A PRIMER ON US HEALTHCARE REFORM AND EVOLVING REIMBURSEMENT MECHANISMS

Professionals working in the healthcare industry must stay abreast of the rapidly changing healthcare delivery system and reimbursement mechanisms. This primer provides a high-level overview of relevant healthcare reform initiatives partially or fully stimulated and supported by the Affordable Care Act. Implications for medical device manufacturers and pharmaceutical companies are also discussed.

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INTRODUCTION

All industries undergo change, and companies that carefully monitor and take the necessary actions to adapt to change are most likely to be successful within their evolving marketplace. While everyone recognizes that the US healthcare system is currently undergoing significant change in how healthcare services are delivered and medical providers are reimbursed, many individuals involved in the design, development, and commercialization of medical products and solutions are not healthcare policy experts. Therefore, they frequently lack the time and resources needed to keep pace with the broad array of changes.

The impetus for developing this primer came as a result of the great interest and participation in our ongoing healthcare reform webinars as well as our interactions with clients who frequently acknowledge the challenge in staying up-to-date with reform efforts. It is quite clear that there is a great need among busy professionals within the medical device, pharmaceutical, and health insurance sectors for information and updates on the changing healthcare market landscape.

This primer is meant to provide a relatively straightforward overview of drivers of reform, key components of the Affordable Care Act, and reform efforts that impact the way in which healthcare services are organized, delivered, and reimbursed. It is not meant to be a comprehensive document explaining all aspects of healthcare reform or the pros and cons of each development. We hope this document provides foundational knowledge that is beneficial to one’s professional and personal lives as a consumer of healthcare.

BACKGROUND

Drivers of Reform

The need for wide-sweeping healthcare reform efforts has been debated nationally among politicians and healthcare policy experts for decades and took over the national spotlight in 2010, surrounded by significant discussion and major skepticism. The Patient Protection and Affordable Care Act (ACA) became law in March 2010 and set into motion a series of initiatives by the federal government intended to improve access to healthcare, change care delivery models, and restructure reimbursement.

The pure economics of providing care for Americans was a major factor stimulating change (Image A). Other drivers for reform included a system with a 20% uninsured rate among those under age 65, misaligned incentives between payers, providers, and healthcare delivery systems, and a fragmented delivery and reimbursement system focused on volume-based sick care rather than population-based prevention.

Image A: Economic Drivers of US Healthcare Reform

For key stakeholders (Image B), as well as pharmaceutical, biotech, and medical device companies, the ACA was a means to stimulate and accelerate reform efforts that would impact both the public and private insurance and delivery systems.

Image B: Key Stakeholders

Aside from the escalation of Medicare and Medicaid costs for the federal government, private commercial payers were also facing increasing costs of care that were driving up insurance premiums and costs to employers and individuals. Rising insurance premiums
stimulated corporations to take a more active role in healthcare reform efforts, seek self-insurance options, and increasingly invest in employee wellness programs to control utilization costs and focus more on prevention and early intervention.

As providers and systems faced declining reimbursement with shrinking margins, the volume of care delivered became more important and health entities increasingly competed for market share. Industry consolidation and the formation of more horizontally and vertically integrated health systems continued to emerge and physicians increasingly selected employment arrangements within these expanded delivery models of care. In many cases, physician Independent Practice Associations (IPAs) were aligning to support these expanding care delivery networks.

While many initiatives were already underway in the public and private sectors, largely to support the Institute for Healthcare Improvement’s (IHI’s) Triple Aim (IMAGE C), the ACA provided significant resources to expand access, focus on population health or “coordinated care”, and shift to “pay for performance” rather than fee for service based reimbursement. (IMAGE D)

**Image C: Institute for Healthcare Improvement (IHI) Triple Aim**

The funding of the Center for Medicare and Medicaid Innovation (CMMI) was also a key component of the ACA to establish an enhanced infrastructure that would stimulate, create, and evaluate new and ongoing reform efforts.

**Image D: Key Goals of the Affordable Care Act (ACA)**

**ACCESS TO CARE**

The ACA also encompassed several provisions aimed at reforming the private or commercial health insurance marketplace. A key component of expanding access to care was expanding Medicaid eligibility criteria and offering sliding scale subsidies for low-income individuals to purchase private health insurance.3, 4 Efforts included the development of state and federal health insurance “exchanges”, employer mandates for coverage, and essential health benefits for commercial plans participating in the exchanges (IMAGE E).

