

**VIA ELECTRONIC SUBMISSION**

The Honorable Seema Verma  
Centers for Medicare and Medicaid Services Administrator  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**RE: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability (TPL) Requirements**

Dear Administrator Verma:

The Robert J. Margolis, MD Center for Health Policy at Duke University (the Duke-Margolis Center or the Center) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS, or the Agency) proposed rule (“Proposed Rule”) captioned above.

The Duke-Margolis Center generates and analyzes evidence across the spectrum of health policy and supports the triple aim of better care, better health, and lower cost. A core mission of the Center is to focus on increasing the value of biomedical innovation to patients. To do so, we study the design, implementation, and feasibility of value-based payment (VBP) arrangements for medical technologies, which shift away from payments based on volume and promote payments based on the value of the provided treatment. The comments below are informed by the Center’s expertise in designing these new payment models; analyzing the impact of the current legal and regulatory environment on their adoption;<sup>1</sup> and working with multiple stakeholders to address the operational challenges to their use. The comments are also informed by the Center’s VBP for Medical Products Consortium. Formed in 2017, this multi-stakeholder initiative addresses practical issues in advancing VBP and is supported through the generosity of the Margolis Family Foundation, in-kind participation at the organizational level from all Consortium members, and membership fees from industry partners.

Duke-Margolis is broadly supportive of the Proposed Rule’s goals to increase the adoption of new payment models for medical products that are accountable to making significant improvements in patient health. The Proposed Rule is a noteworthy step to modernize legacy Fee for Service (FFS) price reporting policies to accommodate new types of VBP that are closely tied to evidence and better outcomes. Medical products often perform differently in post market settings with heterogeneous patient populations. Further new products are being increasingly approved with less evidence of durability and long-term benefits at the time of launch, resulting in significant uncertainty of the technology’s actual impact on health outcomes. VBP models for medical products offer the opportunity to align payment with observed value and align payer and manufacturer interests to rigorously develop and collect better evidence of approved products.

As Duke-Margolis has described,<sup>2</sup> legislative and regulatory barriers limit the development of VBP arrangements. These barriers include concerns about establishing an artificially low Medicaid Best Price (MBP)<sup>3</sup> when a drug does not perform well in a single patient, or violating the federal Anti-Kickback Statute (AKS). We appreciate CMS's acknowledgement in the Proposed Rule of the challenges posed for VBP arrangements by the existing MBP rules, and for proposing, for the first time, specific solutions for addressing the determination of MBP in the context of VBP.

While supportive, Duke-Margolis is concerned that the Proposed Rule, as written, may not facilitate the adoption at scale of meaningful VBP models. We outline three guiding principles for CMS to consider in final rulemaking and propose several specific considerations to the Proposed Rule's regulatory language. We also outline how those considerations can create distinct improvements in the medical technology payment environment relative to the status quo.

## Guiding Principles and How They Impact Final Rulemaking

As CMS undergoes the task of final rulemaking, we propose that its process be guided by the following foundational principles:

1. **Medicaid programs should continue to receive a discount from the best commercial marketplace prices, whether commercial payers use FFS or VBP arrangements.** The best mechanism for meeting the intent of the MBP statute as VBP contracts expand is the weighted average MBP calculation as facilitated by the revised bundled sales provision.
2. To expand VBP arrangements in Medicaid and maximize their impact, **states will benefit from sustained support from CMS to develop new strategies, infrastructure, and partnerships to overcome implementation challenges.** As follow-up to implementing the rule, CMS has the opportunity for new regulatory language for final rulemaking to enhance Supplemental Rebate Agreements to make them more appropriate for state VBP contracting and assistance for longitudinal data tracking and reporting; scaling of best practices; and leveraging expertise of public-private sector partnerships after the rule is finalized.
3. **Payers and manufacturers should have the flexibility to develop a range of models** in order to evaluate which models enable greater risk-sharing, better outcomes, and payment that is commensurate with observed benefits. As stakeholders implement new VBP models, there will be additional need for CMS and the Department of Health and Human Services Office of Inspector General (HHS OIG) to provide targeted, future clarifications on new models or types of contracting processes that emerge.

