

December 20, 2019

VIA ELECTRONIC FILING — <http://www.regulations.gov>

Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Cohen Building, Room 5521
330 Independence Avenue, SW
Washington, DC 20201

Re: 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

Dear Ms. Chiedi:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the proposed rule published by the HHS Office of the Inspector General (OIG) concerning safe harbor protections under the Federal Anti-Kickback Statute (AKS) and exceptions to the Civil Monetary Penalty (CMP) law regarding beneficiary inducements for certain coordinated care, value-based, and patient engagement arrangements.¹ PhRMA is a voluntary, non-profit organization representing the country's leading research-based pharmaceutical and biotechnology companies. PhRMA members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

PhRMA appreciates and applauds HHS' continued commitment to facilitating value-based arrangements that can improve the quality of patient care and optimize healthcare spending. As the OIG recognized in this proposed rule, our health care system is rapidly evolving toward directly compensating health care companies for the value of items and services they provide, rather than reimbursing based on volume alone.

Given OIG's recognition of the critical importance of this shift from volume to value, we were extremely disappointed to see that OIG carved out certain broad categories of entities—including pharmaceutical manufacturers—from the proposed changes. Categorically excluding manufacturers from OIG's newly proposed safe harbors undermines manufacturers' ability to participate in arrangements that improve healthcare quality and efficiency. We understand from discussion in the preamble to the proposed

¹ 84 Fed. Reg. 55694 (October 17, 2019).

rule² and statements from Secretary Azar³ that a proposed rule addressing value-based contracts between manufacturers and purchasers (including payers) is forthcoming. We urge speed in releasing such a proposed rule given its importance—among other needed policy reforms related to government price reporting rules—to incorporating medicines more fully into the value-based care paradigm.

In this letter, we would like to address several overarching themes and statements made by OIG in the proposed rule that seem to suggest that OIG may have an overly narrow view of manufacturers' potential role in the coordination of patient care, and a misunderstanding of their incentives. In addition, we would like to address a related misunderstanding regarding support for patients to promote adherence to their physicians' prescribed treatment regimen.

We hope that our comments on these issues will prompt OIG to reconsider its proposal to exclude manufacturers from the newly proposed safe harbors, especially as each safe harbor includes many safeguards that make the attendant risk of fraud and abuse very low. Specifically, we believe that manufacturers should be able to participate in arrangements that would be protected under the value-based arrangement safe harbors proposed 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).

Finally, we support OIG's proposed changes to the warranty safe harbor, and we hope OIG will consider additional changes to this safe harbor to expand its utility, consistent with what we believe to be OIG's intent in making these proposals. We also support the proposed streamlining changes to the personal services safe harbor; the requirements that OIG proposes to remove from the personal services safe harbor have long kept it from protecting many non-full-time arrangements with low fraud and abuse risks, and we appreciate OIG's efforts to simplify the safe harbor and make it more usable.

I. OIG SHOULD PUBLISH A PROPOSED SAFE HARBOR FOR VALUE-BASED CONTRACTS BETWEEN MANUFACTURERS AND PURCHASERS EXPEDITIOUSLY

As arrangements that tie payment more directly to value become more common, and medicines become increasingly personalized, manufacturers and payers have been exploring innovative payment and coverage approaches that can help improve patient access and affordability. HHS has repeatedly recognized that these approaches can advance its goal of moving from fee-for-service payments toward payment methods that reward quality and value. For example, in 2017, CMS Administrator Seema Verma stated that innovative products “reinforce our belief that the current healthcare payment systems need to be modernized in order to ensure access to new high-cost therapies, including therapies that have the potential to cure the sickest patients.”⁴ CMS emphasized that “[a]s part of larger efforts to support the President's priority [of lowering drug costs], CMS is working actively with all stakeholders . . . on innovative

² 84 Fed. Reg. at 55704.

³ See Michelle M. Stein. Azar: HHS Working on Protections for Value-Based Drug Contracts. Inside Health Policy. October 9, 2019.

⁴ 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>.

payment arrangements” including “outcome-based pricing for medicines.”⁵ In its 2016 final rule on covered outpatient drugs, CMS stated that “[w]e recognize the value of such [value-based payment] arrangements, especially when they benefit patients,” and “since these arrangements are unique, we are considering how to provide more specific [Medicaid rebate] guidance.”⁶ In 2018, CMS approved a State Plan Amendment enabling Oklahoma to negotiate value-based supplemental rebate agreements with manufacturers, and HHS Secretary Azar stated that the Administration “strongly supports innovations like value-based purchasing for prescription drugs.”⁷ Given HHS’ acknowledgment of the importance of value-based arrangements for biopharmaceuticals, we were disappointed to see biopharmaceutical manufacturers largely excluded from the proposed safe harbors. We urge OIG to propose expeditiously practical and administrable safe harbors to protect the range of value-based arrangements applicable to medicines.

Many types of value-based arrangements are already being carried out by manufacturers and health plans within the existing AKS framework. In 2018, PhRMA released an issue brief with a taxonomy of value-based arrangements—including, for example, performance-based contracts such as outcomes-based contracts, indication-based pricing, and variable pricing arrangements such as regimen-based pricing and expenditure caps.⁸ These types of value-based arrangements have the potential to benefit patients and the health care system by improving health outcomes and other endpoints that matter to patients, and reducing medical costs (including the cost of medicines) for both payers and patients. These arrangements can reduce insurers’ cost exposure for treatment failures by allowing the manufacturer to share financial risk. By aligning payments for medicines more directly with their value in improving health outcomes and/or reducing the need for other health care services (such as hospitalizations), value-based arrangements make drug manufacturers accountable for the results their products achieve in a concrete way and can help improve patients’ health and increase the benefits of health care spending.

Importantly, these arrangements also can 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, currently over 1,500 potential gene therapy treatments are in research and development, including nearly 600 targeting cancers and 500 for rare and debilitating or deadly conditions.⁹ 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

⁵ Id.

⁶ 81 Fed. Reg. 5170, 5253 (Feb. 1, 2016).

⁷ CMS. CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers. June 27, 2018. Available at: <https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicare-value-based-arrangements-drug-makers>.

⁸ PhRMA. Delivering Results for Patients: The Value of Value-Based Contracts. February 2018. Available at: <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA-Value-of-Value-Based-Contracts1.pdf>.

⁹ Steven Miller. Gene Therapy Holds Great Promise, But Big Price. September 21, 2017. Available at: <http://lab.express-scripts.com/lab/insights/drug-options/gene-therapy-holds-great-promise-but-big-price>.

drugs more accessible to patients who can benefit from them and increase competition in relevant drug classes.¹⁰

In the longer term, increases in the number and scope of value-based agreements can also generate more information on the effects of different products and treatment regimens on different patient populations.¹¹ Real world evidence on how different treatments affect patients (or patient subgroups) with a certain disease will be available both to providers and patients making individualized, patient-centered treatment decisions, and to payers developing formularies and coverage policies. Over time, this should shift drug utilization toward drugs with greater clinical value and greater ability to reduce hospitalizations and other costly services, resulting in better health outcomes and lower overall health care spending.

