



# CRA Insights: Life Sciences

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February 2017

## The role of manufacturers in value-based healthcare

Providers have traditionally been more focused on improving patient outcomes and less focused on the cost of those outcomes. However, in response to growing cost pressures from payers and patient advocates, providers are becoming more focused on value—a measure of patient outcomes achieved relative to the cost of care.

A shift towards value-based healthcare (VBC) has prompted industry participants to collaborate on innovative approaches to deliver improved outcomes in a more cost-effective manner. Public and private payers are eager to transition from fee-for-service (FFS) arrangements to novel payment models that align cost efficiency with treatment efficacy. Mark Bertolini, CEO of Aetna, noted the company's VBC spending is currently 30% "with a goal to achieve 75% by the end of the decade."<sup>1</sup> Providers are exploring new treatment approaches and tools, including standardized care pathways, coordination of care, and leveraging low-cost technologies and treatment sites to deliver equivalent or better patient outcomes at more cost-effective rates. Meanwhile, patients hope to reap the dual benefits of better care outcomes at lower out-of-pocket costs.

To reset perceptions and realize opportunities in VBC, manufacturers need to be proactive, establishing programs and partnerships that demonstrate outcome benefits and clearly define and articulate the value they add to the healthcare system.

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<sup>1</sup> Bruce Japsen, "Value-Based Care Will Drive Aetna's Future Goals," *Forbes*, May 15, 2015, <http://www.forbes.com/sites/brucejapsen/2015/05/15/value-based-care-may-drive-aetna-bid-for-cigna-or-humana/#18993f9e6512>.

## Current value-based healthcare initiatives generally lack manufacturer involvement

Given the potential savings offered by more cost-effective treatments, it is no surprise that payers are strong proponents of value-based care. The Centers for Medicare & Medicaid Services (CMS) aims to compensate providers “for value, not volume” as is encouraged under the existing FFS model.<sup>2</sup>

Under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS plans to incorporate some form of quality consideration into 85% of its Medicare FFS payments by 2016 and up to 90% by 2018. MACRA also promotes alternative payment models (APMs) that incorporate quality measures. Such APMs include medical homes with financial and performance accountability and bundled payment arrangements based on episodes of care. CMS expects 30% of its Medicare spending to be linked to quality measures via APMs by the end of 2016, increasing to 50% by the end of 2018.<sup>3</sup>

Flexible payment models, that align healthcare stakeholders and encourage a team-based approach to care, can help achieve genuine value-based care. The oncology care model (OCM) is an example of such an initiative. Instituted by CMS as of the spring of 2016, OCM will reward physicians for “managing and coordinating care for oncology patients during episodes of care,” which previously was not discretely compensated. The initiative will also offer performance-based payments for reduced treatment costs and improved care outcomes.<sup>4</sup> The model grants participating physicians the flexibility to develop improvements that work best for their practices, allowing the program to be highly customizable based on each provider’s needs and the specifics of their patient population.

## Advances in value-based healthcare

As CMS steers the US healthcare market toward value-based care, managed care organizations and other third-party payers are partnering with physicians to deliver and document value in healthcare. Certain disease areas and specialties, such as oncology and endocrinology, have been at the forefront of this shift. In this new environment, healthcare product manufacturers must position themselves as both partner and catalyst supporting value-based innovation or risk being left behind as drivers of cost. Several ongoing value-based care initiatives, including patient-centered medical homes, risk-sharing agreements, and predictive analytics and patient

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<sup>2</sup> 2015 CMS fact sheet, “Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume,” CMS, January 26, 2015, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html>.

<sup>3</sup> “The Medicare Access & CHIP Reauthorization Act of 2015: Path to Value,” CMS, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-LAN-PPT.pdf>.

<sup>4</sup> Oncology Care Model 2015 Fact Sheet, CMS, February 12, 2015, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-02-12.html>; Andis Robeznieks, “At home with the specialist: Oncologists and other specialists launching patient-centered medical homes,” *Modern Healthcare*, October 18, 2014, <http://www.modernhealthcare.com/article/20141018/MAGAZINE/310189981>.

segmentation, offer unprecedented opportunities for manufacturers to align with the healthcare market's burgeoning consciousness of value.

