

VIA ELECTRONIC SUBMISSION

The Honorable Alex M. Azar II
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: MEDICARE PROGRAM; MODERINIZING AND CLARIFYING THE PHYSICIAN SELF-REFERRAL REGULATIONS; AND MEDICARE AND STATE HEALTHCARE PROGRAMS: FRAUD AND ABUSE; REVISIONS TO SAFE HARBORS UNDER THE ANTI-KICKBACK STATUTE, AND CIVIL MONETARY PENALTY RULES REGARDING BENEFICIARY INDUCEMENTS

Dear Secretary Azar:

The Robert J. Margolis, MD Center for Health Policy at Duke University (The Duke-Margolis Center) appreciates this opportunity to comment on the above captioned proposed rules (“Self-Referral Regulations Proposed Rule” and “Anti-Kickback Statute Proposed Rule”) from the Centers for Medicare & Medicaid Services (CMS), the Office of Inspector General (OIG), and Department of Health and Human Services (HHS). These proposed rules are an important step to addressing and lessening the barriers existing rules have created to participating in value-based arrangements. The degree to which CMS, OIG, and HHS can provide clarity and foster alignment between these rules and those rules related to other HHS programs will influence how effective these proposed changes will be in advancing the health system’s transition from a fee-for-service (FFS) model to a value-based model designed to improve patient experience and health care quality, encourage more appropriate use of medical technologies, and reduce spending. Our comments aim to provide recommendations for how such clarity and alignment can be achieved.

Established with a founding gift through the Robert and Lisa Margolis Family Foundation, the Duke-Margolis Center brings together capabilities that generate and analyze evidence across the spectrum of policy to practice, supporting the triple aim of health care—improving the experience of care, the health of populations and reducing the per capita cost. The Duke-Margolis Center’s activities reflect its broad multidisciplinary capabilities, fueled by Duke University’s entrepreneurial culture. It is a university-wide program based at the Fuqua School of Business, with staff and offices in both Durham, North Carolina and Washington, DC, and collaborates with experts on health care policy and practice from across the country and around the world.

The mission of the Duke-Margolis Center is to improve health and the value of health care through practical, innovative, and evidence-based policy solutions. The Center’s work includes identifying effective delivery and payment reform approaches that support the transition to value-based care and collaborating with expert stakeholders to identify pathways to increase the

value of biomedical innovation to patients – both through better health outcomes and lower overall health care spending.

The comments provided on the Self-Referral Regulations (SRS) Proposed Rule and Anti-Kickback Statue (AKS) Proposed Rule are informed by the Center’s ongoing work. This work includes multiple ongoing projects related to the in-depth examination of the operations and effectiveness of accountable care organizations (ACOs). The comments are also informed by the ongoing work of the Advisory Group of the Center’s multi-stakeholder consortium on value-based payment reforms for medical products.

In April 2017, The Duke-Margolis Center formed this first-of-its-kind multi-stakeholder consortium to address key practical issues in advancing value-based payment arrangements for pharmaceuticals, including gene therapies and gene editing technologies, and medical devices. The project is supported through the generosity of the Margolis Family Foundation, which provides core resources for the Center, in-kind participation at the organizational level from all Consortium members, and membership fees from industry partners on a sliding scale.

The Consortium Advisory Group—composed of patient advocates, payers, manufacturers, and providers, as well as experts on regulatory affairs, law, and policy—works to develop approaches to payment reform that support better outcomes for patients and better value across the system. The Consortium is providing practical solutions to legal and regulatory barriers, data and operational challenges, and financing methods for high-cost therapies.

