

January 8, 2021

Re: Health Care Innovation Caucus Request for Information: Modernizing the Stark Law, Anti-Kickback Statute and Medicaid Best Price rules for those participating in value-based arrangements

Dear Representatives Bera, Kelly, Kind and Mullin:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to submit comments to the Health Care Innovation Caucus on its request for information (RFI). PhRMA is a voluntary, non-profit association that represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

PhRMA applauds the Health Care Innovation Caucus' commitment to facilitating innovative contracts¹ that can improve the quality of patient care and optimize healthcare spending. Facilitating innovative arrangements that improve affordability and more closely link cost to outcomes represents a key solution for better health care. As recognized in the statement released by Representatives Ami Bera, M.D., Tony Cárdenas, Mike Kelly, Ron Kind, Roger Marshall, M.D., Markwayne Mullin, and Brad Wenstrup, D.P.M.,² many key stakeholders in health care, including biopharmaceutical research companies, are interested in pursuing innovative contracting arrangements and should be subject to consistent rules under the Stark Law and Anti-Kickback Statute (AKS). Categorically excluding certain entities, including manufacturers, from many of the newly finalized safe harbors to the AKS and failing to provide a separate safe harbor specifically covering innovative contracts for medicines³ undermines manufacturers' ability to participate in arrangements that can improve healthcare quality and efficiency. Furthermore, while the Center for Medicare and Medicaid Services has made some progress in clarifying price reporting rules related to value-based arrangements, further clarification may help ensure the full potential of these innovative contracts is achieved.

The goal of innovative contracts, first and foremost, should be to improve care for patients. Updating outdated regulations that inhibit the adoption of innovative contracts will support patient-centered care and help address challenges beneficiaries face with respect to cost-sharing obligations, as this is a

¹ For clarity, we refer to the concept of a "value-based partnership" as an innovative contract throughout these comments to encompass the range of contract types currently in use today. Please note that arrangements based solely on volume or market share are not considered value-based arrangements. For more detail please refer to our updated taxonomy at: <https://catalyst.phrma.org/innovative-contracts-drive-access-for-patients-and-value-for-the-system>

² Bera A, Cárdenas T, Kelly M, Kind R, Marshall R, Mullin M, Wenstrup B. Members of Congress Release Statement on Trump Admin's Rulemaking to Modernize Stark and Anti-Kickback Statutes. Office of Ami Bera. Press Release. November 2020. Available at: <https://bera.house.gov/media-center/press-releases/members-of-congress-release-statement-on-trump-admins-rulemaking-to>

³ HHS-OIG, Final Rule: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (RIN: 0936-AA10).

critical barrier to patients' adherence that negatively impacts patients' health outcomes and increases use of costly medical services.

In response to the topics presented in the RFI, in the remainder of this letter we address the following:

- the benefits of innovative contracts for medicines (including how they promote value-based care) and the barriers they face;
- suggestions for improving the finalized OIG rulemaking on Stark and the Anti-Kickback Statute (AKS); and
- feedback on the recently finalized CMS rulemaking on Medicaid Best Price.

I. BENEFITS OF INNOVATIVE CONTRACTS FOR MEDICINES AND OVERVIEW OF BARRIERS

Innovative contracts for medicines—also known as value-based contracts or alternative financing arrangements—are voluntary arrangements between manufacturers and other entities, such as health plans or risk-bearing providers, in which the price or price concession for a prescription medicine is linked to value as determined by the contracting entities. These arrangements have the potential to lower costs through voluntary, market-based negotiations between manufacturers and payers—as opposed to government or other centralized value assessment.

Importantly, these arrangements can also increase patient access to new therapies, including breakthrough medications for rare and devastating diseases, with the potential to transform the lives of patients in urgent need of medical advances—often people with progressively debilitating diseases who have lacked any effective treatment options. For instance, there are currently nearly 400 cell and gene therapies in development for a broad range of diseases including cancers, rare and debilitating diseases, and cardiovascular disease.⁴ A payer that otherwise might not cover a new drug (or that would only cover the drug with significant utilization management restrictions or high cost sharing) due to uncertainties about the percentage of its patient population who would benefit from the drug might increase access to the drug if the manufacturer shared the risks of its performance. Thus, these agreements may make newer drugs more accessible to patients who can benefit from them and increase competition in relevant drug classes.⁵

Evidence suggests growth in innovative contracts. A 2019 Avalere survey of 50 payers found that more than half (59%) either had an outcomes-based contract in place or were in negotiations.⁶ Sixty-three percent of payers surveyed by Health Strategies Insights in 2020 stated that they plan to utilize one or more

⁴ PhRMA. Cell and Gene Therapy Medicines in Development Report. 2020. Available at <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/MID-cell-and-gene-therapy-2020.pdf>.

