Alliance for Regenerative Medicine

October 26, 2018

Ms. Susan Edwards
Office of Inspector General, U.S. Department of Health and Human Services
Attention: OIG-0803-N, Room 5513, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: Response to OIG Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty (OIG-0803-N)

Dear Ms. Edwards,

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to offer the following input to the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) in response to your August 27, 2018 request for information (RFI) regarding the federal anti-kickback statute and the beneficiary inducements civil monetary penalty (CMP).

About the Alliance for Regenerative Medicine

ARM is an international, multi-stakeholder advocacy organization that promotes legislative, regulatory and reimbursement initiatives necessary to facilitate access to life-saving advances in regenerative medicine. Regenerative medicine is a rapidly evolving, interdisciplinary field that utilizes new technologies and therapeutic strategies to augment, repair, replace or regenerate organs and tissues to cure or significantly change the course of chronic and life-threatening disease. ARM works to increase public understanding of the field and its potential to transform health care, while also providing support for the development and growth of more than 290 member companies, research institutions, investors and patient groups.

The Pressing Need for Innovation

We are at a critical juncture where regenerative technologies and therapies have been and will continue to be brought to market at an incredibly rapid pace. As of the second quarter of this year, there were 977 clinical trials involving regenerative medicine underway worldwide, including 93 late-stage and large-scale Phase 3 trials. In addition, the U.S. Food and Drug Administration (FDA) has granted 20 requests to formally designate products as "regenerative medicine advanced therapies," which under the 21st Century Cures Act serves to expedite access to care for seriously ill patients who stand to benefit most from these new treatments. The majority of regenerative medicine therapies developed by members of ARM focuses on rare or orphan diseases that often lack other clinically effective treatment options.

ARM and its members have long recognized the need for innovation within the very U.S. health care system in which regenerative technologies and therapies must be accessed by patients in need. Over the past several years, ARM has carefully analyzed the health care legislative and regulatory environment to determine the viability of certain alternative payment models that can be leveraged for such

groundbreaking medicine. These payment models, including the use of value-based pricing or financing arrangements to pay for the cost of a treatment over a period of time, help address the fact that many of the one-time, curative treatments proposed may realize their full clinical and economic value only over time. Much of the current system, however, continues to pay according to service versus value, and ARM fully concurs with HHS in its belief that this design "does not necessarily translate to the modern health care system."[1] Regenerative medicine will transform the provision of health care in this country, and we urge the OIG to act timely and definitively in the midst of such change.

Exploring Value-Based Arrangements and Alternative Payment Models

The RFI solicits input on potential arrangements, including value-based arrangements and alternative payment models, that may implicate the anti-kickback statute or beneficiary inducements CMP in order to better understand the terms of such arrangements and how they may be structured to protect against fraud, abuse and other potential harms.

Value-based arrangements serve to link payments to performance in ways that account for both the cost and quality of care provided. The most basic value-based purchasing model may function essentially as a "money-back guarantee," where the cost of the treatment would be refunded if the treatment does not meet certain committed levels of efficacy for a particular patient or group of patients. One variation to this model is to finance the cost of treatment over time through an initial or discounted payment when the therapy is first administered, with future payments for the remaining cost of the treatment contingent on meeting certain defined clinical outcomes or other measures at fixed intervals over a period of time. Both options present significant benefits when such treatments otherwise require a higher upfront investment for a one-time treatment, when in fact the eventual cost savings for a curative therapy accumulates over time. Manufacturers may also consider "indication-based" pricing, with higher reimbursement rates when treatments pose a better therapeutic value for patients with certain medical conditions versus indications for which such therapies offer less of a benefit or value.

We emphasize, however, that there is a wide range in the forms and features of value-based arrangements and other payment models that could be employed for the federal reimbursement of regenerative technologies and therapies. OIG must consider safe harbors that are sufficiently flexible to accommodate the many types of arrangements that innovators may use to accommodate the unique clinical circumstances presented for each type of technology or therapy, whether based on the patient population, site of administration, or technology utilized. While existing anti-kickback safe harbors may offer some degree of protection for these arrangements, the very nature of value-based purchasing precludes the use of certain safe harbors that could have otherwise been leveraged to protect such arrangements from liability under the anti-kickback statute. For instance, the discount safe harbor at 42 C.F.R. § 1001.952(h) does not offer protection for several types of "buyers" in the health care system unless the buyer (1) is a health maintenance organization or competitive medical plan acting in accordance with a risk contract under Social Security Act §§ 1876(g) or 1903(m) or another state health care program, (2) reports its costs on a cost report required by a federal or state health care program, or (3) is a buyer in whose name a claim or request for payment is submitted under a federal health care program. It may be worth noting that the discount safe harbor has not been revised or clarified in formal rule-making in nearly 20 years, during which time the health care system has changed considerably to include a much wider variety of buyers, such as non-charge-based payors, group purchasing organizations and pharmacy benefit managers.