## Duke-Margolis Comments on Specific Provisions of the Rule

To support the guiding principles above, we propose several specific considerations to the Proposed Rule's regulatory language. Our comments and recommendations focus on three areas:

1) defining value-based payment; 2) accommodating VBP when reporting MBP; and 3) addressing the challenges of VBP implementation.

### Area 1: Defining Value-Based Payment

CMS has proposed two broad categories of value-based payment arrangements, one which includes evidence-based measures and a second that includes outcomes-based measures. CMS's definition of value-based arrangements using evidence-based measures is arrangements that *substantially link the cost of a drug product to the existing evidence of effectiveness and potential value for specific uses of that product*. The definition of outcome-based arrangement is similar and defined as: *actual performance in a patient or population, or a reduction in other medical expenses*.

The distinction that CMS proposes between 'evidence based' and 'outcomes based' approaches to designing a VBP arrangement is unclear and introduces potentially confounding language. Performance measures in outcome-based arrangements are inherently based on benchmarks of effectiveness derived from evidence. In addition, the definition CMS proposes for 'evidence-based' would allow for arrangements where a measure is only tangentially related to the product's benefit to the patient or health care system. For example, a manufacturer may propose that payment is at risk solely based on patient adherence. Under CMS' definition, this may be allowable as an 'evidence-based' VBP arrangement because patient adherence is related to existing evidence of the product's potential value. However, if the drug is meant to significantly improve functional status, patient adherence is only indirectly related to this benefit.

#### **We propose that CMS:**

- **Consider the Duke Margolis framework that categorizes value-based arrangements to clarify the payment arrangements included in the regulation.** Duke-Margolis developed a framework for categorizing value-based payment reform for medical technologies<sup>4</sup> that provides a roadmap for the range of reforms that have been characterized as "value-based" payment for medical products. In this framework, for all types of payment arrangements, negotiated payments may be linked to prior evidence on effectiveness. Furthermore, this framework further outlines models where payment can ex-ante reflect differences in expected value across patient groups and can include quality reporting adjustments, or is ex-post adjusted based on actual observed results in a treated patient or population, relative to specific benchmarks of effectiveness; and provides the structure for designing VBP arrangements by outlining varying levels of sophistication in assessing value of a medical technology through outcome or performance measures. Across the spectrum of the types of VBP arrangements, payments are retrospectively adjusted based on performance measures of value that can include patient reported outcomes, clinical outcomes, and total cost of care.
- **Define value-based payment as a voluntary arrangement between a payer and a manufacturer that substantially ties total payments for a product to its expected or observed performance in a patient or population.** In this definition 'performance' is further

clarified to mean that the product is either prospectively or retrospectively evaluated based on a negotiated measure or measures. This definition will allow for indication-based models where a product's payment may be negotiated to reflect uncertainty around its impact or if the product has a benefit for specific uses. Indication-based models would incorporate value assessments like those done by the Institute for Clinical and Economic Review (ICER) where limited initial evidence is used to consider potential pricing thresholds. Clarity in ensuring that the regulatory definition can be operationalized will be essential to ensure accurate reporting of manufacturer-payer arrangements.

#### *Characterizing "substantial" value-based payment arrangements*

CMS also requested comments on how to characterize the term 'substantially' in the value-based payment definition, specifically, how much of a drug's payment should be associated with outcomes-based measures in order for it to be considered a value-based payment. The wide applications of value-based payment for different types of drugs, outcomes, and patient populations precludes defining a single threshold by which payment should be associated with measures. Placing 30% of payment at-risk for a product that is intended to significantly reduce mortality may be reasonably considered to be substantial to many payers and manufacturers; on the other hand, placing 90% of payment at-risk for an outcome only tangentially related to the product's intended benefit may not be considered substantial by stakeholders.

Following our third guiding principle, we believe that payers and manufacturers should have the opportunity to implement value-based payment arrangements in order to develop evidence of what models are appropriate. CMS should be actively involved in this monitoring and evaluation process in order to develop policy responses best suited for this emerging market. To the extent that CMS insists on establishing explicit regulatory language that quantifies "substantial" in the value-based payment definition, we propose that CMS design a threshold that provides a moderate incentive to participate in VBP payment over Fee for Services without discouraging VBP adoption. CMS's proposed illustrative threshold in the Proposed Rule, 80% – 90%, would almost certainly produce a chilling effect for both payers and manufacturers in adopting new VBPs. Instead, if a threshold is required, we would recommend a threshold of at least 25-30% which we think would be broadly enabling for VBP implementation and are similar to the current statutory rebates that Medicaid receives.