The evidence also suggests growth in value-based contracts. For example, 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.¹² 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 percent) of those companies had participated in over 20 of these arrangements.¹³ PhRMA identified 62 publicly announced value-based contracts by 26 pharmaceutical companies for 42 medicines from 2009 through Q2 2019.¹⁴ Further, data from the Academy of Managed Care Pharmacy and PwC's survey confirm that only a portion of value-based arrangements are publicly announced.¹⁵

Despite the growth in value-based pharmaceutical arrangements, outmoded public policies that constrain these arrangements have prevented the biopharma sector 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. For instance, in addition to providing clearer protection for value-based arrangements under the AKS, manufacturers seek clarity from CMS regarding how to address these arrangements under government price reporting rules. Moreover, we are concerned that some of OIG's statements in the proposed rule regarding its perception of manufacturer incentives (which we address more fully below) may discourage value-based arrangements, further restraining the movement toward value-based payment for

¹⁰ 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).

¹¹ For example, one study conducted in Sweden concluded that "stakeholders benefited from analysis of real-world (postmarket) data (in addition to pre-launch, trial-based data)" collected under a value-based pricing agreement. See Deloitte. Value-based Pricing for Pharmaceuticals: Implications of the Shift from Volume to Value. 2012. Available at: <http://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf>.

¹² 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>.

¹³ 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>.

¹⁴ PhRMA. Value-Based Contracts: 2009 - Q2 2019. June 2019. Available at: <https://www.phrma.org/en/Fact-Sheet/Value-Based-Contracts-2009-Q2-2019>

¹⁵ Nirosha Mahendraratnam, PhD et al. Value-Based Arrangements May Be More Prevalent Than Assumed. J Manag Care Spec Pharm. 2019;25(2):70-76.

biopharmaceuticals. In the final rule, we hope that OIG will clarify that its preamble discussions related to manufacturers, and the exclusion of manufacturers from several of the proposed safe harbors, were not intended to discourage manufacturers' participation in value-based arrangements generally. We also continue to encourage HHS to promptly issue a proposed AKS safe harbor for value-based arrangements for the purchase of pharmaceutical products (and other types of products).¹⁶ Such a safe harbor could create broader opportunities for value-based agreements that can offer clinical gains and overall cost savings to payers, providers, and patients throughout the health care system—including Medicaid, Medicare, and their beneficiaries.¹⁷ Given the clinical and cost-saving gains such a safe harbor could bring about, development of a safe harbor for pharmaceutical value-based arrangements should be an HHS priority.

II. OIG SHOULD CONSIDER INCLUDING MANUFACTURERS IN THE CARE COORDINATION, PATIENT ENGAGEMENT, AND OUTCOME-BASED PAYMENT SAFE HARBORS

OIG proposes to exclude manufacturers from key safe harbors in the proposed rule—those that involve care coordination, value-based arrangements, patient engagement tools, and outcome-based payments. In doing so, OIG expresses concern that manufacturers would use these arrangements to market their products, rather than as a means to create value for patients and payers by improving the coordination and management of patient care, reducing inefficiencies, or lowering health care costs.¹⁸ Moreover, OIG argues that manufacturers are less likely to be on the front lines providing care coordination and management tools and services directly to patients. We believe these arguments inaccurately characterize manufacturers' interests and incentives, as well as their role in care coordination, particularly as the entire healthcare industry moves toward value-based care and personalized, patient-centered medicine.

A. Manufacturers' Incentives Align with Drug Efficacy and Safety for Patients

First, OIG seems to suggest that manufacturers' incentives are not aligned with creating value for patients and the healthcare system more broadly. Our members' success in developing and delivering medicines to help patients live longer and healthier lives depends on ethical relationships and behavior. PhRMA and its members strongly support a legal and regulatory framework that facilitates innovation, promotes patient health and safety, and protects against fraud and abuse. Our members voluntarily ascribe to a series of PhRMA-developed ethical codes and guidelines, including the Code on Interactions with Health Care Professionals,¹⁹ which reinforce our intention that our interactions with health care professionals are professional exchanges designed to benefit patients and to enhance the practice of

¹⁶ PhRMA previously submitted this recommendation to the OIG in a series of 2017-2018 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.

¹⁷ 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.

¹⁸ 84 Fed. Reg. at 55703-04.

¹⁹ PhRMA Code on Interactions with Healthcare Professionals. Available at: <https://www.phrma.org/Codes-and-guidelines/Code-on-Interactions-with-Health-Care-Professionals>. All PhRMA codes and guidelines are available at: <https://www.phrma.org/en/Codes-and-guidelines>.

medicine. The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Moreover, the safety and efficacy of our medicines upon which value-based arrangements are based are critical to business success of the biopharmaceutical industry, aligning companies' financial incentives with the best interests of patients. Through a combination of market forces, regulatory frameworks, and legal enforcement mechanisms, manufacturers have strong incentives to ensure that their products produce safe and effective results and avoid harm. Before a prescription drug may be sold in the United States, it must go through the Food and Drug Administration's (FDA's) rigorous approval to assure that the drug is safe and effective. The FDA may remove a drug from the market if safety issues are identified after approval such that the benefit-risk profile is no longer favorable. Additionally, physicians make independent medical decisions about whether to prescribe a drug based on the drug's clinical and safety profile; these trained clinicians will not prescribe products for their patients—and manufacturers therefore will not sell their products—unless they and the FDA have determined that the products' benefits outweigh their risk and that they are safe and effective for the intended use. Thus, a drug's ability to enter and remain in the market and its commercial success are closely tied to its efficacy and safety. Additionally, manufacturers' promotional materials are required to be truthful and not misleading, and all advertising is submitted to the FDA. Furthermore, a highly active plaintiffs' bar in the areas of torts and product liability further reinforces manufacturers' care in ensuring their products are safe.

Second, as discussed earlier, manufacturers are increasingly participating in arrangements that base their payment for medicines on the outcomes those medicines help patients achieve. Among other things, these arrangements enhance incentives for manufacturers to be attentive to how their products are used and whether the patients who use their products are those who benefit clinically. Ironically, for many years now, PhRMA and drug manufacturers have been asking OIG for a safe harbor to reduce anti-kickback uncertainty associated with outcome-based payments—such a safe harbor could expand outcome-based payment arrangements between manufacturers and purchasers (including payers), accelerate the transformation in the pharmaceutical industry from volume to value, and increase manufacturers' already significant incentives to obtain the best possible outcomes for patients. If OIG believes that manufacturers' incentives do not align well with the goal of improving the quality of patient care, then an outcome-based safe harbor applicable to manufacturers would speed the current transition to rewarding manufacturers more directly for the value they bring to patients.

B. Manufacturers' Increasing Role in Care Coordination and Management

Today, manufacturers play a key role in a variety of activities that promote care coordination and management, and this role is likely to increase with the use of technology to optimize patient outcomes and with the personalization of medicine. We are in a new era of medicine in which science is transforming patient care and enabling us more effectively to treat chronic disease, the biggest cost driver in our health care system. These treatments only work as intended, however, if taken in accordance with the prescribed regimen. As of 2016, chronic diseases accounted for more than \$2 trillion in health care spending per year

and about six out of every seven dollars spent on health care.²⁰ Today, more than 7,000 medicines are in development worldwide, of which 42 percent are personalized medicines.²¹ The changing nature of medicine and related technologies provide new opportunities for product manufacturers to support care coordination and management of patients treated with their products. As OIG works to modernize the safe harbors to the AKS, we encourage the agency to consider the characteristics of the therapies of today and tomorrow.

