

# Optimal Oncology Alternative Payment Models

April 2019

VIEWPOINTS

## Managing risk and ensuring effective care delivery in an accountable-care paradigm

### Executive Summary

The Centers for Medicare and Medicaid Services (CMS) has recently reiterated its commitment to transition more providers to two-sided risk alternative payment models (APMs).<sup>1</sup> Ever mindful of CMS's direction and leadership in payment reform, oncologists and commercial payers developing their own APMs in oncology are increasingly focused on the role of risk in incenting a shift to value-oriented care without threatening practices' financial viability.

The question of whether and how much risk is needed for accountable care was top of mind for participants in the oncology APMs advisory council, which gathered in March 2019 in Washington, DC. The council serves as a platform for leading designers and implementers of oncology APMs to learn from one another and catalyze new thinking and approaches to improve pilots in this space. The broad issue of accountability in oncology care underlay other meeting topics. These included the need to meaningfully measure provider performance and inducing effective care delivery through use of clinical pathways, which are quality-focused treatment protocols for specific types and subtypes of cancer.

During the meeting, participants considered the following questions:

- **In two-sided risk models, can reinsurance<sup>2</sup> protect practices from catastrophic loss?**
- **How can outcomes-based quality measures be practically implemented?**
- **What is the near-term direction for clinical pathways in promoting effective, value-based care?**
- **What new APMs are being developed? And do they still matter in today's dynamic policy environment?**

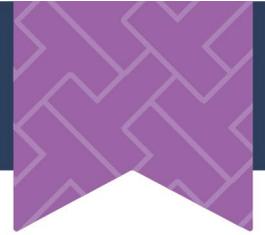
To address these questions, the council welcomed experts from Milliman and the Tufts Center for the Evaluation of Value and Risk in Health (CEVR) to share findings from new research on the value of reinsurance and outcome measures, respectively. At the time of the meeting, both pieces of research had not yet been published. Additionally, representatives of leading oncology guidance organizations discussed their organizations' views on clinical pathways. Key takeaways from these conversations are as follows:



- **Some types of reinsurance can protect practices from significant loss, but the business case is murky.** Representatives from large and small practices agreed that because the analysis by Milliman suggested that the cost of reinsurance would result in a loss even in good years, there was likely little value to such products for individual providers. A minority noted that it could be worth exploring captive insurance pools, which could protect providers at a lower cost to individual practices. Finally, many were concerned at the model's revelation that reinsurance could not prevent consistently understated financial targets in an APM from significantly reducing expected gains—and they therefore questioned the rationale for risk altogether.
- **Many outcome measures still face barriers in practical implementation.** Participants proposed several revisions to a set of core outcome measures proposed in Tufts' research. Provider representatives were concerned with measures that may encompass care decisions that are outside of the treating oncologist's control, as well as the limited availability and interoperability of relevant data sources. Others proposed ways to streamline performance measurement across payers, such as examining how Medicare performance might correlate with performance in commercial populations.
- **Pathways have a valuable role to play in enhancing and streamlining the quality of medical care.** While participants debated pathways' ability to significantly reduce costs over the long term, all stakeholders present agreed that high-quality pathways have value. Some, however, proposed more granular compliance recommendations. These could help direct providers to regimens that should, based on the strength of the clinical evidence, be followed more than the often-quoted *"80/20 rule, or where 20 percent of the time it is appropriate to go off-pathway."*<sup>3</sup> Some regimens, participants noted, should be followed 95% of the time in cases where the standard of care is well established.
- **APMs in this specialty are proliferating and are here to stay.** Many APMs are being designed for oncology care in local or regional markets. Despite several policy proposals that may change the trajectory of drug pricing and provider reimbursement, participants affirmed that they expect APMs to continue to be a prominent part of the United States' transformation to value-based care.

In light of these observations, the group offered several reflections on next steps for the council:

- On risk and reinsurance:
  - Publish the commissioned reinsurance analysis for the broader oncology community to better understand the benefits and drawbacks.<sup>4</sup>
  - Consider educating reinsurers on the specialty APM market to better define their role and what they can offer.



- Explore further how much risk, if any, makes sense as part of new APM designs, and also explore other ways to manage it.
- Investigate further the extent to which Medicare data could be used as a proxy for overall provider performance, to improve quality measurement.
- Explore further how the council can support use of high-quality pathways, given participants' agreement that pathways have value.
- Continue to collaborate as a group, share lessons, and identify opportunities to work with one another.



## Introduction

To the extent possible, we want to enable providers of all sizes to get involved in a system where we pay for value: from direct contracting for primary care and incentive payments for smaller practices all the way up to large provider networks or hospitals taking on full risk. There is an implicit bargain here that I will make explicit: The more risk that you as providers are willing to accept for driving better outcomes, the less we are going to micromanage how you do your work.

– Secretary of Health and Human Services Alex Azar

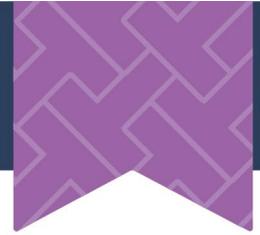
The leadership of the Department of Health and Human Services (HHS) and CMS have made clear their commitment to shifting more American clinicians to two-sided risk APMs. These models provide rewards to providers for reducing costs set by financial targets, while adhering to prescribed quality measures, and places them at financial risk for failing to do so. HHS and CMS leadership have expressed interest in including more specialty practices within this transition, including oncology.<sup>5</sup>

Individual oncologists, oncology patient organizations, and relevant provider associations are concerned about the advent of two-sided risk. Together with commercial payers developing APMs, they are grappling with how much risk, if any, needs to be required in future payment models to ensure that providers are held accountable for the cost and quality of care.