⁵ See, e.g., Lee Staley. A Drug's Worth: Why Federal Law Makes it Hard to Pay for Pharmaceutical Performance. 98 Boston Univ. Law Review 303, at 310. 2018 ("Tying reimbursement to health outcomes presents new opportunities for competition with rival manufacturers...A manufacturer that can demonstrate sustained health benefits in post-market studies may distinguish itself from competitors).

⁶ Avalere Health. More than Half of Health Plans Use Outcomes-Based Contracts. Oct. 1, 2019. Available at <https://avalere.com/press-releases/more-than-half-of-health-plans-use-outcomes-based-contracts>.

non-outcomes-based contract (e.g. pay-over-time, expenditure cap, regimen-based, indication-based, and conditional treatment continuation contracts) over the next year.⁷ A PwC survey found that one quarter of pharmaceutical company executives reported their company has participated in a value-based arrangement, and nearly one-third (29%) of those companies had participated in over 20 of these arrangements.⁸ Between 2009 and Q2 2020, 77 innovative contracts were publicly announced.⁹ These contracts cover nearly 50 brand name medicines from almost 30 biopharmaceutical manufacturers, spanning nearly 30 conditions, including multiple sclerosis, diabetes, and cancer. However, this only represents a small fraction—as little as 30 percent according to one study¹⁰—of the contracts in use, as most contracts are not publicly announced.

Despite recent growth, outdated government policies can create uncertainty around these types of contracts, which may deter biopharmaceutical companies, insurers, and other risk-based providers from adopting or further expanding their move toward innovative contracts, potentially limiting the number, type, and scope of these arrangements. This stops these contracts from benefiting patients, payers, and the government.

Historically, there have been three central barriers to innovative contracts. One barrier, the lack of clarity around permissible communications to facilitate innovative contracts, was addressed in 2018 thanks to FDA guidance on manufacturer communications with payers and communications consistent with the label. The two remaining barriers that still need to be addressed for more parties to enter into innovative contracts are:

- **Innovative contracts should be clearly protected under the federal Anti-Kickback Statute.** Despite the potential benefits of these arrangements, the federal AKS is chilling more widespread adoption. The AKS is a broadly worded statute developed over twenty years ago that can

⁷ Health Strategies Insights. 2020. Online survey of Pharmacy or Medical Directors, Contracting Managers/Directors/VPs or Finance at a managed care organization (MCO) or pharmacy benefit manager (PBM) with relevant topical knowledge of value-based contracts and innovative contracts (25 MCOs, 5 PBMs; n=30). Survey participants stated their MCO or PBM plans to utilize at least one of the following innovative contract types over the next year (percent indicates percent of payers who plan to use that type of arrangement): pay-over-time (37%), expenditure cap (30%), regimen-based (33%), indication-based (30%) and conditional treatment continuation (33%).

⁸ PwC. Pharma's Value-Based Contracting Experience: Successful But Limited. September 2018. Available at: <https://www.pwc.com/us/en/industries/health-industries/library/pharma-value-based-contracting-experience-successful-but-limited.html>.

⁹ PhRMA. Innovative Contracts 2009 - Q2 2020. September 2020. Available at: <https://www.phrma.org/Fact-Sheet/Innovative-Contracts-2009-Q2-2020>

¹⁰ Mahendraratnam N, Sorenson C, Richardson E, et al. Value-Based Arrangements May Be More Prevalent Than Assumed. AJMC. February 13, 2019. Available at: <https://www.ajmc.com/journals/issue/2019/2019-vol25-n2/valuebased-arrangements-may-be-more-prevalent-than-assumed>

inadvertently discourage beneficial low-risk healthcare arrangements through the threat of civil, criminal, and/or administrative sanctions.¹¹

While many types of innovative contracts for medicines may fit within existing regulatory safe harbors to the AKS, a lack of clarity in the safe harbors, variable interpretation by courts, aggressive *qui tam* relators and enforcement officials, and the outdated nature of certain safe harbors creates uncertainty that discourages some payers, providers, and manufacturers from embracing innovative contracts for medicines. Clear AKS guidance addressing innovative contracts would create greater certainty, and payers, providers, and manufacturers would be encouraged to develop and support innovative contracting models.

