

## Developing a Path to Value-Based Payment for Medical Products

### *Value-Based Payment Advisory Group Kick-Off Meeting*

Duke-Margolis Center for Health Policy Conference Center, Washington DC

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### Background Paper

#### Introduction

Amidst the broader shift from a fee-for-service (FFS) payment structure to a value-based U.S. healthcare marketplace, significant concerns have arisen over a medical product pipeline that is full of innovative and transformative—but also high-cost—therapies. These concerns have led to increased interest in developing new payment and alternative financing models for health care that strive to ensure better outcomes for the dollars spent, and thus higher value. Some limited but growing experience exists with these models, broadly referred to here as Value-Based Payment (VBP) arrangements. Value-based payment (VBP) arrangements for medical products are intended to align pricing and/or payments to observed or expected value in a population (i.e. outcomes relative to costs). As with VBP reforms for healthcare providers, implementation of value-based arrangements for medical products might be meaningfully viewed on a spectrum ranging from fee-for-service (FFS) payments that are adjusted based on expected value to outcomes-based contracts with some level of risk sharing.

**Indication-based price contracts** have the goal of tightening the link between the price per use of a product to existing evidence of effectiveness and potential value. Indication-based contracts rely on FFS reimbursements, and do not tie payment to observed outcomes. Indication-based pricing approaches typically review the available evidence on the impact of a drug on key health outcomes and possible dimensions of cost or utilization, and apply an implicit or explicit value framework to that evidence to determine a range of appropriate drug prices. ICER's Value Assessment Framework and estimates of "value-based" indication-specific cancer drug prices by Drug Abacus, developed by Bach and colleagues, are examples of this approach.<sup>1</sup>

**Outcomes-based contracts** link payment for medical products to that product's actual performance in a patient or a population. These arrangements can potentially allow involved parties, including payers, manufacturers, providers (in some cases), and health systems, to align their financial stakes directly with the performance of the medical product, encouraging greater shared efforts to improve outcomes for the patient population treated.

With outcomes-based contracting approaches, accountability for results can be based on clinical or patient-reported outcomes, utilization outcomes, measures of spending, and/or quality of care measures.<sup>2</sup> These measures amount to an observed value-based adjustment to payment, though most outcomes-based contracts do not apply an explicit value framework. Although the terminology associated

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<sup>1</sup> Westrich, Kimberly. *Current Landscape: Value-Assessment Frameworks*. National Pharmaceutical Council. June 2016.

<sup>2</sup> Garrison, L. P. J., Carlson, J. J., Bajaj, P. S., Towse, A., Neumann, P. J., Sullivan, S. D., Westrich, K., Dubois, R. W. (January 01, 2015). Private sector risk-sharing agreements in the United States: trends, barriers, and prospects. *The American Journal of Managed Care*, 21, 9, 632-40.

with these types of agreements can vary (as “risk-sharing agreements,” “outcomes-based agreements,” “performance-based agreements,” “accountable care payments,” or other terms), they share a common feature of linking payment for therapies or interventions to measures of clinical outcomes and costs achieved.

Viewed on a spectrum, initial outcomes-based contracts (such as manufacturer “warranties” that involve full upfront payment) represent only a limited departure from traditional FFS. Approaches that are more comprehensive would not only involve linking a larger share of payments to performance in real-world settings, but also linking total payments to a more complete set of measures of clinical outcomes as well as total cost of care.

While most arrangements are negotiated directly between payers and medical product manufacturers, there is increasing interest in manufacturer-provider arrangements with the growth of value-based payment models for healthcare providers. Manufacturer-provider arrangements potentially allow all involved parties, including payers, manufacturers, providers, and health systems, to align their financial stakes directly with the performance of the medical product encouraging greater shared efforts to improve outcomes for the patient population treated. As experience and capacity to implement such payment reforms increases, contracts could move toward direct alignment of both provider payments and medical product payments with value produced for patients and the health system.

Value-Based Payment arrangements emerged in the 1990s, when Merck guaranteed that it would refund payments for cholesterol-lowering drugs that did not help patients meet target cholesterol levels. Despite mixed results and a relatively slow initial pace of adoption in the United States, interest in VBP arrangements continues to grow in an age of precision medicine, high-cost but potentially highly effective innovative therapies, tightening healthcare budgets, and increasing pressure to balance speedy access to innovative therapies with sufficient evidence to support safety and efficacy.<sup>3</sup> An improving electronic data infrastructure is also enabling the development of better measures of patient results and augmented real-world evidence after treatments are approved.<sup>4</sup> VBP arrangements offer a variety of potential advantages for stakeholders across the healthcare system. For payers and providers, VBP arrangements may help address uncertainty about a product’s performance, mitigate risk to health care providers, and better align manufacturers in supporting their efforts to improve the value of care. For manufacturers, VBP arrangements may help provide earlier market entry and penetration, and better opportunities to demonstrate their therapy’s value. For patients and other health system stakeholders, shifting towards a value-based payment system may help speed access to innovative therapies, better align their payments with a product’s true value, and add to confidence that a product is working as intended.

As experience with Value-Based Payment arrangements accumulates, a set of regulatory, legal, and operational barriers to these efforts has also become clearer. Partly, these barriers result from value-based payment being a substantial departure from the terms, measures, and mechanisms of traditional volume-based payments for medical products. The barriers can also result from the administrative

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<sup>3</sup> Neumann, P. J., Chambers, J. D., Simon, F., & Meckley, L. M. (January 01, 2011). Risk-sharing arrangements that link payment for drugs to health outcomes are proving hard to implement. *Health Affairs (project Hope)*, 30, 12, 2329-37.

<sup>4</sup> *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals*. The Network for Excellence in Health Innovation. March 2017

burden and complexity of arranging and implementing agreements that depend on patient data that are often difficult to access in a timely and reliable way, particularly as patients move across health plans.

In order to advance the use of value-based payment arrangements for pharmaceuticals, medical devices, and innovative gene technologies, the Robert J. Margolis, MD, Center for Health Policy at Duke University formed the Value-Based Payment Consortium. Supported by a multi-stakeholder Value-Based Payment Advisory Group, made up of manufacturers, patient advocates, providers and payers, as well as experts on regulatory affairs, law and policy, the Consortium is addressing a number of barriers and supports practical, actionable solutions that better incentivize better outcomes for patients and more value across the health system.

Building on past experience and current efforts to implement these models, our work will identify and describe promising approaches to addressing key barriers for two types of models for Value-Based Payment agreements: 1) Traditional VBP arrangements developed between product manufacturers and payers (including Pharmacy Benefit Managers (PBMs)); and 2) Emerging VBP arrangements developed between product manufacturers and healthcare providers in alternative payment models such as accountable care organizations. The latter could also be accomplished by VBP arrangements implemented by payers with both providers and product manufacturers, with reinforcing performance measures. Examining common barriers to effective implementation for both of these models, the Value-Based Payment Advisory Group will identify high-priority objectives and concrete strategies for addressing these challenges and advancing the use of these VBP arrangements in pursuit of better value-based care.

## **Value-Based Payment Arrangement Models: A Landscape Assessment**

### *Model I – Traditional Agreements between Manufacturers and Payers*

Although “money-back guarantee” contracts for pharmaceutical products have existed for over two decades, VBP arrangements continue to emerge and evolve as payers and manufacturers gain experience in risk management.<sup>5</sup> Along with heightened interest in Value-Based Payment arrangements between payers and manufacturers, there has been a corresponding effort to better understand these agreements, their utilization, and their impact on stakeholders and health systems. As noted, many VBP arrangements aim to promote higher value, through linking at-risk contractual payments to measures of outcomes, utilization, and spending. Efforts undertaken by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force and others have identified essential components for VBP arrangements,<sup>6,7</sup> developed taxonomies for existing agreements, assembled a knowledge base of public and non-public agreements to date, and identified common implementation issues through payer and manufacturer surveys. While these studies have involved inconsistent

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<sup>5</sup> Carlson JJ, Gries KS, Yeung K, Sullivan SD, Garrison LP Jr. Current status and trends in performance-based risk-sharing arrangements between healthcare payers and medical product manufacturers. *Appl Health Econ Health Pol* 2014; 12: 231–238.