Risk was foremost among several topics discussed by the oncology APMs advisory council on March 18, 2019 in Washington, DC. The council was formed in 2018 to serve as an informal brain trust of leading payers, providers, and other key stakeholders involved in designing and implementing APMs in oncology. Participants recognize the unique challenges that oncology presents to payment reform initiatives, including the increasing cost, personalization, and complexity of treatment. The council aims to serve as a rapid, continuous learning platform on emerging successes and failures in APMs in this specialty and aims to potentially catalyze new initiatives to improve experimentation.<sup>6</sup>

Following a series of agenda-shaping discussions in early 2018, the council held its inaugural meeting in September 2018 where it focused on enabling access to high-quality clinical and cost data; risk design in APMs and potential tools, such as reinsurance, to manage risk; and approaches to encourage more effective care delivery in practices of all sizes, such as the use of clinical pathways.

Following the September meeting, participants determined that taking a deeper look at reinsurance as a possible tool to manage two-sided risk should be a key part of the March 2019 meeting agenda. Participants also reiterated their interest in further discussing quality measures, which were addressed separately in a January 2019 group call with experts from the Hutchinson Institute for Cancer Outcomes Research (HICOR). During that conversation,



and to prepare participants for a deeper discussion in March, HICOR staff shared their experience of assessing the statistical strength of quality measures in a state-wide cost and quality initiative.

Finally, participants chose to continue to focus on clinical pathways. They were keen to further explore whether pathways would be subjected to stronger oversight, how they might prioritize drug value and cost, and how pathways' utilization and compliance might be better incented.

This *ViewPoints* synthesizes the views and recommendations on the issues that were shared during the March meeting and in the conversations that preceded it, along with additional external analysis and perspectives from stakeholders involved in oncology APMs.

## In two-sided risk models, can reinsurance protect practices from catastrophic loss?

Several factors are prompting oncology leaders in the payer and provider communities to think more seriously about two-sided risk. HHS Secretary Alex Azar has informally proposed

mandatory downside risk models for radiation oncologists, thereby reinforcing the current administration's ambitions to increase financial accountability for the field of oncology.<sup>7</sup>

Additionally, practices participating in the Oncology Care Model (OCM), the Center for Medicare and Medicaid Innovation's (CMMI) flagship oncology APM, that have not yet received a performance-based payment will soon decide whether to take on two-sided risk or drop out of the program

altogether.<sup>8</sup> CMMI recently instituted an alternative two-sided risk track that some perceive to be more attractive than the original two-sided option; however, many remain concerned about the level of risk that even that track requires. *For more detail, please see Box 1.*

In the lead-up to the meeting, participants discussed the advent of two-sided risk and whether a reinsurance product could help protect practices against catastrophic losses. This was driven by the recognition that, while reinsurance as a concept was starting to percolate among OCM participants, no one had yet published a detailed study of the rewards and drawbacks of using reinsurance in an oncology APM.

During the meeting, participants considered a new analysis that was commissioned for discussion at the March meeting on the costs and benefits of reinsurance in a simulated OCM-like APM. At the meeting, participants and external experts addressed the fundamentals of reinsurance, the business case for its use in an episode-based chemotherapy model, and the analysis's implications for APM design.

*“Reinsurance will not take care of the problems of poorly-designed models.”*

—Provider representative



## Box 1: The OCM and risk

The OCM provides participants with two options for undertaking two-sided risk. OCM's original two-sided risk track institutes a 20% aggregate stop-loss provision for episode costs that exceed the target amount in a given performance period. Some observers have declared this is too aggressive.<sup>9</sup> Participants are also accountable for the total cost of care, which can include factors outside of their control, such as drug costs or medical costs unrelated to cancer treatment. This constitutes actuarial risk, some participants emphasized, which is akin to the type of risk that payers take.<sup>10</sup>

In December 2018, CMS proposed an alternative two-sided risk track that will be applicable to practices, beginning in performance period six. The track offers less potential for reward, but also less downside.<sup>11</sup>

In this new option, practices are:

- required to spend only 2.5% below the benchmark price, versus 2.75% in the original two-sided risk track<sup>12</sup>
- capped at a potential upside of 16% of total Part B revenue, which includes costs of services and Part B chemotherapy drugs<sup>13</sup>
- capped at a potential downside of 8% of total Part B revenue<sup>14</sup>

Some observers have stated that the new track is “*more attractive*” to some providers. Others have confirmed that it will not be feasible for larger facilities that are part of an academic or integrated system. This is because the financial reconciliation will be based on revenue reported by the tax identification number of the larger institution, meaning that the oncology practice will not be able to segment its Part B revenue from that of its parent institution. Some participants reported that their modeling predicts a worse outcome from the new track versus the original one.

## Understanding what reinsurance can and cannot do

Participants explored various types of reinsurance and how these might apply to an APM that is modeled on chemotherapy episodes. These types include:

- *Specific coverage*, which applies to a specific high or catastrophic claim for an individual<sup>15</sup>
- *Aggregate coverage*, which provides coverage for losses that exceed a defined financial threshold, and which can be accumulated through multiple high claims<sup>16</sup>
- An “*aggregating specific*” approach, which covers multiple mildly catastrophic individual claims—the aggregate of which can present a financial challenge to providers



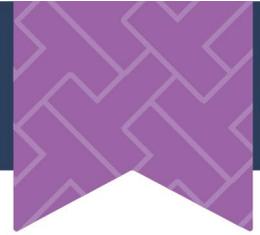
Experts explained the pros and cons of these reinsurance types. The commissioned analysis found that specific coverage would not offer meaningful protection against large losses in the simulated model; that aggregating specific coverage can provide some protection at specific outcome percentiles for practices; and that aggregate coverage was shown to offer the most robust level of protection, especially in the most catastrophic years.<sup>17</sup> *To access the report and its full conclusions, please see it on [Milliman's website](#).*

