

## Delivering medical innovation in a value-based world

Summary of the meeting co-hosted by

Deloitte Center  
for Health Solutions



THE NETWORK FOR  
EXCELLENCE IN  
HEALTH INNOVATION



### Executive summary

The US health care system's transition to value-based care (VBC) holds important implications for medical innovation. New value-based payment models shift financial risk from health plans to providers and other stakeholders, changing how they assess and adopt innovation. Performance measures and financial incentives in these payment models may encourage the use of therapies or technologies that save money in the short term or improve care as defined by a fairly narrow set of quality measures, potentially limiting patient access to innovation.

The Deloitte Center for Health Solutions and the Network for Excellence in Health Innovation (NEHI) convened 21 leaders across the health care system including life sciences companies, health plans, providers, academics, non-profits, and patient groups in fall 2015 to discuss how VBC influences innovation, how current VBC models could evolve to encourage innovation, and the strategic considerations for biopharma and medical technology (medtech) companies. Meeting participants\* pointed out that ongoing cross-stakeholder dialogue is critical to ensure that valuable medical innovations continue to reach patients as VBC models take root and evolve.

\* This paper reflects Deloitte's views and perspective on the key points made during the meeting. The paper does not reflect a consensus view or the views of each individual who participated in the event.

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Meeting participants identified four solutions that could promote the goal of innovation under VBC:

**1. Adoption of a broader set of quality measures**

- Clinical quality measures tied to long-term clinical outcomes in new payment models
- Collaboration with patient advocacy groups to expedite development of patient-centered measures

**2. Improved data availability, transparency, and integration**

- Cross-stakeholder data-sharing partnerships, including creation of patient registries
- Clarification on requirements for generating and communicating economic evidence

**3. Redefinition and identification of unmet and under-met needs**

- Life sciences companies as partners in care delivery, with refocused R&D efforts aimed at not only delivering strong science, but also improving clinical processes and financial goals
- Integrated products and services to fulfill unmet and under-met needs

**4. Shared financial risk between life sciences companies and their product purchasers**

- Adoption of value-based purchasing agreements with private health plans or providers to allow early adoption of innovation
- Increased alignment across decision-makers including physicians, purchasers, and health plans on criteria to evaluate innovative products

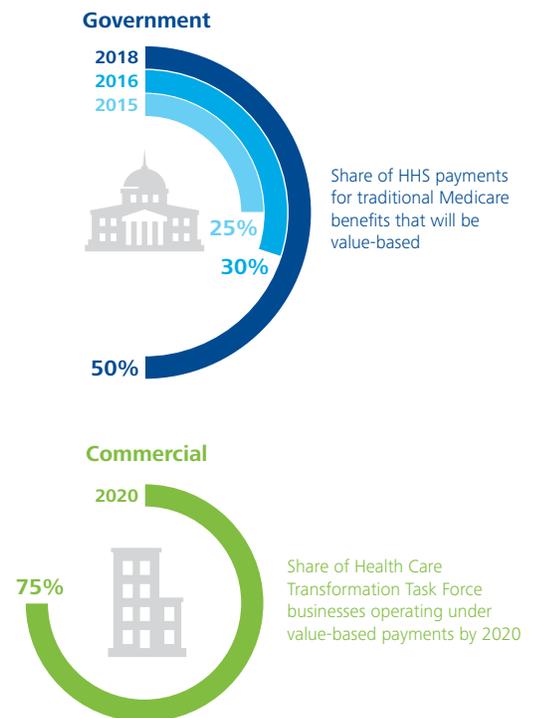
**Table 1. Biopharma and medtech face different challenges under VBC**

	Biopharma	Medtech
<b>1. Adoption of a broader set of quality measures</b>	<ul style="list-style-type: none"> <li>• Limited disease-specific clinical quality measures, including those reflecting patient preferences, in value-based payment models</li> </ul>	<ul style="list-style-type: none"> <li>• Emphasis on short-term financial incentives over quality measures in value-based payment models that cover device costs (e.g., bundles)</li> </ul>
<b>2. Improved data availability, transparency, and integration</b>	<ul style="list-style-type: none"> <li>• Lack of clarity from the Food and Drug Administration (FDA) on how to validate and communicate evidence that falls outside the scope of the label, including economic evidence</li> </ul>	<ul style="list-style-type: none"> <li>• Disparate financial stakeholders with varied evidence requirements</li> </ul>
<b>3. Redefinition and identification of unmet and under-met needs</b>	<ul style="list-style-type: none"> <li>• Demonstrating the value of services that help meet population management goals</li> <li>• Lack of clarity from policymakers on Anti-Kickback Statute boundaries</li> </ul>	<ul style="list-style-type: none"> <li>• Demonstrating product and service value beyond clinical outcomes, including procedure efficiency, patient satisfaction, and other quality goals</li> </ul>
<b>4. Shared financial risk between life sciences companies and their product purchasers</b>	<ul style="list-style-type: none"> <li>• Medicaid best price (under which Medicaid benefits from the best market price)</li> <li>• Utilization management approaches that may hinder patient access to therapies</li> </ul>	<ul style="list-style-type: none"> <li>• Measuring and tracking performance of implantable devices within an appropriate time frame</li> <li>• Distinguishing between the role of the physician and technology in achieving outcomes</li> </ul>

# Value-based care is growing; what are the implications for innovation?

Government and commercial health plans are piloting value-based payment models with provider organizations and have set goals for VBC's implementation. The US Department of Health and Human Services (HHS) aims to link 50 percent of Medicare payments to quality or value through alternative payment models, such as accountable care organizations (ACOs) or bundled payments, by 2018.<sup>1</sup> The Health Care Transformation Task Force, consisting of providers, health plans, and employers, has committed to shift 75 percent of its members' business into contracts with incentives for health outcomes, quality, and cost management by January 2020 (Figure 1).<sup>2</sup>

Figure 1. Government and commercial health plans' goals for value-based care<sup>1,2</sup>



## The shift to value-based care (VBC)

The US health care system's traditional fee-for-service (FFS) based payment model offers incentives for providers to increase the volume of services they deliver. Although providers have professional goals to improve health outcomes, the FFS model does not reward them for this. Due to concerns about rising costs and poor performance on quality indicators, many employers, health plans, and government health care purchasers are pushing for a transition to value-based payment models. Key terms include:

- **Value-based care (VBC):** Health care delivery or payment models that align physician and hospital bonuses and penalties with cost of care and quality measures.
- **Quality measures:** Indicators used to assess the delivery of care by a health care system or clinician, tied to financial incentives included in value-based payment models. Specific sub-types include:
  - **Process measures:** Indicators used to measure the performance of clinicians or care delivery teams in the provision of care and use of services among their patient base.
  - **Clinical measures:** Indicators that describe patient health status, including physiologic and mortality measures. These measures describe the outcome of treatment interventions.
- **Value-based payment models:** Generally, most alternative payment models being tested under VBC could be categorized as shared savings, bundled payments, shared risk, and global capitation.