<sup>6</sup> Value-Based Payment arrangements are referred to as “Performance-Based Risk Sharing Agreements” in the ISPOR report.

<sup>7</sup> Garrison, LP Jr., Towse A, Briggs A, et al. Performance-based risk-sharing arrangements—good practices for design, implementation, and evaluation: ISPOR Good Practices for Performance-based Risk-sharing Arrangements Task Force Report. *Value Health* 2013;16:703-19.e

definitions and data accessibility challenges, reports by Adamski (2010), Garrison (2013 and 2015) and Carlson (2014) all offer an understanding of existing arrangements and trends to date.

In one commonly-cited review, Adamski (2010) attempted to categorize VBP arrangements (here, “Risk Sharing Agreements (RSAs)”) as either “Outcomes-based” or “Financial-based.”<sup>8,9</sup> Outcome-based RSAs are tied to a drug’s observed clinical outcomes and may include an agreement to adjust a drug’s reimbursement based on its ability to meet agreed-upon clinical targets. These types of Outcome-based RSAs might include an agreement to adjust a drug’s price based on clinical outcomes (e.g., Humana’s reimbursement rate for Eli Lilly’s Effient is adjusted based on the hospitalization rate for cardiovascular events for patients taking the drug), an agreement to refund or replace for poor performance (e.g., Ortho Biotech will replace its products for free for patients that don’t respond to treatment), or an agreement to reimburse medical costs related to ineffective treatment (e.g., Proctor & Gamble and Sanofi-Aventis will reimburse the medical costs of bone fractures suffered by Health Alliance beneficiaries taking risedronate sodium). In “Financial-based” RSAs, reimbursement is tied to financial measures and utilization. Examples of Financial-based RSAs might include an automatic adjustment to a drug’s unit price if utilization meets a certain threshold or overall financial burden. These types of arrangements are designed to reduce the risk of a large budget impact on payers and patients.<sup>10</sup>

Reviews of VBP arrangements reflect varying approaches to the extent to which “financial” measures—spending or utilization measures—are meaningfully included along with outcomes-based arrangements as reflections of value for medical products. The ISPOR Task Force Report, detailing a number of definitions and taxonomies developed to date, distinguishes between agreements that are “performance-based” (e.g. based on health outcomes) with those that are primarily “cost sharing arrangements” (e.g. agreements based on cost or utilization measures) which are meant to control for budget impact.<sup>11</sup> For the purposes of our definition, we have included financial agreements that capture utilization measurement as part of a currently limited set of data measures that may relate to quality and cost but exclude price discounting based solely on volume. VBP arrangements can become more advanced as data collection improves, better patient outcome measures are incorporated, and the arrangements are based increasingly on toward value rather than volume.

### Figure 1: Five Characteristics of Performance-Based Risk Sharing Agreements

- **A program of data collection is agreed to by the manufacturer (or the provider) and the payer**
- **Data collection is initiated during the time period following regulatory approval and linked to post-launch coverage decisions**
- **Price, reimbursement, or revenue for the product are linked to the outcome of data collection**
- **Data collection is intended to address uncertainty on a number of issues, including cost effectiveness, adverse events or adherence, or efficacy in different populations**
- **These arrangements provide a different distribution of risk between payer and manufacturer**

**Source: ISPOR Task Force Report**

<sup>8</sup> Garrison 2015, et al.

<sup>9</sup> Adamski, J., Godman, B., Ofierska-Sujkowska, G., Osińska, B., Herholz, H., Wendykowska, K., et al. (December 01, 2010). Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers. *Bmc Health Services Research*, 10, 1, 1-16.

<sup>10</sup> Garrison 2013, et al.

<sup>11</sup> Garrison 2013, et al.

Prior studies of VBP arrangements often characterized these agreements by the outcomes that they tracked (e.g., financial utilization, clinical measures, performance over standard of care, etc.). However, it is worth noting that these agreements can vary widely in their financial mechanisms and timelines for implementation, and may incorporate multiple measures of utilization and other outcomes. Viewed on a spectrum away from FFS and toward value, more incremental approaches may involve refunds or adjustments to rebates based on a drug's performance, while more advanced mechanisms might involve cost-sharing or reimbursement for future medical expenses. By relying on increasingly rich electronic data collection systems (e.g. those used for longitudinal quality improvement by at-risk health systems) and developing new financial models, payers and manufacturers will continue to refine their approach to value-based payment for medical products.

As interest in Value-Based Payment continues to grow, skeptics have pointed to the relatively slow pace of their adoption as evidence that the administrative and operational complexity of VBP arrangements continue to outweigh their benefits. Studies by Garrison (2015) and Carlson (2014), analyzing the University of Washington's PBRSA database,<sup>12</sup> reported on a total of 148 total RSAs worldwide.<sup>13</sup> Of these agreements, only 18 took place in the United States and only seven involved private sector partners<sup>14</sup> (please see Appendix A for our own list of publicly-announced payer-manufacturer VBP arrangements.) Surveys of payers and manufacturers detailing the high administrative burden and data challenges of operating in a multi-payer system, suggest that the United States may have distinct challenges in addressing these operational burdens.<sup>15</sup>

Despite these obstacles, such contracts are growing: the PhRMA-funded survey "Barrier to Value-Based Contracts for Innovative Medicines" identified 16 publicly-announced risk-sharing contracts between 2015 and 2017, more than double the number that had been announced in the previous two decades.<sup>16</sup> This growing interest may reflect both external pressures towards value-based contracting, improved data infrastructure and systems, and a growing experience with and sophistication among actors in Risk-Sharing Agreements. Surveys of agreements and stakeholders to date have shown a trend toward pursuing agreements with a reduced administrative burden<sup>17</sup> as well as a focus on products with simple and observable outcomes,<sup>18</sup> high-priced products with specific target populations,<sup>19</sup> and medium-term timelines (18-36 months) that are potentially feasible for data collection.<sup>20</sup> Given the fundamental trends toward greater use of these contracts, the potential benefits of overcoming the barriers to VBP agreements for medical products continue to rise.

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<sup>12</sup> University of Washington Department of Pharmacy: Performance Based Risk Sharing Database. Accessed April 7, 2017: <https://sop.washington.edu/department-of-pharmacy/performance-based-risk-sharing-database/>

<sup>13</sup> Carlson 2014, et al.

<sup>14</sup> Garrison 2015, et al

<sup>15</sup> Carlson JJ, Garrison LP Jr, Sullivan SD. Paying for outcomes: innovative coverage and reimbursement schemes for pharmaceuticals. *J Manag Care Pharm.* 2009; 15(8):683-687.

<sup>16</sup> *Barriers to Value-Based Contracts for Innovative Medicines.* PhRMA Member Survey Results. March 2017.

<sup>17</sup> Carlson 2014, et al.

<sup>18</sup> Neumann 2011, et al.

<sup>19</sup> De Pourourville G. Risk-sharing agreements for innovative drugs: a new solution to old problems? *Eur J Health Econ.* 2006;7(3):155-7.

<sup>20</sup> Garrison 2015, et al.

*Model II – Emerging Agreements between Manufacturers and Providers in Alternative Payment Models*

With growing, but still limited, experience in VBP arrangements between manufacturers and payers, there has also been growing interest in the use of these contracts to better align manufacturers and providers as part of alternative payment models. Indeed, provider payments have shifted more from volume and into value-based care than medical product payments, as an array of both public and private value-based payment models for providers have emerged over the past decade, including Accountable Care Organizations (ACOs), payer-provider quality contracts, bundled episode payments, patient-centered medical homes, and payment systems for specialized care or populations with results related to spending and health outcomes. All of these alternative payment models are intended to encourage efficiency and cost savings while maintaining or improving patient outcomes – that is, higher-value care – and to provide better support for clinical care innovation and coordination to achieve greater value. Figure 1 summarizes the goals of providers and manufacturers in engaging in VBP arrangements.