Informed by the analysis's findings, participants discussed caveats to employing the various types of reinsurance in a complex specialty APM. Of priority concern were the many factors likely to increase the cost of reinsurance premiums, including:

- **Data gaps and asymmetry:** Experts confirmed that many reinsurers lack robust and relevant datasets, such as the one used to generate the commissioned analysis. One explained: *“One of the reasons that reinsurers need a risk margin is they have a sense—sometimes right, sometimes wrong—that the purchaser of this reinsurance is going to have better data, even if it's not numbers. Reinsurers often feel like they're flying blind and are the ones with less information. That's where some of the risk comes from.”* Experts also noted that reinsurers are likely to look at data on past APM performance, such as OCM data. This concerned some providers who are currently in OCM, given that not all of them have achieved a performance-based payment.
- **Practice volume:** Experts also affirmed that reinsurers are not likely to offer nuanced or customized pricing to smaller practices, even those with good performance data, because smaller practices have less volume. As a result, they will have more volatile costs. One explained, *“If past performance data looks good, they'll look at it and say, ‘You got lucky—you're small, that's going to happen,’ and they would probably tend to use more of an industry rate.”*
- **Lack of policy and payment model knowledge:** Experts from the reinsurance industry and others also pointed to the fact that many reinsurers lack the relevant knowledge in healthcare policy and APMs to inform pricing of their products. One noted, *“Even when reinsurers have data, they don't understand the complexity of these programs ... they understand the insurance angle and risk angle of it, not the healthcare angle.”*
- **Potential target bias and inaccuracy:** Some experts noted that reinsurers often anticipate that the target prices in APMs may be inaccurate or biased. If they suspect that is the case, some will increase the price of products accordingly.

*“Reinsurers try to account for unknown risk, pricing risk, data quality, not understanding how the program is being implemented, the quality of care, and so [the costs] gets padded and padded and padded. The margin goes up. The cost of capital goes up.”*

—Subject matter expert



- **Expectation of pay-outs:** Aggregate reinsurance, which would offer the strongest protection in a provider’s worst years, would also require a lower loss ratio—i.e., higher administrative costs and margin. One expert explained, *“When you look at the variation that a reinsurer has in terms of potential outcomes of these policies, aggregate for reinsurer is a lot more volatile ... Because it’s that much more volatile, reinsurers do require a lower loss ratio in order to take on that risk.”* Simply put, while aggregate offers the best protection, it is also expensive because the reinsurer expects to pay out more frequently.

*“You do need to think of reinsurance not as a way to pass off losses or expected losses to the reinsurance carrier, but as something that you are willing to pay in order to get rid of risk, just like we do with auto insurance or home insurance.”*

—Subject matter expert

Some wondered if these challenges will ease over time as public programs like OCM advance. Indeed, some participants opined that strong data science and enhanced policy education for reinsurers could help build the reinsurance market for specialty APMs.

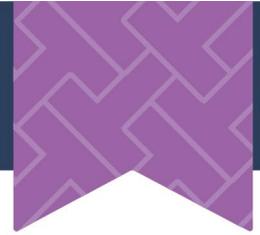
## Evaluating the business case

Reinsurance experts and council participants assessed whether buying reinsurance policies would be worth the cost in the scenarios modeled in the commissioned analysis. The analysis considered the use of reinsurance in scenarios with three different assumptions:

- That the target price was always accurate
- That the target price was mainly accurate, but at times incorrect due to normal levels of variation
- That the target price was systematically understated—or biased

The analysis showed that aggregating specific and aggregate insurance could reduce providers’ losses in some cases and certain outcome percentiles,<sup>18</sup> albeit at a cost. Broadly, many representatives from both large and small practices agreed that there was likely little value to such products for individual providers. This was because the modeling suggested that the cost of reinsurance would frequently result in a loss, even in good years.

Despite some participants’ conclusions that there would not be a business case for reinsurance for some individual practices, several were concerned about the general level of risk-exposure the modeling suggested and reiterated the need for ways to manage it. For some, there was still value in a reinsurance concept, provided the cost of the premiums could be managed.



*“The whole problem right now is most of the practices that are most at jeopardy for survival don't have the means to pay for reinsurance. They can't budget reinsurance for fear of undermining their whole operational budget and have their whole program collapse.”*

—Provider representative

Some shared plans to move forward with creating a data-driven reinsurance product for OCM practices. Another described the concept of forming a captive insurance pool, or a pool where several smaller providers band together to create their own insurance coverage, to cover the aggregating specific risk. Such a pool could work with a reinsurer to cover the aggregate risk beyond a specific, pre-defined high threshold. The participant elaborated, *“I'm looking at a captive because a lot of the profit of the reinsurance company comes in that middle tier, not the very high-risk tier ... So if I pull out that profit and I just manage it internally, then I have a different price point.”* Other industries, including ride-hailing companies such as Lyft, have responded to the lack of historical data and high risks perceived in their business models by creating insurance

subsidies to offset the high cost of coverage from insurers.<sup>19</sup>

## Questioning risk

Others questioned the fundamental design of risk-based APMs. They remain concerned about any transfer of risk to providers that could result in catastrophic losses for individual practices—especially considering the financial distress that many independent community practices already face.<sup>20</sup> Informed by the analysis and its findings, participants cited the following concerns:

- **Likelihood of loss, regardless of reinsurance:** Given community practices' already slim margins, some were concerned about the probability and level of loss the model's findings presented, regardless of whether practices purchased reinsurance. For example, the analysis indicates that in the simulated model, over half of small practices would be in the red in a given year and 25% of them would face a loss greater than 3%—even when targets were not systematically biased.<sup>21</sup> One participant commented: *“No matter what this turns out to be, two-sided risk for practices is a bad situation ... we need to get back to the fundamental question, Do we have to have two-sided risk to move the process [of shifting away from fee for service] forward?”*
- **Potential failure of reinsurance to protect against biased target prices:** Many were struck by the analysis's finding that reinsurance could not prevent consistently understated financial targets from significantly reducing expected gains. As one expert explained, *“The aggregate protects you on the high end, meaning really bad years. It doesn't protect you*

*“If I lose 4 percent, I don't make payroll. And if I do it more than one year, I'm done.”*

—Provider representative



*from the fact that, overall, you're going to lose money if the targets are biased.” Others noted after the meeting that it may be possible for reinsurers to build in some protection against technical risk.*

- **General lack of provider understanding of risk:** For some, the analysis suggested that many practices may not fully understand the level of risk involved in a two-sided risk path. One said, *“Medium-sized and small practices probably have no concept of what they're risking to take on two-sided risk. And [OCM practices] have a deadline [for achieving a performance-based payment], yea or nay, that's going to come due in about five months.<sup>22</sup> So this is a very shaky situation at the moment. We're working to try to get some data analysis available to have the oncology community better understand what they're risking at their own practice sites.”*

In light of the above concerns, many participants questioned whether risk was necessary to motivate providers to change behavior. While provider representatives have underscored this point previously,<sup>23</sup> some payers also questioned the need for risk. One payer explained her organization's approach: *“We use a flight simulator model. We begin all of our models in a no-risk environment for the provider partner. And the idea is that we're all learning together how to create success in the models ... And if you crash the plane while you're in the simulator, you don't die, and nobody gets hurt.”*

Other payers contested that risk can effectively motivate behavior change, provided it accomplishes its intended effect of curbing costs. Finally, some cautioned that two-sided risk can be designed in different ways and advised council participants to think about it in more flexible terms. One noted, *“Two-sided risk is not really one thing. It can be designed in a way that makes providers feel like they're getting judged on something they can control. But if two-sided risk is designed in a way that providers are being given risk for something that they can't control, like insurance risk or for variability that they have no influence over, then it probably won't be as successful of a tool.”*

## How can outcomes-based quality measures be practically implemented?

As the accountable-care paradigm advances, oncologists are increasingly paid based on outcomes associated with an episode of care, not for discrete services. The issue of how best to judge and measure high-quality cancer care has become fraught with diverse opinions and approaches—a situation which has been well documented and debated by other multistakeholder consortiums.<sup>24</sup>

To date, council participants have emphasized ongoing concerns about the selection and implementation of quality measures in oncology APMs. Members continue to call for greater consensus on which quality measures are most meaningful, and for the implementation of such measures to be as streamlined as possible for clinicians.



At the March meeting, participants discussed a set of core outcome measures for oncology APMs that had been proposed by Tufts' CEVR in a report recently submitted for publication in the *American Journal of Managed Care*. Today, 80% of the measures that oncology APMs employ are process measures, not outcome measures, which directly examine the effects of care on patients.<sup>25</sup> Despite the laudable ambitions associated with greater use of outcome measures, meeting participants underscored several ongoing challenges and concerns that impede their practical implementation.

### Challenges posed by elements that are outside of providers' control

Several provider representatives underscored difficulties with measures that are likely to incorporate care decisions not directly under the treating oncologist's control. As they considered measures across five quality domains identified by the CMMI<sup>26</sup>—clinical care, safety, care coordination, patient-reported outcomes (PROs), and population health—they made clear that certain measures would apply to a broad spectrum of clinical interventions, making them problematic.

For example, in discussing a measure in the population health domain that addressed the time from diagnosis to treatment, some providers raised concerns that many early diagnostic interventions are handled by a primary care physician (PCP). The oncologist could therefore be penalized for the PCP's lack of timeliness or other complicating factors, such as a patient's preference to delay treatment until a personal event or milestone. In the latter case, quality measurement conflicts with patient-centered care and shared decision-making.

Individual patient preferences also heavily influence hospice-related measures and end-of-life care. Regarding the many measures for emergency department, inpatient care, and hospitalization in the last 30 days of life, some participants noted that these could overlook cultural preferences and other social determinants of health. One said, *"This is a very Caucasian-centric list. And for some of us who manage more diverse populations, we know it is—for example—taboo to die at home. For some cultures who do not want to die in their house, dying in the hospital is the appropriate use, in that culture, of the hospital. So we have to take into account the cultural sensitivity of the people that you're serving. And the quality measures would have to reflect that."*

Some participants suggested more precise outcome measures that are more likely to capture elements within the treating oncologist's control. For the myriad of measures relating to reducing avoidable hospitalizations, for example, one participant proposed replacing the proposed measures with one currently under consideration by the National Quality Forum on Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.<sup>27</sup>



Other participants recommended more precision in measures that assess the timeliness of treatment following diagnosis. One provider noted, *“This is probably really different in terms of its importance, depending on which cancer type you are talking about and what cancer stage you are talking about. And so, if we are looking at this as a quality measure, we probably have to have it subdivided to some extent.”* Subdividing measures, however, means that patient pools will become smaller, thereby decreasing their statistical power for assessing performance. HICOR has written extensively about the challenge of small numbers in their landmark community cancer care report, which participants addressed with experts there in a separate conversation. *Please see Appendix 1 for more detail on the council’s discussion with HICOR.*<sup>28</sup>

## Gaps in data

In quality measurement, it is not only the content that is important, but also *how* that content is captured. For many participants, outcome measures are impeded by the lack of robust, easy-to-access data sources.