In this document, we discuss:

- I. The importance of value-based arrangements and the challenges associated with their implementation.
- II. Recommendations for expanding the SRS Proposed Rule’s definition of “substantial downside financial risk” to include arrangements under which entities assume greater financial risk over time.
- III. Recommendations for providing more guidance on the SRS and AKS Proposed Rules’ requirements related to performance/quality standards and outcome measures.
- IV. Recommendations to allow manufacturers to assume risk in bundled arrangements beyond the cost of the product itself.
- V. Recommendations that the proposed rule include medical product manufacturers in the definition of “VBE Participant” for the purpose of safe harbor protection.
- VI. Recommendations that the proposed rule create a safe harbor for medical product VBP arrangements between payers and manufacturers.
- VII. Examples of medical product VBP arrangements excluded by the proposed safe harbors.

I. The importance of value-based arrangements and the challenges associated with their implementation.

Value-based arrangements are a key mechanism for transforming how we pay for and deliver health care in the United States. By tying payment to value, these arrangements help advance the goals of improving patient experience and health care quality, encouraging more appropriate use of medical technologies, and reducing health care spending. Value-based arrangements can take a variety of forms, including accountable care organizations (ACOs), bundled or episode-based payments, and contracts between manufacturers of biopharmaceutical and medical devices (together referred to as “medical products”) and payers and/or providers. Participation in these types of arrangements is growing^{1,2} and evidence indicates they can facilitate the provision of high-quality care and reductions in spending.³ However, value-based arrangements, particularly those involving the assumption of some degree of downside financial risk, continue to be a minority of the payment arrangements in the United States.

Reasons for the slow uptake of value-based arrangements are many. Our work found ACOs encounter challenges related to securing start-up resources, building or refashioning existing infrastructure to support new approaches to care, changing organizational culture, and identifying appropriate quality measures or performance standards.⁴ Most participants in value-based arrangements need time at the beginning of such arrangements to build the infrastructure and establish the processes and relationships required to achieve meaningful changes in quality and costs. Challenges for value-based arrangements involving medical products include operational and administrative barriers, as well as legal and regulatory impediments such as government price reporting requirements for drugs.⁵ Trying to succeed in these types of arrangements under FFS-based regulatory structures adds to these challenges. From our work studying value-based arrangements, we’ve learned the shift from traditional FFS to value-based payment and delivery takes time and resources and is a journey that requires continuing changes and advancements, often incremental, if the shift is to be effective and sustainable – and corresponding shifts in regulatory policies are needed as well.

Under a FFS payment system, the Self-Referral regulations and Anti-Kickback statute serve a critical purpose of avoiding waste and incentives for inappropriate or excessive treatment. Regulators have viewed coordination and the sharing of valuable resources across organizations under a FFS payment system as posing an increased risk of fraud and abuse, and have consequently adopted narrow exceptions and safe harbors with expected benefits that exceed any adverse impacts on innovative care models and care coordination and integration. However, as providers and manufacturers move toward assuming greater financial risk in their payment

¹ <http://hcp-lan.org/workproducts/apm-methodology-2019.pdf>

² <https://www.ajmc.com/journals/issue/2019/2019-vol25-n2/valuebased-arrangements-may-be-more-prevalent-than-assumed?p=2>

³ <https://www.healthaffairs.org/doi/10.1377/hblog20180918.957502/full/>

⁴ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00013>

⁵ <https://www.healthaffairs.org/doi/10.1377/hblog20161104.057443/full/>

arrangements, there are less incentives and opportunities to engage in behaviors that lead to excess Federal spending and inappropriate overuse of services and medical products for patients. As payments shift from being based on volume to being based on achieving better outcomes and lowering total costs, with greater financial risk tied to limiting costs, the Self-Referral regulations and Anti-Kickback statute regulations designed for fee-for-service constitute increasingly significant barriers to the adoption of new health care models that achieve the policy goals of better health care with more sustainable spending.

Adaptation of these regulations to this changing environment would encourage the shift away from FFS and help achieve the goals of improving outcomes and lowering spending through value-based payment models. We appreciate the efforts of CMS and OIG to provide greater clarity on existing regulations and for offering new exceptions and safe harbors designed specifically to address the unique nature of value-based arrangements. We are particularly appreciative of the efforts to support arrangements involving the assumption of greater downside financial risk. However, we believe there are opportunities to enhance the proposed changes so they provide the clarity and guidance required to allay uncertainties around the requirements of the proposed exceptions and safe harbors, foster alignment across CMS, state, and private plan value-based payment initiatives, and facilitate more diverse participation in value-based arrangements, especially those involving significant, if not full, financial risk.

