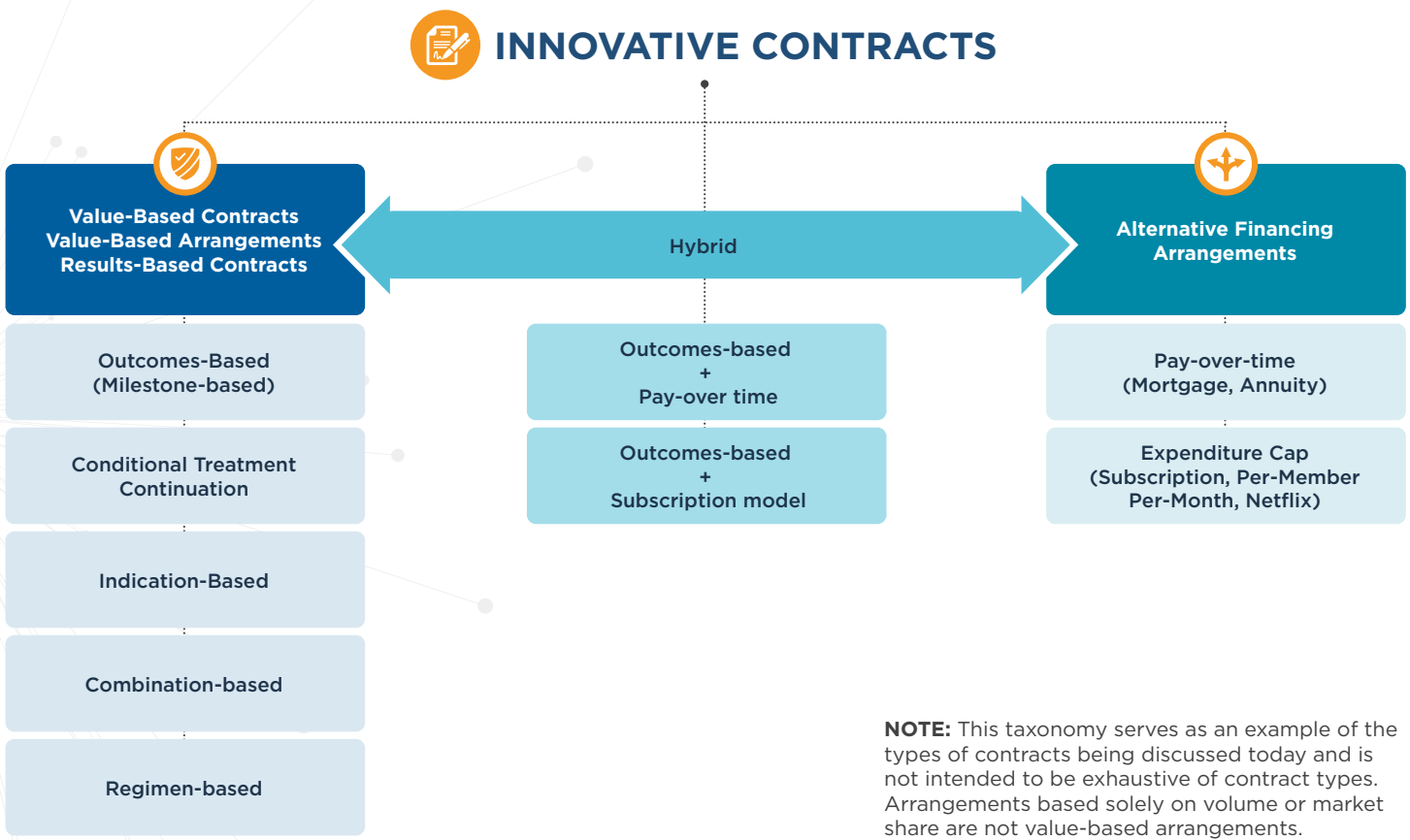


INNOVATIVE CONTRACTING: OPPORTUNITIES AND CHALLENGES

We are in a new era of medicine where breakthrough science is transforming patient care, but these innovations are meaningless if patients can't access them. That's why biopharmaceutical companies are working with other health care stakeholders to develop new ways to pay for medicines, like innovative contracts.

These innovative contracts—also known as value-based contracts or alternative financing arrangements—include results-based contracts that link payment to patient health measures and other outcomes. There are currently 75 publicly announced contracts—and counting—with nearly 50 brands and 30 medicine producers participating. Nearly 30 conditions are covered by a wide variety of innovative contracts, including multiple sclerosis, diabetes and cancer.



