

**TO IMPROVE PATIENT ACCESS TO HIGH-QUALITY
HEALTHCARE OUTCOMES AT LOWER COSTS, THE
FEDERAL HEALTH FRAUD LAWS NEED TO BE
CHANGED AND SIMPLIFIED**

Part 1 of a 3-part Special Series

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I. INTRODUCTION

Following the passage of the Affordable Care Act (hereafter, the "ACA") in 2010, the United States healthcare system began a shift from what was previously a fee-for-service reimbursement model to a value-based payment model.¹ What this meant for healthcare providers is that they would no longer be reimbursed for merely providing services to patients, but that they would instead be reimbursed for successful patient outcomes.² A shift in reimbursement models was needed to incentivize providers to take a long-term approach to providing high quality healthcare services to their patients rather than incentivizing higher bills to patients for various services in a marketplace where healthcare services are becoming increasingly expensive.^{3,4}

The implications of this shift in reimbursement models have several effects on the various health fraud laws that apply to providers who accept federal reimbursement dollars from Medicare, Medicaid, and the State Children's Health Insurance Program ("hereafter, S-CHIP") (hereafter, collectively "payors").⁵ These health fraud laws include the Anti-Kickback Statute (hereafter, "AKS") under 42 U.S.C. section 1320a-7b(b),^{6,7} the Stark law (hereafter, Stark") 42 U.S.C. section 1395nn⁸, and the False Claims Act (hereafter, "FCA") under 31 U.S.C. sections 3729-3733⁹ (multiple other state entities are involved, such as in the case in Medicaid, but the focus of this paper will be on the federal health fraud laws).^{10,11} Although originally passed to protect taxpayers from healthcare waste, fraud, and abuse, and the inherent conflicts of interest implicated if a physician is permitted to financially gain from self-referral, as is usually the case when any similar law is passed, some of the unintended consequences of these laws have included price limitations and overly-complex regulations.^{12,13} There are reasonable arguments to be made both for and against self-referrals, but overutilization of healthcare services is a very real public health problem that needs to be addressed.¹⁴ The public's trust and patient confidence in their healthcare providers is a vital interest.¹⁵

¹ Kathy H. Butler, *Stark Law Reform: Is It Time?*, 18 J. Health Care Compliance 5, 6 (2016).

² Kathy H. Butler, *Stark Law Reform: Is It Time?*, 18 J. Health Care Compliance 5, 6 (2016).

³ Kathy H. Butler, *Stark Law Reform: Is It Time?*, 18 J. Health Care Compliance 5, 6 (2016).

⁴ Corbin Santo, *Walking A Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 Case W. Res. L. Rev. 1377, 1379 (2014).

⁵ Kerry Bollerman, Alexander Egbert, Michael Fazio & Bobby Graves, *Health Care Fraud*, 53 Am. Crim. L. Rev. 1393, 1396 (2016).

⁶ Kerry Bollerman, Alexander Egbert, Michael Fazio & Bobby Graves, *Health Care Fraud*, 53 Am. Crim. L. Rev. 1393, 1401 (2016).

⁷ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b (West 2015).

⁸ *Stark Law*, 42 U.S.C.A. § 1395nn (West 2010).

⁹ *False Claims Act*, 31 U.S.C. §§ 3729–3733 (West 2010).

¹⁰ Corbin Santo, *Walking A Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 Case W. Res. L. Rev. 1377, 1380 (2014).

¹¹ *False Claims Act*, 31 U.S.C. §§ 3729–3733 (West 2010).

¹² Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, Health Law., April 2014, at 24, 25 (2014).

¹³ Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 11 (2003).

¹⁴ Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 13 (2003).

¹⁵ Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 13 (2003).

Moreover, the numbers of exceptions to these laws are numerous and can make the billing and reimbursement process ever more daunting for healthcare providers.¹⁶ Stark, for example is particularly overwhelming due to its multiple pages of exceptions.¹⁷ Exceptions include those for physicians' services,¹⁸ in-office ancillary services,¹⁹ and prepaid plans,²⁰ among others.²¹ The U.S. healthcare system is overly costly, continues to provide limited access to patients for care along with inadequate healthcare outcomes, and changes to the federal health fraud laws will help alleviate this problem by freeing up providers to coordinate on electronic medical records and focus on improved patient healthcare outcomes.