II. Recommendation: Expand the SRS Proposed Rule’s definition of “substantial downside financial risk” to include arrangements under which entities assume greater financial risk over time.

Three of the proposed safe harbors, specifically the Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency, Value-Based Arrangements with Substantial Downside Financial Risk, and Value-Based Arrangements with Full Financial Risk safe harbors, recognize that the degree of financial risk assumed by entities participating in value-based arrangements exists on a continuum. The proposed Care Coordination Arrangements and Full Financial Risk safe harbors would cover arrangements that fall on either end of that continuum (i.e., no financial risk assumed or full financial risk assumed), while the proposed Substantial Downside Financial Risk safe harbor would cover qualifying arrangements that may fall in between. We agree with the general approach of designing and implementing safe harbors that reflect a continuum of risk assumption, but we are concerned the proposed definition of “substantial downside risk” (see below) is not aligned with the levels of risk assumed under other public and private sector value-based payment initiatives and thus may create an unnecessarily high qualifying standard for many providers and organizations that are considering entering into value-based arrangements. Thus, this proposed change may not end up achieving more participation in arrangements that involve downside financial risk and that could improve outcomes without increasing, and potentially reducing, Federal spending.

Definition of “substantial downside financial risk”:

- (1) a shared savings arrangement with a repayment obligation at least 40% of shared losses;
- (2) a repayment obligation under an episodic or bundled payment arrangement of

at least 20% of any total loss; (3) a prospectively paid population-based payment for a defined subset of the total cost of care, where the payment is determined based on historical expenditures; or (4) a partial capitated payment where the payment reflects a discount of at least 60% of the total expected payment for the target population (pgs. 125-126 in the AKS Proposed Rule)

Our work⁶ and work by other researchers⁷ on ACOs indicate taking on downside financial risk, particularly high levels of risk, can lead to health care and public program savings and improvements in care quality. However, taking on substantial downside financial risk is not something most providers and organizations can do at the start of an arrangement. Most entities, or at least those that are new to participating in value-based arrangements, will likely need a capacity building phase, during which it is not feasible to take on financial risk or the risk taken on is minimal. Once the necessary infrastructure is built out – including longitudinal data and analytics, new internal structures and staffing, and reforms in key areas of clinical care delivery – participants will be better situated to assume higher levels of risk. Setting safe harbor qualifying risk levels too high may result in the safe harbor being available to only those organizations that have already been in operation for a long period of time and are able to take on very high-levels of financial risk (e.g., ACOs associated with large health systems).

While the 40% and 20% shared and total losses benchmarks in the proposed definition of “substantial downside financial risk” align with rates used in the Medicare Shared Savings Program’s (MSSP) Enhanced Track⁸ and the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model⁹, it does not reflect the fact that most potential value-based arrangement participants need to work up these levels of risk over a period of time. OIG should consider including in the proposed definition of substantial downside risk, multi-year arrangements under which entities can start out assuming no or low levels of risk, but must assume greater downside financial risk over time and eventually reach the benchmarks included in the current version of the proposed definition. Such arrangements allow time to build the infrastructure and processes needed to be successful in a value-based health care system, while requiring the entity to take on downside financial risk within a specific period of time.