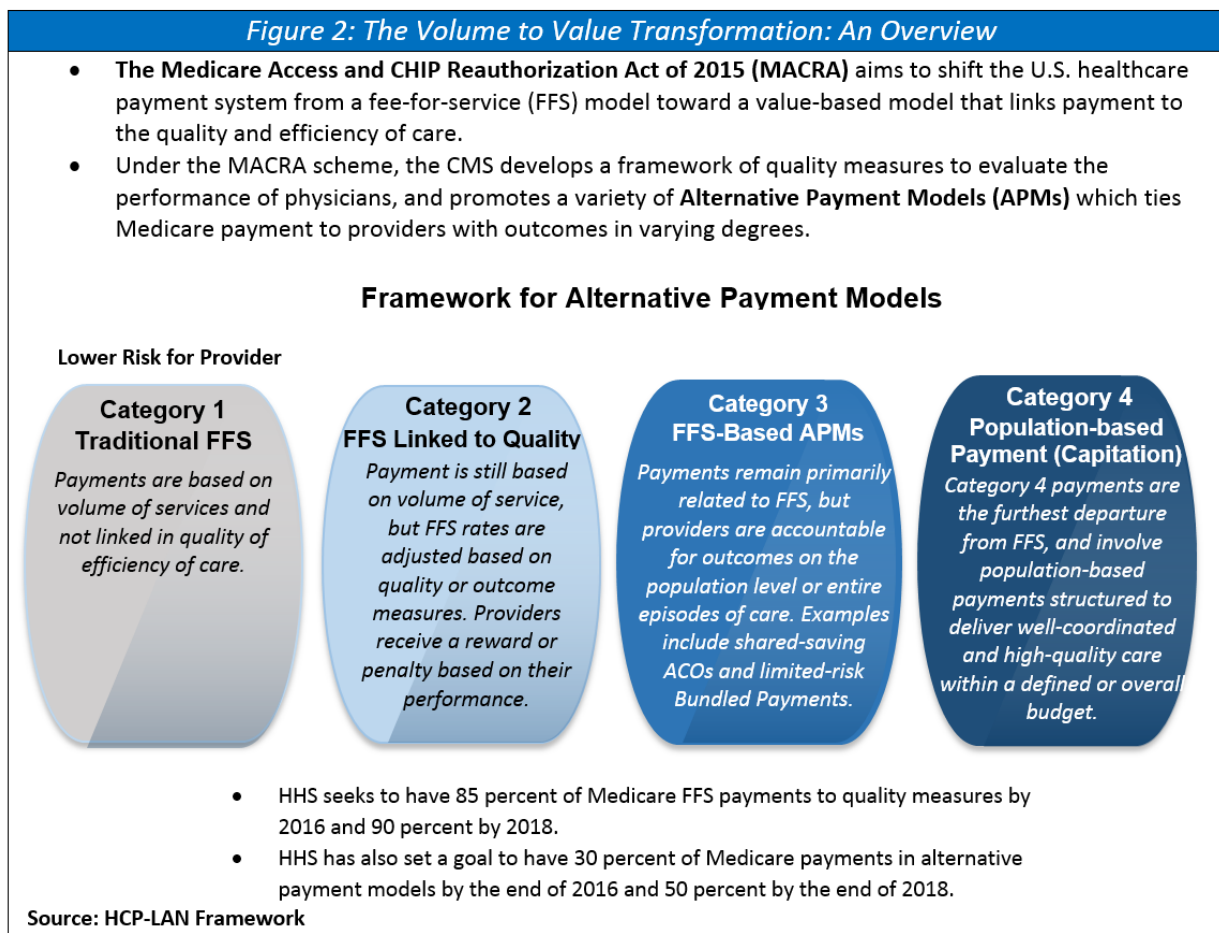
<i>Table 1: Goals of a Provider-Manufacturer Value-Based Payment Arrangements</i>	
<u>Provider</u>	<u>Manufacturer</u>
<b>Cost Savings</b>	<b>Market Share Expansion</b>
Reduce budget impact of medical product purchase, avoid unnecessary costs due to low quality products or uses	Secure full, appropriate utilization of products
<b>Improve Quality</b>	<b>Quality Demonstration</b>
Improve performance and outcomes of care in alignment with performance metrics	Ability to demonstrate higher quality or superiority of products rather than competing on price alone
<b>Potential for Shared Risk</b>	<b>Potential for Shared Savings</b>
Manufacturer shares risk for additional costs due to lack of product effectiveness	Manufacturers may be eligible to share in cost savings resulting from improvement in outcomes

Federal policies have supported this shift towards accountable care. The Medicare Access and CHIP Reauthorization Act (MACRA) provided additional incentives to link payment to quality and efficiency of Care (see Figure 2). As a part of its volume-to-value transition, CMS set a goal of linking 50 percent of traditional Medicare payments to alternative payment models by 2018<sup>21</sup> and many commercial payers and states have also set payment reform goals. The Health Care Payment Learning and Action Network (HCP LAN) APM Framework provides a useful framework for understanding the evolution of alternative payment models shifting from a purely volume-based fee-for-service model (Category 1) to increasing levels of accountability. Payment models in Category 2 continue to rely on FFS payments, with some adjustment for quality or efficiency measures. In contrast, APMs in category 3 or 4 involve an increasing shift from FFS to accountability for patient results. Category 3 APMs remain based primarily on a fee-for-service architecture but have some opportunities for savings or shared risk based on performance and spending. Category 4 APMs move further away from FFS models by tying payments primarily to patient-level results rather than services, e.g., partial or full capitation with substantial adjustments for quality

<sup>21</sup> CMS Quality Strategy 2016. Accessed April 7, 2017: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf>



performance.<sup>22 23</sup> In each progression through the framework, models shift from paying for volume to paying for value. These provider APM changes create opportunities for stronger alignment with VBP arrangements for medical products: sharing some of the increasing provider APM risk with manufacturers may enable more opportunities to drive toward higher value care with medical products.



Despite these shifts, arrangements in which medical product developers participate in VBP for health care providers are only beginning to emerge, in particular in the medical device space. Our own analysis of publicly-announced provider-manufacturer agreements shows seven such agreements, mostly within the cardiac device space (see Appendix B), although more non-public agreements may exist. While each agreement is individually negotiated, many provider-manufacturer agreements include provisions to share in either excess costs or cost-savings (e.g., Baxter will receive 50 percent of cost savings or share 50 percent of excess costs with Duke Health for procedures using Baxter equipment), agreements that the manufacturer will cover or subsidize the cost of replacement or additional required therapies (e.g., St. Jude will pay a 45 percent rebate to HealthTrust for cardiac resynchronization therapies if lead revision is required within a year), or agreements that the manufacturer will reimburse for the cost of treatment if certain goals are not met (e.g., Medtronic will reimburse multiple hospitals for the cost of

<sup>22</sup> Health Care Payment Learning & Action Network. Alternative Payment Model (APM) Framework. January 12, 2016. Accessed April 17, 2017: <https://hcp-lan.org/workproducts/apm-whitepaper.pdf>

<sup>23</sup> McClellan, M., Richards, R., and Japinga, J. Evidence On Payment Reform: Where Are the Gaps? *Health Affairs Blog*. April 25, 2017. Accessed April 26, 2017: <http://healthaffairs.org/blog/2017/04/25/evidence-on-payment-reform-where-are-the-gaps/>

infection-related treatments if procedures with Tyrex devices have higher rates of infection than competitors).