Value-based payment models shift financial risk from health plans to providers and other stakeholders, changing how these stakeholders evaluate innovation. Many biopharma and medtech<sup>1</sup> meeting participants said they welcome the shift to a health care system that encourages product evaluation across multiple dimensions of value, especially if it opens the door to conversations that extend beyond price. The recent national debate on drug prices, however, has concentrated primarily on lowering the cost of life sciences innovation, with less attention paid to products' contributions to improving outcomes or their long-term impact on avoidable costs. One hurdle has been the lack of a clear and consistent approach to assess that value.

To address some of these challenges, several professional organizations have been creating their own "value assessment" frameworks in an attempt to draw a relationship between price and perceived value. For example, the American Society of Clinical Oncology (ASCO) recently published a conceptual framework to compare the relative clinical benefit, toxicity, and cost of various treatments.<sup>3</sup> Additionally, the Institute for Clinical and Economic Review (ICER) has established a model to help health plans assess the financial impact that some potentially high-value, high-cost drugs and devices may have.<sup>4</sup> Each value assessment framework uses a unique analytical approach to evaluate products. Biopharma and

medtech meeting participants pointed out that more work needs to be done to refine the frameworks and analytical methods used, and to ensure they reflect distinctions between drugs and devices. Even if they are early, these efforts signal the beginning of a broader discussion about which dimensions of value are important to include in defining value for medical innovation.

The shift to VBC offers an opportunity to begin defining these dimensions of value by creating financial incentives that encourage providers to use products that help to achieve quality goals. If these quality goals encouraged providers to not only achieve, but also improve the standard of care, they could encourage the adoption of innovation and fuel more focused research and development (R&D) efforts across life sciences companies. However, VBC payment models remain in their infancy, and regulators, health plans, and providers should consider the potential impact on innovation as these models evolve.

Current value-based payment models offer incentives for improving care using formulas that incorporate quality measures. These models focus primarily on process measures; clinical measures tend to be narrow and measured over relatively short timeframes. Process measures typically emphasize resource utilization (e.g., length of stay, emergency room [ER] use); clinical measures focus on major outcomes (e.g., readmissions) and patient safety (e.g., complications).<sup>5</sup>

Some VBC payment models emphasize improvement against financial goals, with limited quality measures that mainly focus on better utilization of hospital resources. For example, bundled payment programs, such as the Centers for Medicare and Medicaid Services' (CMS) Bundled Payments for Care Improvement (BPCI) initiative, defines payment targets for 48 different episodes of care and offers incentive payments for reductions in reimbursement rates.<sup>6</sup> Providers are expected to achieve certain standards of quality, as defined by a limited number of quality measures included in these models (Table 2). Another example, the mandatory Comprehensive Care for Joint Replacement (CJR) bundled payment model, only includes two quality measures (related to complications and patient experience); likely skewing measures of success towards financial targets.

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“Depending on how you define the incentives, they might only value the older, cheaper products. We [the health care system] need to structure incentives to accommodate innovation but demanding value demonstration is going to be really important. Lots of value-based models are setting targets based on the current standard of care and have little flexibility for innovation.”

— Biopharma executive

<sup>1</sup> With more than 500,000 distinct forms, medtech encompasses a wide range of health care products used to diagnose, monitor, or treat the diseases and other conditions known to affect humans. These products may include: 1) technologies that enable treatment for specific therapeutic classes (excluding consumer care products); 2) diagnostics (in-vitro), products, and services that enable the detection of diseases and conditions; and 3) durable medical equipment, including instruments, equipment, and other products that assist providers and hospitals in delivering care. Meeting participants included representatives from companies that primarily manufacture implantables and therapeutic devices; patient monitors; and diagnostics, including imaging.

Table 2. Few quality measures are included in BPCI payment models<sup>7</sup>

Quality measures	Measurement period
Unplanned readmission rate following inpatient hospital discharge (Models 2 and 4)	30-day post-discharge, 60-day post-discharge, 90-day post-discharge
Emergency department (ED) use without hospitalization following inpatient hospital stay (Models 2 and 4)	30-day post-discharge, 60-day post-discharge, 90-day post-discharge
All-cause mortality (Models 2 and 4)	30-day post-discharge

VBC payment models typically evaluate performance within a short timeframe — for instance, 30-90 days for a bundle payment or one year for shared savings and global capitation. Most participants believe that these timeframes are too short to measure the impact that various drug and device interventions have on clinical outcomes and patients' health.

Emphasizing improvements in financial goals or quality over short time frames can make it difficult for manufacturers to demonstrate the value of new technologies. In fact, providers participating in value-based payment models are increasingly standardizing care pathways in order to achieve cost-effectiveness goals created by incentives under value-based payment models. This standardization may

leave little room for provider adoption and patient access to breakthrough technologies that challenge existing standards of care. Recognizing this risk, CMS has supported the use of new drugs, technologies, and services in bundled payment models by excluding their cost in both the BPCI and CJR initiatives through the New Technology Add-on Payments (NTAPs) program. NTAPs is intended to avoid "hamper[ing] beneficiaries' access to new technologies" deemed to be of "substantial clinical benefit."<sup>8</sup> However, medtech meeting participants pointed out that the standards applied in determining "substantial clinical benefit" are inconsistent, and reforms are needed for the NTAPs program to achieve its stated goal. They also noted that it would be beneficial to implement similar programs in the private sector.