### **Patient-centered medical homes**

Payers and providers have partnered to establish patient-centered medical homes (PCMHs) that combine the core functions of healthcare with a patient-centered focus on services to improve access, quality, and safety.<sup>5</sup> PCMHs achieve greater treatment quality and safety through a higher level of care coordination across a team of healthcare providers, which could include specialists such as mental health and pain management professionals. The National Committee for Quality Assurance, a private, not-for-profit organization, offers a recognition program for PCMHs.<sup>6</sup>

Several studies of US PCMHs indicate promising improvements in outcomes, including a 13% reduction in readmissions, 61% reduction in cost and emergency room visits, and 31% fewer inpatient admissions.<sup>7</sup> For example, the University of Pittsburgh Medical Center Health Plan (UPMC Health Plan) has implemented PCMHs in 372 of its practices, covering 17,688 of its patients.<sup>8</sup> A recent study found the UPMC Health Plan's PCMH sites incrementally reduced readmissions and emergency department visits by 16.9 and 3.6%, respectively, while generating a 160% return on investment through cost avoidance.<sup>9</sup> UPMC continues to evolve the PCMH model with new variants focused on specific disease areas, such as its Total Care-IBD program targeting the treatment of inflammatory bowel disease.<sup>10</sup>

While PCMHs offer significant value-based potential, they also require significant up-front investment and a long time horizon before investment costs are recouped through avoided costs and improved outcomes. Cost estimates to set up a PCMH range from \$23,000 to \$90,000 per physician due primarily to greater spending on technology.<sup>11</sup> Manufacturers may be instrumental in mitigating some of these risks for PCMHs, for instance by supporting outcomes measurement, identifying and educating ancillary healthcare specialists to provide comprehensive care, and promulgating best practices among PCMHs.

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<sup>5</sup> "Defining the PCMH," Patient Centered Medical Home Research Center, US Department of Health and Human Services, <https://pcmh.ahrq.gov/page/defining-pcmh>.

<sup>6</sup> NCQA Recognition Programs, The National Committee for Quality Assurance, <http://www.ncqa.org/Programs/Recognition.aspx>.

<sup>7</sup> Nielsen, et al., "The Patient-Centered Medical Home's Impact on Cost & Quality: An Annual Update of the Evidence, 2012–2013," Patient-Centered Primary Care Collaborative, January 2014, p. 6, [http://www.milbank.org/uploads/documents/reports/Patient-Centered\\_Medical\\_Homes\\_Impact\\_on\\_Cost\\_and\\_Quality.pdf](http://www.milbank.org/uploads/documents/reports/Patient-Centered_Medical_Homes_Impact_on_Cost_and_Quality.pdf).

<sup>8</sup> Siminerio et al., "An Insurer-Based Diabetes Educator-Community Partnership: Leveraging Education and Diabetes Support (LEADS)," American Diabetes Association, 2015.

<sup>9</sup> Rosenberg et al., "Results from a Patient-Centered Medical Home Pilot at UPMC Health Plan Hold Lessons for Broader Adoption of the Model," *Health Affairs*, November 2012, <http://content.healthaffairs.org/content/31/11/2423.full.html>.

<sup>10</sup> Miguel D. Regueiro and Eva Szigethy, "Total Care-IBD: UPMC's IBD Medical Home," *Pitt Digest Newsletter*, University of Pittsburgh Division of Gastroenterology, Hepatology, and Nutrition, Winter 2016, <https://www.dept-med.pitt.edu/gi/files/PittDigest/PittDigestWinter2016.pdf>.

<sup>11</sup> Rachael Zimlich, "The costs of becoming patient-centered," *Medical Economics*, May 25, 2013.

## Risk-sharing agreements

Payers and providers have also entered into risk-sharing agreements (RSAs) to encourage value-conscious treatment decisions. One of the most common types of RSAs involves penalties if costs exceed preset levels or certain cost or quality thresholds are not achieved. Blue Cross Blue Shield of Massachusetts and Blue Cross Blue Shield of Illinois both have entered into such RSAs with providers. Other payers, such as Blue Cross Blue Shield of Minnesota, offer bonus payments contingent on quality and efficiency metrics. Shared-savings programs, such as Aetna's accountable care organizations (ACO) and Anthem's capitation agreement, are other variations of RSAs that transfer the financial risk for treatments that exceed predetermined budgets from payers to providers.<sup>12</sup>

As physicians assume a greater share of the risk of treatment outcomes, manufacturers may be able to alleviate some of those risks by providing additional services to physicians. Manufacturers may augment physicians' treatment decision-making processes by offering additional support services to improve care coordination and symptom communications between patients and physicians, or providing access to stratification tools and processes to optimize patient treatment and compliance. Pfizer and Novartis are already making strides toward the latter goal. In 2015, the two manufacturers partnered with Thermo Fisher Scientific to develop a companion diagnostic for oncological applications that can test multiple genes simultaneously from a single sample. The diagnostic tool will support prescriber decision-making by stratifying each patient's risk to determine which treatment options will be most effective.<sup>13</sup>

Equipping practices with better tools to manage care should enable physicians to be more confident in their risk-sharing agreements with payers, particularly when physicians are purchasing medications or when they have assumed pharmacy risk. Manufacturers may also support payers and providers engaging in RSAs by guaranteeing certain cost reductions and outcome improvements if providers comply with specified care pathways or treatment regimens. As more and better data are accumulated, manufacturers could enter into more refined agreements with providers and payers, or even assume treatment risk of patients meeting certain criteria (i.e., patients of a certain age with diagnostic results within a specified range and favorable treatment response for at least six months), as Amgen has done with Harvard Pilgrim on REPATHA™ and Merck with Cigna on JANUVIA®.<sup>14</sup>

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<sup>12</sup> Delbanco et al., "Promising Payment Reform: Risk-Sharing with Accountable Care Organizations," The Commonwealth Fund, July 2011, p. 6, <http://www.commonwealthfund.org/~media/files/publications/fund-report/2011/jul/1530delbancopromisingpaymentreformrisksharing-2.pdf>.