This approach would be better aligned with the glide path implemented in the 2018 Pathways to Success Rule for MSSP.¹⁰ This rule redefined the program tracks in an effort to encourage more ACOs to take on downside financial risk, after low rates of ACOs participating in the program’s two-sided, shared savings and shared losses models in the previous years of the program. The new tracks allow ACOs to gain experience with more modest levels of risk before advancing to the 30% or higher shared loss rates required in the program’s more advanced tracks. Our examination of the program’s 2018 performance data found 17% of participating ACOs were in

⁶ <https://www.healthaffairs.org/doi/10.1377/hblog20191024.65681/full/>

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5368036/pdf/nihms819769.pdf>

⁸ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index>

⁹ <https://innovation.cms.gov/Files/x/bpci-advanced-faqs.pdf>

¹⁰ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-27981.pdf>

tracks with downside financial risk.¹¹ While a significant increase over the previous performance year, this rate suggests taking on financial risk is still challenging for many program participants and they will likely need the transition time allowed under the program's new tracks to build the capacity needed to take on the higher levels of downside financial risk required in the program's advanced tracks.

To address the need for more support to prepare for assuming financial downside risk, we propose modifying the proposed definition of substantial downside financial risk to cover multi-year arrangements that include a capacity building period. As in the MSSP Pathways to Success model, this would help entities build and establish the infrastructure and administrative and care processes required for sustainable success under a value-based arrangement. During this period, the entity would take on lower levels of downside financial risk and gradually build up to the 20% or 40% benchmark (depending on the arrangement) included in the current proposed definition. Our previous work examining ACO exits from MSSP found organizations may need between one to three years to build up the infrastructure and processes necessary to take on downside financial risk.^{12,13}

The minimum amount of time required for capacity building likely varies by certain entity characteristics (e.g., size, location [rural vs. urban]). One possibility is for the proposed definition to include arrangements that allow for a capacity building period of up to two years. This approach would align with the amount of time allowed for the assumption of financial risk in programs such as MSSP. As more evidence accumulates around how much time is needed for entities to be able to take on more financial risk, the time allowed for capacity building may need to be adjusted. Allowing arrangements with capacity building period to be included in the definition of substantial downside financial risk in the updated SRS rule will open the safe harbor up to more arrangements and foster diversity of the types of entities participating in value-based arrangements. OIG should also seek to maintain alignment with further developments of transition phases in Medicare and commercial models, as those payer reforms are likely to reflect accumulating further evidence on needed transition support.

III. Recommendation: Provide more guidance on the SRS and AKS Proposed Rules' requirements related to performance/quality standards and outcome measures.

The inclusion of a performance/quality standard requirement within the SRS Proposed Rule's Value-Based Arrangements exception and the inclusion of an outcome measure requirement in the AKS Proposed Rule's Care Coordination safe harbor are worthwhile efforts to ensure quality of care is maintained under value-based arrangements. We agree that performance/quality standards and measures should be requirements for the proposed exception and safe harbor, but more guidance is needed regarding what standards and measures would comply with the proposed requirements.

¹¹ <https://www.healthaffairs.org/doi/10.1377/hblog20191024.65681/full/>

¹² <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05097>

¹³ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05097>

The push to value-based care over the years has contributed to the development and implementation of numerous standards and measures used to track the quality of care delivered under value-based arrangements. These measures can range from those developed by health systems for quality improvement and care management purposes, to more rigorously tested and reviewed measures that are more suitable for use in public-reporting and other accountability programs. This proliferation contributes to concerns about measurement burden¹⁴ and has spurred efforts to streamline measurement and performance requirements to ensure that the standards and measures used provide meaningful and actionable information to consumers, providers, payers, and other stakeholders (e.g., CMS Meaningful Measures Initiative).¹⁵

We are concerned the current SRS and AKS requirements related to measures and standards are too vague and create uncertainty around a specific value-based arrangement's ability to qualify for the Value-Based Arrangement exception or the Care Coordination safe harbor. We are also concerned about the Care Coordination safe harbor requirement regarding the use of evidence-based outcome measures given there are many areas of clinical care and patient populations for which few or no outcome measures are available. For example, our study of ACOs caring for the seriously ill found it can be very difficult to identify or construct measures that capture the outcomes considered indicative of high-quality care for this population (e.g., delivery of goal concordant care).¹⁶ If a value-based arrangement includes or specifically focuses on an area of care or patient population for which outcomes measures are not available, it is likely the arrangement would not meet the proposed requirements of the Care Coordination safe harbor.