[1] Testimony of HHS Deputy Secretary Eric D. Hargan before the House Ways and Means Subcommittee on Health, July 17, 2018.

In addition, value-based arrangements may require certain ancillary services necessary to the use of such arrangements, such as care coordination services or items or services that may be used for the collection and monitoring of clinical data to assess outcomes or value. Such services could fall under the definition of "remuneration" under Social Security Act § 1128B because, for example, the personal services safe harbor at 42 C.F.R. § 1001.952(d) requires aggregate compensation paid under the arrangement to be set in advance, a condition that cannot be met where the payments themselves cannot be determined until one can assess the value of treatment as defined under the arrangement.

Value-based arrangements may also implicate beneficiary inducement concerns despite the substantial benefits that such arrangements provide to patients in terms of access to care and affordability. Patients responsible for copayments or coinsurance should also share in any refunds or cost reductions that a payor would receive under a value-based arrangement if the treatment does not meet expectations for clinical efficacy or other value or quality-based measures. This refund, however, would not be reliably protected under the beneficiary inducements CMP. For example, a refund or cost reduction offered to the patient under a value-based arrangement is not "the waiver of coinsurance or deductible amount," which is allowed limited protection under the CMP in certain circumstances, and even then only based on a good faith, individualized assessment of financial need. Other general safe harbors under the beneficiary inducements CMP for "access to care" or "financial need" cannot be consistently applied to value-based arrangements because the qualifying criteria can be applied only on a case-by-case basis and remain subject to interpretation.

We include below other considerations for value-based arrangements and alternative payment models, some unique to regenerative medicine, but all of which pose further anti-kickback statute and beneficiary inducements CMP implications:

- **Initial Assessments**. Given the groundbreaking nature of regenerative technologies and therapies, health care services that may be required to determine the clinical appropriateness of a treatment, e.g. specific types of genetic testing, may not be covered by public or private payors and/or can be performed only by certain, specialized health care providers. Value-based arrangements may be structured to assume or factor in the costs of this initial assessment, whether for the test itself or for the expense related to the coordination of the care or services needed to perform the assessment. However, manufacturers, physicians and payors alike may be deterred from entering into such arrangements by both anti-kickback as well as Stark Law concerns due to the referral of items and services or the negotiations of price concessions related to the value-based arrangement.

- **Limited Access**. As noted above, the testing and administration of regenerative therapies will be limited, at least initially, to certain "centers of excellence" qualified to treat patients using these technologies. This will especially be the case for treatments intended for rare and orphan diseases, as a broader roll-out of these therapies is unlikely. Patients, and in pediatric cases, their parents or caregivers, may require greater financial or logistical assistance for assuming travel expenses, which could be provided through an institution's or manufacturer's patient assistance program. However, the anti-kickback statute safe harbor for local transportation, also incorporated as a CMP safe harbor,[2] does not protect arrangements involving air travel or

[2] 42 C.F.R. § 1003.110 also protects "any permissible practice as specified" in the anti-kickback statute or regulations.

transportation which exceeds 25 miles (or 50 miles for patients residing in rural areas).[3] This and other forms of beneficiary assistance intended to promote access to care to therapies that are not widely available should be protected, especially since the risk of overutilization of treatments for rare and orphan diseases is necessarily lower due to the decreased number of affected patients.

- **Continuing Evaluation**. Value-based arrangements require a continuing evaluation of clinical outcomes and efficacy in order to determine the value of the treatment in the first place. For the new and transformative therapies in queue, the collection and analysis of patient data over 10 or even 15 years is crucial to move the entire field of regenerative medicine forward. A key difference, however, is that with one-time, potentially curative therapies, a patient is soon unlikely to require the same level and frequency of post-treatment care. Ironically, this situation both demonstrates the value of regenerative medicine in the reduction of future health care services, while at the same time limiting the ability of manufacturers, payors and other stakeholders to collect patient data during more frequent physician visits that would otherwise be required. As with initial assessments for the suitability of regenerative technologies and therapies, continuing evaluations may need to be arranged between manufacturers, physicians and payors to ensure the on-going collection of necessary patient data. In addition, manufacturers and payors may need to explore the use of patient incentives to encourage continued participation, whether in the form of patient clinical monitoring devices or tracking and reporting apps to report medical data, or patient reimbursement for time and costs assumed for undergoing additional clinical evaluations.