In recent OIG rulemaking, pharmaceutical manufacturers were explicitly excluded from some of OIG's newly developed coordinated care safe harbors, and OIG declined to issue a safe harbor specifically for innovative contracts between manufacturers and payors (although they indicated such rulemaking may be coming). We agree with the statements referenced above that all stakeholders should be subject to consistent rules under Stark and AKS and are hopeful that the Caucus will urge OIG to continue rulemaking specifically on the issue of innovative contracting for medicines.

- **Innovative contracts necessitate a more modern and flexible approach to price reporting.** Biopharmaceutical companies must adhere to a complex set of government price-reporting rules for calculating Best Price and Average Manufacturer Price (AMP) in Medicaid. These highly technical price-reporting rules were established prior to the introduction of innovative payment approaches. While the price-reporting rules do permit biopharmaceutical companies to make reasonable assumptions, to the extent there is ambiguity about how to capture innovative pricing methods in an innovative contract this can create uncertainty for innovators and payers.

Detailed recommendations for specific price reporting clarifications can be found in our comment letter responding to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs¹² and our comment letter to CMS on the Medicaid Rule proposed in June 2020¹³ While CMS' final Medicaid rule of December 31st represents a step forward, we believe further clarifications are needed to reduce barriers to innovative, value-based contracts. We would be pleased to provide additional recommendations regarding this barrier and how the Health Care Innovation Caucus could encourage CMS to provide guidance and regulatory changes to clarify price reporting rules and encourage more innovative contracting.

¹¹ Today, the risk of discouraging beneficial arrangements is even greater than in the past. The Affordable Care Act added language to the AKS stating that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the civil False Claims Act]." 42 U.S.C. § 1320a-7b(g).

¹² PhRMA. RFI Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. July 2018. Available at: <https://www.phrma.org/public-communication/rfi-comments-on-hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs>. *Recommendations for specific price reporting clarifications begin on page 103.*

¹³ PhRMA. 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>

If the laws governing innovative contracts are modernized to alleviate uncertainty, innovative contracts would be a tool more easily accessible to manufacturers and payers and could potentially reduce the cost of medicines for patients and payers. For example, 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.¹⁴ 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.¹⁵

II. SUGGESTIONS FOR HEALTH CARE INNOVATION CAUCUS' EFFORT TO CONTINUE TO MODERNIZE STARK AND ANTI-KICKBACK STATUTES AND MEDICAID BEST PRICE TO SUPPORT INNOVATIVE CONTRACTS

A. Feedback on OIG Regulatory Sprint AKS Rulemaking

We hope that our comments on these issues will prompt the Health Care Innovation Caucus to urge OIG to continue modernizing and updating AKS regulations to reflect the changing nature of health care. We agree with statements that suggest that AKS standards should apply consistently across stakeholders and we would urge the Caucus to review the new value-based arrangement safe harbors created at 42 C.F.R. § 1001.952(ee), (ff), and (gg); the patient engagement and support safe harbor proposed at § 1001.952(hh); and the outcomes-based payments provision of the personal services and management contracts safe harbor, proposed at § 1001.952(d)(2) with an eye toward clarity and consistency for all stakeholders. Certain of those safe harbors contain numerous conditions with significant ambiguity, which may make it difficult for stakeholders to confidently comply, and which may benefit from clarification. We also hope that the involvement of the Health Care Innovation Caucus will help generate rulemaking specifically providing AKS protection for innovative contracts between manufacturers and purchasers (including payers), which Secretary Azar,¹⁶ and the preamble of OIG's proposed rule¹⁷ suggested was forthcoming.