# Focused evolution of VBC models could encourage innovation

Based on meeting participants' discussion, four changes will likely need to take place to evolve VBC models and encourage innovation adoption: 1) adoption of a broader set of quality measures; 2) improved data availability, transparency, and integration; 3) redefinition and identification of unmet and under-met needs; and 4) shared financial risk between life sciences companies and their product purchasers.

## 1. Adoption of a broader set of quality measures

Expanding the set of quality measures used in new-payment models could stimulate innovation adoption. Specifically, cross-stakeholder groups including measure developers, health plans, providers, and academic researchers should consider:

- Incorporating more clinical quality measures tied to long-term clinical outcomes in new payment models
- Collaborating with patient advocacy groups to expedite development of patient-centered measures, reflecting a broad-array of patient preferences.

Life sciences companies might increase their participation in these cross-stakeholder groups to gain an early understanding of what measures matter to health plans and providers, and how these measures may evolve. Further, taking an active role could create opportunities for companies to help identify new measures and share their expertise on the diseases that drugs and devices treat.

**Quality measure development.** Several cross-stakeholder groups are working towards standardizing quality measures that are tracked and quantified across provider organizations. The Core Quality Measures Collaborative, which consists of several health plans, CMS, the National Quality Forum (NQF), and national physician organizations, is one example. The Core Quality Measures Collaborative recently pointed out the need to shift the focus of existing measures from process to patient outcomes.<sup>9</sup> In addition, they cited the lack of relevant measures for specialists and specialty disease areas. Noticeably absent from the Core Quality Measures Collaborative are life sciences representatives — companies or industry associations may want to become engaged in this and similar initiatives.

**Patient-centered measures.** Incorporating patient-centered measures, such as patient experience, quality of life, improvements in functional status, and evidence-based behavioral interventions is gaining importance in quality measure discussions and could be transformative for patient access to innovation. The concept of patient-centered measures embraces the notion that optimal outcomes are achieved when they are personalized to incorporate patients' and caregivers' individual goals and the value they place on possible outcomes.

Although patient-centered measures are a goal for many value-based models, work remains, as current quality measures are limited in their ability to reflect collaboration with patients and their families.

Further, financial incentives based on population-level quality measures may lead to greater use of standardized care pathways while overlooking individual, patient-specific goals. Including non-traditional measures and non-traditional participants in the development of quality measures will likely be important to the evolution of value-based care.

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“If you really want to get to the right therapy and the right intervention based on what’s important to me [as a patient], that’s one lens. But if you’re going to go at risk, you’ve got to come out with more standardized measures. I think the time horizon to get to a risk model around what each patient cares about is going to be beyond 2025.”

— Medtech executive

## 2. Improved data availability, transparency, and integration

Most meeting participants agreed that, under VBC, companies might need to develop more evidence to demonstrate that innovative offerings are both clinically and economically superior to existing products. Generating this evidence will likely require improved availability, transparency, and integration of clinical outcome data across stakeholders including health plans, providers, patients, and life sciences companies. This integrated data could create a better understanding of which patients use the product, how it is delivered or used in a procedure, and the degree to which physicians and patients adhere to related treatment guidelines. It could also enable comparative effectiveness research (CER), providing a better understanding of how products perform in different real world settings against other products and clinical interventions. A few meeting participants stated that it is important to design studies that align stakeholders on data, methodology, and approach. Further, the participants said, trust is paramount to effectively integrate data sets and draw insights from data analysis.

Getting to this future state may require that stakeholders:

- Develop cross-stakeholder data-sharing partnerships, including creation of patient registries
- Clarify the requirements for generating and communicating economic evidence.

**Registries.** A few meeting participants suggested that life sciences companies could collaborate with third parties who are working to create cross-product and cross-stakeholder registries to capture quality, outcome, and financial data. Currently, registries sponsored by manufacturers or provider systems are limited in the scope of products or provider systems they include.<sup>10</sup> Integrating data across both stakeholders could create a robust data set for analysis to support CER and to understand variability in care and outcomes.

**Economic evidence.** Almost all meeting participants agreed that health plans and providers would likely seek economic evidence before adopting innovation under VBC. However, it is not always clear what level of evidence will be required, and by whom, over the adoption curve. In today's diverse VBC landscape, providers and health plans may have different goals and values and, thus, require different evidence types. Further, they may evaluate that evidence against different measures and over different time periods. Biopharma meeting participants pointed out that regulatory limitations on what evidence can be shared, and with whom create additional hurdles. Medtech meeting participants pointed to new challenges created when physicians and a broader set of purchasers take on financial risk.

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“I think there’s going to be a pretty significant shift to not just have it [evidence] be the data from the providers, the data from the product manufacturers, the data from the payers...really this is an opportunity for a whole lot more data transparency from all players so that data gets combined and you can get to your answers faster. I think that’s been one of the rate-limiting steps.”

— Non-profit leader

### 3. Redefinition of identification of unmet and under-met needs

Progressing medical innovation under VBC will likely require new products and services that improve clinical outcomes as well as the way providers deliver and manage care. To date, R&D at life sciences companies has focused primarily on advancing science and developing safe and effective medicines and technology, with less emphasis on clinical process and financial goals. The transition to VBC will likely require life sciences companies to reevaluate R&D approaches and portfolio strategies to refocus innovation on serving unmet needs as defined by a combination of scientific, clinical process, and financial considerations. Companies should consider collaborating with their customers to identify these unmet needs. Specifically, stakeholders should consider:

- Life sciences companies as partners in care delivery, with refocused R&D efforts aimed at delivering strong science as well as improving clinical processes and financial goals
- Integrating products and services to fulfill unmet and under-met needs.

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“Many new medical technologies such as telehealth can enable providers to meet VBC goals when they are wrapped around services provided to the patient. In this environment, it’s not always about selling the individual ‘device’ but about what services are packaged around the technology that help it achieve its full value.”

— Medtech executive

### Customer engagement to define unmet and under-met needs.

Partnering with customer groups, including health plans and providers, may help life sciences companies identify unmet or under-met needs and test product or service concepts that might enable VBC goals. Doing this is particularly important in a heterogeneous health care market where VBC goals may vary across customers.