Anti-Kickback Safe Harbor for Value-Based Arrangements

ARM previously submitted comments in response to OIG's annual solicitation of new anti-kickback statute safe harbors and special fraud alerts, as issued on December 27, 2017. In our letter, we proposed a safe harbor that included specific protections to provide firm guidance to a wide range of stakeholders wishing to enter into value-based arrangements, while still protecting federal health care programs from overutilization, increased costs, or other abuses that would impact patient freedom of choice and access to quality care. This proposed safe harbor, submitted for a second time with this letter as Appendix A, provides for the following:[4]

1. The terms and conditions of the value-based arrangement, including the time period for the measurement of the clinical outcomes and metrics, are fixed prior to the purchase.
2. The purchase price for the health care item or service would be disclosed by the buyer and the seller to Medicare and Medicaid as required by law.
3. The value-based arrangement insulates patients from undue financial burden, so that the patient shares in any beneficial adjustment to the purchase price of the health care item or service and is "held harmless" for any increase in price to the buyer.
4. Any ancillary items or services used solely or primarily for the measurement of clinical outcomes necessary to determine payment or other terms under the value-based arrangement cannot be separately billed by the buyer or seller.

[3] 42 C.F.R. § 1001.952(bb).

[4] The original proposed safe harbor referred to "value-based purchasing arrangements" rather than "value-based arrangements." This has been updated to conform to OIG's use of the term in the RFI.

Beneficiary Inducements CMP Safe Harbor for Value-Based Arrangements

As a corollary to the proposed anti-kickback safe harbor above, we also propose in Appendix B a safe harbor to the beneficiary inducements CMP for value-based arrangements. This proposed safe harbor is designed to protect two elements necessary for value-based purchasing that directly benefit the patient, specifically (1) a patient's ability to share in any beneficial adjustment to the purchase price of the health care item or service, and (2) reasonable patient incentives to secure the submission of post-treatment clinical data required for the execution of a value-based arrangement.

OIG Guidance Versus Regulation

Finally, ARM would like to address the question posed in the RFI as to whether there are opportunities for the OIG to clarify its position through sub-regulatory guidance as opposed to regulation. While value-based arrangements may be examined on a case-by-case basis for potential anti-kickback implications,[5] our members and many other stakeholders in the health care industry are grappling with a lack of clarity and certainty from the OIG from a regulatory and enforcement perspective. ARM members are now negotiating value-based arrangements and alternative payment models for its regenerative technologies and therapies consistent with HHS goals and priorities, all the while assessing potential risks implicated with a reliance on ambiguous and undefined compliance standards governing such arrangements. OIG advisory opinions, for example, to the extent they even address these types of arrangements, are issued based solely on the facts and circumstances presented by the requestor and require extensive legal and regulatory interpretation to determine their applicability to a stakeholder's own arrangement under evaluation. We acknowledge that sub-regulatory guidance may be administratively easier and more timely to produce, so ARM fully supports OIG's use of definitive and reliable guidance or policy statements in the interim to clearly set forth its position on value-based arrangements. Still, we believe there has long been a persistent need for regulation from the OIG to successfully usher in new payment models that will transform our current health care system.

We would be pleased to engage in further discussion with the OIG on the above. Thank you in advance for your consideration of the comments and recommendations included in this letter. If you have any questions or need any additional information, please contact me at rfalb@alliancerm.org or at 202-320-7602.

Sincerely,

Robert Falb
Director, U.S. Policy and Advocacy
Alliance for Regenerative Medicine

[5] Appendix G, OIG Semiannual Report to Congress, April 1, 2017 to September 30, 2017.