II. BACKGROUND

Because of the shift in reimbursement models by government payors, there is a pressing need to review the existing health fraud laws and to amend or eliminate provisions of them in a manner that is consistent with the shifting fee-for-service system to the value-based payment system and better serves the interests of healthcare systems and public health as is discussed above in Part I of this paper.²² The health fraud laws have various statutory, regulatory, and administrative exceptions to the rules in the form of safe harbors and Advisory Opinions (hereafter, "AOs") that will be reviewed and discussed in this paper in Part II. This paper will address each of the three health fraud laws and arguments for changes in Part III, and it will make specific recommendations for policy changes in the laws in Part IV. The paper will briefly conclude in Part V.

Anti-Kickback Statute

The AKS was passed to stop the knowing or willful payment of bribes or other payments (hereafter, "remuneration") based upon or in return for referrals.²³ This law also applies to the marketing of drugs and medical devices to providers prescribing such medical products with federal reimbursement.²⁴ Violation of the AKS "is a felony" or misdemeanor criminal act and can result in "significant civil and criminal penalties."²⁵ Conviction under AKS could result in up to a \$25,000 fine or up to five years in prison.²⁶ The AKS applies to any federally-funded healthcare

¹⁶ Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, Health Law., April 2014, at 24, 27 (2014).

¹⁷ Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 Law & Psychol. Rev. 1, 11 (2003).

¹⁸ Stark Law, 42 U.S.C.A. § 1395nn(b)(1) (West 2010).

¹⁹ Stark Law, 42 U.S.C.A. § 1395nn(b)(2) (West 2010).

²⁰ Stark Law, 42 U.S.C.A. § 1395nn(b)(3) (West 2010).

²¹ Stark Law, 42 U.S.C.A. § 1395nn(c)-(i)(6) (West 2010).

²² Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, Health Law., April 2014, at 24, 25 (2014).

²³ Kerry Bollerman, Alexander Egbert, Michael Fazio & Bobby Graves, *Health Care Fraud*, 53 Am. Crim. L. Rev. 1393, 1402 (2016).

²⁴ Kenneth R. Pina (ed.) and Wayne L. Pines (ed.), *A practical Guide to FDA's Food and Drug Law and Regulation Fifth Edition*, The Food and Drug Law Institute, p. 431 (2014).

²⁵ Deborah Gordon, *Esquire, Healthcare Finance: A Primer*, American Health Lawyers Association, pp. 19-20 (2008).

²⁶ *2015 Medicare Explained*, Wolters Kluwer, p. 720 (2015).

program, including allowable reimbursement for individuals who are study subjects in a clinical trial for a new drug or medical device product.²⁷ Under AKS, 42 U.S.C. section 1320(b):

"whoever knowingly and willfully solicits or receives remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in case or in kind [in return for the furnishing of something in value] for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony..."²⁸

Moreover, whomever makes *any* false statement of material fact, under the AKS, either "knowingly or willfully," or has knowledge of such a falsity and a payment is induced by a federal payor, shall also be sentenced up to \$25,000 or five years in prison.²⁹ If such a statement is made and therefore an occurrence of a "representation, concealment, failure, conversion, or provision of counsel, or assistance by any other person shall be guilty of a misdemeanor" can be fined up to \$10,000 or be forced to serve up to a year in prison.³⁰ The AKS makes it illegal to receive any form of remuneration, meaning any compensation or fee "in cash or in kind" in return for any referral, or for "purchasing, leasing, ordering, or arranging" of the same.³¹ The AKS also makes it illegal to give any form of remuneration including items or services, or "purchase lease, order, or arranging of the same" shall also be guilty and sentenced up to \$25,000 or five years in prison.³²

There are several statutory exceptions in the AKS referred to as statutory "safe harbors," that limit liability under the AKS in certain situations.³³ Additionally, The U.S. Department of Health and Human Services (hereafter, "HHS") and its Office of the Inspector General (hereafter, "OIG") has the authority to issue additional regulatory safe harbors.³⁴