Manufacturers are well-positioned to support healthcare providers' care coordination and management. Through drug discovery, candidate refinement, clinical trials, manufacturing, and post-marketing surveillance activities, manufacturers acquire unique and deep knowledge about their products, the related diseases and conditions, and the conditions that can optimize patient outcomes. Sharing that knowledge and providing related information and support to patients and their providers in appropriate circumstances can improve outcomes and reduce risks. We are concerned that OIG's statements do not sufficiently recognize the potential value of manufacturers' contributions to patient care. Because manufacturers know the most about their own products, they are a vital source of data and real-world experience. By analogy, Ford—as the expert on its own vehicles—is a valuable source of information regarding those vehicles. It would make no sense to prevent a buyer or the buyer's mechanic from accessing that expertise, using Ford-created resources, or contacting Ford for technical support to understand how to use the car's features or to optimize performance of the car. Here too, patients and providers should be able to access information and support from experts on the selected medication.

Today, manufacturers increasingly support patient care coordination and management through tools such as data analytics and technology tied to medications. For instance, wearable devices and other devices linked to medicines can allow healthcare providers to monitor patient conditions and medication adherence remotely.²² Pairing a “smart” pill that can track medication adherence with a wearable device to measure a patient's vital signs can help healthcare professionals remotely monitor patient responses to treatment regimens and adjust treatment plans if needed.²³ Similarly, manufacturers of drugs intended to treat asthma and chronic obstructive pulmonary disease (COPD) have partnered with medical technology companies to place sensors on inhalers, which are linked to patient and provider software applications²⁴; these sensors track information about usage of the inhaler, as well as environmental triggers for respiratory

²⁰ Aspen Health Strategy Group. Reducing the Burden of Chronic Disease, at 10. 2019. Available at https://assets.aspeninstitute.org/content/uploads/2019/02/AHSG-Chronic-Disease-Report-2019.pdf?_ga=2.173209259.983765558.1575917923-2024544556.1575917923.

²¹ Long G. The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development. Analysis Group. 2017; Tufts Center for the Study of Drug Development (CSDD). Personalized Medicine Gains Traction But Still Faces Multiple Challenges. Tufts CSDD Impact Report. 2015;17(3).

²² David Champagne et al. The Road to Digital Success in Pharma. McKinsey & Co. August 2015. Available at: <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-road-to-digital-success-in-pharma>.

²³ *Id.*

²⁴ Propeller. Press Release: Propeller Health Enters Into Collaboration to Connect Breezhaler Devices to the Propeller Platform. February 8, 2017. Available at: <https://www.propellerhealth.com/2017/02/08/propeller-health-enters-into-collaboration-to-connect-breezhaler-devices-to-the-propeller-platform/>; Propeller. Press Release: Propeller Health Announces Expansion of Digital Health Collaboration with GlaxoSmithKline to Improve Management of Asthma and COPD. August 24, 2017. Available at: <https://www.propellerhealth.com/2017/08/24/propeller-health-announces-expansion-of-digital-health-collaboration-with-glaxosmithkline-to-improve-management-of-asthma-and-copd/>.

events,²⁵ and can pass this information back to healthcare providers.²⁶ Use of these sensors in conjunction with drugs to treat asthma have been shown in clinical trials to support adherence and reduce acute asthma events.²⁷ Additionally, wearable drug delivery systems can allow patients with chronic conditions or patients requiring delivery of a large dose of a biologic product over time to administer treatments at home.²⁸ Bluetooth capabilities can be built into these wearable drug delivery systems, allowing healthcare providers to monitor patient adherence.²⁹

Beyond supporting individual patients' treatment, manufacturers can use these technologies to support post-approval surveillance and to gather important real-world evidence. For instance, researchers have used the Verily Study watch to capture health information from clinical research participants using biometric, environmental, and movement sensors. The watch received 510(k) clearance from the FDA as a Class II medical device for its on-demand electrocardiogram (ECG) feature. By providing these types of technologies to patients, manufacturers can not only improve individual patient outcomes, but gather important real-world evidence about the safety and effectiveness of their biopharmaceutical products. This evidence can be used for a variety of purposes, such as (i) identifying areas for product improvement; (ii) identifying supports or practices that optimize product effectiveness; (iii) identifying patterns with respect to adverse events and product safety; (iv) supporting healthcare providers' clinical decision-making; and (v) forming the basis for value-based contracts.

In addition, pharmaceutical manufacturers have access to a wide range of data generated through preclinical and clinical trials and post-marketing studies, and patient support activities, among other sources.³⁰ This data can be used and analyzed in a variety of different ways to improve care management for patient populations or particular patients. For instance, predictive analytics that use this data can be an indispensable tool for clinicians and has been applied successfully in several areas of medication management, such as in the identification of complex patients or those at highest risk for noncompliance or adverse events.³¹ Conversely, data may be used to help healthcare providers identify patients or groups of patients for whom a specific treatment may be particularly beneficial.³² This type of data may be particularly

²⁵ Propeller. How it Works. Available at: <https://www.propellerhealth.com/how-it-works/> (last visited Nov. 7, 2019).

²⁶ Propeller. Press Release: Propeller Health Announces Expansion of Digital Health Collaboration with GlaxoSmithKline to Improve Management of Asthma and COPD. August 24, 2017. Available at: <https://www.propellerhealth.com/2017/08/24/propeller-health-announces-expansion-of-digital-health-collaboration-with-glaxosmithkline-to-improve-management-of-asthma-and-copd/>.

²⁷ Chris Gale. Pharma and Wearables Need Each Other - and Communities. European Pharma. Mfr. October 29, 2018. Available at: <https://www.epmmagazine.com/opinion/pharma-and-wearables-need-each-other-and-communities/>.

²⁸ Wearable Injectors. On Drug Delivery. September 2019. at 4. Available at: <https://www.ondrugdelivery.com/wp-content/uploads/2019/09/Wearable-Injectors-ONdrugDelivery-Issue-100-September-2019-MR.pdf>. See also Enable Injections. Press Release: Enable Injections Enters into Strategic Partnership with Sanofi. June 3, 2019. Available at: https://www.prnewswire.com/news-releases/enable-injections-enters-into-strategic-partnership-with-sanofi-300859890.html?tc=eml_cleartime.

²⁹ *Id.* at 7.

³⁰ Nigel Walker. The Evolution of Pharma Depends on Data Integration and Application. Pharma's Almanac. October 26, 2018. Available at: <https://www.pharmasalmanac.com/articles/the-evolution-of-pharma-depends-on-data-integration-and-application>.

³¹ Inmaculada Hernandez & Yuting Zhang. Using Predictive Analytics & Big Data to Optimize Pharmaceutical Outcomes. 74 Am. J. Heal.-Sys. Pharmacy 1494, 1499. Sept. 15, 2017.

³² *Id.*

valuable for patients with rare diseases, where manufacturers may have better information about patient experience on a product than providers, who may have less direct experience with the particular disease due to its rarity. One example of a manufacturer/provider care management initiative that leverages manufacturer data and expertise to improve risk assessment and associated care management is a partnership between pharmaceutical manufacturer and an Integrated Delivery Network (IDN) to assess how to operationalize and apply existing models for bone fracture risk into an Electronic Medical Record (EMR) system. Osteoporosis has a significant impact on patients and the healthcare system. Roughly half of all women and more than a quarter of all men develop a fracture after the age of 50 due to osteoporosis. Proper identification, screening, diagnosis and treatment of this population is essential to long term disease management and outcomes (i.e., avoiding fractures). In this partnership, both the manufacturer and IDN contribute staffing and resources. The manufacturer has unique expertise and data regarding osteoporotic fractures and the IDN has unique expertise regarding its EMR and patient touch points with the IDN.