Several developments have led to increased interest in VBP arrangements between hospital systems and manufacturers of medical devices. First, such contracts are relatively straightforward extensions of current payment models. Medical devices are often purchased directly by hospital systems, which receive one diagnosis-related group (DRG) global payment for the procedure (or, in the case of an outpatient service, one ambulatory patient classification (APC) global payment for the procedure) regardless of medical product cost.<sup>24</sup> Under prior payment schemes, medical devices competed primarily for hospital contracts on cost with little direct financial incentive to consider quality.<sup>25</sup> With hospital reimbursements now directly affected by patient outcomes such as readmission rates, hospital-acquired infection rates, quality adjustments, including “episode” quality measures, both hospitals and manufacturers are now moving towards solutions focused on value. Penalties related to poor outcomes for congestive heart failure patients may be a driving force behind the proliferation of cardiac device VBP arrangements, which compose the bulk of products currently covered under these provider-manufacturer arrangements.<sup>26</sup> Additional benefits of increased provider-manufacturer contracts may include manufacturer specialized knowledge and capabilities for targeting products, using them effectively, and avoiding complications, and manufacturer resources that could support investments in care redesign needed for provider success in APMs.

Although VBP arrangements between providers and manufacturers are emerging, there are several major barriers to their more widespread adoption. First, many manufacturers in both the pharmaceutical and device space may be wary of jumping into a still-developing market for alternative payment models, with uncertainty about both the pace and nature of payment reforms that will occur, as well as inexperience in how to collaborate to reform care successfully. Second, direct value-based purchasing for devices requires fewer fundamental changes than are required for broader inclusion of other medical products in APMs, which have a complex system of largely volume-based contract arrangements among purchasing organizations, Pharmacy Benefit Managers, payers, pharmacy systems, and other stakeholders. For example, Medicare APM contracts do not include accountability for pharmaceutical spending for self-administered drugs (i.e., covered under Medicare Part D), and relatively little has been reported about the extent to which commercial ACO contracts require accountability for pharmaceutical spending.<sup>27</sup> Navigating this added complexity in contract negotiations may increase operational burdens. Third, existing regulatory requirements (e.g., the Medicaid “best price” provision of the Medicaid prescription drug rebate program) are an active disincentive for the implementation of VBP arrangements for private payers. Lastly, Garrison (2015) found that manufacturers expressed skepticism around population-based agreements given the many unknowns

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<sup>24</sup> The Medicare program contains a pass-through system designed to compensate for the costs of new technologies that are not captured in the global DRG or APC payment. These pass-through payments last for two to three years, until their costs are ultimately folded into the DRG or APC. See Social Security Act §§ 1886(d)(5)(K) and (L) and 1833(t)(6). These payments, which arguably foster adoption of new technologies, are still made on a volume, not a value, basis.

<sup>25</sup> Garfield, S. S., & Armstrong, S. O. (May-June 2014). Risk Sharing for Medical Devices: Has the Time Come? *ISPOR Connections*, 20(3), 4-5.

<sup>26</sup> Lee, J. (December 8, 2014). Devicemakers explore risk-based contracts with hospitals. *Modern Healthcare*, 44(49), 14.

<sup>27</sup> Colla CH, Lewis VA, Beaulieu-Jones BR, Morden NE. Role of pharmacy services in accountable care organizations. *J Manag Care Spec Pharm*. 2015;21(4):338-44. Available at: <http://www.jmcp.org/doi/10.18553/jmcp.2015.21.4.338>.



around compliance, prescribing, and other factors that cannot be controlled by the manufacturer.<sup>28</sup> This reluctance to embrace indirect risk could inhibit future agreements with providers in APMs.

## **Obstacles to Increased Implementation of Value-Based Payment arrangements in the United States**

Several recent publications, including the PhRMA-funded “Barriers to Value-Based Contracts,” NEHI’s “Rewarding Results” white paper, and Ward et al.’s 2016 *Health Affairs* article report results of attempts to survey payers, pharmaceutical benefit managers, manufacturers, and other health system stakeholders to identify common concerns, barriers, and possible solutions to advance the implementation of Value-Based Payment agreements. All of these reports show that stakeholders involved in VBP negotiations face significant operational and administrative challenges, and that questions about legal and regulatory issues impede negotiation and execution of Value-Based Payment agreements. Ward (2016) found that uncertainty created by legal and regulatory issues – including price reporting requirements, Medicaid rebate requirements, the federal Anti-Kickback Statute, the physician self-referral statute and regulations for off-label communication – were viewed as the most critical barriers, although the degree to which stakeholders viewed these as obstacles ranged from prohibitive to minor.<sup>29</sup> PhRMA’s recent survey found that while Medicaid’s “best price” rule and anti-kickback concerns were considered significant barriers, the issues rated a “high” or “very high” level concern by the most respondents were operational challenges such as the inability to measure outcomes reliably.<sup>30</sup> Many of the legal and regulatory barriers to Value-Based Payments stem from legal structures built on a largely FFS model, with different methods required to develop a more flexible approach to value-based care. The major legal, regulatory, and operational barriers are described below, along with potential solutions that have been proposed.

### *Anti-Kickback Statute*

To reduce fraud and abuse, the federal Anti-Kickback Statute<sup>31</sup> prohibits any exchange of remuneration (or offer of exchange of remuneration) that would reward the referral of business paid for by federal healthcare programs.<sup>32</sup> Because VBP arrangements are not explicitly rebates or discounts, the payment arrangement itself could be considered an incentive, or the inclusion of certain types of ongoing evaluations of health outcomes related to the use of the drug or device.<sup>33</sup> Many cooperative arrangements have the possibility of being interpreted as improper incentives to increase utilization, so

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<sup>28</sup> Garrison 2015, et al.

<sup>29</sup> Ward, A. S., Linthicum, M., Drozd, M., Silverstein, A. R., & Vandigo, J. (2016, November 4). Regulatory, Legal Uncertainties Are Barriers To Value-Based Agreements For Drugs. *Health Affairs Blog*. Retrieved April 11, 2017, from <http://healthaffairs.org/blog/2016/11/04/regulatory-legal-uncertainties-are-barriers-to-value-based-agreements-for-drugs/>

<sup>30</sup> *Barriers to Value-Based Contracts for Innovative Medicines*. PhRMA Member Survey Results. March 2017.

<sup>31</sup> 42 U.S.C. § 1320a-7b

<sup>32</sup> Nussbaum S. and Ricks D. (January 29, 2016.) Discovering New Medicines And New Ways To Pay For Them. *Health Affairs Blog*, Available at: [<http://healthaffairs.org/blog/2016/01/29/discovering-new-medicines-and-new-ways-to-pay-for-them/>]

<sup>33</sup> Farber D, Shakow J, and Pinto PN. (March 4, 2016). All Foam, No Beer: Broad Uptake of Value-Based Pricing for Prescription Drugs Unlikely Without Serious Legislative Change. *Bloomberg Pharmaceutical Law & Industry Report*, 14 PLIR 10. Available at: [[http://www.kslaw.com/imageserver/KSPublic/library/publication/2016articles/3-4-2016\\_Bloomberg\\_BNA.pdf](http://www.kslaw.com/imageserver/KSPublic/library/publication/2016articles/3-4-2016_Bloomberg_BNA.pdf)]

a variety of “safe harbors” have been created within the law to allow for things like price reductions to managed care plans and referral agreements for specialty services.<sup>34</sup>

There are a variety of views about the extent to which VBP arrangements fall under the Anti-Kickback Statute; clearly, some manufacturers and payers have concluded that the VBP arrangements they have already executed are not implicated by the Statute.<sup>35</sup> If a VBP arrangement is strictly limited to the commercial insurance space, it is not subject to the Anti-Kickback Statute. But participants are hesitant to institute VBP arrangements in the context of public programs.<sup>36</sup> Certain contracting strategies can be pursued to limit Anti-Kickback Statute liability. One example is a manufacturer offering a stepwise discount on a drug along with funding interventions to improve patient adherence for all products in the therapeutic class. If adherence goals across the class are met, the manufacturer’s contract partner gets a limited discount on the manufacturer’s drug, and if adherence goals are not met, the partner gets a larger discount on the drug. This way, the manufacturer’s offer of an intervention is not tied to the volume of prescriptions, since it addresses adherence to the entire therapeutic class, and it is thus unlikely to be considered an incentive for prescribing the manufacturer’s drug.<sup>37</sup> However, the law is still sufficiently broad to create uncertainty for manufacturers and payers, particularly in “pay for results” discounts or arrangements in which manufacturers agree to provide medication adherence information or other support.<sup>38</sup>