Rather than imposing different or additional regulatory standards regarding the use of performance/quality standards or measures, we recommend the proposed exception and safe harbor requirements align, to the maximum extent possible, with the measures required under CMS (e.g., MSSP, Direct Contracting Model) and other value-based payment models. CMS and OIG have a shared interest in developing and fostering the use of meaningful measures, especially measures capturing information directly from patients (i.e., patient-reported outcomes). CMS has already invested significant resources into the development and implementation of measures for a variety of value-based payment models (e.g., MSSP 2019 measures¹⁷; Direct Contracting Model 2021 measures [pg.78]¹⁸).

Alignment between the proposed exception and safe harbor standards and measurement requirements and existing measurement requirements for other CMS or private value-based payment models would provide clarity to potential value-based arrangement participants as to whether their arrangement would qualify for the proposed exception or safe harbor. It would also foster the use of meaningful measures in value-based arrangements, drive measurement

¹⁴ <https://jamanetwork.com/journals/jama/fullarticle/2685141>

¹⁵ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page>

¹⁶ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.00013>

¹⁷ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2019-quality-benchmarks-guidance.pdf>

¹⁸ <https://innovation.cms.gov/Files/x/dc-rfa.pdf>

alignment across payment models, and help reduce measurement burden – all leading to greater incentives for payment reforms to improve outcomes meaningfully while avoiding excess spending. For those areas of care or patient populations for which outcome measures are not yet available, we encourage CMS to allow the time-limited use of process measures to fulfill the requirements for organizations that are committed to implementing more advanced measures over time.

Finally, we would like to respond to CMS’s request for comment on “... whether to require that performance or quality standards be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care” (pg. 75 of the SRS Proposed Rule). Building on extensive work by CMS and CMS-supported entities like the Core Quality Measures Collaborative, it would be helpful for CMS to identify the areas of measurement (e.g., patient safety, care coordination) that could drive meaningful improvements in performance and align those areas of measurement with the measurement requirements of CMS and other value-based payment models. In addition, given the concerns around measurement burden, we suggest CMS provide a definition of “meaningful improvements” or guidance on how such an improvement can be determined if such language is to be added to the rule. Without a clear definition or additional guidance, there may be uncertainty regarding an arrangement’s eligibility for the SRS exception.

IV. Recommendation: Allow manufacturers to assume risk in bundled arrangements beyond the cost of the product itself

The Administration has encouraged the adoption of potentially high-value technologies using risk-sharing arrangements in bundled payments, as an area of focus and further action. In *Putting America’s Health First*, the President’s Budget for HHS for FY 2020, HHS proposes¹⁹ that the Center for Medicare and Medicaid Innovation (CMMI) develop bundled payment demonstrations involving high-value medical devices for which there are delays or deficiencies in access under the prevailing payment system. These bundled payment demonstrations envision device manufacturers sharing in some or all of the risk in the bundle.

In the AKS Proposed Rule, OIG proposes to extend protection to bundled arrangements that provide a warranty for one or more items and related services, provided that the warranty covers at least one item (e.g., a medical device). This proposal modifies and expands the current warranties safe harbor, which only protects a warranty offered on the single product. This change would potentially allow manufacturers to offer additional protections for purchasers that go beyond the cost of a faulty product, to also cover the costs of related services associated with that product.

We appreciate and support the Administration's efforts to find ways to enable manufacturers to take risk for items and services that extend beyond the cost of the device itself. The Administration should also consider arrangements that allow manufacturers to take on risk that

¹⁹ <https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf>

exceeds the replacement value of the device. For example, a manufacturer could enter into an agreement to cover hospital expenses related to complications that their device is designed to prevent, or to cover some or all of the costs of a replacement procedure in the event of an early failure of their device.

Supporting the utilization of high-value products that deliver better outcomes and allow manufacturers to share more meaningful risk in bundled payment arrangements necessitates OIG's inclusion of manufacturers in the proposed value-based arrangements safe harbors. We discuss this point in more detail below.