A health plan executive at the meeting remarked that the shift to VBC could also create opportunities for health plans to take more proactive roles in identifying unmet needs. Rather than reacting to new product ideas, health plans could proactively assess their internal data sets and identify areas where there is a need to improve care for select populations, through either products or services. Health plans could then partner with life sciences companies to define and test solutions with patients that address these needs, creating value for the health care system overall.

In addition, life sciences companies and patient advocacy groups could partner to identify unmet needs. Patient representatives at the meeting highlighted patients’ desire for stronger partnerships with industry, as well as ongoing dialog around unmet needs and products in development. Incorporating the patient’s perspective may help life sciences companies design solutions that substantially improve outcomes.

**Services.** Some areas of unmet or under-met need may be addressed by services rather than products — especially in care delivery, where the need may be in managing patients to achieve outcomes associated with a product that is already available. In fact, medtech meeting participants observed that services may be the only way to achieve differentiation for products that do not vary from a clinical or economic standpoint. Some life sciences companies are already investing in “wraparound” services, such as adherence solutions, post-discharge care management, or other educational tools. Such services offered on a consistent basis and for multiple patient populations could be valuable to providers and health plans.<sup>†</sup> For life sciences companies, the cost of offering these services extends beyond traditional cost of goods and, therefore, the services are likely most valuable when they drive increased utilization of one or more products in the portfolio.

<sup>†</sup> Regulatory restrictions, such as broadly worded prohibitions that were designed to prevent improper inducements to providers or patients, may impair companies’ ability to offer certain services to Medicare or Medicaid beneficiaries.

#### 4. Shared financial risk between life sciences companies and their product purchasers

In a future world where innovation flourishes, health plans, providers, and life sciences companies could tie payment to achieving agreed-upon outcome measures. This type of risk-sharing might mitigate a primary barrier to entry for innovation by reducing the burden on health plans and providers when they adopt products into care. Achieving this goal may require that industry stakeholders:

- Accelerate the adoption of value-based purchasing agreements with private health plans or providers to allow early adoption of innovation
- Increase alignment of decision makers including physicians, purchasers, and health plans on criteria to evaluate innovative products.

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“There’s a need for flexibility for continuous learning while recognizing we have an obligation in a value-based system to demonstrate value.”

— Biopharma executive

#### Private sector adoption of value-based purchasing, including coverage with evidence development.

Meeting participants discussed ways to share financial risk associated with new technologies, including outcomes-based contracts, financial risk guarantees, and coverage with evidence development (CED). Outcomes-based contracts tie payment to product performance.<sup>11</sup> For example, a company may offer to discount treatment if a certain clinical outcome is not achieved. Financial risk guarantees offer to cover payment for either initial or unanticipated treatment cycles. For instance, if a patient is not cured within a certain number of treatment cycles, subsequent treatment cycles are offered at no additional cost. CED<sup>‡</sup> is a performance-based reimbursement approach that grants coverage contingent upon gathering additional real-world evidence.

Several biopharma, medtech, and health plan meeting participants emphasized private sector adoption of CED as a potential avenue to encourage new technology use under VBC. CED originated to address the issue that even when a new drug or device is approved, some level of uncertainty remains about its real-world efficacy, safety, and cost-effectiveness. This is especially true for breakthrough products that follow an expedited regulatory pathway. Without this evidence, health plans often find it difficult to justify coverage. CED, if adopted in the private sector, could allow health plans to balance two competing concerns: paying for potentially ineffective or non-differentiated treatments versus depriving patients of access to potentially beneficial treatments.

**Decision-maker alignment.** Several meeting participants suggested that value-based purchasing contracts are more likely to be successful when there is greater alignment of the physician, purchaser, and health plan on the criteria to evaluate innovative products. In the current, fragmented US health care system, these roles and decision criteria are distinct and not aligned, creating challenges in identifying which stakeholders benefit from the value of specific drugs and devices, and what price they would be willing to pay under what circumstances.

In the past, individual physicians had considerable autonomy to decide which medical products to use. Now, other system stakeholders are influencing that decision, such as technology assessment committees. Also, even if products are on formulary or kept in inventory, they will likely only be used if the insurance company will pay for the drug or procedure. With these layers of decision-makers, it is not always clear who is using what framework to drive product decisions. For example, the physician who performs a knee replacement will decide which product to use based on the patient’s individual needs, but choices may be limited to options the hospital administration defines. The health plan that reimburses for the procedure will determine coverage. In this scenario, everyone wants to achieve the best outcome for the patient, but each stakeholder may define that outcome differently based on competing goals.

However, as VBC unfolds, organizations that integrate physician, purchasing, and payer capabilities may enable greater alignment of goals and incentives across important decision-makers through a combined product valuation that considers clinical evidence, the impact on medical practice and operations, and economic outcomes. This integration also may enable risk-sharing contracts that define success against an aligned set of goals.

<sup>‡</sup> Medicare established CED in the United States and has applied the approach to less than 20 national coverage decisions, mostly for devices. To date, Medicare’s experience with CED for drugs have been limited and its impact unclear. Medicare and private health plans have not widely adopted CED due to the financial and administrative burden of collecting data and the need for repeated reviews.

# Strategic considerations: **Biopharma**

Biopharma companies should seek avenues to support quality measure development, communicate economic evidence, offer value-added services, and develop performance-based agreements. Achieving these goals requires clarity from policymakers on FDAMA 114, Medicaid Best Price, and the Anti-Kickback Statute.

### 1. Adoption of a broader set of quality measures.

Several biopharma, health plan, and provider meeting participants discussed the need to expand quality measures to include more clinically focused measures in value-based payment models. They also emphasized the importance of incorporating patient outcomes, specifically quality of life and patient preferences.

Biopharma meeting participants recognized that the development of evidence-based clinical quality measures is not easy. Concerns around data accuracy and consistency make it difficult to validate and implement new measures. In the absence of clinical measures for many diseases, biopharma meeting participants suggested that process measures may be able to serve as a proxy.

Biopharma meeting participants also emphasized that patient preferences are important determinants of health outcomes, and should be incorporated into quality measures. Patients may weigh the risks and benefits of two therapies considered therapeutically equivalent quite differently. Meeting participants expressed a desire to see this type of patient-specificity incorporated into quality measures as they continue to evolve.