#### Area Two: Accommodating VBP when Reporting MBP

CMS has introduced two different methodologies by which manufacturers can accommodate VBP arrangements when reporting MBP: (1) as qualified bundled sales, and (2) using multiple best prices.

#### *Bundled Sales Definition*

Currently used in FFS arrangements, the regulatory bundled sales construct allows manufacturers to allocate discounts proportionately across qualified drug sales for the purpose of price reporting. We applaud the Agency for proposing to amend the bundled sales definition so that

VBP arrangements could be included in it if they contain a performance requirement such as an outcome measurement metric. Importantly for VBP, this would facilitate a weighted average calculation of MBP, reflecting the failures *and* the successes of the therapy in a patient population,<sup>5</sup> so as not to “reset the manufacturer’s best price based upon the ultimate price of one unit of a drug” (NPRM, p. 37292). This would still provide states with the best marketplace prices.

However, we offer three refinements to CMS’s Proposed Rule. First, as described above, the Proposed Rule’s VBP definition requires a “substantial” link between the final drug cost and the outcome metrics, with 90% given as an example of a threshold. Because the proposed regulatory language in the revised bundled sales provision includes the term “VBP”, CMS should clarify whether it plans to apply its definition of VBP, as it is currently being proposed, in the bundled sales context as well. We are concerned that if CMS affirms the bundled sales approach that manufacturers have been currently using (through reasonable assumptions), but only in the context of its proposed definition for VBP arrangements, then the potential usage of the bundled sales provision might be significantly limited. **We request CMS clarify that it does not intend to carry over its proposed definition of a VBP arrangement and apply it to its proposed codification of existing reasonable assumptions used by manufacturers under the bundled sales provision.**

Second, in some cases, such as for a gene therapy for a very rare condition, an outcome for a single patient can dramatically affect the weighted average rebate in a given VBP contract. In such cases where the number of patients covered by an individual contract is so low as to make the average price unreliable, **we propose that MBP could potentially be calculated over a set of contracts with aligned outcome provisions, or even on a national level, to help determine MBP more reliably.** While we recognize that CMS has put forward the multiple MBP option in part to address reporting MBP in contracts for small populations, **we propose that the Agency consider addressing this challenge under the bundled sales mechanism as well and issue further guidance on how it should apply to contracts with small patient populations so that this important reporting scheme can be realized.**

Finally, we are concerned that manufacturers might group VBP arrangements for multiple products under one bundled contract, thereby equally allocating the rebates in a weighted average fashion across the different VBP arrangements. **We would appreciate CMS’s clarification that in such cases of more than one VBP under a single bundled contract, the Agency would apply the rebates in accordance with its 2007 rulemaking that provided an illustrative example of how to allocate pricing in a bundled sale involving multiple products.** In that rulemaking, CMS clarified that it would apply the discounts across the different products based on the level of undiscounted sales of *each* product and not as a single uniform discount for both products combined.<sup>6</sup>

### *Challenges with Multiple Best Prices*

The second methodology that CMS proposes for MBP reporting is multiple best prices: in addition to the FFS MBP, the manufacturer could report a set of ‘best prices’ based on the range of outcome measures for that drug under the VBP arrangement. The language of the Proposed Rule seems to suggest that states would need to adopt identical arrangements to those that are given to commercial payers and track the therapy’s performance and outcomes so that this MBP reporting methodology could be applied. Doing so would enable states to benefit from the same rebate levels offered in the commercial market, although the actual rebates provided to the state from the manufacturer would depend on the performance of the drug in the state’s participating Medicaid population.

The multiple MBP reporting mechanism appears to be more conducive to small patient population arrangements than the bundled sales option because as CMS notes, the rebate due to the state from the manufacturer for a given patient would only be due for that patient and not all patients. In other words, it would not set MBP for the entire Medicaid market. However, as outlined below, there are various operational and other challenges that are associated with the multiple MBP proposal. For this reason, we are concerned that the multiple MBP proposal would introduce complexities that would outweigh the benefits for states that this proposal envisions.