**Image E: Expanding Access of Health Insurance Benefits**

Employer mandates for providing coverage, and the advent of federal and state-run health insurance exchanges with bronze, silver, gold, and platinum level insurance products gave consumers a spectrum of options from low cost products to policies with premium coverage. Low cost options frequently include what are known as consumer-directed health plans (CDHPs) or “high deductible” health plans (HDHPs). The advent and adoption of such plans have shifted some of the responsibility of controlling utilization of services to the patient or healthcare consumer. As of January 2014, over 17 million Americans had HDHPs and Health
Savings Accounts (HSAs) with an annual growth rate of approximately 15%.^5

**ACO Insurance Reform:**
- Ends Pre-Existing Condition Exclusions (except Grandfathered Individual Plans)
- Keeps Young Adults Covered (under 26 on parent's health plan)
- Ends Arbitrary Withdrawals of Insurance Coverage
- Guarantees Right to Appeal Denial of Payment
- Ends Lifetime Limits on Coverage
- Review of Premium Increases (~10%)
- Removes Barriers to Emergency Services
- Covers Preventive Care at No Cost
- Expands Women's Health and Mental Health (Parity) Coverage

**POPULATION HEALTH**

A renewed focus on improving the health of populations is a true shift in how medical care in the US is currently organized and delivered. In the US, the **clinical care delivery model** has been rooted in a “sick care” model and a provider reimbursement structure referred to as “fee for service.” This is often referred to as a “volume based” system and is credited for increasing costs of care. On the other hand, our **public health system** focuses on the health of communities and, to a large extent, social determinants of health and preventive care.

Population health leverages the principles of epidemiology and public health including a focus on communities and considering the social influencers of health. Bridging the gap between the clinical care delivery system and community and social services agencies is a critical premise of population health.

There are typically five core elements of a population-based health approach. (IMAGE F) Once the population is defined, community assessments utilizing existing data sources or collecting new primary research among the population is used to identify the magnitude and distribution of health issues and unmet needs, including barriers to achieving good health and better health outcomes.

**Image F: Elements of a Population-Based Health Approach**

The principle of “risk stratification” or identifying groups within the population most “at risk” for poor health and outcomes is applied to focus energies where the largest impact can be realized. At the same time, some efforts are geared toward the larger population to improve and maintain the overall health of the wider community. These strategies apply to both prevention efforts and chronic disease management programs with a goal to reduce the need for costly acute care and long-term chronic care services.

**CARE COORDINATION**

The current healthcare delivery model is very fragmented and better “care coordination” is needed to improve health outcomes. The Agency for Healthcare Research and Quality (AHRQ) defines coordinated care as “deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient’s care to achieve safer and more effective care.”^7
Aspects of care coordination include the use of care management to assist with transitions in care, medication management, and linking to community based resources. These efforts delivered through a multidisciplinary team of providers aim to provide the right care, to the right person, at the right time, in the right place. Effectively implementing coordinated care models focused on outpatient care and in-home services should result in reducing unnecessary emergency room visits and hospitalizations.

A centerpiece of care coordination is the use of healthcare information systems. Investment in advanced IT infrastructures that include clinical care charting or patient electronic medical records across the large network of providers and patients encounters is paramount to effective care coordination. Incentives and resources to invest in IT systems are sometimes included in care coordination programs.

The most recognized model of coordinated care is the patient centered medical home (PCMH), also known as the advanced primary care model with five core functions (IMAGE G). The National Committee for Quality Assurance (NCQA) currently recognizes nearly 7,000 primary care practices as PCMHs.8, 9

Image G: Core Function of Patient Centered Medical Homes9

The ACA also authorized the creation of the Medicaid Health Home State Plan Option. This gives states the opportunity to provide and be reimbursed for care coordination to Medicaid beneficiaries with certain chronic conditions. These programs focus on social services and mental health support and there are currently 19 states offering 26 health home models.10

With funding from the ACA, the Center for Medicare and Medicaid Innovation (CMMI) has developed two programs aimed at improving care coordination and outcomes:

The Community-based Care Transitions Program (CCTP) evaluates new models of care delivery that focus on improving care transitions from the hospital with the goal of reducing readmissions. There are currently 72 programs comprised of community-based organizations and acute care hospitals across the country.11

The Comprehensive Primary Care (CPC) initiative is a collaboration between public and private healthcare payers to strengthen primary care. It currently provides a $20 per-member, per-month (pmpm) management fee for members. Provisions of the CPC program at each practice site, via various models of payments and leveraging health IT infrastructures, are aimed at improving outcomes and lowering costs for over 400,000 Medicare and Medicaid beneficiaries as well as 38 other commercial insurer beneficiaries participating in these programs. In total, there are 2,725 providers serving approximately 2.7 million patients across the US.12