V. Recommendation: Include medical product manufacturers in the definition of “VBE Participant” for the purpose of safe harbor protection

While the AKS Proposed Rule aims to create safe harbors for risk sharing and care coordination efforts between “value-based participants that include providers, clinicians and others,” it explicitly excludes drug manufacturers from this group and considers whether it should also exclude medical device manufacturers.

We appreciate the OIG's solicitation of comments on these exclusions. While we support the OIG's intent to limit potential industry fraud in this AKS Proposed Rule, we believe that concerns about program misuse and increased volume billings—that the AKS aims to prevent—diminish when value-based payments require outcome improvements and meeting spending targets. This reduces the need for the AKS' restrictions that apply in volume-based arrangements. VBP arrangements that include providers, payers, *and* medical product manufacturers have significantly greater potential to improve outcomes for the patient population treated, compared to provider-payer relationships that seek to move away from volume-based payment while still requiring volume-based payment methods for medical products. The OIG's assumptions that provide the basis for excluding manufacturers from the proposed safe harbors and the payment and regulatory regimes that go along with these assumptions have contributed to limited manufacturer participation in care coordination and support for higher-value treatment decisions, and limited manufacturer accountability for the actual impact of use of their treatments on spending and outcomes in Medicare and other populations.

Currently, manufacturers are for the most part excluded from the risk-sharing-based contracts entered into by providers and payers. Yet manufacturers' specific expertise and ability to develop and target programs involving their products, such as care coordination, risk prediction, remote monitoring, and more, may provide resources that fill important gaps in care coordination and data collection that providers and payers could not address alone in trying to achieve more value in care delivery and from particular medical products. Such manufacturer participation would need to be accompanied by a shift to substantial manufacturer accountability (financial risk sharing) for achieving spending benchmarks for the affected populations.

As experience and capacity to implement care delivery payment reforms increase, contracts could move toward direct alignment of both provider and medical product payments with value produced for patients and the health system – i.e., accountability for better patient outcomes and

for limiting total spending. These arrangements could prove especially effective if adopted by health systems or different providers that are aligned through their own VBPs, giving them the ability to coordinate patient care. Many provider-led VBPs, which the Administration aims to support through initiatives such as the Regulatory Sprint²⁰ and this Proposed Rule, could become much more effective with the inclusion of medical products. We provide several examples for such arrangements below in Section VII.

Indeed, the OIG recognizes the role played by manufacturers in care coordination and management, and in the AKS Proposed Rule it notes that:

“We also acknowledge that some pharmaceutical manufacturers may help facilitate care coordination and management of care through, for example, data analytics associated with their pharmaceutical products furnished to purchasers of their products. These kinds of manufacturer arrangements raise different program integrity issues from those addressed in this rulemaking and would likely require different safeguards. We are considering pharmaceutical manufacturers’ role in coordination and management of care and may address it in future rulemaking.”

(P. 55 of the AKS Proposed Rule)

We therefore urge the OIG to incorporate medical product manufacturers under the protection of the proposed value-based arrangement safe harbors for health care providers.

VI. Recommendation: Create a safe harbor for medical product VBP arrangements between payers and manufacturers

The AKS’ *existing* safe harbors do not generally accommodate medical product payment arrangements that shift away from FFS to models in which product reimbursement depends on measures of value. The Discount Safe Harbor, for example, provides stakeholders with some flexibility to engage in VBP arrangements by allowing payers and manufacturers to link payment, in the form of rebates, to measures relating to a drug’s impact on outcomes, utilization, and spending for affected populations of patients. However, this safe harbor also includes several restrictions, such as a requirement that, in some circumstances, the benefit from the discount must be realized within a maximum two years. This might significantly hinder VBP arrangements, especially for some gene and other transformative therapies where the durability is only confirmed over a significantly longer²¹ time horizon.