To reduce this uncertainty, the Department of Health and Human Services Inspector General could create additional safe harbors and define value-based arrangements in a manner that would make them permissible under the Anti-Kickback Statute. As part of the Affordable Care Act, Congress authorized waivers from the Anti-Kickback Statute for hospitals that participated in ACO arrangements.<sup>39</sup> NEHI recommends new safe harbors in three areas: 1) data and analytics (allowing cost-sharing for the determination of outcomes defined in the agreements), 2) warranties of performance (allowing refunds for non-response or when a drug otherwise doesn’t meet the level of effectiveness set in the agreement), and 3) medication adherence support services and interventions (allowing manufacturers to provide adherence support, as long as it is not tied to volume of drugs dispensed).<sup>40</sup> Such “safe harbors” for joint investments and activities involving different types of providers have been proposed and developed for ACOs and other APMs in Medicare. In 2011, when CMS released the final rule on ACOs under the Affordable Care Act, CMS and HHS OIG jointly issued a rule outlining waivers from certain restrictions, including those related to the Anti-Kickback Statute, which would be accessible to

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<sup>34</sup> Homchick, R. Federal Anti-Kickback Statute Primer. Davis Wright Tremaine LLP. Available at:

[[https://www.healthlawyers.org/events/programs/materials/documents/fc12/101\\_homchick\\_williams.pdf](https://www.healthlawyers.org/events/programs/materials/documents/fc12/101_homchick_williams.pdf)]

<sup>35</sup> *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals*. The Network for Excellence in Health Innovation. March 2017.

<sup>36</sup> Kelly, C. (November 6, 2016). US Outcomes-Based Contracts: Big Uptick In Interest, But Not Execution. Available at: <https://invivo.pharmamedtechbi.com/IV004953/US-OutcomesBased-Contracts-Big-Uptick-In-Interest-But-Not-Execution>

<sup>37</sup> Studin, I. (February 2002) Reframing the Pharmaceutical Manufacturer/Health Plan Relationship in Managed Care. *Managed Care Magazine*. Available at: <https://www.managedcaremag.com/archives/2002/2/reframing-pharmaceutical-manufacturerhealth-plan-relationship-managed-care>

<sup>38</sup> Ward et al.

<sup>39</sup> Social Security Act § 1899(f). The Inspector General applied similar waiver authority for participants in the pioneer ACO program.

<sup>40</sup> *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals*. The Network for Excellence in Health Innovation. March 2017.

ACOs participating in the Medicare Shared Savings Program.<sup>41</sup> Thus, coordinated regulatory action is possible in the context of enabling value-based cooperation, and should be approached with these examples in mind when seeking similar changes to enable VBP arrangements.

### *Government Pricing Challenges: Best Price in Medicaid and 340B; Average Sales Price in Medicare Part B*

Discounts triggered by provisions in VBP arrangements can have implications for other sales of that particular product. For every outpatient drug covered by Medicaid, manufacturers must pay quarterly rebates to state Medicaid agencies. These rebates are determined based in part on the Average Manufacturer Price (AMP) and the “best price” for each drug, which must be provided to CMS quarterly.<sup>42</sup> The best price is set by the single lowest price for which the manufacturer sold the drug during the quarter with limited exceptions such as sales to government payers, sales outside of the United States, and sales to Medicare Part D plans. The unit rebate for generic drugs is a set percentage (currently 13 percent) of AMP. For brand-name drugs, however, the unit rebate amount is set as the greater of either a fixed percentage (currently 23.1 percent) of the AMP or the AMP minus the best price (with some exceptions).<sup>43</sup> Though there are some complicating factors, this can be thought of as the manufacturer offering to all Medicaid agencies the best price anyone received on that drug during the quarter. For drugs with large Medicaid markets – such as the new Hepatitis C therapies, for example – this is a significant concern, since, hypothetically, a discount for even one patient’s use of the drug (such as a non-responder, for which the payer may receive a full rebate under a VBP arrangements) could significantly raise the rebate liability for the manufacturer to Medicaid programs across the country – requiring full rebates on all uses of the drug in every Medicaid program.<sup>44</sup>

Best price ripple effects are also seen in the 340B Drug Pricing Program,<sup>45</sup> which requires manufacturers who wish to participate in the Medicaid program to provide discounts on outpatient drugs to eligible (“covered”) healthcare entities. The discounted prices for covered entities are established through calculations that, again, involve the AMP and best price, so setting a new, lower best price through provisions of a VBP arrangement could require deeper discounts on that drug for thousands of 340B-covered entities.<sup>46</sup>

Medicare Part B doesn’t include explicit discounts or rebates, but the reimbursements to providers for these physician-administered drugs are calculated with a volume-weighted average (known as ASP) of all various prices offered by the manufacturer on that drug, including rebates and discounts in other settings.<sup>47</sup> Therefore, discounts provided in the context of performance on VBP arrangements could lower the ASP for the drug, causing providers to receive lower reimbursements from Medicare Part B when they use it.<sup>48</sup> Despite price calculation concerns, a number of VBP arrangements for oral and physician-administered drugs have been implemented. One strategy manufacturers may be using to contract around this issue is the inclusion of a clause that stipulates that the combined total of rebates and outcomes-based discounts under the agreement will never exceed the Medicaid rebate, essentially

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<sup>41</sup> See 76 Fed. Reg. 67992 (Nov. 2, 2011) (setting forth requirements for waivers).

<sup>42</sup> section 1927(b)(3) of the Social Security Act [42 U.S.C. § 1396r-8]

<sup>43</sup> Medicaid.gov. Medicaid Drug Rebate Program. <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>

<sup>44</sup> Farber D. 2016 et al.

<sup>45</sup> established in Section 340B of Public Health Service Act, codified at 42 USC 256b

<sup>46</sup> Farber D. 2016 et al.

<sup>47</sup> 42 U.S.C. § 1395w-3a

<sup>48</sup> Farber D. 2016 et al.

creating a failsafe to ensure the VBP arrangement doesn't create any additional Medicaid rebate liability.<sup>49</sup> Of course, such a constraint may limit the utility of the arrangement as an incentive to improve value.

Though careful contract formulation can be helpful, best price issues are still frequently cited as a significant obstacle to increased participation in VBP arrangements.<sup>50,51</sup> To further address this problem, experts and stakeholders have recommended that CMS, with stakeholder input, develop a consensus definition of value-based contracts to support additional guidance, support pilots of value-based contracting projects, and release guidance that clarifies and refines the applicability of best price.<sup>52,53</sup> CMS has issued previous guidance that encourages negotiation of supplemental rebates which would be excluded from best price calculations, but concerns have been raised that not enough detail was provided on how to structure those agreements in such a way to be sure that best price determinations will not be affected.<sup>54</sup> Moreover, that CMS guidance only applies in the context of sales to Medicaid agencies, not private payers. An explicit legislative exemption of prices in the context of VBP arrangements from the determination of Medicaid best prices and calculation of Medicare Part B ASP is a potential broader solution; this approach was used to exempt Medicare Part D drug prices from best price determination.<sup>55</sup> Additionally, a variety of Medicaid stakeholders, including the National Academy of State Health Policy, the National Association of Medicaid Directors, and the Medicaid Health Plans of America, have urged CMS to allow for more flexibility for state Medicaid programs to negotiate VBP arrangements with manufacturers.<sup>56,57</sup> CMS itself has asked for stakeholder input on this question in the context of payment arrangements for direct acting antivirals used in the treatment of Hepatitis C.<sup>58</sup>

#### *FDA Regulation of Payer-Manufacturer Communication*

FDA currently regulates communication between manufacturers and other entities through a patchwork of rules and guidance documents. The agency's regulation of such communication largely hinges on the relationship of the information being shared to the approved product label. Of particular note for VBP arrangements are statutory guidelines that provide for the sharing of health care economic information (HCEI) between manufacturers and payer groups, which were first established in Section 114 of the 1997

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<sup>49</sup> Kelly, C. (November 6, 2016). US Outcomes-Based Contracts: Big Uptick In Interest, But Not Execution. Available at: <https://invivo.pharmamedtechbi.com/IV004953/US-OutcomesBased-Contracts-Big-Uptick-In-Interest-But-Not-Execution>

<sup>50</sup> Ward, et al.