AKS Statutory Safe Harbors

The AKS itself provides for a number of statutory safe harbor exceptions to the law under 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3).³⁵ These include a discount offered for a healthcare service or product so long as it is "properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program" under 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(A).³⁶ Also, money paid to an employee by an employer is acceptable so long as a "bona fide employment relationship" exists under 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(B).³⁷ 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(C-C(ii)) allows for a vendor acting "as a purchasing agent" to

²⁷ *2015 Medicare Explained*, Wolters Kluwer, p. 720 (2015).

²⁸ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(1-2) (West 2015).

²⁹ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(a)(1-6) (West 2015).

³⁰ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(a)(1-6) (West 2015).

³¹ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(1) (West 2015).

³² *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(2) (West 2015).

³³ Kerry Bollerman, Alexander Egbert, Michael Fazio & Bobby Graves, *Health Care Fraud*, 53 Am. Crim. L. Rev. 1393, 1407-09 (2016).

³⁴ Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, Health Law., April 2014, at 24, 26 (2014).

³⁵ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3) (West 2015).

³⁶ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(A) (West 2015).

³⁷ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(B) (West 2015).

be exempted from the law if there is both (1) "a written contract" specifying a "fixed amount or a fixed percentage of value of the purchases made by each such individual or entity under the contract *and* (emphasis added)" (2) a disclosure to the Secretary of Health and Human Services' designee.³⁸ 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(D) allows a waiver to be granted under the Public Health Services Act "for an individual who qualifies for subsidized service" thereunder.³⁹

By law, under the Medicare and Medicaid Patient and Protection Act of 1987, certain payments may be exempted under 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(E).⁴⁰ An exemption may also be granted for an organization "through a risk-sharing arrangement" under 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(F).⁴¹ 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(G) allows for discounting by pharmacies who participate in Medicare Part D.⁴² 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(H) allows for an exemption for transactions between a "federally qualified health center" under a contract with another organization.⁴³ 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(I) allows for an exemption relating to "medically underserved population[s]."⁴⁴ Lastly, 42 U.S.C. section 1320a-7b, specifically section 1320(b)(3)(J) allows for an exemption for "a discount in the price of an applicable drug" by a "manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program."⁴⁵

Following the statutory safe harbors are the definitions under 42 U.S.C. section 1320a-7b, specifically section 1320(f),⁴⁶ and an important provision under 42 U.S.C. section 1320a-7b, specifically section 1320(h), that starts with "actual knowledge or specific intent not required" and goes on to further state, in relevant part, that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section."⁴⁷

AKS Regulatory Safe Harbors

There are multiple regulatory safe harbors concerning diverse matters such as investors, leases, and sales of practices.⁴⁸ Following are a few examples:

Space Rental and Personal Services and Management Controls

In order to comply with the AKS, space rental agreements must satisfy the following regulation provisions: (1) the lease is to be in writing and signed by all parties;⁴⁹ (2) that it covers the premises

³⁸ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(C-C(ii)) (West 2015).

³⁹ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(D) (West 2015).

⁴⁰ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(E) (West 2015).

⁴¹ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(F) (West 2015).

⁴² *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(G) (West 2015).

⁴³ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(H) (West 2015).

⁴⁴ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(I) (West 2015).

⁴⁵ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(b)(3)(J) (West 2015).

⁴⁶ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(f) (West 2015).

⁴⁷ *Anti-Kickback Statute*, 42 U.S.C.A. § 1320a-7b, § 1320(h) (West 2015).

⁴⁸ 42 C.F.R. § 1001.952.