Moreover, manufacturers' involvement in care coordination may be necessary with the advancement of therapies like personalized cell therapies, which use modified versions of patients' own cells to treat disease. For instance, adoptive cell transfer (ACT) is a rapidly emerging immunotherapy approach to treating cancer. This approach involves collecting and using patient's own immune cells to attack cancerous tumors. There are several types of ACT, but thus far, the one that has advanced furthest in clinical development is called CAR-T cell therapy. Manufacturing of the drug requires providers to draw blood from a patient and separate their T cells. Those T cells are then shipped to the manufacturer, which genetically engineers the drug from the cells and ships it back to the provider for infusion into the patient. The process of successfully manufacturing and administering CAR-T cell therapies requires close coordination between healthcare providers and manufacturers to ensure that the process is timed correctly and appropriately managed. This type of collaboration between manufacturers and providers will likely increase with the advancement of these types of personalized medicines and the AKS safe harbors should not only take these realities into account, but foster arrangements that will promote the successful use of these treatments.

C. Including Manufacturers in the Finalized Safe Harbors is Appropriate to Promote Care Coordination and Quality of Care

We hope that based on the points discussed above, the OIG will revisit its proposal to exclude manufacturers from the key safe harbors in the proposed rule related to value-based arrangements, patient engagement and support, and outcomes-based payments. We believe that including manufacturers in the finalized safe harbors is appropriate to promote care coordination and quality of care, especially given that the proposed safe harbors all include a comprehensive set of safeguards, which are more than adequate to prevent fraud and abuse. In fact, we understand that many providers have expressed concern that the complexity of the proposed safe harbors and potential subjectivity of certain standards may limit the utility of the proposed safe harbor, due to uncertainty about technical non-compliance.

If our collective societal goal is to drive toward better outcomes and less waste, then that goal can be strengthened by allowing manufacturers to participate in sharing data, expertise, and technology (e.g., health apps) with others to, for example, increase health literacy, reinforce adherence, and address access hurdles by helping connect patients to supporting services. Medicines are effective and efficient tools to address and even cure disease, and as such pharmaceutical companies should be able to share clinical data and patient insights with others to understand and address shortcomings in care coordination and management. In addition to research, development, and manufacturing, our members expend significant

resources identifying how their medicines can best optimize patient outcomes and sharing that information with, and providing related support to, healthcare providers and patients. As experts in their medicines, our members have specialized knowledge that should be leveraged to optimize care.

Moreover, pharmaceutical manufacturers increasingly are diversified entities that include corporate affiliates and business units that provide health technologies, care coordination and clinical management, and other offerings and services. There is recognition³³ and evidence that improving the health of our nation requires partnership and breaking down silos among manufacturers, pharmacists, healthcare social services providers, and public health officials, as no single entity is able to address the environmental factors that can influence 80 percent of health outcomes.³⁴ In a recent survey of 200 specialist physicians, 85 percent agreed there is a role for biopharmaceutical companies in value-based arrangements—specifically around providing services that can help patients remain adherent and reach the agreed upon outcome.³⁵ Given this diversification, need for coordination, and innovative functions that all entities can perform, we respectfully submit that the coordinated care safe harbors proposed by OIG should be entity-agnostic, based on the nature of the agreement and attendant safeguards. Discouraging manufacturers from full participation in value-based care by excluding them from safe harbor protection is not in the best interest of patients or the healthcare system more broadly.³⁶

While making these safe harbors entity-agnostic would expand the ways in which all entities could contribute to value-based care, it would not diminish the need to create a separate safe harbor to specifically address value-based contracts between manufacturers and purchasers (including payers) for product purchases. OIG recognizes in the preamble to the proposed rule that it may consider such rulemaking, and we urge the OIG to move forward with this proposal as soon as possible.

III. BACKGROUND ON THE IMPORTANCE OF MEDICATION ADHERENCE AND THE ROLE OF ADHERENCE SUPPORT

Based on OIG's comments in the preamble to the proposed rule, we are concerned that the agency misunderstands the purpose and effect of manufacturer adherence support. Specifically, while discussing its proposal to protect warranties applicable to a combination of items and services, OIG states:

³³ See, e.g., Health Care Transformation Task Force, An Actionable Framework for Health Care and Public Health Collaboration 2019. Available at: <https://hcttf.org/comprehensive-community-wellness-framework/>.

³⁴ Bachrach, D., Guyer, J., Meier, S., et al. Enabling Sustainable Investment in Social Interventions: A Review of Medicaid Managed Care Rate-Setting Tools. The Commonwealth Fund. January 2018. Available at: www.commonwealthfund.org/publications/fund-reports/2018/jan/enabling-sustainable-investmentsocial-interventions-review. In a separate 2018 survey by Waystar's Consumer Perspectives on How Social Determinants Impact Clinical Experience report found that 68 percent of Americans have at least 1 social determinant challenge and 52 percent have moderate to high SDoH risk in at least 1 SDoH category—financial insecurity, social isolation, housing insecurity, addiction, transportation access, food insecurity, or health literacy. See <https://www.ajmc.com/focus-of-the-week/survey-highlights-high-prevalence-of-social-determinant-challenges-need-to-better-address-them>.

³⁵ Health Strategies Insights. 2019. Online survey of board-certified physicians treating a minimum of 100 patients per month (35 cardiologists, 35 endocrinologists, 34 rheumatologists, 26 oncologists, 35 neurologists, 35 primary care physicians; n=200) [hereinafter 2019 Health Strategies Insights survey].

We are mindful that the provision of certain warranted services, such as medication adherence services by manufacturers and suppliers, could increase the risk of patient harm and inappropriate utilization because manufacturers and many suppliers do not necessarily have direct patient care responsibilities and thus may not have the same patient safety considerations that physicians and providers with direct patient care responsibilities have. Using medication adherence services offered by drug manufacturers as an example, we are concerned that manufacturers may promote patients' adherence to prescribed medications, even when a patient is experiencing harmful side effects, or the medication is not achieving the purpose for which it was prescribed. Because manufacturers have financial incentives for patients to use and reorder their medications but do not have the medical expertise the prescribing physicians have to determine whether continued use of medications is clinically appropriate for a specific patient, medication adherence services offered by manufacturers, such as phone or message communications directing patients to take their medications, could result in patient harm or inappropriate utilization of drugs.³⁷

First, we take exception to the idea that because manufacturers do not have direct patient care responsibilities they are less concerned with patient safety than providers. PhRMA's member companies are devoted to discovering and developing safe and effective medicines that enable patients to live longer, healthier, and more productive lives; our member companies have invested over \$900 billion in the search for new treatments and cures since 2000, including an estimated \$79.6 billion in 2018 alone. In other words, the mission of our member companies is to improve patients' health and well-being.

Second, as described in Section II.A, above, manufacturers' financial, regulatory, reputational, and legal incentives are aligned with patient safety. Adherence support by manufacturers is intended to help a patient follow the treatment regimen recommended by his or her healthcare provider, which should be designed to optimize the benefits of the medication for that patient. Medication adherence support can enhance the efficacy of the product in patients and improve patient health and quality of life and healthcare system efficiencies, and they present a low risk of fraud and abuse when properly structured.