The Administration recognizes the existence and importance of value/outcomes-based arrangements for medical products, and notes that:

“We may also consider specifically tailored safe harbor protection for value-based contracting and outcomes-based contracting for the purchase of pharmaceutical

²⁰ <https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf>

²¹ <https://www.forbes.com/sites/joshuacohen/2019/04/12/how-are-gene-therapies-going-to-get-paid-for/#1f7d5b832090>

products (and potentially other types of products) in future rulemaking.”
(p. 55 of the AKS Proposed Rule).

We strongly support the OIG’s further development of the approach reflected in this statement and believe that it should develop additional VBP safe harbor guidance in the final rule to enable VBP arrangements for medical product payments to expand and move further away from FFS. In addition to including drug and device manufacturers as VBE participants in the proposed value-based safe harbors of the AKS Proposed Rule, the OIG should establish a safe harbor framework specific to manufacturer-payer VBP arrangements. VBP arrangements could encourage greater adoption of personalized medicine, improved medication adherence, greater development of robust real-world data and evidence, and other benefits that would increase the value of medications, care, and access. To facilitate health care reform and the increasing transition towards value-based reimbursement, we believe that it is crucial that any AKS reforms be implemented in a way that (1) advances the Administration’s goals of promoting VBP arrangements, while (2) preserving the AKS’ central purpose of limiting fraud and abuse in federal health care programs.

Recognizing concerns related to the realization of spending reduction from these arrangements and supporting the OIG’s general approach of creating safe harbors that reflect a sliding scale of risk assumption in the health care providers’ context, we believe that a similar approach could also be pursued for VBP arrangements for medical products, where advanced VBP arrangements that represent a very substantial shift away from FFS payments could be protected by a more flexible safe harbor, whereas limited risk arrangements could be protected by a more limited safe harbor.

VII. Examples of medical product VBP arrangements excluded by the proposed safe harbors

In its request for comments, the OIG seeks examples of manufacturer-based care coordination and management efforts (P. 56 of the AKS Proposed Rule). Duke-Margolis VBP Consortium has developed a number of scenarios in which the manufacturer may be heavily involved in care coordination for the betterment of patient and population health. We present some of these below.

Example 1: Medical Products in Provider-based VBPs

In addition to emerging VBP arrangements between payers and manufacturers, there has also been growing interest in the use of these contracts to better align manufacturers and providers as part of alternative payment models (APMs) that are intended to encourage efficiency and cost savings while maintaining or improving patient outcomes. These provider APM changes create opportunities for stronger alignment with VBP arrangements for medical products: sharing some of the increasing provider APM risk with manufacturers may enable more opportunities and redirect more resources to drive toward higher value care with medical products. Such arrangements could include, for example, provisions to share in either excess costs or cost-savings (e.g., the manufacturer will receive a share of cost savings and share in excess costs with

the provider for procedures using the manufacturer's equipment), or agreements that the manufacturer will reimburse for the cost of treatment if certain goals are not met.

Example 2: Medical Product Population/ Subscription Models with Observed Savings (using in-kind support of wraparound care coordination services)

Analogous to VBP for providers, implementation of VBP arrangements for medical products can be viewed on a spectrum, beginning with payments that remain FFS-based but that are adjusted based on expected value, as determined by *existing* evidence (e.g., indication-based pricing). More advanced models exist along the spectrum and include outcome-based contracts (OBCs) that link payments to a product's *actual* performance or *demonstrated* value in a patient or a population.

At the other end of the spectrum from volume-based payments, population-based payments for a drug or other medical products could be centered entirely on a per-person or per-population basis, with payment adjustments based on improved population outcomes and costs of care. That is, these “subscription” models include a fixed amount for unlimited access to the medical product for a covered population, while the payment is tied to the product's observed performance in that population. We describe such an extreme shift from FFS payments not because these arrangements are common today – though some “subscription-type” payment models have been described in such areas as Hepatitis C treatment and antimicrobials– but because they help highlight the importance of taking steps now to enable a framework for arrangements that shift away entirely from FFS.