Today, many quality measures employed in APMs are measured through claims data.<sup>29</sup> For some of the outcome measures proposed by Tufts, providers questioned whether claims data suffice. Regarding the metric on the timeliness of treatment following diagnosis, one provider commented, *“EHR data would theoretically be better. But we’re talking about unstructured data and mining, and how do you actually operationalize that? That is a pretty big issue.”*

Other sources of data are simply hard to obtain and generate. For the many measures associated with hospice admissions, participants noted that hospice data and end-of-life care can be hard to access. One explained, *“We can retrospectively, with auditing and a lot of work, find who went to hospice and what was the time of death. But there is usually a transfer [of the patient] from one payer to another payer.”*

Data to reflect PROs, which engage patients to report on their physical function, symptoms, and so forth, are also difficult to capture. These are typically generated by survey instruments, which need to be validated, effectively integrated into EMRs and the clinical workflow, and engage patients appropriately. The implication is that validation costs time and money. Some participants reported on validation efforts that are currently taking place and hold promise. These include the Pacific Business Group on Health’s multistakeholder initiative to develop and implement oncology PROs in partnership with the International Consortium for Health Outcomes Measurement, supported through a CMS grant.<sup>30</sup>

## Ongoing need to streamline quality measurement

In prior meetings, participants have stressed the provider burden associated with quality measurement, particularly reporting that requires manual data-entry. This becomes especially burdensome for practices that participate in multiple APMs and for quality measures relating to data that is difficult to come by.



*“The question is, can Medicare data for all of the private insurers and everything be, essentially, the source of truth?”*

—Provider representative

To respond to this challenge, a participant asked whether providers’ performance with Medicare patients would correlate with general performance in commercial populations. He expanded: *“The question is, does data reflect, in general, if you do poorly in the Medicare population, you probably do poorly, generally speaking? ... I think that is certainly a testable hypothesis, that the two correlate and that Medicare could serve as the creator of the quality metrics.”*

Some participants were intrigued by this idea, given that a robust data set can be obtained on the Medicare population.

However, some cautioned that the Medicare population is unique and may not offer a direct correlation with commercial patients. One participant opined, *“It’s a different demographic that’s treated differently than a commercial population. I think that’s where the challenge is going to be, because it’s going to be different, the type of cancers are going to be different.”* However, with further thought, the same participant acknowledged, *“But technically, that’s how OCM was built; right? There’s supposed to be practice transformation. You are potentially not going to treat Medicare differently than Aetna or Cigna patients. As a doctor, you’re just going to manage them the same way.”* Therefore, even skeptics agreed that this concept could be a compelling starting point for further research.

## What is the near-term direction for clinical pathways in promoting effective, value-based care?

In principle, oncology pathways provide detailed treatment protocols for high-quality cancer care for specific types and subtypes of cancer, while accounting for factors such as toxicity and cost of treatment.<sup>31</sup> Across the United States, more oncologists and payers are embracing pathways as tools to guide clinician decision-making in the face of increasing pressure to enhance the quality of cancer care and reduce waste in the system. Indeed, the American Society of Clinical Oncology (ASCO) has reported a 42% increase in use of pathways from 2014-2016.<sup>32</sup>

In prior discussions, council participants have debated the benefits and drawbacks of pathways programs, as have many other forums. *See Box 2 for a more detailed explanation of these.* During the meeting, participants discussed the evolving role of pathways in fostering cost containment, care quality, and standardization across providers. They also discussed leading guidance organizations’ role in pathway development and utilization in the near future.



### Box 2: The pros and cons of pathways

Council participants and other stakeholders believe pathways have many significant benefits. They are well-positioned to drive providers to the most efficacious care for patients, based on the patient's cancer type, sub-type, and biomarker status. Some payers and providers also believe that increasing use of and adherence to pathways is an important starting point in encouraging a shift to high-quality oncology care that minimizes waste in the system. Participating in a pathway entails less financial risk and cost to providers and payers when compared with an APM.<sup>33</sup>

Pathways also offer other potential benefits to providers in alleviating administrative burdens. These will depend on how pathway utilization advances, and include:

- **Quality measure reporting:** Automated reporting on adherence to pathways could help reduce some of the burden associated with reporting on quality measures in APMs. This approach is at the heart of the Making Accountable Sustainable Oncology Networks APM proposal that was recently approved by HHS's Physician Focused Payment Model Technical Advisory Committee.<sup>34</sup>
- **Eliminating prior authorizations:** Providers are hopeful that more payers will waive prior authorization processes in exchange for compliance with pathways. However, several stakeholders remain skeptical that this will occur. One said, "*Payers don't see a way forward without huge reinvestment in their own infrastructure to remove prior authorization if you use a pathway.*" They are also wary, participants reported, of diminishing any defense against overutilization.

Participants have also recommended that pathways include the full spectrum of patient care, from initial diagnostics to palliative and end-of-life care. Some have underscored that pathways become murkier at the third- and fourth-lines of therapy. Council participants addressed this and related topics on advanced and palliative care in a value-based paradigm in an earlier discussion with experts from the Coalition to Transform Advanced Care. *For more detail on that discussion, please see Appendix 2.*



### Box 2: The pros and cons of pathways contd.

Despite the many current and potential benefits of pathways, participants and other leading organizations, such as the National Comprehensive Cancer Network (NCCN) and ASCO, have expressed concerns about how they are developed and utilized today:

- **Dubious transparency** about the expertise and leadership involved in making content decisions, and the **strength of evidence** used to inform content and a regimen's placement
- Potential conflict of interest in **payer-driven pathways**, given payers' interest in containing costs
- Increased **administrative burden** on providers who are participating in multiple pathways programs
- Unclear impact on **controlling drug costs**

### Do pathways have a role to play in reducing costs?

Participants debated the level of cost containment pathways can generate. One cited a study that showed using a pathway-like online decision support tool was able to decrease drug spending by 20% in Florida.<sup>35</sup> Others noted studies where pathways that incorporated biomarker testing and triage pathways showed meaningful cost-savings.<sup>36</sup>

Some participants also opined that NCCN's categories of preference, which recommend the two or three top options from NCCN's broader guidelines, could have a role to play in containing costs in certain circumstances. Indeed, some referred to NCCN's categories of preference as a *"a pathway within the guideline,"* but cautioned that affordability is only considered when the distinction is stark and other factors—namely, efficacy, toxicity, and strength and consistency of the evidence—are more or less equal.

