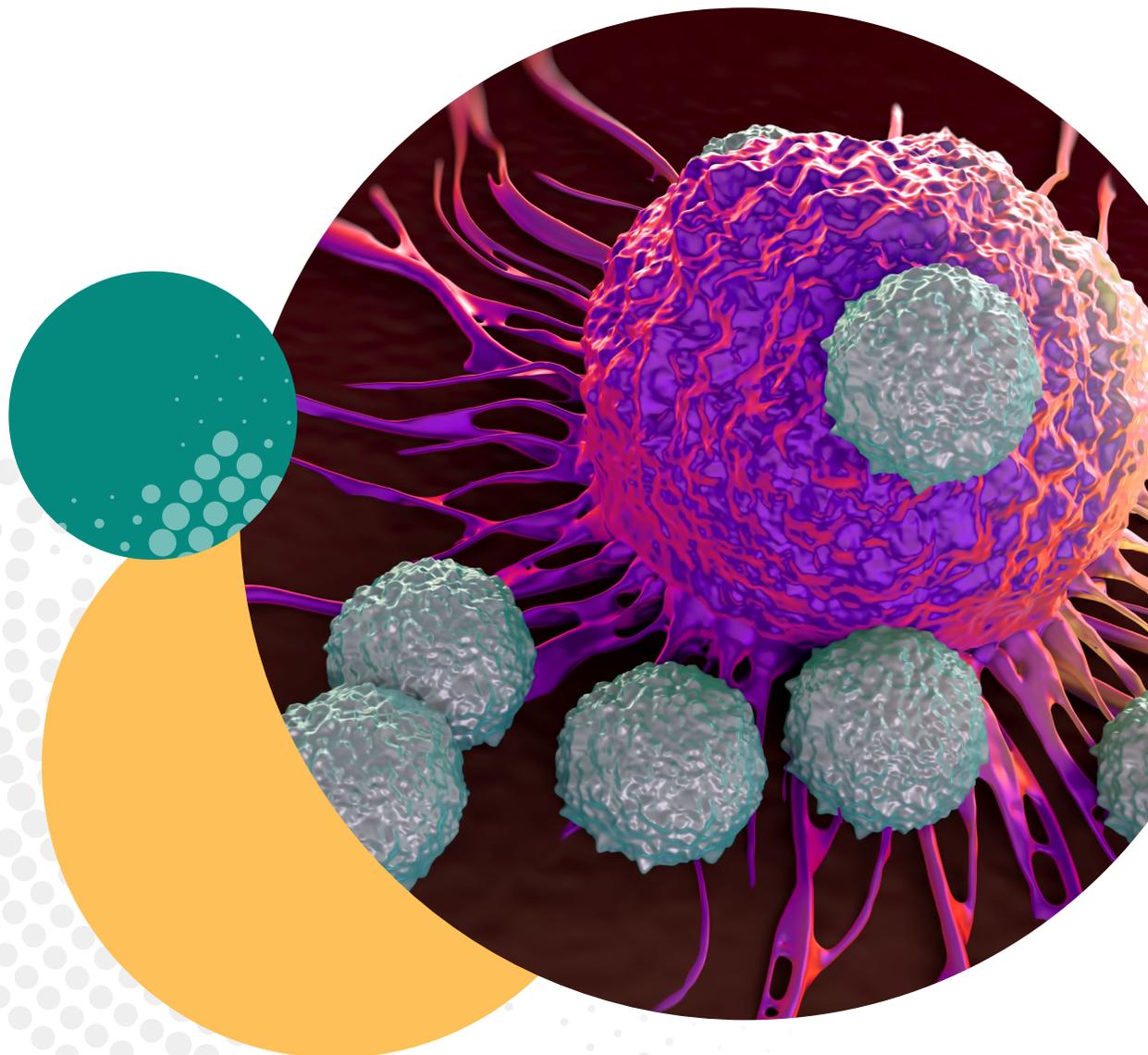




# Value-Based Contracting for Oncology Drugs:

A NEHI White Paper



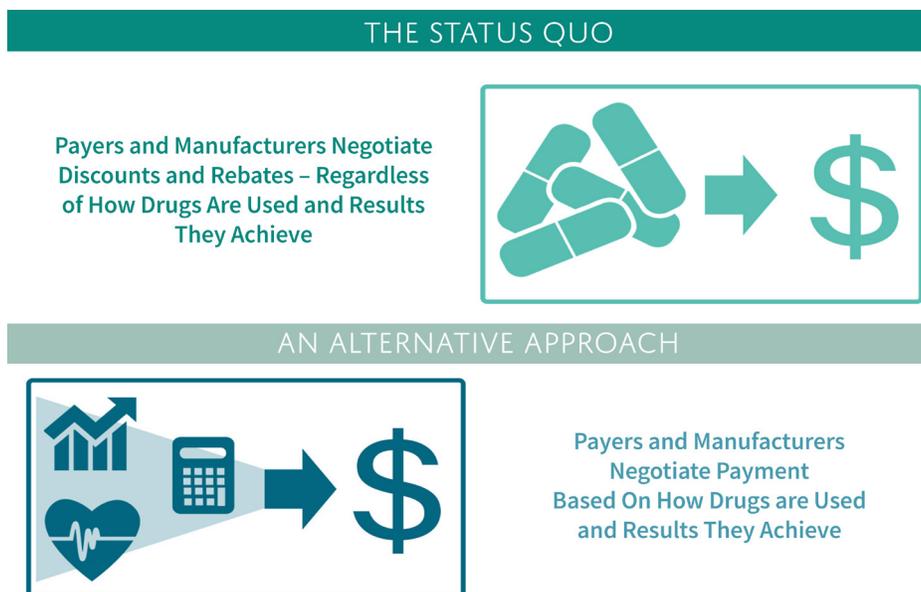
# Executive Summary

A revolution is occurring in cancer treatment, based on new insights into the biology of cancer, and resulting in dozens of new drugs on the market or in the development pipeline. Many of these new drugs are “targeted” therapies that are tailored to the specific genetics and molecular pathways of different types of cancer. The drugs have demonstrated very successful outcomes for some patients and some cancer types; for example, they can produce added months of survival without any progression of disease, or total remission for some patients with previously untreatable or relapsed cancers. Yet stakeholders have expressed anxiety and concerns about these drugs’ high list prices.<sup>1</sup> For all payers, for patients, and for society, the potential benefit and costs heighten the need to understand the drugs’ value, and to know which patients will benefit from specific drugs.

Newer cancer drugs would thus seem to be prime candidates for value-based contracting – an emerging strategy under which payers and biopharmaceutical manufacturers agree to specific terms that tie payment to results, and that compensate manufacturers based on whether they obtain improved patient outcomes, or better financial outcomes, from the successful use of drugs in patients. In many instances, these contracts also involve shared financial risks between payers and biopharmaceutical

manufacturers; for example, drug manufacturers may have to pay more if drugs don’t work as well as demonstrated in clinical trials. There are multiple varieties of these contracts, but the overall objective is to hold manufacturers more accountable for value than more common arrangements that tie the net prices paid for drugs to the volume of drugs that are purchased. These emerging strategies are deemed by payers to be one part of a multi-pronged solution to the challenge of paying for high- cost medications.

A previous NEHI white paper described these value-based contracts in detail and set forth recommendations for policy, regulatory, and other changes that could facilitate their broader use. The U.S. Centers for Medicare and Medicaid Services (CMS) have now begun to examine these and other innovative payment models, and CMS recently agreed to enter one for Novartis’ new pediatric leukemia drug, Kymriah. Although other oncology drugs may also appear to be prime candidates for new pricing models, including



value-based contracting, multiple challenges still stand in the way. Some are unique to cancer drugs. Others, including legal and regulatory barriers, apply across all types of drugs and were discussed in NEHI's earlier paper, but also could have distinct impact on contracting for cancer drugs, as outlined further below.