<sup>13</sup> Thermo Fisher Scientific, "Thermo Fisher Scientific Signs Development Agreement for Next-Generation Sequencing-Based Companion Diagnostic," November 18, 2015, <http://www.businesswire.com/news/home/20151118005396/en/Thermo-Fisher-Scientific-Signs-Development-Agreement-Next-Generation>. Pfizer, "Next-Generation Sequencing-Based Companion Diagnostics Collaboration," 2015, [https://www.pfizer.com/files/investors/financial\\_reports/annual\\_reports/2015/peer-collaborations.htm](https://www.pfizer.com/files/investors/financial_reports/annual_reports/2015/peer-collaborations.htm).

<sup>14</sup> Stephen Barlas, "Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing," *Pharmacy & Therapeutics*, vol. 41, no. 1, January 2016, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4699485/pdf/ptj4101039.pdf>.

## Practice support programs

Physicians moving toward value-based healthcare may lack the support services and capabilities to make the VBC transition a seamless one. Manufacturers have a unique opportunity to lay the foundation for practice support programs to ease this transition. Such programs could include additional education for patients and staff, improved coordination of care between physicians and patients, and enhanced decision support tools through predictive analytics that evaluate patient health data to project disease progression and optimize treatment regimens.

To reduce the burden on physicians and practices regarding newly diagnosed patients, manufacturers could offer educational resources so patients are informed and empowered to better manage their diseases. In diabetes care, for example, manufacturer-sponsored diabetes educators provide patients with general disease information, emotional and behavioral support, and disease management knowledge. The impact of these educational programs is notable: patients have gained better glycemic control, lower blood pressure and cholesterol readings, and fewer diabetic foot complications.<sup>15</sup> As a result of these types of manufacturer-led initiatives, practices could devote fewer resources to general education and focus on higher value-additive services. Coordinating patient care with payers and other healthcare providers is another administrative task borne by practices. Manufacturers may be able to assume certain care management tasks, such as relaying information to patients about their insurance coverage and affordability programs, identifying suitable treatment sites, building platforms that enable patient/provider communication, and managing appointments with other care providers.

Patient outcomes might also improve if providers could segment patients based on disease severity and tailor patient treatment to apply the most efficacious option for the patient's current condition. Predictive analytics tools use technology to enhance decision making by integrating previously disparate information sources (electronic medical records data, diagnostics results, genetic information) and building algorithms to predict disease severity or outcomes. Payers and physicians could treat patients more accurately when armed with a clinical decision support tool that improves their capability to forecast each patient's disease progression. In 2013, Kaiser Permanente launched the Archimedes IndiGO clinical decision support tool which creates five-year, health risk predictions for patients with cardiovascular disease. Empowered by this information, patients have shown a higher tendency to fill their prescriptions and comply with the treatment, thus avoiding costly future interventions.<sup>16</sup> Over time, improved patient segmentation based on predictive models may demonstrate cost savings through avoided ER visits and hospitalizations, and reward value and outcomes improvements.

## Manufacturers as leaders in value-based care

As the examples discussed above show, healthcare market participants are eager to collaborate and explore innovative value-based care approaches. Payers, providers, and patients all recognize the opportunity of incorporating cost efficiency into treatment considerations. Forward-

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<sup>15</sup> Worsick et al., "Improving quality of care for persons with diabetes: an overview of systematic reviews – what does the evidence tell us?" *Systematic Reviews*, 2013, <http://www.systematicreviewsjournal.com/content/2/1/26>.

<sup>16</sup> Jennifer Bresnick, "IndiGO predictive risk scores reduce heart attacks, strokes," *HealthIT Analytics*, September 13, 2013, <http://healthitanalytics.com/news/indigo-predictive-risk-scores-reduce-heart-attacks-strokes>.

thinking manufacturers will recognize this shift in the healthcare marketplace, embrace it, and adapt. At the provider level, manufacturers could enable innovation to equip physicians with the tools and support needed to succeed in an increasingly value-focused environment. At the payer level, manufacturers could engage in more refined RSAs or help to develop more comprehensive approaches to care for specific diseases and their associated comorbidities. Success in the future will require that manufacturers embrace a role as leaders in VBC, developing capabilities and offerings that extend beyond their current role as a product suppliers.

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