In light of the challenges and complexities of the multiple MBP proposal, discussed in the next few paragraphs, **we propose that CMS adopt the weighted average MBP calculation as facilitated by the revised bundled sales provision as the new and primary approach for calculating MBP.** In addition, we discuss our recommendations for creating a federal framework to better enable states to enter into VBP arrangements with manufacturers (see pages 8-9).

As CMS considers how to proceed, we lay out the following main challenges that we believe are associated with this proposal, and where applicable, propose the following modifications if the multiple MBP methodology is adopted:

First and foremost, it is our understanding that the Proposed Rule intends that states would be entitled to the lowest price available absent a VBP arrangement, *i.e.*, the traditional FFS MBP, for Medicaid patients that are not included in the state-adopted VBP arrangement, therefore, potentially not supplying the state with the best marketplace prices for many of its Medicaid beneficiaries. In addition, CMS suggests that states could choose between a VBP MBP reporting and a non-VBP price reported as MBP when offered a multiple MBP reporting model. It appears that it is CMS’s intention to allow states to decline adopting the VBP arrangement, and by doing so, similarly to the point above, states would only be receiving an MBP that is based on the traditional FFS formula absent any VBP and not on the basis of a bundled sales calculation. This means that if states do not have the capacity to enter into a VBP arrangement, they would be losing out on a VBP MBP. **If the multiple MBP approach is finalized by CMS, we propose that it adopts bundled sales as the default mechanism for MBP reporting for patients that are not included in the state’s VBP arrangement and when the state chooses not to adopt the arrangement offered by the manufacturer, while calculating the weighted average across**

**contracts as proposed above on page 5, to account for the volatility challenge associated with contracts for small populations.**

In addition, the existence of multiple MBPs might have implications on the calculation of ceiling prices under the 340B drug pricing program. CMS is not clear as to whether it intends for there to be multiple 340B ceiling prices based on the multiple MBPs that could be reported for a given drug, which also raises questions on which 340B patients will be entitled to which ceiling prices. **We propose that CMS clarify these issues, together with the Health Resources and Services Administration (HRSA) that administers the 340B program, so that any potential impact on the program does not deter adoption of VBP arrangements.**

CMS appears to suggest that when using the multiple MBP pathway, Medicaid agencies would pay the multiple MBPs and receive rebates using the existing statutory rebate scheme and therefore the design and implementation of any Supplemental Rebate Agreements (SRAs) would not be required. Using the multiple MBP model while eliminating the need for using the SRA pathway would allow the rebates to be paid to the state on FFS and Medicaid Managed Care (MCO) utilization alike, and provide the negotiating parties with greater flexibility to design VBP arrangements than has been allowed so far using SRAs. **We would appreciate CMS's confirmation that this is its intention.**

Finally, in the event that a drug manufacturer has multiple VBP structures in place with commercial payers for a given drug, the Proposed Rule seems to require the manufacturer to report all of these arrangements to the state, with the lowest price for each performance level, so that Medicaid can pick the "best deal". **While this is our reading of the Proposed Rule, we would appreciate CMS's clarification that this is its intention.**

### [Area 3: Addressing the challenges of VBP implementation](#)

Duke-Margolis has written extensively about the operational challenges of implementing VBP arrangements for medical technologies.<sup>7</sup> Based on our experience with this topic, we see numerous areas that the Proposed Rule could better clarify how these contracts might be operationalized and signal how CMS will serve as a resource to enable their progress. We divide our comments into the implementation considerations for states and all payers and what CMS should prioritize in final rulemaking and address in future agency actions.

#### ***Recommendations to Facilitate State VBP Implementation***

We previously raised concerns against the multiple MBP approach outlined in the Proposed Rule because there appears to be simpler, more straightforward vehicles to enable value-based payment arrangements. However, a standalone and substantial problem with the multiple best price approach is that a given state's ability to "choose" one of the VBP best prices will be limited by that state's ability to implement the VBP arrangement. Typically, a payer in a VBP arrangement will need reliable data on utilization, diagnoses, and clinical outcome measures. In many cases, a state or managed care entity must collaborate or receive support from the

manufacturer. There is no way to implement that arrangement if that state does not have adequate and timely access to data. We recommend two sets of actions that CMS can take to address this challenge in final rulemaking: new regulatory language for final rulemaking to enhance Supplemental Rebate Agreements to make them more appropriate for state VBP contracting and sustained support for states after the rule is finalized.