Overall, value-based contracting for biopharmaceuticals is in its early stages, and the consensus among expert panels convened by NEHI is that thoughtful experimentation in these contracts should proceed. This NEHI white paper recommends a combination of strategies to foster innovation and experimentation, address operational challenges, and advance policy measures, including appropriate legislative or regulatory relief.

**1 Recommendation #1: Payers, biopharmaceutical companies, data collection organizations, and other stakeholders should address challenges in collecting and analyzing data to execute value-based contracts.**

The demand for data is rapidly increasing in cancer, from the research end of the spectrum all the way to tracking patients' responses to therapy. Greater standardization and sharing of routinely collected cancer data, albeit with appropriate privacy safeguards, could also make it easier and less costly to design, implement, and evaluate value-based contracts for cancer drugs. NEHI recommends that biopharmaceutical manufacturers, payers, and even health systems that are parties to value-based contracts consider adopting the Core Measure Set created for the Oncology Care Model, a multi-payer, performance-based payment model launched in 2016 by the Centers for Medicare and Medicaid Services to improve cancer care and lower costs. As these organizations develop their own cancer-related data sets for the purposes of value-based contracting, they also should commit to linking these to the larger cancer data ecosystem to benefit all stakeholders, including patients.

**2 Recommendation #2: A cross-sector group of stakeholders, including patients, payers, and biopharmaceutical manufacturers, should develop a set of patient-centered and patient-reported measures for oncology care.**

A related issue in the realm of data collection and analysis is the need for a core set of patient-centered and patient-reported outcomes measures. No such set of measures currently exists. In its absence, little is known about aspects of cancer treatment that anecdotal evidence suggests matter to patients nearly as much as common clinical metrics, such as survival or progression-free survival.

NEHI recommends that a cross-sector stakeholder group be established to take up this effort, and propose a set of core patient-centered and patient-reported cancer outcomes measures. Payers and biopharmaceutical manufacturers in particular should commit to helping to develop these measures and incorporating them into future value-based contracts. Importantly, a core measure set should gather information on financial toxicity, or the problems that cancer patients have that are related to their costs of treatment.