Others were skeptical of pathways' ability to contain costs for several reasons:

- **Current cost-savings assessments may be skewed.** One payer noted that the cost-savings achieved by pathways in reducing drug spending, such as in the Florida example, may be inflated by poor previous provider performance: *"The only way you get a 20% decline is if you're not managing your population very well."*
- **The ability of pathways to save costs over the long term is uncertain.** Some providers shared their belief that the rising cost of drugs may have already negated pathways' ability to produce significant cost-savings. One said, *"I think that the days of big cost savings from pathways may have passed, now that everything costs \$10,000 per dose or more."*



- **Aligning pathways with value-based care may not be straightforward.** Some intimated that integrating value frameworks for drugs into pathways may be challenging. To calculate a drug’s value, one needs to understand the total cost of care, a participant emphasized. Given that a more expensive drug can help avoid other costs, arriving at this assessment is complex. Broadly, however, several stakeholders underscored their support for frameworks and approaches that prioritize efficacy and safety first.

## Who should drive development and use of pathways?

A major concern for several participants is, who is developing pathways and for what purpose? As noted in Box 2, one of the primary concerns about pathways to date is a lack of transparency in decision-making around pathway content and treatment placement. Specifically, participants emphasized the need for pathways to be designed by the medical community based on the latest and best evidence. Their content should not be influenced by payers, industry, or others that may have different motivations for choosing a specific treatment, such as lowering costs or encouraging utilization of their products.

Council participants, including payers, were supportive of this principle. Indeed, ASCO recently developed a set of criteria for assessing the quality of pathways, and many of its recommended factors relate to transparency, appropriate expertise, and a strong, updated evidence base.<sup>37</sup> Some suggested that ASCO or another organization take a step further and use such criteria to formally “deem” –or accredit– pathway quality.

Although payers in the room largely agreed with the above concepts, other participants saw a role for payers in making pathway utilization more meaningful. Some intimated that CMS should be encouraged to take a broader leadership role in promoting the use and quality of pathways. Others, including payers, emphasized that *“I don’t think CMS should deem [pathway quality]. I think it has to be the medical community. It cannot be a payer. It has to be the medical community so then they can hold themselves accountable.”*

Finally, some also called into question the role of pathways in standardizing care. If individual payers and providers continue to push their own pathways programs, this may lead to more fragmentation across the country, one argued.

*“Industry should have no role in developing pathways. And payers should also have no role in developing pathways. And one of the concerns that we have about many of the pathways that are currently in existence is that while industry, because of the regulatory environment, is pretty much excluded from influencing pathway development and guideline development, payers are not.”*

—Subject matter expert



## What, if anything, needs to change?

Despite some of the above concerns about pathways, all stakeholders present agreed that pathways—when designed and developed appropriately—have value in promoting high-quality cancer care and, to an extent, reducing variation. As one participant observed, *“I think that we have agreement that pathways makes sense. That is huge across payers, providers and industry. That’s not a small thing that we come away all nodding our heads. I wouldn’t have believed that two years ago.”*

Participants offered several recommendations for next steps they would like to see materialize for pathway development and utilization. Some of these are as follows:

- Pathways should be easily embedded into EMRs to streamline the clinical workflow and administrative process
- Compliance requirements should be more granular—for example, while many in the community recommend 80% compliance as a general rule, some stakeholders believe that for some treatments, compliance should be more like 95%; conversely, for treatments with weaker or less consistent evidence, 40% compliance may be reasonable
- Pathway compliance should be adopted as a quality measure to help automate some of the quality measure reporting processes in APMs
- Payers that employ pathways programs should be open to removing prior authorization
- A relevant third party, leadership organization such as ASCO should serve as a more formal “deemer” of high-quality pathways

The above recommendations were made by individual participants and may not have the support of the full group; however, some were particularly interested in the concept of more granular compliance recommendations and how those might be developed and pursued.

## What new APMs are being developed? And do they still matter in today’s dynamic policy environment?

Oncologists, payers, and others continue to consider several fundamental questions about APMs, including appropriate risk and risk-management tools and effective quality measurement. They also continue to assess the appropriate use of clinical pathways—all while grappling with a policy environment that continues to be dynamic. During the meeting, participants reflected on their own APM experiments against the backdrop of an uncertain policy landscape.



## Oncology APM concepts and pilots continue to proliferate

While many are looking to CMS to set the direction of value-based cancer care, others are experimenting with new APMs, especially in local and regional markets.

A commercial payer-provider duo shared their commitment to exploring an oncology APM in their local market. Emphasizing that their collaboration is nascent, they explained that they are starting with a deep dive on data and analytics to ensure their design is sound. Close collaboration between the payer and provider partner will be key to success, they expect.