SHIFT TO VALUE-BASED CARE

Bundled, Episodic and Capitated Payments

At the center of reform is how to move away from a fee for service model into payment mechanisms based on quality and outcomes. Bundled payments (shared payments between various providers) and episodic payments (payments for all care between designated start and end points) are not new mechanisms of reimbursement, and many suggest that expanding bundled/episodic payments is a way to further reduce unnecessary care. A focus on conditions and populations considered “high cost” are of greatest interest.

The Bundled Payments for Care Improvement (BPCI) initiative of CMMI uses four different bundled payment models covering 48 different clinical conditions.13
Within each of these models lies the basic premise of stimulating hospitals and providers to come together to identify ways to improve quality and reduce costs with the opportunity to share in the “savings” (reimbursement received minus all costs) as a result of their collective care coordination and quality efforts.

Global or capitated payments represent another reimbursement mechanism that is also not new and many see as the ultimate manner in which providers share in the risk of providing care to designated groups of individuals. HMOs and Managed Medicare and Managed Medicaid programs utilize this mechanism with the commercial payers assuming financial risk for the care of these populations.

**Accountable Care Organizations (ACOs)**

Accountable Care Organizations, or ACOs as they are commonly referred to, have received quite a bit of attention and represent a major initiative toward value-based payment reform and risk sharing between payers and providers. ACOs have formed between providers and government payers as well as commercial payers. Medicare ACOs include the original Pioneer ACO model, the Medicare Shared Savings Plan (MSSP), and the recently announced Next Generation ACO models.

**Pioneer ACOs**

Pioneer ACOs are the original ACO model and often considered the demonstration or pilot model. These initial ACO arrangements included organizations and providers who were already experienced in providing coordinated care prior to their establishing the ACO. There were originally 32 such entities and 19 remain. A number of the original participants decided to leave the Pioneer model opting to pursue the MSSP arrangement.

The **MSSP** is the predominant ACO model with 404 currently operating ACOs. Nearly 7.3 million people are assigned beneficiaries of a MSSP ACO and another 600,000 people fall under a Pioneer ACO. Medicare ACOs include Medicare fee for service beneficiaries rather than those enrolled in Medicare Advantage Plans. The MSSP model supports investment of resources into the development of the infrastructure needed to redesign care processes.

**Accountable care organizations consist of a group of doctors, hospitals, other healthcare providers and payers who come together voluntarily to give coordinated high-quality care to patients. The goals of ACOs are to tie reimbursement to 1) better outcomes for patients and 2) reduced costs rather than the current volume driven model.**

The Centers for Medicare and Medicaid Services (CMS) vision for what they refer to as the next generation ACOs is aimed at ACOs experienced in coordinating care for populations of patients. The arrangement allows provider groups to assume higher levels of financial risk and reward than current Pioneer and MSSP models. The goal is to see if greater financial incentives will generate improved health outcomes and lower expenditures for Medicare FFS beneficiaries. Medicare expects approximately 15-20 ACOs to participate.

Commercial payers have also been actively forming accountable care-like or coordinated care organizations with their provider networks and health systems. Last year there were an estimated 600 ACOs in the US, but tracking the number of commercial ACOs is difficult. For example, United Healthcare alone reports having more than 520 active ACOs with another 250 new ACOs forming in 2015.

The speed of adoption of “alternative payment models” is not likely to slow down. Sylvia Burwell, the US Secretary of Health and Human Services, recently announced that the Department of Health and Human Services (HHS) has set goals for tying traditional fee-for-service Medicare payments to quality or value via alternative payment models (IMAGE I).
HEALTHCARE DELIVERY CONSOLIDATION

A Growing Byproduct of Reform Efforts

Hospital mergers and acquisitions have continued to persist for the past several years and there are few signs of these slowing. The move toward population health, developing coordinated care models (including ACOs and bundled payments) as well as declining FFS reimbursement rates are all factors in driving ongoing consolidation. Besides the “horizontal” integration of acute care hospitals, the integration and consolidation of non-acute and post-acute care providers is also on the rise. This “vertical” integration of hospitals (with outpatient offices, surgical centers, pharmacies, radiology and lab services, and post-acute care services) may also include offering their own insurance products and thus forming what is often termed a closed integrated delivery network (IDN) like the Kaiser Permanente model. Hospitals and other providers forming formal affiliations without the financial ties of merging, often referred to as clinically integrated networks (CINs), are also on the rise.18, 19

These expanding healthcare systems and IDNs, besides looking at improving care coordination, are also looking for ways to control and lower the costs of delivering high quality care and ideally sharing in the savings from risk sharing agreements. Purchasing and materials management, as well as expanding multidisciplinary value analysis committees, are also taking center stage as they are tasked with identifying opportunities to streamline purchasing and make more informed decisions regarding the clinical and economic benefits of products from IV catheters to artificial knee replacements and cardiac stents.