A. Medication Adherence Improves Patient Outcomes and Reduces Healthcare System Costs

Nonadherence—the problem of patients not taking medications in accordance with their healthcare providers' directions, or otherwise not following their providers' treatment recommendations—is a major health problem, leading to poor clinical outcomes and increased healthcare spending. As the World Health Organization reported:

Poor adherence to long-term therapies severely compromises the effectiveness of treatment making this a critical issue in population health from both the perspective of quality of life and of health economics.

³⁷ 84 Fed. Reg. at 55748.

Interventions aimed at improving adherence would provide a significant positive return on investment through primary prevention (of risk factors) and secondary prevention of adverse health outcomes.³⁸

For patients with chronic conditions, the estimated medication adherence rate is only 50 to 60 percent.³⁹ An estimated 125,000 people die each year as a result of medication nonadherence, although studies of medication nonadherence in patients with specific conditions such as heart failure suggest that this number may be even higher.⁴⁰ Engaging with patients to support their medication adherence can lead to improved patient outcomes and reduced healthcare costs.⁴¹ Improving medication adherence has been shown to lead to better patient outcomes, including fewer hospitalizations and emergency room visits.⁴² Moreover, annual costs of medication nonadherence in the United States are estimated to be in the hundreds of billions of dollars,⁴³ with suboptimal medication usage (including nonadherence) costing an estimated \$528 billion per year and representing 16% of total healthcare costs in the United States in 2016.⁴⁴ Thus, improved medication adherence can result in significant cost savings, even taking into consideration spending aimed at improving adherence.⁴⁵

B. Manufacturer-Sponsored Adherence Support Has Important Clinical Benefit for Patients and Presents a Low Risk of Fraud and Abuse

Properly structured manufacturer-sponsored adherence support does not implicate the Anti-Kickback Statute and presents a low risk of fraud and abuse that is far outweighed by the clinical benefit for patients. First, consistent with existing OIG guidance, adherence support is not “remuneration” under the AKS because it does not have independent value. Perplexingly, the preamble to the proposed rule

³⁸ World Health Organization. Adherence to Long-term Therapies: Evidence for Action. 2003. Available at: https://www.who.int/chp/knowledge/publications/adherence_report/en/.

³⁹ Fred Kleinsinger. The Unmet Challenge of Medication Nonadherence. Perm. J. 2018, at 1.

⁴⁰ *Id.* at 1,3.

⁴¹ Leah L. Zullig & Hayden Bosworth. Engaging Patients to Optimize Medication Adherence, NEJM Catalyst. May 14, 2017. Available at: <https://catalyst.nejm.org/optimize-patients-medication-adherence/>.

⁴² See, e.g., Sarah E. Curtis et al., Medication Adherence and Improved Outcomes Among Patients with Type 2 Diabetes. Am. J. Managed Care. July 2017. Available at: <https://www.ajmc.com/journals/issue/2017/2017-vol23-n7/medication-adherence-and-improved-outcomes-among-patients-with-type-2-diabetes>.

⁴³ Viswanathan et al., Medication Adherence Interventions: Comparative Effectiveness. Closing the Quality Gap: Revisiting the State of the Science, Evidence Report/Technology Assessment prepared for the Agency for Healthcare Research and Quality. September 2012. at 3; Prescriptions for a Healthy America. A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination. October 2017.

⁴⁴ Jonathan H. Watanbe, et al., Cost of Prescription Drug-Related Morbidity and Mortality. 52 Annals of Pharmacotherapy 829. 2018.

⁴⁵ Julie A. Patterson et al., Cost-Benefit of Appointment-Based Medication Synchronization in Community Pharmacies. Am. J. Managed Care. September 2016). Available at: <https://www.ajmc.com/journals/issue/2016/2016-vol22-n9/cost-benefit-of-appointment-based-medication-synchronization-in-community-pharmacies>; Jennifer Kim, et al., Medication Adherence: The Elephant in the Room. U.S. Pharmacist. January 19, 2018. Available at: <https://www.uspharmacist.com/article/medication-adherence-the-elephant-in-the-room>.

suggests that the provision of medication adherence services has independent value and thus implicates the AKS when offered for free or below fair market value.⁴⁶

In fact, adherence support activities are not services with an “independent value” apart from the underlying product: the OIG has said that support provided by a manufacturer connected to its own product, such as limited reimbursement support, has no independent value and does not implicate the AKS.⁴⁷ The OIG consistently has distinguished between free items and services that are integrally related to the offering provider’s or supplier’s services and those that are not. For instance, in the preamble to the 1991 Final Rule implementing certain AKS safe harbors, OIG stated that a free computer provided to a physician by a laboratory would have no independent value to the physician if the computer could be used only, for example, to print out test results produced by the laboratory. In contrast, a free personal computer that the physician could use for a variety of purposes would have independent value and could constitute an illegal inducement.⁴⁸

Adherence support’s exclusive value is to help ensure that patients follow the treatment regimen prescribed by their doctor, and therefore are using the product in question in a way that optimizes its results. Activities that promote adherence to a prescribed medicine are a classic example of activities integrally related to the underlying product that do not have independent value apart from the medicine itself. With respect to patients, OIG has long held that these activities provide “no actual or expected economic or other actionable benefit” and do not implicate the AKS.⁴⁹

We believe that manufacturer activities to support adherence also provide “no actual or expected economic or other actionable benefit” to physicians or other health care providers, and thus have no independent value to providers that would implicate AKS concerns. While the OIG has suggested previously that certain manufacturer-sponsored adherence supports could have independent value to providers by “replac[ing] actions the [health care providers] might otherwise take, and consequently defray[ing] expenses the [providers] might otherwise incur,”⁵⁰ we think the likelihood of manufacturer adherence supports leading providers to reduce their own efforts to improve their patients’ medication adherence is very small and we are not aware of any evidence of this occurring. Given the importance of adherence, a variety of strategies to promote adherence are currently being used,⁵¹ and the chance that a manufacturer-supported strategy would duplicate the provider’s strategy (which most likely is focused on discussing a patient’s adherence and any problems with adherence he or she is having, in the context of office visits) seems minimal. Further, research and observations suggest that in some cases combining

⁴⁶ 84 Fed. Reg. at 55478 n.83.

⁴⁷ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735 (May 5, 2003).

⁴⁸ 56 Fed. Reg. 35952, 35978 (July 29, 1991).

⁴⁹ See, e.g., OIG Adv. Op. No. 11-07, at 7 (June 1, 2011).

⁵⁰ OIG Adv. Op. No. 11-07, at 7. Importantly, the OIG concluded that the program at issue (a vaccine reminder program) presented a low risk of fraud and abuse and increased the quality of health care services and thus the OIG would not impose sanctions in connection with the arrangement. *Id.* at 8.

⁵¹ See, e.g., Costa E et al., Interventional tools to improve medication adherence: a review of literature. *Patient Preference and Adherence* 2015:9 1303-1314 (article reviews most frequent interventions employed to improve medication adherence (including behavioral interventions, educational interventions, integrated care interventions, self-management interventions, and risk communication interventions) as well as outcomes achieved).

several adherence interventions may be the best approach to improve patients' adherence⁵²—making it even less likely that providers would respond to a third party supporting certain adherence interventions by cutting back on their own efforts. In addition, it should be noted that some third-party adherence supports could increase (rather than diminish) providers' work (such as tools that furnish providers with data on their patients' adherence patterns, which would require providers to monitor and evaluate the data, and could facilitate more informed and expanded conversations with patients). Given all these considerations, we do not think that manufacturer adherence supports can reasonably be seen as leading providers to reduce their efforts to help their patients improve adherence, and thus as enabling providers to cut costs. Accordingly, we encourage the OIG to revisit this idea and recognize that manufacturer adherence supports do not have independent value to providers.

