April 8, 2019

Mr. Aaron Zajic
Office of Inspector General, U.S. Department of Health and Human Services
Attention: OIG-0936-P, Room 5527, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: Response to OIG Proposed Rule on the Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Mr. Zajic,

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to offer the following comments to the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) in response to your February 6, 2019 proposed rule to amend the discount safe harbor under the anti-kickback statute to explicitly exclude certain price reductions under Medicare Part D and Managed Medicaid, and to implement two new safe harbors to protect point-of-sale reductions on prescription drugs as well as certain service fees charged by pharmacy benefit managers (PBMs) (the "Proposed Rule").

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 300 leading life sciences companies, research institutions, investors, and patient groups that represent the regenerative medicine and advanced therapies community.

The Importance of Value-Based Arrangements and Alternative Payment Models

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 purchasing, 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 for the quantity of services versus their 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.

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 an initial or discounted payment upfront when the therapy is first administered, and to continue to evaluate clinical outcomes and other measures to determine future payments for the remaining cost of the treatment. Both of these 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.

Impacts of the Proposed Rule on Value-Based Purchasing

While ARM is supportive of the OIG's efforts to reexamine the applicable regulatory safe harbors currently in place under the anti-kickback statute, our members are very concerned that the proposed change to exclude manufacturer price reductions in connection with the sale or purchase of a prescription drug under Medicare Part D or Managed Medicaid (unless the price reduction is required by law) would serve to also exclude arrangements involving the application of price concessions based on value. In addition, the very nature of value-based purchasing often requires that price concessions linked to value be applied after the point of sale, when clinical outcomes and other metrics can be measured. As such, the proposed new safe harbor to protect point-of-sale price reductions offers little benefit to – and could result in hampering – value-based purchasing arrangements here either.

We understand that the HHS "does not intend for this proposal to have any effect on existing protections for value-based arrangements between manufacturers and plan sponsors," and that the OIG has expressed interesting in learning "the extent to which the proposed amendment and accompanying proposed safe harbor may affect any existing or future value-based arrangements." 84 Fed. Reg. 2340, 2348 (February 6, 2019). Without more explicit protections in place to protect value-based purchasing, ARM believes that the Proposed Rule, if finalized, may have the unintended consequence of restricting the ability of manufacturers to offer value-based purchasing arrangements that involve any form of price concession or reduction after the point-of-sale. There are no current safe harbors in place that otherwise reliably protect the wide range of value-based arrangements and other payment models that could be employed for the federal reimbursement of regenerative technologies and therapies.

In addition, although the Proposed Rule focuses primarily on the use of rebates and price concessions in Medicare Part D and Managed Medicaid, we note that the OIG has also solicited comments on whether this amendment "should apply to prescription pharmaceutical products payable under other HHS programs," for example, under Medicare Part B. 84 Fed. Reg. 2347. Given that regenerative technologies and therapies would more commonly be covered under programs other than Medicare Part D due to the methods of administration and sites of care, the extension of the proposed safe harbor exclusion to additional government health care programs will have an even more pronounced, deleterious impact.

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

ARM opposes further expansion of the applicability of the proposed safe harbor exclusion to any other HHS programs, until, at a minimum, the OIG is able to reliably assess the results under the Medicare Part D and Managed Medicaid programs. We strongly urge the OIG to reconsider the adoption of such a broad safe harbor exclusion that, on its face, would also serve to also exclude many value-based purchasing arrangements.

The Need for an 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, as well as in response to the OIG's request for information on the anti-kickback statute and beneficiary inducement civil monetary penalty on October 26, 2018. These comments proposed a safe harbor that includes 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 is especially critical if the OIG were to implement the Proposed Rule as currently drafted. ARM's proposed safe harbor, submitted again with this letter, provides for the following:

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.

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

Appendix: 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.