### 2. Improved data availability, transparency, and integration.

Biopharma companies typically have the most data on how their product performs at the time of its launch, but their ability to proactively share this data may be limited, as companies are unable to proactively share data that falls outside of the approved product labeling. However, biopharma companies are generating additional bodies of evidence, particularly around economic endpoints, and are seeking further clarity from regulators on how to appropriately communicate this information with provider and health plan customers. Most meeting participants felt that with the move towards value-based payment models, the need for health plans, patients, and the public at large to assess all available evidence, including biopharma-sponsored evidence, is becoming more acute.

Biopharma companies are beginning to incorporate additional data sources, including real-world evidence (RWE) — data generated from sources other than randomized clinical/controlled trials — into their evaluations of the clinical and economic value of their products. For example, during R&D, some companies may have chosen to collect data on outcomes that might not correlate with clinical trial endpoints. Further, biopharma meeting participants remarked, companies usually gather data on genomics, subgroups, risk prediction models, and other topics that would support population management. In order to integrate this data into frameworks assessing the value of drug therapies, companies require guidance on the standards for appropriate generation, assessment, and application of this type of RWE within the regulated environment. Public-private partnerships (PPPs) are working towards achieving this goal, such as the Innovation in Medical Evidence Development and Surveillance (IMEDS) program, which sits within the Reagan-Udall Foundation (RUF) for the FDA. This PPP is designed to help the FDA — and regulated industry and clinicians — to improve patient care and medical product safety by using an increasing body of evidence.

Biopharma meeting participants also stated that they are seeking clarity to an existing FDA policy, FDAMA 114, which regulates how biopharma companies can communicate economic evidence. FDAMA 114 was passed to prevent communication of false or misleading claims. The policy states that health care economic information provided to “a formulary committee, or other similar entity,” should be “based on competent and reliable scientific evidence” and would not be considered false or misleading if it “directly relates” to an FDA-approved indication.<sup>12</sup> Thus, stakeholders are looking for clarity as to which economic evidence is permissible for biopharma companies to share, and with whom. For example, in a study conducted by Tufts Medical Center, the authors pointed out that adherence claims or economic analysis of comparative effectiveness claims may not be considered to “directly relate” to approved label claims.<sup>13</sup>

Regulators interested in encouraging richer, more comprehensive conversations to facilitate VBC may want to consider prioritizing the advancement of standards for RWE use and interpretation, and clarifying the boundaries intended by FDAMA 114.

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“We need to evolve [the regulatory environment] to enable companies to be able to communicate to highly sophisticated, financially risk-bearing decision-makers who will know what to do with that information.”

— Biopharma executive

**3. Redefinition and identification of unmet and under-met needs.** Health plan and provider meeting participants identified three areas in which biopharma companies could offer services that would help them meet population management goals: adherence, targeted interventions for patient populations, and patient self-care. However, federal laws such as the Anti-Kickback Statute create hurdles in executing programs that might be misconstrued as inappropriate inducements.

The cost of patient non-adherence was estimated to be \$337 billion in 2013,<sup>14</sup> making adherence a top priority for stakeholders under VBC. Some health plans and providers are already being measured against adherence quality goals. This may create an opportunity for health plans to partner with biopharma companies to improve adherence scores.

Another area where health plan and provider participants desire to partner with biopharma companies is targeting interventions to the right patient populations. Many biopharma companies are developing solutions aimed at better engaging patients in their care, while health plans have claims data to identify those patients. Combining these capabilities could enable targeted interventions to the right patient at the right time. Further, as the industry moves towards personalized and precision medicine, these types of programs may become even more meaningful. Programs that help to identify and target sub-populations are more likely to be executable and have measurable value.

The third area of interest that health plan and provider participants identified is self-care. Health plans are seeking help from biopharma companies to engage consumers and keep them healthy. This includes targeted coaching and lifestyle tools.

While biopharma companies may be interested in partnering with providers and health plans in these opportunity areas, they face regulations that were enacted to prevent fraud and abuse, including the federal Anti-Kickback Statute. Services, including adherence programs or coaching tools, might be considered “inducements” under this law. Life sciences companies, therefore, are becoming more risk-averse about offering certain services, particularly under arrangements that would be novel or that cannot be structured to meet the requirements of a “safe harbor” to the Anti-Kickback Statute. Many individuals and health care entities voluntarily choose to avoid partnerships or business practices which may appear to implicate the Anti-Kickback Statute due to the breadth of the statutory language and a lack of clarity about how the law will be applied to the types of business practices that would support value-based care. If biopharma companies are to partner with other stakeholders to provide value-added services, they may need more regulatory clarity on what is considered allowable.

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“We are innovating with very targeted therapies and we can go with meaningful [service] programs to payers. We can absolutely help [payers] since we know the patients and the biomarkers that are going to be required for precision medicine.”

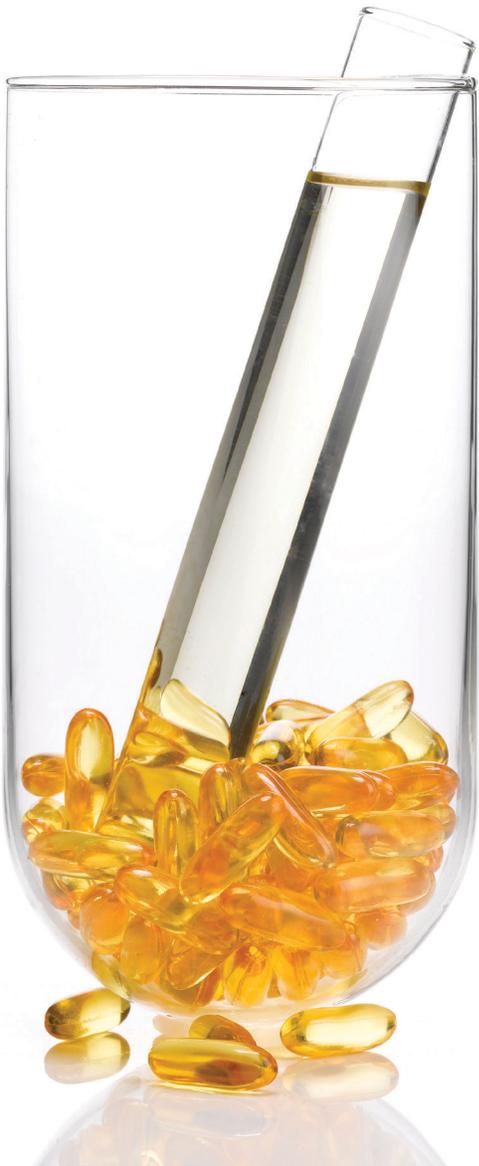
— Biopharma executive

#### 4. Shared financial risk among life sciences

**companies and their product purchasers.** Health plan meeting participants expressed strong interest in risk-sharing agreements that would tie payment for a drug or device to its ability to achieve a value measure. The attending health plans participants suggested that risk-sharing was especially important for high-priced specialty drugs. In addition, they wanted longer-term contracts and more creative ways to share risk. Biopharma executives also expressed a desire to partner in this manner, but cited hurdles such as Medicaid best-price issues and controlling for outcomes tied to appropriate product utilization.