Moreover, adherence support presents a low risk of fraud and abuse while providing important benefits to the Federal health care programs. For example, as the Department of Justice argued in seeking dismissal of a series of *qui tam* suits related to manufacturer-sponsored nurse support activities, "given the vast sums the government spends on the medications at issue, federal healthcare programs have a strong interest in ensuring that, after a physician has appropriately prescribed a medication, patients have access to basic product support relating to their medication."⁵³ Further, manufacturer-sponsored adherence support is characterized by the same mitigating prudential factors that the OIG has cited favorably in past advisory opinions regarding adherence and reminder programs.⁵⁴

First, these programs would not interfere with clinical decision-making. These programs are available to patients only after providers have made independent clinical decisions about their patients' treatment.⁵⁵ Moreover, manufacturers make this support available to patients irrespective of their choice of

⁵² See, e.g., Neiman AB, Ruppert T, Ho M, et al., CDC Grand Rounds: Improving Adherence for Chronic Disease Management—Innovations and Opportunities. MMWR Morb Mortal Wkly Rep 2017; 66. Available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm> (reporting that "[s]uccessful efforts to improve rates of adherence often incorporate multiple strategies across the continuum of care" and "[i]nterventions that include team-based or coordinated care have been shown to increase adherence rates. In a recent study, patients assigned to team-based care, including pharmacist-led medication reconciliation and tailoring; pharmacist-led patient education; collaborative care between pharmacist and primary care provider or cardiologist; and two types of voice messaging (education and medication refill reminder calls) were significantly more adherent with their medication regimen 12 months hospital discharge (89%) compared with patients not receiving team-based care (74%)"). See also CDC, Medication Adherence—Strategies and Emerging Interventions for Improving Medication Adherence. Available at: https://www.cdc.gov/dhsp>pubs>docs>SIB_feature_Aug2017 (no gold standard solution exists to improve medication adherence, although "studies have identified several strategies that can improve adherence...[a] combination of evidence-based strategies and emerging practices is likely the best approach to increasing medication adherence for cardiovascular disease.... Combining two or more intervention strategies across different dimensions may work best").

⁵³ See, e.g., U.S. ex rel. Health Choice Group, LLC v. Bayer Corp. et al., No. 5:17-cv-00126 (N.D. Tex.); U.S. ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co., No. 5:17-cv-123 (E.D. Tex.).

⁵⁴ For arrangements that may implicate the AKS but fall outside a safe harbor, the OIG's enforcement efforts typically focus on factors that could create risks to federal healthcare programs or their beneficiaries (commonly referred to as "prudential factors"). OIG has expressed most concern with arrangements that may (i) interfere with clinical decision-making; (ii) increase costs to federal health care programs; (iii) cause overutilization or inappropriate utilization; (iv) raise patient safety or quality of care concerns; (v) or (vi) result in unfair competition. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734 (May 5, 2003). See also OIG Adv. Op. No. 12-19 (Dec. 7, 2012).

⁵⁵ See, e.g., OIG Advisory Opinion No. 11-07 ("The Requestor has little opportunity to influence referrals, because the only recipients of the Program reminder messages are the parents and guardians of children who already have been prescribed and received at least one dose of the Requestor's vaccine").

insurance or provider, and thus without regard to any health insurer's or healthcare entity's overall volume or value of expected or past prescribing of the manufacturers' products.⁵⁶ Thus, these activities are unlikely to serve as a "reward" or "inducement" for referrals.

Second, these programs do not lead to patient steering. Adherence support is unlikely to influence patients' selection of a provider, practitioner, or supplier because these programs are broadly available and typically offered only after the patient had made those decisions.⁵⁷ In addition, they will not steer patients to particular treatments because the patient's provider must have already selected the treatment.

Third, these programs do not encourage overutilization. The goal of adherence programs is to help patients use their medication or other recommended treatments consistent with their healthcare providers' independent instructions. Thus, while utilization of recommended treatments may increase as a result of adherence services, such an increase likely would result in appropriate utilization.⁵⁸

Fourth, these programs promote quality of care and improve health outcomes. As described above, significant research demonstrates that better medication adherence improves patient outcomes. A recent survey across a wide variety of physician specialties found that 97 percent agree that a patient with high adherence will be more likely to see positive outcomes.⁵⁹ Adherence programs increase the quality of care by helping patients correctly follow the treatment regimen recommended by their provider, and should thus help improve health outcomes.⁶⁰ In the preamble to the proposed rule, OIG seems to express concern that "manufacturers may promote patients' adherence to prescribed medications, even when a patient is experiencing harmful side effects, or the medication is not achieving the purpose for which it was prescribed." While we appreciate and agree with OIG's focus on patients, there are important core elements of the healthcare system in the U.S. that would substantially diminish the possibility of this result. First, manufacturers have an obligation to report adverse events to FDA, and a patient support program with direct contact between manufacturers and patients could tend to result in more reports to FDA by manufacturers, not fewer. Second, as noted above, a highly active plaintiffs' bar in the areas of torts and products liability further reinforces manufacturers' care in ensuring their products are safe and creates incentives opposite to those that OIG fears. Third, as we discussed above, manufacturers' business and regulatory incentives, risk of reputational harm, and their corporate missions all weigh against any

⁵⁶ See, e.g., OIG Advisory Opinion No. 11-07 ("The [vaccination reminder] Program services are made available on an equal basis to all health insurers and healthcare entities without regard to any health insurer's or healthcare entity's overall volume or value of expected or past referrals to the Requestor's products.").

⁵⁷ See, e.g., OIG Advisory Opinion No. 13-10 (regarding a program that provides 24-hour assistance in compliance with a particular hospital's discharge plans, "the Proposed Arrangement would not involve providing any rewards or incentives to Participating Patients that would be likely to influence their selection of a provider, practitioner or supplier; the Proposed Arrangement primarily makes available a person to remind Participating Patients to follow a discharge plan that was established independently of the Proposed Arrangement and assist Participating Patients with administrative tasks.").

⁵⁸ See, e.g., OIG Advisory Opinion No. 13-10 ("Although the Services could increase utilization (e.g., by reminding participating Patients to take their medications or attend necessary follow-up visits), such an increase likely would result in appropriate utilization by helping the Participating Patient comply with the hospital's discharge plan.").

⁵⁹ 2019 Health Strategies Insights survey, supra.

⁶⁰ See, e.g., OIG Advisory Opinion No. 11-07 ("[T]he [vaccination reminder] Program increases the quality of healthcare services by helping health insurers and healthcare entities remind the parents and guardians of Eligible Children that their children might need to finish a course of previously prescribed vaccinations.").

manufacturer activity that could potentially worsen the results that patients achieve from the manufacturers' medicines; instead, manufacturers have every reason to strive for improved outcomes, especially today as manufacturers increasingly receive net payments tied more closely to patient outcomes. Finally, as for a drug not achieving the purpose for which it was prescribed, the patient's health care provider acts as a built-in control. The health care provider, and only the healthcare provider, is in charge of deciding whether a prescription can be renewed.

