-sponsored health coverage. How might implementation impact employers and the health care industry? What steps have organizations taken in anticipation of the Cadillac taking effect?

Anytime, anywhere care: Accelerating the adoption of connected health

Prompted by an increased demand for value and connectivity, health care organizations are making services more accessible and potentially less expensive while enabling “anytime and anywhere” patient-provider connectivity through Connected Health (cHealth). cHealth is transforming the patient-provider relationship with technology-enabled, integrated care delivery that facilitates remote communication, diagnosis, treatment, and monitoring. Are health care providers ready for this transformation? Will patients adhere to using connected health to monitor their conditions?

Beyond compliance: Leading governance practices for health care cyber security and privacy

Analysts expect the worldwide biosimilars market to reach approximately \$35 billion by 2020. While developed markets will remain important for biosimilars manufacturers, Deloitte analysis indicates that long-term growth may be fueled by emerging markets. To remain competitive, manufacturers should develop a global biosimilars strategy that includes “where to play” and “how to win.”

Health care fraud and abuse enforcement: Relationship scrutiny

Relationship scrutiny is likely to rise as health care industry collaboration increases. Organizations can follow the lead of federal regulators by using analytics to identify improper relationships that may present fraud and abuse risks.

The quest for value in health care: A place for consumers

Three key disrupters are driving an increasingly consumer-centric health care system. How are consumers responding? What are the implications for the industry? And what steps can health care providers, health plans, and life sciences companies consider to help win in this new marketplace?

Connected health: How digital technology is transforming health and social care

With more than 100,000 health apps, rapid growth in wearables and 70 per cent of the U.K. population now owning a smartphone, digital technology looks set to revolutionize the future of health and social care.

The road to value-based care: Your mileage may vary

Value-based payment models for health care have the potential to upend traditional patient care and business models. What can your organization do to effectively make the shift?

Healthcare and Life Sciences Predictions 2020: A bold future?

Healthcare and Life Sciences Predictions 2020 is based on an observation of trends, events, and bold steps that, if accelerated over the next five years and beyond, will paint a picture of a very different world in 2020. The report aims to challenge assumptions and provide thought-provoking visions to enable you to have rich dialogue within your organization about future scenarios and how best to respond.

Digital Health in the U.K.: An industry study for the Office of Life Sciences

Digital Health is an emerging industry arising from the intersection of health care services, information technology and mobile technology. Digital health innovations are only just starting to be more widely accepted as necessary for the future of efficient health care service delivery. As we address the behavior, social, legal and technical challenges, over time, digital health advances have the potential to help increase access, decrease health care system costs and improve health outcomes.

The current and future state of companion diagnostics

Companion diagnostics are an indispensable part of personalized medicine and will likely continue to rapidly increase in number and application to disease areas. The commercial success of some drugs that require testing with companion diagnostics before they can be prescribed has moved the entire companion diagnostic field forward.

Health care consumer engagement: No “one-size-fits-all” approach

Imagine a future in which more consumers engage with the health care system — a future that holds the promise of more effective, efficient, and satisfying care experiences and better health outcomes for those individuals and the accountable care populations to which they belong. Findings from Deloitte’s *2015 Survey of U.S. Health Care Consumers* suggest we are moving closer to that future as consumer engagement increases in three important areas.

The convergence of health care trends: Innovation strategies for emerging opportunities

The convergence of powerful trends — new technologies, the demand for value, a growing health economy, and the government as an influencer — is transforming the traditional U.S. health care market. While this convergence is creating substantial challenges for health care stakeholders, it is also creating opportunities for innovation in four major areas.

Health system analytics: The missing key to unlock value-based care

Talk of analytics and “big data” is everywhere in the health care industry these days. Many stakeholders agree that analytics provide insights that can enable organizations to improve quality and reduce costs, a combination that is essential to implementing effective value-based care programs. As health systems continue to face shrinking margins, tightening budgets, and evolving payment models, analytics are being touted as the missing key to unlock new sources of value.

Next-generation “smart” MedTech devices: Preparing for an increasingly intelligent future

Exponential technological progress is advancing scientific knowledge, reducing costs, and presenting the health care and life sciences marketplace with innovative medical devices and procedures that diagnose, monitor, and treat patient conditions.

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