**We propose that CMS develop a federal framework for state Medicaid agencies for designing and implementing VBP arrangements.** A first step in building this regulatory framework could be expanding the existing Supplemental Rebate Arrangement (SRA) requirements to better enable state VBP arrangements. These ‘VBP SRAs’ would have specific characteristics and requirements, such as:

- A VBP arrangement, as defined in the final rule, between a state or state(s) and a manufacturer;
- Manufacturer rebates to the state that are at least as large as rebates the states may receive *from the bundled sale weighted average approach proposed by Duke-Margolis*;
- Payment in the arrangement that is at-risk based on an observed outcome(s);
- Price negotiation between the state and manufacturer that is confidential, mirroring the current FFS SRA requirement;
- Payment from the state to the manufacturer that is not required to be on a per-unit basis and can occur before a product is used.

There are several compelling benefits with developing this enhanced type of SRA meant to allow states to benefit from arrangements negotiated in the commercial market. It closely follows the Section 1927 statutory language enabling Supplemental Rebate Arrangements and explicitly allows states to enter into pooled arrangements. It also guarantees that states can negotiate a price that is anchored to existing VBP best prices, creating an avenue for states to receive uniquely higher levels of rebates than even all other VBP markets. Finally, it removes FFS limitations that have prevented certain types of payment models in the current environment, such as truly prospective, population-based models. This proposal offers states special authorities beyond the Proposed Rule that may mitigate concerns that states will not have options to receive potential savings associated with implementing VBP arrangements.

Since many states direct managed care entities to administer their programs, Medicaid programs also need to clear ways to direct MCOs to implement VBPs that ultimately benefit their state and beneficiaries. Currently, CMS-authorized supplemental rebates provided by manufacturers to states are specifically excluded from AMP and MBP reporting. However, as some states have been allowing supplemental rebates to be paid by drug manufacturers to MCOs, this practice has raised questions regarding the status of those rebates in the context of MBP reporting. The Proposed Rule seeks to address this issue by creating a definition for “CMS-authorized supplemental rebate agreements” that would only permit supplemental rebates that are paid under a State Plan Amendment (SPA) and to a state Medicaid program, to be excluded from MBP reporting. We are concerned that this change might adversely impact the rebate calculation for

some manufacturers and as a result limit their ability to enter into VBP arrangements with Medicaid MCOs. Providing Medicaid MCOs with the flexibility to negotiate VBP arrangements independently of state Medicaid agencies would broaden the scope of the types of VBP arrangements that manufacturers and Medicaid MCOs could enter into for Medicaid managed care populations, especially as managed care has become prevalent in most state Medicaid programs.

We believe that these recommendations are most appropriate to shape final rulemaking but urge CMS to consider a broad set of actions to support state VBP implementation after the rule is finalized. Specifically, we think that CMS should begin to support state VBP implementation efforts in the following ways:

- **If CMS decides to finalize a multiple best prices approach, we recommend that CMS should provide a mechanism for manufacturer communication of multiple best prices to states.** We believe that the agency must provide a mechanism that allows states to proactively understand what multiple best price options exist for them while preserving some capacity for manufacturers' proprietary details of the VBP arrangements to be kept confidential. Ideally, this reporting mechanism would be described in subsequent guidance to allow manufacturers to know exactly what standardized elements to report to CMS and when. CMS would record these in a timely way and have a mechanism to confidentially disclose to states what types of VBP arrangements are available for a given product and their guaranteed net price. Because of the novelty of VBP payment models for medical technologies, there is an elevated need for clear reporting requirements and for states to know exactly what their VBP model options are at any time.
- **CMS should consider additional policies such as supporting the collection of important outcome measures as a type of meaningful EHR use. In designating a new type of meaningful EHR use, CMS should play an active role in the harmonization of performance measures across states to avoid duplicative measurement efforts.** This aligns with CMS efforts toward "meaningful measures" to reduce provider burden<sup>8</sup> as well as advancing VBP use.
- **CMS should provide opportunities for cross-state learning or multi-state initiatives to support state VBP implementation: developing internal state capacity for VBP arrangements, contracting with managed care organizations, and guiding the development of a cross-sector, multiple-payer data system.** To For states seeking to develop this capacity themselves, CMS could give clear guidance on some potential strategies that states could use to direct managed care organizations to enter VBPs on the state's behalf, or provide guidance regarding the extent to which manufacturers can appropriately be involved in data monitoring.