⁴⁹ 42 C.F.R. § 1001.952(b)(1).

and includes all leased premises between the parties;⁵⁰ (3) that the access to a premise that is not full-time be specified along with the rent amount;⁵¹ (4) that the lease is for more than a year;⁵² (5) that the rent is fair market value, set out aggregately in writing, and is not adjustable based upon referrals;⁵³ and (6) that the leased space not be in excess of "that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental."⁵⁴ The same provisions apply in the satisfaction of personal services and management contracts under a separate provision.⁵⁵

Equipment Rental

Equipment rentals are similarly treated under the regulations under the AKS:⁵⁶ (1) the lease must be in writing;⁵⁷ (2) it must cover "all off the equipment leased between the parties;"⁵⁸ (3) it must provide for equipment use in "periodic intervals of time";⁵⁹ (4) the term must be a year or more;⁶⁰ (5) the payment must be based upon fair market value;⁶¹ and the aggregate amount must be reasonable.⁶²

Personal Services and Management Contracts

Also exempted are the above-referenced personal services and management contracts.⁶³ Such services and contracts must include the following: (1) a written agreement;⁶⁴ (2) an agreement that covers all services to be provided;⁶⁵ (3) specified in the contract a "periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement;"⁶⁶ (4) term must be greater than one year;⁶⁷ (5) compensation is to be set out in advance and consistent with the fair market value;⁶⁸ (6) services performed do not involve the promotion of any other business;⁶⁹ and (7) the services rendered must be "reasonably necessary."⁷⁰

⁵⁰ 42 C.F.R. § 1001.952(b)(2).

⁵¹ 42 C.F.R. § 1001.952(b)(3).

⁵² 42 C.F.R. § 1001.952(b)(4).

⁵³ 42 C.F.R. § 1001.952(b)(5).

⁵⁴ 42 C.F.R. § 1001.952(b)(6).

⁵⁵ 42 C.F.R. § 1001.952(d)(1).

⁵⁶ 42 C.F.R. § 1001.952(c).

⁵⁷ 42 C.F.R. § 1001.952(c)(1).

⁵⁸ 42 C.F.R. § 1001.952(c)(2).

⁵⁹ 42 C.F.R. § 1001.952(c)(3).

⁶⁰ 42 C.F.R. § 1001.952(c)(4).

⁶¹ 42 C.F.R. § 1001.952(c)(5).

⁶² 42 C.F.R. § 1001.952(c)(6).

⁶³ 42 C.F.R. § 1001.952(d).

⁶⁴ 42 C.F.R. § 1001.952(d)(1).

⁶⁵ 42 C.F.R. § 1001.952(d)(2).

⁶⁶ 42 C.F.R. § 1001.952(d)(3).

⁶⁷ 42 C.F.R. § 1001.952(d)(4).

⁶⁸ 42 C.F.R. § 1001.952(d)(5).

⁶⁹ 42 C.F.R. § 1001.952(d)(6).

⁷⁰ 42 C.F.R. § 1001.952(d)(7).

AKS Advisory Opinions

An amendment to the social security act empowered the Office of Inspector General under the U.S. Department of Health and Human Services to issue Advisory Opinions (AOs) wherein the OIG could examine voluntarily submit "specific factual situations" on industry healthcare and healthcare-related business relationships or prospective relationships and publish the results of its analysis for the world to read and review.⁷¹ These AOs are first redacted to block proprietary information from being shared and are then published online.⁷² AOs offer legal opinions on the OIG's current thinking regarding existing or proposed business relationships, but "are binding and may legally be relied upon only by the requestor, the healthcare entity requesting an OIG AO]."⁷³ Despite this limitation, AOs can provide meaningful insight into how the OIG would assess an existing or potential business relationship for non-compliance with the AKS, but it is important to note that AOs are not issued for Stark by the OIG, to be discussed below.⁷⁴

The OIG provides a checklist, "for informational purposes only," that has not been updated since 1999, but it still is a useful tool to outline what would need to be submitted by a requestor of an AO.⁷⁵ Technical requirements include that the requestor is actually a party in the existing or potential business relationship; that the requestor is part of an existing relationship or that it will "in good faith" become one; financial assurances, among others, including a payment for \$250 and an estimate of how much time and money would be involved in assessing the request; the identity of the requestor, and full information on the existing or potential relationship, and "a statement that some or all of the information or documents provided are trade secrets or are privileged or confidential commercial or financial information and are not subject to disclosure under the Freedom of Information Act."⁷⁶ The subject of the AO request must also be specified.⁷⁷ The subject areas are lumped into three groups in an OIG reference source entitled "Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 1008."⁷⁸ The first group covered by Attachment A of that reference addresses "what constitutes prohibited

⁷¹ *Advisory Opinions*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/compliance/advisory-opinions/index.asp> (citing to, § 1128(D)(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 CFR part 1008).