Finally, these programs will not increase costs to Federal health care programs. As discussed above, adherence programs are likely instead to decrease Federal health care program costs by reducing hospitalizations, emergency room visits, and avoidable complications.⁶¹

C. The Role of Medication Adherence in Value-Based Arrangements

For several reasons, adherence has a central role in value-based agreements. Appropriate adherence is a crucial component of outcome-based contracts, where payments vary based on the product's effect on patient outcomes and/or costs of care. In outcome-based contracts, manufacturers receive smaller net payments when a medication does not result in specified outcomes, which cannot be accurately assessed unless patients take the medicine as prescribed. Thus, many outcomes-based contracts include provisions to track adherence so as to distinguish outcomes associated with nonadherence from those associated with correct use of the product. For instance, an agreement may stipulate that patients must have taken a medication correctly for six months before a certain adverse clinical event (e.g., a hospitalization) for the manufacturer to pay an outcome-based rebate as a result of that clinical event. Patients who are not appropriately adherent to their medications may thus be excluded from calculation of the outcomes metrics because the benefit of the medicine (or lack thereof) cannot be accurately measured in those patients.⁶² As noted above, adherence programs can play an important role in helping patients follow their prescribed treatment regimens. When these programs are part of outcomes-based contracts, manufacturers are rewarded for their product working as intended to promote patients' health and safety, and penalized for their product not working well for patients. In other words, instead of creating risks to patient safety, adherence activities improve the alignment between manufacturers' incentives and patients' health and safety. This further reduces any perceived risks associated with manufacturers providing adherence services.

For all these reasons, adherence services are important and integral parts of the shift from volume-based to value-based care, and manufacturers can provide these services without creating patient safety risks. In fact, discouraging adherence services could have adverse consequences for patient outcomes and undermine efforts to move to value-based care. We urge the OIG to rethink its position on these services.

⁶¹ See, e.g., OIG Advisory Opinion No. 13-10 ("The Services [which assist patients in following their hospital discharge plan] could potentially save the Federal health care programs money if the Proposed Arrangement is successful in furthering its goal of decreasing excess hospital readmissions.").

⁶² Further, in some cases medication adherence may be a relevant proxy for clinical outcomes and some value-based agreements thus base manufacturers' net payments on patients' adherence. See Mahendraratnam, N, et al. Value-based arrangements may be more prevalent than assumed. *Am J Manag Care* 25.2 (2019): 70-76. Adherence can be the best available evidence of whether the patient is benefitting from the medicine in certain cases where direct measurement of the clinical outcome may be difficult. See Kevin McCaffrey, *Armed with Predictive Analytics, PBMs Push Adherence as a Stand-In for Outcomes*, MM&M. Nov. 9, 2017. Available at: <https://www.mmm-online.com/home/channel/commercial/armed-with-predictive-analytics-pbms-push-adherence-as-a-stand-in-for-outcomes/>.

Moreover, we encourage OIG, when developing a value-based safe harbor for pharmaceutical arrangements, to specify explicitly that protected arrangements may include adherence measures and to allow decisions about who carries out adherence services to be made by mutual agreement of the parties.

IV. OIG SHOULD FINALIZE MOST OF ITS PROPOSED MODIFICATIONS TO THE WARRANTIES SAFE HARBOR

The warranties safe harbor protects exchanges of value pursuant to a warranty agreement "provided by a manufacturer or supplier of an item to a buyer (such as a health care provider or beneficiary)," as long as certain conditions are met.⁶³ PhRMA supports OIG's proposals to make certain changes to the safe harbor, including the technical update to the definition of "warranty," the expansion of the safe harbor to encompass warranty arrangements for one or more items and related services, and the exclusion of beneficiaries from the reporting requirements otherwise applicable to buyers.

A. Definitions

PhRMA supports the OIG's proposed changes to the definition of "warranty." We appreciate OIG's confirming that the safe harbor applies to FDA-regulated drugs and devices and proposing to revise the safe harbor language to prevent any confusion on this issue. We also support OIG's proposal to define "warranty" to include warranties that affirm or promise that the item(s) (and services) will meet a "specified level of performance" over a specified period of time. We interpret this provision to mean that the parties have flexibility to set the terms of the warranty, and that the safe harbor could protect certain outcomes-based arrangements and warranty payments that were triggered by a range of suboptimal performance metrics. We also appreciate OIG's stating clearly that the safe harbor protects clinical outcome guarantees. We urge OIG to provide examples of what it means by clinical outcome guarantees, and to include (1) warranties regarding the cost of treatment or partial cost of treatment (e.g., hospitalization costs avoided) and (2) warranties involving surrogate outcomes (e.g., adherence).

Because the warranty safe harbor speaks of warranties to a "buyer," we also encourage the OIG to make clear that (as under the discount safe harbor) a "buyer" includes an indirect buyer such as a payer or PBM. Additionally, in order to facilitate low-risk warranty arrangements, we ask OIG to coordinate with CMS to recognize that reimbursement for, or replenishment of, items and services, pursuant to a warranty arrangement is excludable from price reporting under CMS' government pricing regulations and guidance.

B. Warranties for Bundled Items and Services

PhRMA supports OIG's proposal to protect "bundled" warranties involving multiple products and/or related services. However, we urge OIG not to finalize the proposal that "all federally reimbursable items and services subject to bundled warranty arrangements must be reimbursed by the same Federal health care program and in the same payment," as we believe this would be overly restrictive and would prevent manufacturers and suppliers from offering beneficial, low-risk warranties. OIG's alternative proposal—to require that all items and services included in the warranty be reimbursed according to the same payment methodology—may also be overly restrictive.⁶⁴ For instance, under the proposal, a manufacturer would not

⁶³ 42 C.F.R. § 1001.952(g).

⁶⁴ We note that the proposed rule does not define "payment methodology" for this purpose. This approach might be less problematic if "separate payment" or "bundled payment"—as opposed to the exact same payment formula—were considered the

be able to warrant a particular federally reimbursed drug product when used in conjunction with a companion diagnostic. In that case, the drug would be reimbursed under Medicare at the negotiated price (if a Part D drug) or at ASP + 6 percent (if a Part B drug), while the companion diagnostic would be reimbursed under the clinical laboratory fee schedule.

The proposed rule preamble also states that OIG is considering exceptions to the “same payment” idea due to cases where “bundled items are reimbursed according to the same payment under the Medicare program but are reimbursed separately under Medicaid” (citing OIG Advisory Opinion No. 18-10, where a warranty covered items that were reimbursed under the same Medicare MS-DRG but that might be separately reimbursable under several state Medicaid programs).⁶⁵ We encourage OIG not to require that all federal health care programs that cover a certain product pay for the product using the same payment methodology; this could foreclose protection for even one-drug warranties, as drugs are virtually always reimbursed by Medicare, Medicaid (and usually additional federal health care programs), with each program having different payment methodologies for outpatient drugs.⁶⁶ Further, most state Medicaid programs have different payment formulas for outpatient drugs (even though these formulas all should represent “average acquisition cost” for the drug in that particular state⁶⁷), and even within a single state, typically some Medicaid beneficiaries are covered by the state’s fee-for-service program and some are covered by a managed care plan, which could have different drug payment methodologies. Therefore, we are concerned that for pharmaceuticals—and likely many other health care items and services—any requirement that all relevant federal programs use the same payment methodology for an item or service could undo the benefits of OIG’s other proposals to expand and clarify the warranties safe harbor (depending in part on how the “same” payment methodology were defined).⁶⁸

“same” payment methodology. The proposed rule gives some indication that OIG is thinking of “separate payment” or “bundled payment” as being the “same” payment methodology but does not say this explicitly. 84 Fed. Reg. at 55749.