Restrictions around the Medicaid best price guarantee (under which Medicaid benefits from the best market price) may inadvertently limit the degree to which biopharma companies are able to share risk.<sup>15</sup> Under a hypothetical risk-sharing agreement in which the manufacturer agrees to rebate the cost of a drug if a targeted outcome is not achieved, the discounted price may be considered to be as low as zero. If the company is required to offer the product to Medicaid and 340B program participants at no charge (or if the calculation results in setting a new, lower best price for the drug), the proposed risk-sharing agreement may be untenable for the manufacturer. Health plans have suggested solutions to account for these types of repayments, but the Medicaid program has not stated its opinion of them.<sup>16</sup> Recognizing the importance of this issue, CMS recently approached manufacturers to understand how Medicaid best price regulations might restrict companies' abilities to offer value-based purchasing agreements.<sup>17</sup> In the absence of policy changes, biopharma companies should consider partnering with health plans to identify ways to share risk that don't negatively impact Medicaid market profitability.

Benefit and formulary design are other considerations when developing risk-sharing arrangements. Patients' use of high-cost new products is often tightly controlled through tiered formularies or the use of prior authorization to restrict the number of patients who receive the drug. Some of these mechanisms may increase cost sharing for new drugs, which could reduce access or adherence and, ultimately, limit product effectiveness.



# Strategic considerations:

## **Medtech**

Medtech companies should identify and engage a broad set of stakeholders to support quality measure development, determine evidence requirements, demonstrate the value of services, and engage in performance-based contracts.

### 1. Adoption of a broader set of quality measures.

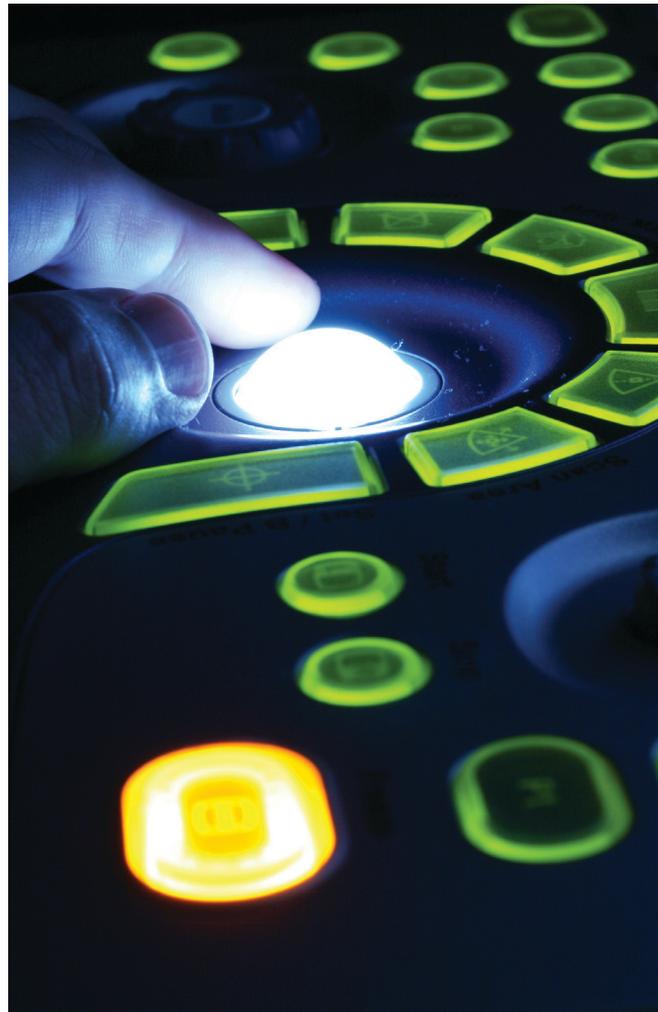
Medtech meeting participants discussed how value-based payment models that emphasize financial measures over a short time frame may increase the risk that patients will not receive innovative technologies. They recommended incorporating a broader set of quality measures in these new payment models.

Medtech meeting participants pointed out that many of the new bundled payment models incorporate a very limited number of quality measures. As a result, providers may not fully appreciate innovations' value, especially if the quality measures they are being evaluated against focus on short time horizons. Even worse, providers may not be paid for using technology that delivers health improvements, creating a lack of incentives to support promising innovation. For example, the CJR initiative only includes two quality measures, placing emphasis primarily on cost management.<sup>18</sup> One of the measures included, "hospital-level, risk-standardized complication rates (RSCR)," may be useful to track variability in surgical outcomes over the short term, but this measure does not track device effectiveness in terms of improvement in patient mobility or the potential future need for either replacement or revision surgery. Without accountability for these longer-term outcomes, providers may choose to use lower cost products.

In fact, in its response to CMS about the CJR initiative, AdvaMed pointed out that providers participating in the current BPCI initiative have shifted towards utilizing "almost exclusively lower utility implants without respect to patient needs." Despite these implants being associated with lower short-term cost, their use may result in other complications or the need for revision surgery sooner. Incorporating additional quality measures could shift emphasis away from cost management. In its letter, AdvaMed supported CMS in developing additional quality measures that could be "indicators of improvement in patients' functional status, pain levels, mobility, and quality of life following total hip and knee replacement procedures."<sup>19</sup>

### Diagnostics and quality measures

Diagnostics typically provide information that impacts a clinician's decision on the course of treatment for a patient, which then leads to actions that directly impact patient outcomes. Better patient outcomes result not only from the appropriate utilization and accuracy of the diagnostics, but also from the clinician's skill in integrating the diagnostic results into patient care and how effective the available treatments are to address the medical problem. Because of this, it is difficult to link the value of a diagnostic directly with clinical quality measures.