⁷² *Advisory Opinions*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/compliance/advisory-opinions/index.asp>.

⁷³ *Advisory Opinions*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/compliance/advisory-opinions/index.asp>.

⁷⁴ *Advisory Opinions*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/compliance/advisory-opinions/index.asp>.

⁷⁵ *Preliminary Checklist for Advisory Opinion Requests*, U.S. Department of Health and Human Services: Office of Inspector General (Jul. 1999), <https://oig.hhs.gov/fraud/docs/advisoryopinions/precheck.htm>.

⁷⁶ *Preliminary Checklist for Advisory Opinion Requests*, U.S. Department of Health and Human Services: Office of Inspector General (Jul. 1999), <https://oig.hhs.gov/fraud/docs/advisoryopinions/precheck.htm>.

⁷⁷ *Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 1008*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm>.

⁷⁸ *Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 1008*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm>.

remuneration" and "whether an activity, or proposed activity, constitutes grounds for the imposition of sanctions."⁷⁹ The group in Attachment B addresses "whether an arrangement, or proposed arrangement, satisfies the criteria for activities which do not result in prohibited remuneration;" "whether an arrangement, or proposed arrangement, satisfies the criteria for activities which do not result in prohibited remuneration;" or "whether an arrangement is sufficiently similar to other permissible activities that it should not constitute grounds for the imposition of sanctions."⁸⁰ The last group, under Attachment C addresses "what constitutes an inducement to reduce or limit services to individuals entitled to benefits."⁸¹

Sampling of Recent AKS Advisory Opinions

AKS Advisory Opinion No. 17-03

A recent AO, No. 17-03, posted August 25, 2017.⁸² The AO begins by acknowledging the request for an AO, and identifies the subject matter the requestor is inquiring about.⁸³ The information that the OIG relied upon is that which was submitted by the requestor; the AO acknowledges this as a limitation and states outright that it does not go outside of the information submitted, but rather, it sticks to the limited universe of information as submitted by the requestor.⁸⁴ The letter warns that, "if material facts have not been disclosed or have been misrepresented, this opinion is without force and effect."⁸⁵ In other words, the entity requesting the AO cannot then use the AO to defend against a charge or charges of violation(s) of the AKS, a significant penalty a requestor must be aware of.⁸⁶ The AO then explains that the OIG have concluded potential remuneration could exist under the proposed relationship in violation of the AKS.⁸⁷

⁷⁹ *Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 1008*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm>.

⁸⁰ *Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 1008*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm>.

⁸¹ *Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 CFR Part 1008*, U.S. Department of Health and Human Services: Office of Inspector General (last accessed Aug. 28, 2017), <https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm>.

⁸² OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 1, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁸³ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 1, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁸⁴ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 1, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁸⁵ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 1, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁸⁶ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 1, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁸⁷ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 2, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

The requestor in this particular AO engages in the manufacturing and selling of biologics and that a particular product it makes and sells can spoil quickly once reconstituted.⁸⁸ Under the proposed relationship, the requestor would, free of charge, replace spoiled product with their customer, "a single location" if one of the following criteria were met: (1) it was mishandled, (2) improperly stored, (3) improperly reconstituted, or (4) was not administered to a patient.⁸⁹ A legal analysis is then set forth wherein the OIG reveals its basis for its analysis and grounds that basis in the AKS law.⁹⁰

The AO then turns toward the safe harbor protections under the AKS, and determines that the warranties safe harbor "potentially applies to the Proposed Arrangement."⁹¹ In this case, the AO cites to the AKS safe harbor and includes the definition of a warranty under 15 U.S.C. section 2301(6):

(A) any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time, or

(B) any undertaking in writing in connection with the sale by a supplier of a consumer product to refund, repair, replace, or take such other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking, which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product.⁹²

The analysis continues by concluding that because the requestor would be replacing product that was not itself defective, it would fail to meet the standard set forth in 15 U.S.C. section 2301(6)(A).⁹³

Additionally, because the product's "labeling specifies the required storage and handling requirements," and time limits in certain cases when it is not held in conformance with those requirements, that the acts of the customer in improperly administering the product or failing to do so due to their own "unforeseen inability," implicates that the standard set forth in 15 U.S.C.