In a subscription model, the payment mechanism does not allow for additional financial risk to payers or the government related to volume of sales – payments would only increase in the context of significant outcome improvements and total spending reductions as measured by performance against benchmarks agreed to in the payment contract. The AKS inhibits such population-based arrangements as different activities by the manufacturer, such as sharing data, supporting and training providers in case finding or care management, as well as financial risk-sharing, might implicate AKS rules because the various activities would be intended to facilitate utilization of specific products, to achieve the population outcome and spending goals. While such manufacturer activities should be restricted under volume-based arrangements, AKS regulations could impede efforts that enable manufacturers, providers, and payers to share in the savings from such care reforms in payment models that are substantial shifts from FFS.

In those full-risk payment models that are not tied to the volume of sales, CMS programs are unlikely to be harmed by manufacturer collaboration with health care providers to better coordinate care and reduce costly downstream complications. Rather, those activities would be aligned with the intended goals of the safe harbors in the AKS Proposed rule. However, if there is only a small payment component related to outcomes while most of the payment remains volume-based, then AKS concerns remain.

As VBP arrangements for medical products have, by and large, yet to fully shift away from FFS but still contain different levels of volume-based payments, there could be a spectrum of VBP

safe harbors that reflects a sliding scale of risk assumption taken by manufacturers participating in VBP arrangements. The safe harbors could provide increasingly greater flexibility in designing VBP arrangements as the manufacturer takes on greater financial risk and incentives and opportunities for program abuse and inappropriate product overuse diminish. This would be consistent with the approach described in the AKS Proposed Rule with respect to the proposed safe harbors for VBE participants, discussed in Section II above.

Without a safe harbor protecting alternative medical products arrangements that are delinked from volume, the public health benefits captured in this alternative payment model (e.g., in the case of Hepatitis C, additional prevented reinfections of the virus, prevented complications and costs associated with hepatocellular carcinoma, and other health and economic benefits), might not be possible. This scenario is particularly relevant to Medicaid, where states are developing or have implemented subscription-type payment contracts for Hepatitis C treatments and may continue to consider expanded models for other therapies that rely on greater coordination with manufacturers and providers to achieve effective medical product use.

Moreover, the OIG is proposing to exclude manufacturers from the proposed safe harbor for patient engagement and support to improve quality, health outcomes, and efficiency. Under this proposed safe harbor, in-kind patient engagement tools or supports provided directly by a VBE participant to a patient would not violate the AKS, under certain conditions, if they are directly connected to the coordination and management of care. While the AKS helps limit fraud, waste and inappropriate spending in federal programs, its restrictions are not well-suited to arrangements such as the subscription model described in this example, where manufacturers are not paid based only or mainly on volume, but assume greater risk and accountability to improve the health outcomes of the covered population and lower total cost of care. These models might be hindered by the exclusion of manufacturers from this safe harbor, as their effectiveness will also likely depend on the ability of manufacturers to directly engage with patients and their providers to facilitate the goals of a given VBP arrangement. At a minimum, continued manufacturer incentives focused on increasing volume of sales will be at odds with provider incentives based on outcomes and total costs – conflicting with the intended goal of the proposed reforms for health care providers. As we have noted, arrangements that do not fully shift away from FFS could be protected by more limited safe harbors, as described in this section.

In conclusion, more action is needed to allow stakeholders to continue to develop and implement VBP arrangements that include medical products to help deliver on their promise. We urge the OIG to develop a safe harbor framework that encourages VBP arrangements for medical products that represent a significant enough shift from FFS to warrant relief from traditional AKS restrictions.

The Duke-Margolis Center appreciates the CMS's and OIG's consideration of our comments, and the Administration's support for advancing high-value, affordable health care. We and our colleagues would be pleased to provide more information on these issues if that would be

helpful. These comments are those of the authors at Duke-Margolis and are not necessarily reflective of the view of Duke University leadership, staff, or other affiliated individuals or organizations.

Sincerely,

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