Appendix A: Proposed Anti-Kickback Statute Safe Harbor for Value-Based Arrangements

Value-Based Arrangements. As used in section 1128B of the Act, "remuneration" does not include an adjustment to the purchase price for an item or service reimbursable in whole or in part under Medicare, Medicaid or other Federal health care program pursuant to a value-based arrangement, nor the provision of health care items and services provided pursuant to a value-based arrangement that are necessary for the evaluation and attainment of the clinical and/or cost outcomes upon which the arrangement is based, so long as the following five standards are met —

(1) The terms and conditions of the value-based arrangement are fixed and agreed upon between buyer and seller through a written agreement signed by the parties before or at the time of the initial purchase of the item or service;

(2) Buyer and seller shall fully and accurately disclose, report, or otherwise account for an adjustment to the purchase price for the item or service resulting from the value-based arrangement to the extent required by any law or regulation requiring buyer or seller, as applicable, to disclose its purchase price or costs for such items or services in order to be eligible to receive payment under Medicare, Medicaid or other Federal health care program;

(3) Buyer shall ensure any subsequent adjustments to the purchase price of the item or service pursuant to the value-based arrangement that serve to lower the purchase price of the item or service for the buyer are proportionately applied to any coinsurance or deductible amounts paid by the patient under the value-based arrangement, and buyer shall not hold the patient liable for any additional amounts owed by the buyer to the seller due to any subsequent adjustment to the purchase price of the item or service pursuant to the value-based arrangement;

(4) Neither buyer nor seller shall submit any claim to Medicare, Medicaid or other Federal health care program for any item or service provided by buyer or seller as a requirement of the value-based arrangement solely or primarily to measure, collect, record or otherwise evaluate the patient's clinical metrics or outcomes upon which the value-based arrangement is based, but excluding those health care items or services required for the routine care and monitoring of the patient's medical condition; and

(5) The time period for the measurement, collection, recording or evaluation of the patient's clinical metrics or outcomes is fixed, not indefinite, and set in advance in the written agreement.

For purposes of this paragraph, the term value-based arrangement means an agreement that adjusts the purchase price for an item or service reimbursable by Medicare, Medicaid or other Federal health care programs based upon clinical and/or cost outcomes (determined through the use of one or more measureable metrics) of one or more patient(s) or patient population(s) resulting from the use of the item or service to which the arrangement applies.

For purposes of this paragraph, buyer means an individual or entity that bears financial responsibility, in whole or in part, directly or indirectly, for payment for an item or service pursuant to a value-based arrangement.

For purposes of this paragraph, seller means an individual or entity that, directly or indirectly, supplies an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care program, to the buyer and who permits an adjustment to the purchase price of the item or service pursuant to a value-based arrangement.

Appendix B: Proposed Beneficiary Inducements CMP Safe Harbor for Value-Based Arrangements

Remuneration, for the purposes of § 1003.1000(a) of this part, is consistent with the definition in section 1128A(i)(6) of the Act and includes the waiver of copayment, coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include:

(1) An adjustment to the purchase price for an item or service reimbursable in whole or in part under Medicare, Medicaid or other Federal health care program pursuant to a value-based arrangement as defined in [cross-reference to section for anti-kickback safe harbor's definition of value-based arrangements] that is proportionately applied to any non-reimbursable coinsurance or deductible amounts directly paid by the beneficiary under that value-based arrangement;

(2) Items or services provided to a beneficiary under a value-based arrangement as defined in [cross-reference to section for anti-kickback safe harbor's definition of value-based arrangements] that solely or primarily measure, collect, record or otherwise evaluate that beneficiary's clinical metrics or outcomes upon which the value-based arrangement is based, if the duration for the provision of such item or service coincides with the time period set forth in that value-based arrangement for the measurement, collection, recording or evaluation of the patient's clinical metrics or outcomes in accordance with [cross-reference to section for anti-kickback safe harbor for value-based arrangements];

(3) Incentives given to a beneficiary with the intent to promote the measurement, collection, recording or evaluation of that beneficiary's clinical metrics or outcomes under a value-based arrangement as defined in [cross-reference to section for anti-kickback safe harbor's definition of value-based arrangements]. Such incentives may not include –

(i) Cash or cash equivalents, unless in an amount that does not exceed the reasonably expected or actual out-of-pocket and non-reimbursed expenses directly incurred by the beneficiary for the measurement, collection, recording or evaluation of that beneficiary's clinical metrics or outcomes under the value-based arrangement.

(ii) Any incentive the value of which is disproportionately large in relation to the reasonably expected or actual out-of-pocket and non-reimbursed expenses directly incurred by the beneficiary for the measurement, collection, recording or evaluation of that beneficiary's clinical metrics or outcomes under the value-based arrangement.

(iii) Any incentive provided outside of the time period set forth in the value-based arrangement for the measurement, collection, recording or evaluation of the patient's clinical metrics or outcomes, in accordance with [cross-reference to section for anti-kickback safe harbor for value-based arrangements].