Others discussed their efforts to create APMs in local and regional settings by closely engaging plan sponsors—i.e., employers—as well as traditional payers. One noted that their concept for an employer-based regional APM will focus on using a single pathway solution. He explained, *“The regional approach would have an oversight committee that makes the decisions on things like one pathway for everybody, what choices you would make on that pathway, and what quality metrics you would want for your particular region.”*

Other stakeholders discussed proposals for new models that embrace data science to create more granular targets. One provider developed an APM that uses the data practices generated during their participation as a real-world evidence revenue stream. Such an approach can enhance practices’ rewards for participating in the proposed APM and will likely appeal to industry and payers: *“The data would be owned by the group of practices, so they will be much more motivated to make sure that the data that they put in is accurate ... We’ll be able to take these patients and say we’ve compared Regimen X with Regimen Y, and how many times did they invoke the triage pathways that we embed in this project so we know what interventions were required, and then we would be able to get the total cost of care.”*

## APMs still matter

Participants also considered whether their concepts for new APMs would be relevant if proposed policy changes become a reality. These include the administration’s proposal to benchmark prices for Medicare Part B drugs against international prices,<sup>38</sup> which has prompted some stakeholders to wonder about relevant implications for the OCM given that, if it advances, it will “dramatically alter the landscape of reimbursement for Part B therapies.”<sup>39</sup>

Despite the myriad of policy proposals from the current presidential administration, participants reiterated their belief that APMs will continue to be a part of ongoing healthcare reform. However, some provided observations on trends from APM implementation to date that remain concerns:



- **Finding a role for oncology APMs—and other specialty APMs—in accountable care organization (ACO)-dominated areas is difficult:** Some shared challenges launching oncology APMs in markets where ACOs dominate. One provider who attempted to explore oncology models in such a market lamented that any proposed APM had a weak business case. This was because shared savings would need to be split with PCPs, even if PCPs

*“Very few ACOs I’ve spoken to have actually cut a check to physicians in the network ... A lot of the money went to the IT infrastructure to create the data that got the thing and to, you know, harass the people who didn’t get their mammogram that year and all those kinds of things. So most of the money seems to be absorbed back into the system.”*

—Provider representative

were not involved in any oncology-relevant care. This prompted some participants to question the management of oncology patients in ACO-dominated markets. One envisioned the following scenarios that might occur as a result: *“Either the cancer patients don’t get managed at all, in which case costs go crazy because the primary care physicians say, I don’t even want to step there—in which case, I don’t think that’s good for patients. And it’s certainly not good for the payer. Or, the primary physicians start making cost decisions completely non-transparently in terms of where they send the patients. They send them to providers who are cheaper. And that also is poor for patients.”*

- **Provider rewards are offset by participation costs:**

Some also observed that in current APMs, much of the savings achieved by providers are offset by providers’ payments to IT and data vendors that enable them to participate. This raises questions about the models’ longer-term sustainability and value for providers.

- **Shared savings will be time-limited:** As APMs move forward and as data science matures, providers will only be able to improve their performance and manage medical costs so much. As a result of better experience and better data, shared savings will diminish. Some envision a more definitive shift to an oncology bundled payment informed by real-world data: *“If we continue using data science to narrow and narrow and narrow oncology payments, it will become accurate enough that the amount of shared savings will very quickly become minimal. In this case, then you have a bundle, and you have the ability to say, ‘This is the bundled price. We are taking care of a patient with this level of breast cancer or these comorbidities.’ And that will be the eventual goal.”*

## Conclusions and the way forward

The number of APMs in oncology that are being developed underscores the enthusiasm of leading providers, provider associations, payers, and other stakeholders for continued experiments to deliver high-quality cancer care while attempting to rein in costs. Participants in the council are committed to reducing waste and unnecessary interventions, and to delivering the right treatment to the right patient at the right time. However, they are exploring all these



issues in an environment that they anticipate may soon—and, in the eyes of some, *too* soon—raise the stakes for accountable care in oncology. The prospects for shifting to two-sided risk models, whether mandatory or not, are not entirely certain, but the topic weighs heavily for many stakeholders. Some welcome it; many support a more cautious, iterative approach.

Based on their discussions, council participants and guests offered their suggestions for next steps for the council that could benefit the broader community of payers, providers, and other stakeholders experimenting in oncology payment reform:

- On risk and reinsurance:
  - Publish the commissioned reinsurance analysis, completed by Milliman and referenced here, for the broader community to better understand the benefits and drawbacks.
  - Consider educating reinsurers on the specialty APM market to better define their role and what they can offer.
  - Explore further how much risk, if any, makes sense as part of new APM designs, and also explore other ways to manage it.
- Investigate further the extent to which Medicare data could be used as a proxy for overall provider performance, to improve quality measurement.
- Explore further how this multistakeholder group can support the use of high-quality pathways, given the degree of alignment across different stakeholders that pathways have value.

Finally, participants commented on the value of coming together as a group of leaders to accelerate progress and learning in oncology payment reform. One said, *“My takeaway is that we need to continue to collaborate. Here we have payers, providers. We have manufacturers. We are already collaborating, but I think we need to enhance that, and take it two or three notches higher.”*



## About this document

*This ViewPoints reflects the use of a modified version of the Chatham House Rule whereby comments are not attributed to individuals, corporations, or institutions. Italicized quotations reflect comments made by participants before the meeting in individual and group calls or during the meeting.*

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## Appendix 1: Hutchinson Institute for Cancer Outcomes Research (HICOR) case study

### Measuring quality in a local, state, or regional setting

HICOR's landmark [cost and quality report](#) aimed to make available to the public detailed cost and quality data about 28 cancer care providers in Washington, a first in the United States. Given that providers' quality and cost scores would be fully transparent, HICOR relied on close engagement with those providers, as well as payers, patient organizations, and others, to elicit buy-in, support, and inputs. Stakeholders also enabled the report's publication by agreeing to a two-year moratorium on using the published data for contracting purposes.

HICOR faced several important methodological decisions for their analysis. Given the uniqueness of the Medicaid population, HICOR decided to conduct a separate analysis on Medicaid patients and omitted them from the report's patient pool. Additionally, while they used measures from national guidelines, discrepancies were analyzed in house and through external consultations and were adapted accordingly. Measures had to be capturable through claims and cancer registry data, which HICOR combined to create a single database. This bypassed the challenges of drawing data from different practices' electronic medical record systems. In doing so, participating providers did not have to separately report their own data, eliminating any administrative burden to practices.