NOTE: This taxonomy serves as an example of the types of contracts being discussed today and is not intended to be exhaustive of contract types. Arrangements based solely on volume or market share are not value-based arrangements.

INNOVATIVE CONTRACTS CAN BE BENEFICIAL TO PATIENTS AND LOWER OUT-OF-POCKET COSTS WHILE PROVIDING SAVINGS FOR THE HEALTH SYSTEM.

Innovative contracts can potentially improve patient outcomes.

This could occur if payers are able to provide broader access to innovative medicines, as biopharmaceutical companies take increasing responsibility for outcomes. It could also occur as these contracts allow payers or biopharmaceutical companies to do more to support appropriate patient use of medicines. An analysis found 58% of payers that use results-based contracts saw improved patient outcomes.¹

Innovative contracts can potentially reduce medical costs.

Supporting better use of medicines through innovative contracts can reduce spending on medical services by reducing hospitalizations, emergency visits or other costly results of poorly controlled disease. For example, if innovative contracts lower the burden of diabetes in the United States by 5%, the United States could save more than \$12 billion annually.² Another analysis found that 45% of payers believe that wider implementation of innovative contracts could lead to lower patient out-of-pocket costs.³

Innovative contracts can potentially reduce the out-of-pockets cost of medicines for patients.

In value-based programs between biopharmaceutical companies and pharmacy benefit manager Express Scripts last year, patients taking cholesterol-lowering medicines saved nearly \$800,000 out of pocket. And in Medicare, after a value-based arrangement for a cardiovascular medicine went into effect, patients' out-of-pocket costs were reduced to just \$10 a month, on average. These patients used to pay, on average, over \$40 for a month-long supply of the medicine.⁴

Unfortunately, government policies can create uncertainty around these contracts, which may deter biopharmaceutical companies and insurers from adopting them. Historically, there have been three central barriers to innovative contracts. One barrier, the lack of clarity for engaging in communications in facilitating innovative contracts, was resolved in 2018. The two remaining barriers, the lack of clarity in the anti-kickback statute and in price reporting rules, still need to be addressed for higher and more effective use of innovative contracts. The Centers for Medicare and Medicaid Services recently released proposed rulemaking that could address some issues in price reporting,⁵ but without further clarification and modernization of current anti-kickback guidance, the full benefits of innovative contracts will not be realized.

ADDRESSED BARRIER

Lack of Clarity for Engaging in Communications that Facilitate Innovative Contracts

BARRIER: Lack of clarity in the Food and Drug Administration (FDA) regulations and policy regarding biopharmaceutical company communications presented obstacles to communicating health care economic information critical to negotiating innovative contracts.

ACTION: In 2018, the FDA released two guidance documents that provide clarity on how biopharmaceutical firms may communicate certain information, including health care economic information, consistent with FDA regulations.

REMAINING BARRIERS

Lack of Clarity in the Anti-Kickback Statute

Complex Price Reporting Rules

Addressing these remaining barriers to innovative contracts would support an innovative, market-based solution that can help provide patients with affordable access to new medicines.

To learn more, visit www.PhrMA.org/value-collaborative.

¹Avalere. More than Half of Health Plans Use Outcomes-Based Contracts. October 2019. Available at: <https://avalere.com/press-releases/more-than-half-of-health-plans-use-outcomes-based-contracts>

²PhRMA. Value-Based Contracts May Lower Patients' Out-of-Pocket Costs by 28 Percent, February 2018. Available at: <https://www.phrma.org/en/Press-Release/Value-Based-Contracts-May-Lower-Patients-Out-of-Pocket-Costs-by-28-Percent>

³PhRMA discussions with Verpora. Full results of survey forthcoming in 2020.

⁴PhRMA. ICYMI: Patients saved nearly \$800,000 out of pocket through innovative contracting arrangements. April 2020. Available at: <https://catalyst.phrma.org/icymi-patients-saved-nearly-800000-out-of-pocket-through-innovative-contracting-arrangements>

⁵PhRMA. PhRMA Comments on CMS Proposed Rule on Changes to Medicaid. July 2020. Available at: <https://www.phrma.org/Public-Communication/PhRMA-Comments-on-CMS-Proposed-Rule-on-Changes-to-Medicaid>. Recommendations for specific price reporting clarification begin on page 29.