



February 26, 2018

Ms. Patrice Drew, Regulatory Affairs
Office of Inspector General, U.S. Department of Health and Human Services
Attention: OIG-127-N, Room 5541C, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: Response to OIG Solicitation of New Safe Harbors and Special Fraud Alerts, OIG-127-N

Dear Ms. Drew,

The Alliance for Regenerative Medicine (ARM) appreciates the opportunity to provide the following comments and recommendations for the development of new or revised safe harbors to the federal anti-kickback statute, § 1128B(b) of the Social Security Act, as solicited by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (DHHS) on December 27, 2017.

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 275 member companies, research institutions, investors and patient groups.

The Need for an Anti-Kickback Safe Harbor for Value-Based Purchasing Arrangements

We are at a critical juncture where groundbreaking regenerative technologies and therapies have been and will continue to be brought to market at an incredibly rapid pace. By the end of last year, 946 clinical trials involving regenerative medicine were underway, including 82 late-stage and large-scale Phase 3 trials. In addition, the U.S. Food and Drug Administration has granted 16 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.

ARM and its members have long recognized the need for alternative payment models to make regenerative technologies and therapies available in the U.S. health care system, and have actively engaged with the Centers of Medicare and Medicaid Services (CMS) as well as private payors to discuss the adoption of more innovative approaches to reimbursement. Value-based purchasing strategies are particularly well-suited for regenerative treatments due to complexities in how such therapies are administered, the severity of the conditions treated, and the fact that many of the one-time, curative treatments proposed will realize their full clinical and economic value over time.

ARM obviously is not alone in recognizing the growing importance of value-based purchasing in health care. Since 2009, the OIG has cited value-based purchasing as a method to improve quality and efficiency in the delivery of care in the Medicare and Medicaid programs. In December 2013, the OIG recognized as a top management and performance challenge the transition to value-based payment models “to produce higher quality care at lower costs,” though acknowledging that such arrangements “present long-standing and new program integrity challenges.”¹ In a little more than a year after OIG emphasized the need “to prioritize the effective transition to value-based payment mechanisms,” the DHHS announced that it would seek to have 50% of all Medicare payments and 90% of all Medicare fee-for-service payments linked to value-based purchasing by 2018.²

Still, our members and many other stakeholders in the health care industry are faced with a lack of clarity and certainty associated with how such value-based reimbursement approaches are likely to be viewed by the OIG from a regulatory and enforcement perspective. ARM members are negotiating value-based purchasing arrangements for its regenerative technologies and therapies consistent with DHHS goals and priorities, all the while assessing potential risks implicated with a reliance on ambiguous and undefined legal and regulatory compliance standards governing such arrangements.

We understand that the OIG is not necessarily seeking additional public comment within this solicitation on six previously proposed safe harbors related to value-based payments, and instead continues to rely on a case-by-case examination of potential anti-kickback implications associated with such reimbursement methods.³ However, ARM strongly believes that regenerative medicine will necessarily transform both the provision of health care in the U.S. and how our current systems are structured to pay for these therapies. We urge the OIG to act timely and definitively in the midst of such change.

Value-Based Purchasing Arrangements Require Additional Protection Under the Anti-Kickback Statute

Value-based purchasing 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 that 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.

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

¹ “OIG Top Management and Performance Challenges Facing the Department of Health and Human Services in Fiscal Year 2013.

² “Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume,” CMS Press Release, Jan. 25, 2015.

³ Appendix G, OIG Semiannual Report to Congress, April 1, 2017 to September 30, 2017.

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.

In addition, value-based purchasing 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 the “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.

Proposed Safe Harbor for Value-Based Purchasing Arrangements

We have drafted a proposed safe harbor to protect value-based purchasing arrangements as attached as an appendix to this letter. This proposed safe harbor includes the following key protections that would provide firm guidance to a wide range of stakeholders wishing to enter into value-based purchasing 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:

1. The terms and conditions of the value-based purchasing 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. Buyer must ensure that the patient shares in subsequent adjustments to the purchase price of the health care item or service that benefit the buyer, and that the patient is “held harmless” for any increase in the buyer’s purchase price.
4. Ancillary health care items or services used solely or primarily for the measurement of clinical outcomes necessary to determine payment under the value-based purchasing arrangement, but excluding those health care items or services required for the routine care and monitoring of the patient’s condition, 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 Michael Werner at 202.419.2515 or at michael.werner@hklaw.com.

Appendix: Proposed Safe Harbor for Value-Based Purchasing Arrangements

Value-Based Purchasing 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 purchasing arrangement, nor the provision of health care items and services provided pursuant to a value-based purchasing 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 purchasing 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 purchasing 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 purchasing arrangement that serve to lower the purchase price of the item or service for the buyer is proportionately applied to any coinsurance or deductible amounts paid by the patient under the value-based purchasing 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 purchasing 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 purchasing arrangement solely or primarily to measure, collect, record or otherwise evaluate the patient’s clinical metrics or outcomes upon which the value-based purchasing 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 purchasing 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 measurable 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 purchasing 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 purchasing arrangement.