### ***Recommendations to Support Multiple Payer VBP Implementation***

We emphasize that the Proposed Rule is a significant step to creating a new payment environment for medical technologies that aligns payment with outcomes. However, we think

that there are additional regulatory and operational concerns that the agency should address in order to continue to support VBP adoption.

In the current environment, there is misalignment regarding which entity (payer, manufacturer, or both) is responsible for tracking outcomes. We do believe that CMS should not prescribe in rulemaking how this should be determined but should instead promote policies that allow for sharing of best practices, opportunity for stakeholders to collaborate on long-term data tracking, and consider developing multi-payer reporting systems. One significant barrier that the Proposed Rule does not address are regulatory challenges that payers and manufacturers face when attempting to collaborate on shared reporting systems. The Proposed Rule does not address issues that might arise from the AKS, which might consider manufacturers' data monitoring and outcome tracking activities as unlawful inducements.<sup>9 10</sup> This obstacle might become even greater in light of the HHS OIG's proposal to exclude drug manufacturers from its newly-proposed safe harbor protection for value-based enterprises in October 2019. We recommend that CMS **consider coupling the Proposed Rule with an OIG NPRM to create a safe harbor for VBP arrangements for medical products or pursuing future rulemaking to produce a new safe harbor.**

## Conclusion

We support the Proposed Rule's intent to address barriers to greater adoption of VBP arrangements. We encourage the Agency to consider our recommendations as a means of adhering to the proposed guiding principles. With thoughtful additions to the sections focused on the VBP definition, MBP methodologies, and implementation challenges, the final rule can be a significant and positive improvement to the pricing and payment environment that supports a higher-value health care system. This Proposed Rule is an important and commendable step in the transition to system where medical product payment is accountable for outcomes. To meet these goals and truly make value-based payment a reality, sustained effort beyond this Proposed Rule is necessary.

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

Sincerely,

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<sup>1</sup> Duke-Margolis Center for Health Policy. Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products. Accessed July 16, 2020. Available At [https://healthpolicy.duke.edu/sites/default/files/2019-11/overcoming\\_legal\\_and\\_regulatory\\_hurdles\\_to\\_value-based\\_payment\\_arrangements\\_for\\_medical\\_products.pdf](https://healthpolicy.duke.edu/sites/default/files/2019-11/overcoming_legal_and_regulatory_hurdles_to_value-based_payment_arrangements_for_medical_products.pdf)

<sup>2</sup> Id

<sup>3</sup> Duke-Margolis Center for Health Policy. Clarifying Medicaid Best Price Regulations in the Context of Value-Based Payment Arrangements. Accessed July 10, 2020. Available at <https://healthpolicy.duke.edu/news/clarifying-medicaid-best-price-regulations-context-value-based-payment-arrangements>

<sup>4</sup> Lopez MH, Daniel GW, Fiore NC, Higgins A, McClellan MB. Paying for Value From Costly Medical Technologies: A Framework For Applying Value-Based Payment Reforms. Health Affairs. 2020 Jun 1;39(6):1018–25.

<sup>5</sup> Id at ii

<sup>6</sup> 72 Fed. Reg. 39158 (July 17, 2007)

<sup>7</sup> Mahendraratnam N, Sorenson C, Richardson E, Daniel GW, Buelt L, Westrich K, et al. Value-Based Arrangements May Be More Prevalent Than Assumed. The American Journal of Managed Care.

<sup>8</sup> Center for Medicare and Medicaid Services. Meaningful Measures Framework. Accessed July 20, 2020. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>

<sup>9</sup> Mahendraratnam N et al. Value-Based Arrangements May Be More Prevalent Than Assumed. Accessed July 20, 2020. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>

<sup>10</sup> Health and Human Services Office of the Inspector General. Duke Margolis Self Referral and Anti Kickback Comment Letter. Accessed July 16, 2020. Available at: <https://www.regulations.gov/document?D=HHSIG-2019-0002-0247>