<sup>51</sup> *Barriers to Value-Based Contracts for Innovative Medicines*. PhRMA Member Survey Results. March 2017.

<sup>52</sup> *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals*. The Network for Excellence in Health Innovation. March 2017

<sup>53</sup> Eli Lilly and Company and Anthem. (January 29, 2016). Promoting Value-Based Contracting Arrangements. Available at: <https://lillypad.lilly.com/WP/wp-content/uploads/LillyAnthemWP2.pdf>

<sup>54</sup> Margulies R. CMS releases guidance to states and manufacturers on Medicaid value based purchasing arrangements. Foley Hoag LLP. July 15th, 2016. Accessed at: [<http://www.medicaidandthelaw.com/2016/07/15/cms-releases-guidance-to-states-and-manufacturers-on-medicaid-value-based-purchasing-arrangements/>]

<sup>55</sup> Farber D. 2016 et al.; see also Social Security Act at § 1927(c)(1)(C)(i)(VI).

<sup>56</sup> *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals*. The Network for Excellence in Health Innovation. March 2017

<sup>57</sup> "States and the rising cost of Pharmaceuticals: A Call to Action." National Academy for State Health Policy, October 2016.

<sup>58</sup> The letters are available on CMS' website. See <https://www.medicaid.gov/medicaid/prescription-drugs/hcv/index.html>.

Food and Drug Administration Modernization Act (FDAMA).<sup>59</sup> As written, however, the original text of FDAMA Section 114 provided limited clarity for manufacturers around key terms, with no formal definition for what constituted HCEI. Ambiguity in what information could be shared and the process for sharing it has been sufficient to discourage some attempts at VBP arrangements.

A range of recent efforts have aimed to address this ambiguity. Language in the 21<sup>st</sup> Century Cures Act, passed in December 2016, detailed the underlying definition of HCEI, broadened the types of payer groups that could be considered acceptable audiences for HCEI, and potentially allowed for some flexibility in how closely HCEI must relate to the approved product label. In January 2017, FDA issued subsequent draft guidance that incorporated these statutory changes and sought to provide additional clarity on the types of information that it considers to constitute HCEI.<sup>60</sup> The draft guidance also introduced the possibility of sharing HCEI with payer groups prior to FDA approval of a new drug. Still, some questions remain around these processes as the agency continues to solicit feedback on its draft guidance.<sup>61</sup>

Value-based contracts for medical products also involve analysis of quality and health outcome data. To the extent that information relevant to contract negotiations for VBP arrangements may *not* be considered HCEI or related to an approved indication as defined by guidance, lack of clarity about other off-label communication oversight by FDA in the context of new payment models may also hamper uptake. Draft guidance was issued in January 2017 related to manufacturer communications consistent with product labeling,<sup>62</sup> as well as a memorandum outlining FDA's current stance on communication related to unapproved uses and the First Amendment rights of sponsors.<sup>63</sup> These draft documents largely establish an FDA approach in which *some* information that is not contained within an approved label may be communicated, but must still, at minimum, be related to the approved indication, population, dosing, and directions for handling.

While the Agency is seeking input to refine these communications-related guidance documents, VBP arrangements will depend on how well the information that needs to underpin such agreements comports with the definition of HCEI and of information contained within the approved product label. If outcomes measures that could potentially form the basis of an agreement can only be related to approved populations, indications, or other properties defined within the label, VBP arrangements may continue to face challenges at the intersection of off-label communications and real-world use. Expecting the FDA to issue finalized guidance on provision of HCEI in 2017, stakeholders have recommended continuing conversations between FDA and stakeholders on VBP arrangements and the effects of communication restrictions.<sup>64</sup> Further consideration of the impact on manufacturer incentives of value-based contracts may also be important. To the extent that manufacturer revenues depend on improvements in valid outcome measures rather than volume of sales, the risk-benefit assessment of

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<sup>59</sup> Food and Drug Administration Modernization Act of 1997 § 102, 42 U.S.C. § 4332 (1997).

<sup>60</sup> FDA Guidance: United States Government. U.S. Food and Drug Administration. (2017). *Drug and Device Manufacturer Communications with Payors, Formulary Committees, Similar Entities*. Silver Spring, Maryland. FDA.

<sup>61</sup> FDA Federal Register Notice: Manufacturer communications Regarding Unapproved Uses of Approved or Cleared Medical Products, Federal Register. 82(12):6367 (January, 19, 2017).

<sup>62</sup> FDA Guidance: United States Government. U.S. Food and Drug Administration. (2017). *Medical Product Communications that are Consistent with the FDA-Required Labeling*. Silver Spring, Maryland. FDA.

<sup>63</sup> FDA Memorandum: United States Government. U.S. Food and Drug Administration. (2017). *Public Health Interests and First Amendment Considerations Relation to Manufacturer Communication Regarding Unapproved Uses of Approved or Cleared Medical Products*. Silver Spring, Maryland. FDA.

<sup>64</sup> Recommendations included in NEHI, PhRMA, and *Health Affairs* publications.

off-label communications may change. That is, if manufacturer revenues have little relation to sales volume but are primarily based on improved outcomes or demonstrated higher value, it may be reasonable to conclude that off-label communications between manufacturers and providers in the contract are more likely to be beneficial for public health.

### *Operational Challenges*

As previously noted, concerns related to administrative burden, ability to identify and agree on outcome measures, data infrastructure and accessibility issues for tracking and monitoring patient data, and alignment of payer and manufacturer incentives remain top concerns for stakeholders in value-based payment scenarios. Ensuring the requisite expertise and resources to properly execute these agreements can be a major barrier, particularly for smaller or public payers. While some administrative burdens have been ameliorated as payers and manufacturers gain more experience in negotiating agreements, significant challenges remain with regard to the health system's capacity to access, track, and analyze patient outcomes. According to the PhRMA Survey, the "inability of the payer, manufacturer, or third party to measure outcomes" rates as the highest stakeholder concern (75 percent), with "lack of payer culture and capabilities for tracking and measuring outcomes" (68 percent) a close second.<sup>65</sup> Given the trade-offs between complexity of outcomes and operational burden, many payers have expressed a preference towards VBP arrangements that decrease administrative burden and rely on clear, measurable clinical outcomes such as blood glucose levels or tumor shrinkage.<sup>66</sup> Although each individual VBP agreement may reflect different costs and benefits related to patient population, treatment, duration of treatment, and difficulty of monitoring outcomes, defining and agreeing upon outcomes measurements within a VBP arrangement that balances potential benefits with their administrative costs is a key operational challenge.

### *Data Constraints*

Data collection, accessibility, and interoperability are related challenges for the execution of VBP arrangements. The difficulty of monitoring and analyzing the type of patient data needed to execute VBP arrangements can be considerable. Many payers do not have access to the EHR data or lab results that would be needed to track longitudinal outcomes, and those that do often still face data that is incomplete or does not reliably capture information on outcomes of concern for the agreement, such as patient adherence, toxicity, desired endpoint, etc.<sup>67</sup> With increasing pressure to demonstrate value for high-cost therapies, interest in "Real-World Evidence" including patient-reported outcomes are increasingly seen as crucial to determining effectiveness and patient satisfaction in chronic conditions such as cancer, multiple sclerosis, chronic obstructive pulmonary disease, and rheumatoid arthritis.<sup>68</sup>

To improve the capability of stakeholders to execute and monitor Value-Based Payment agreements that require access to patient data, stakeholders have emphasized the need to improve data systems and interoperability, including improved access to relevant patient data such as medication adherence, pharmacy, or laboratory results. Within the NEHI report, support for the development of validated

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<sup>65</sup> *Barriers to Value-Based Contracts for Innovative Medicines*. PhRMA Member Survey Results. March 2017.