In surveys to identify barriers limiting innovative contracts conducted with PhRMA members and payers, both groups identified concerns about implicating the AKS as a barrier.¹⁸ While PhRMA

¹⁴ Michaelson C. SafeGuardRx Saved Enrolled Plans \$4.3 Billion in 2019. March 25, 2020. Available at: <https://www.express-scripts.com/corporate/safeguardrx-value-2019>

¹⁵ Suarez RR. Guest post: Value-based agreements can improve outcomes and even save patients money at the pharmacy counter. PhRMA Catalyst Blog. November 7, 2019. Available at: <https://catalyst.phrma.org/guest-post-value-based-agreements-can-improve-outcomes-and-even-save-patients-money-at-the-pharmacy-counter>

¹⁶ See Michelle M. Stein. Azar: HHS Working on Protections for Value-Based Drug Contracts. Inside Health Policy. October 9, 2019.

¹⁷ CMS. Innovative Treatments Call for Innovative Payment Models and Arrangements. August 30, 2017. Available at: <https://www.cms.gov/newsroom/press-releases/cms-innovative-treatments-call-innovative-payment-models-and-arrangements>.

¹⁸ PhRMA, Barriers to Innovative contracts for Innovative Medicines: PhRMA Member Survey Results (Mar. 2017), available at https://www.statnews.com/wp-content/uploads/2017/03/PhRMA_ValueBased_MemberService_R2122-2.pdf; Alison Ward et

acknowledges that additional hurdles to innovative contracts exist, including Medicaid Best Price issues, addressing the AKS uncertainty may help expand the adoption of low-risk and potentially beneficial arrangements. In a 2018 survey of payers, 76 percent indicate that a modification or addition to existing AKS safe harbors would increase their likelihood of entering into innovative contracts in the next two years.¹⁹

B. Feedback on the CMS Medicaid Best Price rulemaking

Given the substantial benefits that innovative contracts can create, we greatly appreciate CMS' efforts to facilitate innovative contracts through its rulemaking. Specifically, we support CMS' recognition that manufacturers need flexibility when reporting certain Value-Based Purchasing (VBP) sales and discounts we were glad to see the final rule move in that direction, for example, permitting restatements of VBP contracts for periods exceeding 12 quarters with certain clarifications. We believe this rule represents an important step forward and appreciate CMS recognizing the need for regulatory clarity on this issue. However, the rule leaves several important issues unclear, and we are continuing to evaluate the need for potential additional changes with our members. We look forward to continued discussions with the Health Care Innovation Caucus on steps to further support innovative contracts.

III. CONCLUSION

Despite recent growth in innovative contracting arrangements, outmoded public policies that constrain these arrangements have prevented biopharmaceutical research companies from fully participating in the broader movement to promote value-based payment in health care, and limited the number, scale, and types of these arrangements. Through the recent rulemaking from CMS and OIG, parts of these barriers were addressed. However, the lack of AKS protection specifically addressing innovative contracts is still a large barrier. Further, although the recent Medicaid rule provides more flexibility in some areas related to Medicaid rebate price reporting, additional clarity may be needed. We are looking forward to working with the Health Care Innovation Caucus to help find ways to improve clarity under the AKS for innovative contracts for the purchase of pharmaceutical products (and other types of products).²⁰ Such AKS clarity could create broader opportunities for innovative contracts that can offer clinical gains and overall cost savings to payers, providers, and patients throughout the health care system—including Medicaid,

al., Regulatory, Legal Uncertainties Are Barriers to Value-Based Agreements, Health Affairs Blog (Nov. 4, 2016), available at <https://www.healthaffairs.org/doi/10.1377/hblog20161104.057443/full/>.

¹⁹ 2018 Health Strategies Group survey, supra.

²⁰ PhRMA previously submitted this recommendation to the OIG in a series of 2017-2020 comment letters. See, e.g., PhRMA comments to OIG-125-N. Solicitation of New Safe Harbors and Special Fraud Alerts. February 2017, and to OIG-127-N; Solicitation of New Safe Harbors and Special Fraud Alerts. February 2018; PhRMA comments responding to August 2018 OIG Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements, CMP RIN 0936-AA10, October 2018; PhRMA comments responding to OIG-0936-AA10-P. Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to the Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements. December 2019.

Medicare, and their beneficiaries.²¹ Given the clinical and cost-saving gains innovative contracts could bring about, clarifying the AKS standards governing innovative contracts for medicines should be a priority.

²¹ Removing barriers to value-based arrangements with Medicare Advantage plans, Medicare Part D plans, and Medicaid Managed Care plans could lead to government savings by lowering the cost of medicines, improving the use of medicines, and reducing spending on other medical services, ultimately reducing plan spending and plan bids.