**2. Improved data availability, transparency, and integration.** Under VBC, providers and health plans are elevating the standards for evidence to support product adoption. Medtech companies would like to understand what the decision criteria will be for reimbursement, particularly for innovative products, while these products are still in development.

have strong safety and clinical data, which clinicians also demand. Medtech companies will need to provide evidence that goes beyond safety and clinical data in order to start a conversation with purchasers.

Some health plans and providers are partnering to gain scale, create price transparency, and strengthen purchasing power against medtech companies. These groups are working to increase the availability and quality of clinical information about existing medical devices, to better inform decisions on what products should be adopted in practice. Group members share data with the goal of aligning on which products are clinically better, either through informal surveys or customized CER. Additionally, these groups create price transparency and negotiating leverage for organizations to obtain discounts with companies. Medtech meeting participants pointed out that these groups, with their aggregated resources, may want to consider partnering with medtech companies on evaluation of breakthrough technologies, for which there may be limited evidence to support a reimbursement decision at the time of launch. This type of collaboration could allow patient access to innovation while evidence is being gathered to support longer-term pricing and reimbursement decisions.

A product may not reach its market potential if not all of the stakeholders across the various influence points in care delivery are on board with making the change. One cautionary example described by a medtech participant is the invention and subsequent lack of adoption of MRI-compatible pacemakers. Pacemakers initially were incompatible with MRI and, therefore, health plans did not reimburse MRI for patients who had pacemakers, as it was considered dangerous. Innovators recognized the unmet need and developed MRI-compatible pacemakers, got buy-in from physicians, and secured reimbursement from health plans. But after the product reached the market, adoption lagged because radiologists were not encouraged to break with existing standard of care.

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“We can’t guarantee the level of coverage, but we have those discussions all the time, around what data elements are required, and whether economic analysis is necessary or unnecessary. We politely decline if the conversation is better had with the hospitals.”

— Health plan executive

Reimbursement for innovative products will likely depend on the site of care delivery; for example, most devices used in the hospital setting are covered as part of an existing procedure or diagnosis-related group (DRG) code. However, breakthrough products that provide value outside of existing procedures are likely to require separate reimbursement coverage. In this case, companies should consider approaching health plans early to discuss what evidence is necessary to support reimbursement for the new technology. In the event that separate reimbursement is not required, companies should consider engaging likely purchasers (e.g., physicians or hospitals) of the innovation to understand their decision criteria for adopting the product into practice.

As hospitals begin to participate in value-based payment models, they will have incentives to more closely control the cost of care for their populations. Hospital purchasers typically assume that breakthrough technologies will

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“You can race to the innovation to meet an unmet need, secure the payment, [and] get the evidence but still have disconnects between [physician groups]. You can do the best work but, at the end, have a challenge with penetration — not because of reimbursement, not because it’s not good technology, not because of coverage, but because of [lack of] health care systems connectivity.”

— Medtech executive

### **3. Redefinition and identification of unmet and under-met needs.**

A medtech product's value is not defined solely by clinical outcomes; value can be delivered by attaining greater procedure efficiency, patient satisfaction, and other quality goals. Medtech meeting participants agreed that purchasers will view clinically undifferentiated products without services as interchangeable and product selection will be based on price. Medtech companies should consider investing in developing services, and engaging with providers and health plans to understand which services would help improve care delivery.

Identifying unmet needs for medical technology means identifying and understanding value gaps in the health care system and how a particular innovation might fill those gaps. One medtech meeting participant suggested that manufacturers ask themselves, "What is the problem we are trying to solve and is it big enough that someone will want to pay for it?" Providers are likely to adopt technology that helps them meet objectives or goals such as improved throughput, quality, or patient satisfaction. For instance, providers would recognize the value of technology that increases throughput by helping patients move in and out of the system faster, or a less invasive/less painful test that improves patient satisfaction.

### **4. Shared financial risk among life sciences companies and their product purchasers.**

Technologies with significant promise and limited evidence may lend themselves to CED or risk-sharing reimbursement approaches. However, a few meeting participants pointed out that not all medtech products are appropriate for risk-sharing. Providers may be less inclined to share financial risk on products that provide value in ways that cannot be easily quantified; for example, products that improve procedure efficiency. Even for products that achieve measurable clinical

outcomes there may be challenges in structuring risk-sharing agreements, including determining the appropriate time frame to measure and track those outcomes, and distinguishing between the role of the operator (physician and patient) and the technology in achieving outcomes.

Many implantable devices such as hips and knees are designed to last decades. However, there are no broad-based approaches to set performance guarantees. If a device fails a few years after it is implanted, it is unclear how the original health plan would find that patient, and who would be reimbursed. The employer who purchased the health plan under which the patient was covered may not be working with that same health plan anymore. Also, the patient may be entitled to some portion of the reimbursement and may no longer be covered under the same health plan or treated by the same provider.

Medtech meeting participants also pointed out that operator error could contribute to negative clinical outcomes associated with devices. Operators may include the surgeon who implants the device, or the patient who receives the device. New sensor technology embedded into devices could be used to track factors that influence outcomes. This data, in turn, could improve the ability to understand and engage in risk-sharing around potential product failures.

Several medtech and health plan meeting participants agreed there needs to be reasonable limits as to how long these contracts remain open so that repayments can be appropriately distributed. What is reasonable will need to be determined by balancing the time required to capture the patient benefits with employer, health plan, and provider financial goals.

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“There’s value in devices that isn’t all achieved through hard patient outcomes. If you can improve procedure efficiency — standardize the procedure, standardize the approach, make things work smoothly — these things start to matter. How it translates into a 30-day readmission avoided is really hard. But there are multiple lenses of medtech value and some of them are really tough to quantify and none of them are a singular home run.”

— Medtech executive



# Looking forward

“We need to ensure that the conversation keeps going and that we continue to push the envelope, so that the ecosystem can continue to drive and generate cures in addition to helping to reduce costs and improve care.”