<sup>66</sup> Garrison et al, 2015.

<sup>67</sup> Fox J and Watrous M. "Overcoming Challenges of Outcomes-Based Contracting for Pharmaceuticals: Early Lessons From the Genentech-Priority Health Pilot." April 3, 2017.

<sup>68</sup> *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals*. The Network for Excellence in Health Innovation. March 2017

measures through the National Quality Forum and Patient-Centered Outcomes Research Institute (PCORI) is seen as a priority, as are continued efforts to build better data infrastructure through common data standards and principles and Electronic Health Record interoperability to make meaningful real-world outcomes accessible to payers.<sup>69</sup> More broadly, efforts and incentives are needed to build the data infrastructure and robust analytic methods needed to support Value-Based Patient models for increasingly complex real-world and patient-centered longitudinal data. Systems currently used for other real-world evidence applications, such as the Sentinel System and longitudinal research studies of medical products (e.g. MDEpiNet and the new NEST) likely need significant enhancements to support VBP contracts.

### *Aligning Incentives across Stakeholders*

Another ongoing non-regulatory challenge to execution of VBP arrangements aligning incentives for manufacturers and payers under the time constraints of most insurance arrangements. Year-to-year changes in patients' insurance coverage have been cited as a disincentive for payers to finance expensive treatments that may only see cost savings or outcome improvements in the long-term. To address the unique considerations for both chronic-use and curative therapies, stakeholders may need to develop payment innovations such as a consistent framework for contracts across payers to properly align risk and cost-savings,<sup>70</sup> or explore joint contracts with providers who are likely to be involved in a patient's care for the longer term. Better evidence on the validity of early indicators or markers of long-term performance would also support value-based payments. Of course, the extent that better performance encourages patients to stay with a particular insurer or provider, promoting competition and patient choice based on value can foster these contracts – for example, through such steps as better information for consumers about their quality of care, risk adjustment mechanisms that better reward providers and payers for attracting and retaining high-risk patients, and value-based insurance designs.

### **Developing a Path Forward**

Despite these obstacles, the pressure for financing arrangements that support higher-value models of care is rising along with health care costs and evidence of inefficiencies in care delivery. In the preceding sections, we have summarized work to date on addressing perceived legal, regulatory, and operational barriers to value based contracts, as well as steps to reduce administrative burdens. Building on this progress, the Value-Based Payment Consortium Advisory Group has begun work on achievable goals to advance effective VBP arrangements for medical products.

In the months ahead, the Consortium Advisory Group—composed of patient advocates, payers, manufacturers, and providers, as well as experts on regulatory affairs, law, and policy—will work to develop approaches to payment reform that support better outcomes for patients and better value across the system. Specific workgroups will explore unique challenges and innovations for advancing value-based payment in chronic-use pharmaceuticals, medical devices, and gene therapies, while the Consortium will address common issues across these domains and identify strategies for addressing barriers that have prevented additional progress. Specifically, the Consortium will produce issue papers and other resources to provide practical solutions to common barriers in four common areas: legal and regulatory barriers, data and operational challenges, financing high-cost therapies, and developing models for aligning VBP arrangements for providers and manufacturers. Building on this work, the

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<sup>69</sup> NEHI, 2017.

<sup>70</sup> NEHI, 2017.



Consortium will also be producing a Value-Based Payment Framework, which will include approaches for structuring such arrangements and setting forth guidelines for potential pilot testing for innovative payment approaches.

Much has been learned about the value that can be created through value-based partnerships, as well as barriers that have impeded their progress to date. Looking ahead, we must continue to work together to develop common-sense solutions to addressing common legal, regulatory, and operational issues while work continues to innovate payment models that can create the most value for the health system and patients.

## Appendix A: List of Payer-Manufacturer Value-Based Payment Arrangements Implemented in the United States, 1994-2016

This table summarizes all publicly-available VBP agreements between payers and manufacturers implemented in the United States. The terms and conditions come from a variety of sources, including peer-reviewed articles, news reports, company press release, CMS public data, and company financial statements.

Drug or Device	Year	Therapeutic Area	Manufacturer	Payer	Terms
Procrit	1994	Anemia	Ortho Biotech	All insurers and patients	Ortho Biotech entered an agreement with payers about its anemia treatment Procrit. Ortho will <b>replace the product for free</b> if the product is <b>used appropriately</b> but the patient <b>does not respond to treatment</b> .
Proscar	1994	Prostatic hyperplasia	Merck	All insurers and patients	Merck will refund the value of Proscar therapy if compliant patients <b>do not respond to the therapy after six months</b> . Individual contracts are made between Merck and specific payers who covers Proscar.
Foley Catheter	1995	Invasive procedures	Bard Medical	Multiple Hospitals	The list price of Bard Medical's antimicrobial catheter is <b>\$10.85</b> , while a normal catheter is priced <b>\$5.85</b> . Bard Medical offers to sell the antimicrobial catheter for the cheaper price of a traditional catheter (\$5.85), as long as the hospital will <b>split any savings from the prevention of UTIs with Bard Medical</b> .
Hospital equipment and supplies	1995	Multiple indications	Baxter	Duke Health	1. After purchasing Baxter's products, if Duke Health's spending are <b>lower</b> than the budgeted costs per procedure, Duke will pay Baxter <b>50 percent of its cost savings</b> ; 2. In the opposite, if the supply costs <b>exceed</b> Duke's budget, Baxter must pay Duke <b>50 percent of the excess cost</b> .

Erythropoiesis-stimulating agents	1997	Hemodialysis	Amgen, Ortho Biotech	CMS	CMS entered the call with Amgen and Ortho Biotech on their <b>erythropoiesis-stimulating drugs</b> for hemodialysis patients. CMS will <b>fully reimburse</b> erythropoiesis-stimulating agents until a patient achieves a hemoglobin level of <b>10 g per dl</b> .
Simvastatin	1998	High cholesterol	Merck	Multiple insurers and patients	Merck promised to refund patients and insurers <b>up to 6 months of their prescription costs</b> if simvastatin did not help them <b>lower LDL cholesterol</b> to a certain degree identified by their doctors.
Oxaliplatin; Irinotecan; Cetuximab; Bevacizumab.	2005	Colorectal cancer	Sanofi-Aventis, BMS, Pfizer, Genentech	CMS	CMS entered a group contract with four pharmaceutical companies on cancer drugs. CMS promises to cover <i>oxaliplatin, irinotecan, cetuximab, or bevacizumab</i> for the treatment of colorectal cancer if these drugs <b>show a satisfactory level of efficacy</b> in a registered clinical trial.
Home-use oxygen product	2006	Chronic hypoxemia	Multiple manufacturers	CMS	The home use of oxygen is covered for those beneficiaries with arterial oxygen partial pressure measurements from <b>56 to 65 mmHg</b> or oxygen saturation <b>at or above 89 percent</b> , who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI).
OncotypeDx	2007	Breast cancer	Genomic Health	United Healthcare	<ol style="list-style-type: none"> <li>1. United Healthcare agreed to reimburse the Oncotype Dx test for <b>18 months</b>, while it and Genomic Health monitor the results.</li> <li>2. If the number of women receiving chemotherapy <b>exceeds an agreed threshold</b>, even if the test suggests they do not need it, the insurer will <b>negotiate a lower price</b> because the test is not having the intended impact on actual medical practice.</li> </ol>