SUMMARY AND IMPLICATIONS

For many it may be hard to believe that it has been over five years since the Affordable Care Act was enacted into law. With the recent Supreme Court ruling supporting the legality of the ACA to allow advanced premium tax credit for those receiving subsidies from health insurance purchased via federal AND state exchanges, many increasingly feel that “Obama Care” will continue to move forward and not be repealed despite the political tension and ongoing efforts to do so.

While the goal of healthcare reform is aimed at improving access to care for millions and improving the overall quality of care provided to patients, the major hurdle is doing so while reducing the overall cost of care. Whether you support reform efforts or not, the reality is that the host of reform initiatives being implemented impact all stakeholders including patients, providers, payers, pharma, and medical device manufacturers.

Despite the increased numbers of Americans with health insurance coverage, healthcare companies must examine the impact of high deductible plans along with high co-payments and co-insurance. Patients are more likely to be seen as healthcare “consumers” as they increasingly have a stake in how their healthcare insurance dollars are spent. As a result, many patients will increasingly compare offerings and become more price sensitive when purchasing medical products, prescriptions, and supplies.

Companies should also closely examine how new care coordination models and other population health efforts may influence the demand and uptake of their products and services. With cost reduction efforts aimed at reducing hospitalizations and skilled nursing facility use, products and services that can find their way into
care coordination pathways and resonate with these expanded multidisciplinary teams of providers are likely to find success. As will those offerings that can be safely and effectively adopted within the lowest cost environment, including the home.

With the transition to alternative payment mechanisms such as bundled, episodic, and global (capitated) payments, one must also examine the impact these reimbursement mechanisms have on one’s offerings. With ACOs and other ACO-like entities rapidly expanding and taking on increasing financial risk to manage populations of patients, products and services that can demonstrate better outcomes and reduced short and long term costs will be attractive. Thus, understanding how ACO-like organizations and providers evaluate and track outcomes (performance metrics used) is an important task. For these reasons, ACOs (responsible for helping drive quality improvement and control costs) represent another potential call point for sales and marketing efforts.

Identifying new areas of opportunity to improve patient outcomes and control excess expenditures within a healthcare system is paramount and having a well-developed IT infrastructure is becoming increasingly important. Being able to easily measure, track and report patient outcomes and costs means IT solutions and services that can address these needs will be in high demand.

The way in which providers are measured on performance and how care is reimbursed will surely continue to drive behaviors such as preferences for products, therapeutics, and other services that improve outcomes and prevent disease progression. Assessing the trade-offs between costs and outcomes is increasingly being considered, even scrutinized, as a means to achieve financial goals and clinical outcomes. Hospitals and healthcare systems are increasingly looking for manufacturers to share in the risk of providing care for patients and a move toward “risk-sharing” arrangements between providers and suppliers is likely to expand in the future.

Keeping pace with healthcare reform requires time and resources. Developing and maintaining a high level of understanding of the ongoing and changing market dynamics has increasingly become a prerequisite for developing and commercializing successful new products and solutions. This primer provides a high-level overview of many of the new programs and changes occurring, but it does not replace the need for ongoing monitoring and surveillance of the marketplace.

In summary, with so much emphasis being placed on improving patient outcomes and controlling costs, it is imperative that companies closely examine these continuing reform efforts to determine how best to address these market changes through new product innovation, marketing, and sales strategies. Products, services, and therapeutics that can clearly demonstrate clinical and economic value will gain market share. Thus, being able to demonstrate value with health economics and outcomes studies is increasingly important to gain market access. However, for some organizations, just recognizing that healthcare has and will continue to change rapidly is the first step in adapting to and succeeding in the new marketplace. As Dorothy from the Wizard of Oz said, “Toto, I’ve a feeling we’re not in Kansas anymore.”
SOURCES

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KJT Group, Inc.  July 2015