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### **Recommendation #3: The Food and Drug Administration (FDA) should finalize draft guidance on communication among manufacturers, payers, and other entities deemed qualified under the agency's proposed guidance.**

Several issues under the FDA's purview stand in the way of value-based contracts, and particularly for cancer drugs. These issues fall mainly into two categories: communications about drugs, including potential new indications, that are under review by the FDA but not yet approved, and communication about off-label uses.

The FDA should finalize its draft guidance issued in January 2017 to fully authorize exchange of health care economic information about new, not-yet-approved products, including potential new indications, from manufacturers to payers and entities deemed qualified under its proposed guidance, such as health system formulary committees. In the absence of FDA action, Congress should enact H.R. 2016, the Pharmaceutical Information Exchange Act of 2017, to make clear that such information can be communicated by biopharmaceutical manufacturers to payers and entities deemed qualified under the proposed FDA guidance without fear of sanction.

NEHI also recommends that FDA should consider issuing new guidance on communication between payers and manufacturers on off-label uses, at least as pertains to cancer therapies, and that as a reasonable first step, FDA should allow manufacturers to communicate off-label information to payers that is clinically relevant and also consistent with the approved clinical indications (for example, patient-reported outcomes).

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### **Recommendation #4: The Centers for Medicare and Medicaid Services should provide a reasonable accommodation to Government Best Price and other price reporting requirements.**

Such accommodation would prevent certain value-based contracts, such as "money-back guarantees," from triggering deeper rebates and other unintended adverse federal price reporting consequences across government programs. If CMS does not provide this accommodation in a reasonable time frame or address the substance of these issues, Congress should step in to make relevant changes in law to enable such contracts.

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### **Recommendation #5: The Office of the Inspector General of the Department of Health and Human Services should develop new safe harbors to the Anti-Kickback Statute to enable certain activities that support value-based contracting.**

New safe harbors should specifically allow biopharmaceutical manufacturers and payers to determine how to share the costs of analytical models, collection of data, services to support medication adherence, care coordination, and similar services, without triggering enforcement actions under the statute. New safe harbors should also provide clear authority for manufacturers to extend discounts and rebates to payers based on pre-

determined patient outcome and other value-based measures, in addition to discounts and rebates based on volume of sales, which are already permitted and regulated under an existing safe harbor.

**6 Recommendation #6: The Office of Civil Rights of the Department of Health and Human Services should develop guidance on HIPAA compliance in the context of value-based contracts between manufacturers and payers.**

Such guidance would pertain to sharing protected health information among providers, payers and manufacturers. Although not limited in importance to value-based contracting in oncology, as noted above, clarification of the applicability of the statute will be critical to building the cancer data ecosystem.

**7 Recommendation #7: Stakeholders should continue discussion and investigation of new long-term financing approaches for high-cost therapies and cures in major disease states such as cancer.**

For all the promise of value-based contracting, payers and purchasers on NEHI’s expert panels voiced doubts that the strategy will be a singular solution to the challenge of high-cost drugs. Particularly for breakthrough therapies that may come onto the market in future years – not just in cancer, but in other areas of unmet need, such as Alzheimer’s disease – the costs are likely to be so high, and the need so immense, as to impose a major burden on existing programs and payment mechanisms. Alternative approaches to financing high-cost therapies are needed. Congress should adopt into law a formal request of the National Academy of Medicine to study possible approaches, or should appoint an advisory panel focused on the same topic to advise to the Secretaries of Health and Human Services, the Treasury Department, and other relevant agencies.

## Conclusion

The revolution occurring in cancer treatment is producing breakthrough medications that offer great benefit to many patients, at considerable cost. Many of these drugs could be strong candidates for value-based contracts that hold biopharmaceutical manufacturers more accountable for improved patient outcomes than conventional purchasing arrangements, while also offering the potential for more affordable pricing. A period of experimentation is needed to develop such contracts and learn from them. It is also important to establish the legal and regulatory framework to help facilitate these contracting opportunities. Some regulatory relief is needed to support these arrangements, as is a robust commitment from stakeholders to build the data systems and take other steps to shape a true “learning health system” in cancer care.

Although value-based contracts, and the lessons learned from their execution, will help all stakeholders better understand the value of many cancer drugs, they will not themselves solve the overarching challenge of affordability of high-cost medications for cancer or other conditions. A broader inquiry is also needed into possible long-term financing solutions that will support provision of high cost and potentially curative therapies. Cross-sector organizations such as NEHI, and the expert panels it assembled to create this white paper, can be instrumental in helping to forge solutions to benefit all.

## Reference

- 1 See [http://www.asco.org/sites/new-www.asco.org/files/content-files/blog-release/documents/2017-ASCO-Position-Statement-Affordability-Cancer-Drugs.pdf?et\\_cid=39454952&et\\_rid=1760459169&linkid=position+statement](http://www.asco.org/sites/new-www.asco.org/files/content-files/blog-release/documents/2017-ASCO-Position-Statement-Affordability-Cancer-Drugs.pdf?et_cid=39454952&et_rid=1760459169&linkid=position+statement)