Januvia/Janumet	2009	Diabetes	Merck	Cigna	<p>1. Merck will <b>increase the discount to Cigna</b>, if a higher percentage of patients showing an improvement of blood sugar values by the end of the agreement period, compared to a negotiated baseline.</p> <p>2. Merck will <b>offer a further discount to Cigna</b> if a certain percentage of Cigna members meet the benchmark for medication adherence.</p>
Risedronate sodium	2009	Osteoporosis	Proctor & Gamble/Sanofi-Aventis	Health Alliance	<p>1. Proctor &amp; Gamble and Sanofi-Aventis <b>guarantee</b> that Health Alliance plan beneficiaries who take Risedronate sodium will <b>reduce their incidence of bone fracture</b>.</p> <p>2. If a patient still suffers from fracture after taking the drug (which proves the drug's inefficacy), the manufacturer will <b>reimburse the medical cost</b> for treating the fracture.</p>
Rebif (interferon beta-1a)	2012	Multiple sclerosis	Merck (EMD Serono)	Prime Therapeutics	<p>EMD Serono will pay rebates to Prime Therapeutics on its multiple sclerosis drug Rebif if:</p> <p>1. Patients treated with Rebif have a <b>higher overall total cost</b> than patients treated on a different, older multiple sclerosis drug;</p> <p>2. The patient adherence rate of Rebif remains above a specified level.</p>
Molecular Diagnostic Tests	2012	Diagnostic tests	Multiple diagnostic developers	Palmetto GBA (Medicare Contractor)	<p>Palmetto GBA, a Medicare contractor, uses <b>evidence-based technical assessments</b> to determine Medicare coverage for genetic tests. Test developers are required to submit evidence demonstrating the <b>analytical validity, clinical validity, and clinical utility</b> for each diagnostic test. Based on these evidence, Palmetto determines the reimbursement amount for each test.</p>

Effient	2014	Cardiovascular diseases	Eli Lilly	Humana	<p>1. The basic structure is a pay-for-pill model. The payer and provider will <b>negotiate a baseline price</b> for each unit of Effient.</p> <p>2. The drug price is adjusted by the <b>hospitalization rate</b> due to cardiovascular events for patients taking the drug.</p> <p>3. If hospitalization rate is <b>higher</b>, the drug price will go <b>down</b>; if hospitalization rate is <b>lower</b>, the drug price will go <b>up</b>.</p>
Brilinta	2014	Cardiovascular diseases	AstraZeneca	Univ. of Pittsburgh Health Plans	<p>1. AstraZeneca offers to <b>cover a certain portion of treatment costs</b> of patients who have <b>additional heart attacks</b> after taking the drug Brilinta, if the rate of heart attacks exceeds an agreed threshold.</p> <p>2. The threshold is calculated based on Brilinta’s patient outcomes data showing the <b>degree of heart attacks reduction</b> in patient population.</p>
Repatha	2015	High cholesterol	Amgen	Harvard Pilgrim/CVS Health	<p>1. CVS health will <b>get a discount</b> if it keeps “preferring” Repatha –keeping the drug under the tier-1/tier-2 formulary list.</p> <p>2. The insurer will <b>get an additional rebate</b> if the <b>drug fails to lower the cholesterol</b> of patients to the degree indicated by the drug's clinical trials.</p> <p>3. The insurer will get <b>a third rebate</b>, if more patients are using the drug than was anticipated.</p>
Iressa	2015	Breast and lung cancers	AstraZeneca	Express Scripts	<p>1. If a patient <b>stops treatment</b> before the third prescription fill, AstraZeneca will <b>fully reimburse</b> Express Scripts for the Iressa costs of that patient.</p> <p>2. This arrangement aims to <b>encourage patient adherence</b>, which will improve the utilization of the drug.</p>
Entresto	2016	Chronic heart failure	Novartis	Aetna/Cigna	<p>1. The payer and manufacturer agree on an initial baseline rebate for Entresto payment;</p>

					<p>2. The payer and manufacturer use <b>heart failure hospitalization rate</b> as a key predictor of patient outcomes.</p> <p>3. If the heart failure hospitalization rate of patients using Entresto <b>exceed a pre-specified threshold</b>, Novartis will <b>reduce the price</b> of Entresto to payers.</p> <p>4. Conversely, if patients using Entresto experience a lower rate of heart failure hospitalization, Novartis will <b>charge a higher price</b> for the drug.</p>
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## Appendix B: List of Provider-Manufacturer Value-Based Payment Arrangements Implemented in the United States

This table summarizes all publicly-available VBP agreements between providers and manufacturers implemented in the United States. The terms and conditions come from a variety of sources, including peer-reviewed articles, news reports, company press release, CMS public data, and company financial statements.

Product Name	Manufacturer	Provider	Terms
Antimicrobial Catheter	Foley Catheter	All purchasing hospitals are eligible	<ol style="list-style-type: none"> <li>1. The list price of Bard Medical’s antimicrobial catheter is <b>\$10.85</b>, while a normal catheter is priced <b>\$5.85</b>.</li> <li>2. Bard Medical offers to sell the antimicrobial catheter for the <b>cheaper price</b> of a normal catheter (\$5.85), as long as the hospital will <b>split any savings from the prevention of UTIs with Bard Medical</b>, as a result of using its antimicrobial catheter.</li> </ol>
Hospital equipment	Baxter	Duke Health	<ol style="list-style-type: none"> <li>1. After purchasing Baxter’s products, if Duke Health's spending is <b>lower</b> than the budgeted costs per procedure, Duke will pay Baxter <b>50 percent of its cost savings</b>;</li> <li>2. In the opposite, if the supply costs <b>exceed</b> Duke's budget, Baxter must pay Duke <b>50 percent the excess cost</b>.</li> </ol>
Brilinta (cardiovascular drug)	AstraZeneca	University of Pittsburgh Medical Center	<ol style="list-style-type: none"> <li>1. AstraZeneca offers to <b>cover a certain portion of treatment costs</b> of patients who have <b>additional heart attacks</b> after taking the drug Brilinta, if the rate of heart attacks exceeds an agreed threshold.</li> <li>2. The threshold is calculated based on Brilinta’s patient outcomes data showing the <b>degree of heart attacks reduction</b> in patient population.</li> </ol>
Cardiovascular	Boston Scientific	Minneapolis Heart Institute; Allina Health System; Several other health systems.	<ol style="list-style-type: none"> <li>1. Boston Scientific offers value-based programs to help hospitals <b>improve cardiovascular care delivery</b> to patients suffering from <b>heart failure, atrial fibrillation, structural heart, and ischemic heart disease</b>.</li> <li>2. The value based program include: <b>performance optimization, capital financing, care pathway transformation, and patient management</b> programs.</li> <li>3. Boston Scientific claims that the use of its platform in single hospital sites has resulted in up to <b>\$1.5 million</b> in cost and operational savings.</li> </ol>



<p>Quadra heart rhythm device</p>	<p>St. Jude Medical</p>	<p>HealthTrust, a GPO representing nearly 1,400 hospitals</p>	<p>1. St. Jude promises to <b>share the financial risks with providers</b> who purchased its cardiac products.  2. St. Jude promises to pay hospitals a <b>45 percent rebate</b> on the net price for cardiac resynchronization therapies if a lead revision is needed within the first year of implantation as a result of four specific factors.</p>
<p>Thermocool catheter ablation procedure</p>	<p>J&amp;J Devices</p>	<p>Multiple Hospitals</p>	<p>If the provider needs to repeat the same procedure <b>within a year of treatment</b> using its Thermocool catheter ablation for atrial fibrillation, J&amp;J guarantees a <b>discount</b> on the cost of the device during the second procedure.</p>
<p>Tyrx (antimicrobial mesh pouch for cardiac devices)</p>	<p>Medtronic</p>	<p>Multiple Hospitals</p>	<p>1. Medtronic guarantees that hospitals using its Tyrx device will see <b>lower rates of infection</b> than in similar procedures performed without it.  2. If the device does not lower infection rates compared to other products, Medtronic will <b>cover the cost of treating the infection</b> for providers.</p>