— Medtech executive

In a VBC world, medical innovation will likely be measured against an evolving definition of value, based on clinical and economic factors, as well as the ability of products to optimize care delivery. Continued conversation among all health care stakeholders would be beneficial to ensure that this definition of value gives patients access to today’s and tomorrow’s life-changing innovations. While there is uncertainty around how the future of value-based care and supporting policies might evolve, life sciences companies should consider engaging health plans, providers,

consumers, and policymakers now to shape how the value delivered by their products is assessed. Specifically, industry leaders should consider next steps outlined in Table 3 to promote innovation under VBC.

And for the sake of continued medical innovation, meeting participants highlighted the importance of all US health care system stakeholders working collectively together to direct the future of VBC.

Table 3. Smart next steps for biopharma and medtech companies

	Biopharma	Medtech
<b>1. Adoption of a broader set of quality measures</b>	<ul style="list-style-type: none"> <li>Participate in cross-stakeholder groups to understand what quality measures are included in value-based payment models and how they might evolve</li> </ul>	
<b>2. Improved data availability, transparency, and integration</b>	<ul style="list-style-type: none"> <li>Support conversations to clarify regulations that limit the types of evidence that can be shared with stakeholders</li> <li>Encourage appropriate design of studies supporting value assessment that align stakeholders on data, methodology, and approach</li> </ul>	<ul style="list-style-type: none"> <li>Identify financial and clinical stakeholders early in development and generate evidence to demonstrate the value of products and services</li> <li>Collaborate with health plans and providers to generate real-world evidence on breakthrough products</li> </ul>
<b>3. Redefinition and identification of unmet and under-met needs</b>	<ul style="list-style-type: none"> <li>Begin discussions with health plans and providers to identify unmet needs that help to achieve population management goals, such as adherence and patient education</li> </ul>	<ul style="list-style-type: none"> <li>Develop technologies and services aimed at helping providers address value gaps in the system, including improved throughput, quality goals, or patient satisfaction</li> </ul>
<b>4. Shared financial risk between life sciences companies and their product purchasers</b>	<ul style="list-style-type: none"> <li>Engage health plans in conversations around approaches and tools to track patient access, adherence, and outcomes to support value-based purchasing agreements</li> </ul>	<ul style="list-style-type: none"> <li>Engage providers and health plans in conversations around appropriate time frames and tools to measure outcomes to support risk-sharing</li> </ul>

## Appendix A. List of meeting participants

First name	Last name	Title	Organization
Amrinder	Singh	Director, Business Development and Strategy, Medtronic Care Management Services	Medtronic
Don	May	EVP for Payment and Health Care Delivery Policy	AdvaMed
Ed	Pezalla	National Medical Director for Pharmacy Policy and Strategy	Aetna
Elizabeth	Fowler	Vice President, Global Health Policy	Johnson & Johnson
Gene	Kirtser	President & Chief Executive Officer	ROI
Gregory	Daniel	Deputy Director	Duke-Robert J. Margolis Center for Health Policy at Duke University
Helen	Burstin	Chief Scientific Officer	National Quality Forum
John	Rother	President and Chief Executive Officer	National Coalition on Healthcare
Josh	Ofman	Senior Vice President Global Value, Access, and Policy	Amgen
Kristen	Augspurger	Director, Consumer Innovation	Humana
Laurel	Sweeney	Senior Director, Health Economics and Market Access	Philips
Martin	Coulter	Chief Executive Officer	PatientsLikeMe
Michael	Reiner	Senior Director, Payment Policy and Reimbursement	BD
Murray	Ross	Vice President, Kaiser Foundation Health Plan, and Director, Kaiser Permanente Institute for Health Policy	Kaiser Permanente
Nick	Bluhm	Director, Strategy and Government Policy	Remedy Partners
Parashar	Patel	Vice President, Global Health Economics and Reimbursements	Boston Scientific
Peter	Bach	Director, Center for Health Policy and Outcomes	Memorial Sloan Kettering Cancer Center
Randy	Burkholder	Vice President of Policy and Research	PhRMA
Robert	Popovian	Senior Director, US Government Relations	Pfizer
Sheri	Dodd	Vice President and General Manager, Medtronic Care Management Services	Medtronic
Steve	Phillips	Senior Director, Global Health Policy	Johnson & Johnson

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### Authors

#### Greg Reh

Principal  
Life Sciences Sector Leader  
Deloitte & Touche LLP  
grreh@deloitte.com

#### Mary Cummins

Principal  
Deloitte Consulting LLP  
mcummins@deloitte.com

#### Terry Hisey

Principal  
Deloitte Consulting LLP  
rhisey@deloitte.com

#### Sonal Shah

Senior Manager  
Deloitte Center for Health Solutions  
Deloitte Services LP  
sonshah@deloitte.com



### Acknowledgements

The authors would like to especially acknowledge the Network for Excellence in Health Innovation (NEHI) for collaborating on the fall 2015 meeting. The insight provided by NEHI and its staff in the planning process was instrumental in our effort to facilitate thinking on the issue of medical innovation under value-based care. In particular, we would like to thank Rebecca Paradis, Tom Hubbard, and Jonathan Fleming for their support, as well as their contributions in developing this piece.

The authors would also like to acknowledge Gaurav Vadnerkar for his help in researching and writing; as well as essential contributions from Jodi Reynolds and Aleem Khan.

We wish to thank Glenn Snyder, Michael Raynor, Erik Smith, Jed Hwang, Tom Fezza, John Phillips, Joe Coppola, Hussain Mooraj, Casey Korba, Claire Cruse, Kiran Vipparthi and the many others who contributed their ideas and insights into this project.



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Harry Greenspun, MD  
Director  
Deloitte Services LP  
hgreenspun@deloitte.com

Sarah Thomas, MS  
Research Director  
Deloitte Services LP  
sarthomas@deloitte.com

Deloitte Center for Health Solutions  
555 12th St. NW  
Washington, DC 20004  
Phone: 202-220-2177  
Fax: 202-220-2178  
Email: [healthsolutions@deloitte.com](mailto:healthsolutions@deloitte.com)  
Web: [www.deloitte.com/centerforhealthsolutions](http://www.deloitte.com/centerforhealthsolutions)



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