⁶⁵ 84 Fed. Reg. at 55750.

⁶⁶ Even considering just Medicare and Medicaid, a particular drug can have many different payment methodologies under Federal health care programs. Medicare Part B pays for most drugs at 106% of Average Sales Price (ASP). Part B drugs furnished in a hospital outpatient department usually are paid at 106% of ASP, but some are paid as part of a bundle with related services. For Part B drugs furnished to Medicare Advantage (MA) enrollees, the MA plan pays a network provider an agreed-upon rate (CMS generally does not regulate MA plan payment rates for Part B drugs). Medicare Part D drugs are reimbursed by Part D plans to network dispensing pharmacies at the drug’s “negotiated price” (generally the price negotiated between the plan and the pharmacy in question for the dispensed drug). Note that typically a certain outpatient drug will be a “Part B drug” or a “Part D drug” but not both; however, in a small but non-trivial percentage of cases a certain drug can be covered by Part B in some circumstances and Part D in other circumstances. Under Medicare Part A, drugs are generally paid as part of bundle with the other items and services used in the hospital inpatient stay, but in a few cases Part A pays hospitals an extra “new technology add-on payment” when an innovative new drug is used during the hospital stay. On the Medicaid side, Medicaid fee-for-service programs are generally required to pay for most brand outpatient drugs at “average acquisition cost” (AAC), but AAC is a broadly defined term and different states have different reimbursement formulas designed to equal AAC in that state (also the same state may have different reimbursement formulas designed to equal AAC for different types of outpatient brand drugs). Under Medicaid managed care, Medicaid MCOs are not required to pay AAC and generally pay rates they negotiate with their network pharmacies or providers.

⁶⁷ 42 C.F.R. § 447.512(b)(1).

⁶⁸ If OIG decides to move forward with reimbursement-related requirements as part of this safe harbor, we would appreciate OIG explicitly clarifying that a warranted bundle of items and services could encompass limited support services offered by the manufacturer that are not federally reimbursable and are offered free-of-charge. We read the currently proposed condition that “all federally reimbursed items and services subject to the bundled warranty arrangement must be reimbursed by the same

The preamble also suggests that the proposal to protect bundled items only when reimbursed in the “same payment” would inhibit “population-based” warranty arrangements. Specifically, OIG states that a “same payment” requirement “might inhibit warranties based on the collective performance of warranted items across a patient population (population-based warranties) because these items would not be reimbursed in the same payment.”⁶⁹ The OIG states that to permit population-based warranties without creating risk of increased costs to the Federal health care programs it is considering a requirement that all items and services be paid under the “same methodology.”⁷⁰ As discussed above, we have concerns that a “same methodology” requirement may still be too restrictive. We would be concerned if the final safe harbor did not protect warranties that were based on the collective or average outcome experienced in a specified population.

Accordingly, for all of the reasons described above, we urge OIG not to finalize either the proposed “same payment” or alternative “same methodology” requirements, and to instead eliminate this reimbursement-related requirement from the revised warranty safe harbor altogether, as it would be overly restrictive and would undermine OIG’s stated goal of updating and promoting increased utilization of the safe harbor.

C. Reporting Requirements

In the preamble to the proposed rule, OIG notes that stakeholders have expressed concern that the reporting requirements under the current safe harbor may not allow for outcomes-based warranty arrangements in which buyers could receive warranty payments from manufacturers several years after the initial purchase, or over several years if a therapy does not meet clinical outcomes at designated points in time. Our view is that the current safe harbor clearly protects warranty payments made after the initial sale. Specifically, 42 C.F.R. § 1001.952(g)(3)(ii) describes a manufacturer’s obligations where the amount of the price reduction related to the warranty is not known at the time of sale and instructs the manufacturer to provide certain information to the buyer when the price reduction becomes known so that the buyer can meet its reporting obligations under subsection (g)(1). Likewise, we believe the safe harbor would protect multiple payments related to the same item or bundle.

If, however, other stakeholders believe that additional clarity or flexibility with respect to reporting would better facilitate warranties tied to clinical outcomes, we are supportive of such changes. For example, the safe harbor could clarify explicitly that multiple warranty payments related to the same item or bundled items and services could be reported and that buyers are obligated to report such payments at the time they are received. OIG could also clarify that the warranty safe harbor would protect an arrangement

Federal health care program and in the same payment” to allow a warranty that includes non-reimbursed product support services. OIG, in fact, explicitly cites product “support and educational services,” which typically are not reimbursable and are provided free-of-charge, as an example of the type of services that could be included in a warranty bundle protected by the modified warranties safe harbor. 84 Fed. Reg. at 55748. However, the preamble also states that the modified safe harbor would “not protect free or reduced price items or services that sellers provide either as part of a bundled warranty agreement or ancillary to a warranty agreement.” *Id.* at 55748 n. 83. We would appreciate OIG expressly clarifying that a warranted bundle could include support services that are not federally reimbursable and are offered free-of-charge. For example, assuming all other conditions of the safe harbor are satisfied, the safe harbor would protect a manufacturer’s warranty of the clinical effectiveness of a self-injected drug contingent on the patient receiving post-prescribing, product administration and use education through nurse support offered by the manufacturer.

⁶⁹ 84 Fed. Reg. at 55749.

⁷⁰ 84 Fed. Reg. at 55749.

in which a warranty payment could vary depending on the product's performance on one or more dimensions specified in the warranty agreement as opposed to the warranty payment being a fixed amount.

We also support OIG's proposal to expressly exclude beneficiaries from the reporting requirements applicable to other buyers since beneficiaries do not report costs to the government.

V. OIG SHOULD FINALIZE PROPOSED REVISIONS TO STREAMLINE THE PERSONAL SERVICES AND MANAGEMENT CONTRACTS SAFE HARBOR

We strongly support the two streamlining changes proposed by the OIG to the personal services safe harbor. These changes will make the protection offered by the personal services safe harbor available for many low-risk arrangements for services that are not full-time (such as contracts for services to be performed on a part-time or sporadic basis) that meet the other requirements of the safe harbor.⁷¹ We agree with the OIG that the requirements proposed for removal or modification are not needed given the safe harbor's other safeguards.⁷² Moreover, the proposed changes would allow parties to pay for services only as needed, reflecting the nature of many common, beneficial, low-risk arrangements. These changes also would make it easier for parties to ensure that they meet other requirements of the safe harbor, such as limiting services to only those that are reasonably necessary to accomplish the purpose of the services.

* * *

PhRMA appreciates your consideration of these comments. Please feel free to contact us if there is any further information we can provide.

Sincerely,



James C. Stansel
Executive Vice President and General Counsel



Randy Burkholder
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Julie Wagner
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⁷¹ Specifically, the proposed rule would: (1) remove the requirement that aggregate compensation be "set in advance" (which is difficult to satisfy in the case of many arrangements for periodic services) and substitute a requirement that the methodology for determining compensation be set in advance; and (2) eliminate the current requirement that a contract for periodic, sporadic, or part-time services must specify the schedule, length, and the exact charges for each "interval" of service.

⁷² 84 Fed. Reg. at 55744.