The law of small numbers was a significant challenge for the HICOR team to manage. To generate statistically robust quality measures, HICOR employed several strategies, most notably the following:

- **Use of composite metrics.** HICOR merged some metrics to yield a sizeable enough patient population. This was especially helpful across subtypes, such as lung and colon cancer. For some of the breast cancer-related metrics, there was a sizeable enough patient population to employ standalone measures.
- **Expanded timeframe.** HICOR used data from a three-year period to ensure each clinic had a minimum number of eligible patients. The minimum number that HICOR eventually set exceeded guidance from the Medicare Access and CHIP Reauthorization Act of 2015.



### Measuring quality in a local, state, or regional setting *contd.*

The report generated several takeaways. Certain metrics had a more significant range of variation in quality than others. Hospice care within three or more days prior to death was foremost among these, with a 37% difference.<sup>40</sup> By comparison, chemotherapy administration in the last 14 days of life only had a +/- 6% variation between the top and bottom.<sup>41</sup> This observation raises questions about the extent to which metrics indicate clinically meaningful differences. Additionally, metrics for chemotherapy during hospitalization, follow-up testing for breast cancer, and end-of-life care were associated with higher variation in both quality and cost.

Council participants discussed the report, its findings, and implications for their own APMs in January 2019. Participants were eager to understand the drivers behind variations in quality. This was a topic, HICOR experts underscored, that remained to be further explored. Participants were also curious whether specific measures correlated with one another, indicating that for council participants, understanding how to streamline measures is continuously top of mind. One asked, for example, *“How many of these measures correlate so highly that you could get away with one measure? For example, Are the practices that are good at the hospice care-related metrics also good at ICU? Is there a small set of metrics that reflect a larger correlation?”* HICOR leaders replied that, in fact, they observed some negative correlations—for example, clinics that did well on emergency-department measures tended to do poorly on inpatient care, showing that there is currently no easy way to use a small set of anchor measures.

HICOR experts, together with council members, noted additional areas for further research that build from the study:

- Examining how the participating providers are absorbing HICOR’s data to drive change in their practices
- Assessing how artificial intelligence and machine learning technology can augment the risk adjustment process
- Improving collection of patient-reported outcomes, potentially on a statewide basis
- Adapting the methodology to new measures that have since been introduced into national guidelines since HICOR’s work began five to six years ago
- Broadly, exploring how to replicate HICOR’s work in another state, such as those states that have similar gold-standard cancer registries with the National Cancer Institute’s Surveillance, Epidemiology, and End Results Program<sup>42</sup>



## Appendix 2: Palliative and advanced care case study

### Learning from palliative and advanced care models

Some participants are grappling with managing appropriate palliative and advanced care within a value-based paradigm.<sup>43</sup> Payers and providers alike have observed that the greatest opportunities for cost savings and containment lie with managing patients who have failed first-, second-, or third- line treatments.<sup>44</sup> Currently, significant variation exists in how providers manage end-of-life and palliative care. Given these observations, participants, alongside experts from the Coalition to Transform Advanced Care (C-TAC), considered new advanced- and palliative-care APMs and these models' implications for oncology APMs.

In a discussion with council participants, C-TAC leadership discussed the clinical and payment model for advanced illness that is currently under consideration by CMS and is based on recommendations from C-TAC and the American Academy of Hospice and Palliative Medicine to the Center for Medicare and Medicaid Innovation in 2018.<sup>45</sup> These recommendations also align with those outlined in the advanced-care APM C-TAC proposed to HHS's Physician Focused Payment Model Technical Advisory Committee, which subsequently recommended the model for limited-scale testing.<sup>46</sup>

The pending APM is likely to have the following characteristics:

- A quality bonus based on a pool of funds collected from savings
- Two risk tracks, including one for practices with low volume (less than 100 patients per year) and a standard track for all others
- A \$450 per-member-per-month (PMPM) proposed payment to offset additional care coordination or personnel costs associated with expanded services offered

In December 2018, C-TAC leadership and council participants addressed how providers that are already participating in the OCM may be able to participate in such a model. C-TAC leadership noted that it is unclear whether the PMPM payment will be considered part of the total cost of care that OCM participants are accountable for or whether they will be allowed to accept additional PMPMs for staff retraining or hiring, given the potential for overlap with the OCM's existing Monthly Enhanced Oncology Services payments. That said, experts expect that the model will be able to lower the overall total cost of care and trend for participating patients based on analogous models that commercial payers have piloted.



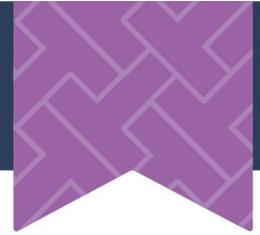
**Learning from palliative and advanced care models *contd.***

Such a model, if approved by CMS, could prompt oncology practices to consider whether advanced/palliative-care services are worth building in house or buying through contracts with vendors. Experts noted that practices that already have palliative- or advanced-care specialists might be able to work with external team members that receive the proposed PMPM as a wraparound service—for example, through a collaboration or partnership with a home health agency. Some anticipate that service providers will emerge the moment payment for these services becomes available from CMS, and these will be good partners for small oncology practices. Experts noted that based on the experience of commercial models, the more tightly integrated the services, the greater the achieved savings—an important factor given the likely advent of two-sided risk models.



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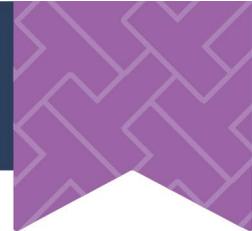


## Endnotes

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