⁸⁸ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 2, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁸⁹ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), pp. 2-3, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹⁰ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 3, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹¹ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 4, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹² OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 4, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹³ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 5, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

section 2301(6)(B) would also not be met.⁹⁴ Therefore, the safe harbor would not apply in this particular proposal, and there is some risk of illegal remuneration under the AKS.⁹⁵

The AO, then relies on the OIG's ability to make its own determinations in AOs "on a case-by-case basis."⁹⁶ The OIG first considers the public health implications in the sense that the requestor would be able to prevent patient exposure to spoiled product if this customer relationship is allowed.⁹⁷ Second, the OIG considers that the risk of increased costs to federal payors is low.⁹⁸ Third, the OIG determined that the risk of harm in the form of competition would also be low.⁹⁹ Lastly, the OIG further determined that the proposal was like "an insurance policy" and that it contained "an administrative process, including" the proof requirement that customers submit photos for the requestor to determine whether or not the product was spoiled because of the reasons aforementioned, and that it was unlikely to "be abused by customers."¹⁰⁰ The OIG concluded the AO by indicating the risk of AKS remuneration in this case was very low and that it would not pursue sanctions in this case.¹⁰¹ The AO ends with the OIG restating the limitations of this AO as already discussed above.¹⁰²

AKS Advisory Opinion 17-02

Another recent AO, No. 17-02, covers "a hospital outpatient facility's proposal to reduce or waive, on a non-routine, unadvertised basis, cost-sharing amounts owed by financially needy Medicare beneficiaries for related items and services furnished in connection with a clinical research study."¹⁰³ The requestor is a hospital that supports a wound care center.¹⁰⁴ Study subjects with Medicare benefits are randomized before inclusion in the study as either part of a control group or the group receiving the experimental wound care therapy but still are responsible for the payment of Medicare copays.¹⁰⁵ The major concern of the OIG in the context of this AO is that certain

⁹⁴ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 5, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹⁵ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 5, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹⁶ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 5, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹⁷ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), pp. 5-6, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹⁸ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 6, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

⁹⁹ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 6, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

¹⁰⁰ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 6, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

¹⁰¹ OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 6, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

¹⁰² OIG Advisory Opinion No. 17-03, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), pp. 7-8, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf>.

¹⁰³ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 1, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹⁰⁴ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 2, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹⁰⁵ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 3, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

Medicare recipients are also Medicaid recipients, and under Medicaid, the study subject may not have coverage for the aforementioned "related items and services."¹⁰⁶ That the subjects, because of Medicaid not covering these items, may prevent their participation in this clinical trial.¹⁰⁷

The Center in this case, in response to these concerns, has proposed a waiver of these "related items and services."¹⁰⁸ The "requestors certified that neither" party to this proposed relationship would issue any promotion or promotional materials to the public or anyone else regarding this proposal.¹⁰⁹ The center also documented that a written procedure would be implemented wherein the waivers would only be granted to study subject who pass muster through means-testing of their financial need.¹¹⁰

The OIG in this AO started its legal analysis grounded in the definition of "remuneration" and of the considerations that it can make "on the waiver of coinsurance and deductible amounts" if:

- (i) the waiver is not offered as part of any advertisement or solicitation;
- (ii) the person does not routinely waive coinsurance or deductible amounts; and
- (iii) the person making the waiver—
 - (I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
 - (II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts.¹¹¹

The OIG found first that "requestors certified that" they would not advertise this waiver.¹¹² Second, the OIG found that the waiver would not be routine, instead that the waiver would be made if the study subject demonstrated financial need and that the center would make the determination on "case-by-case basis."¹¹³ Third, the OIG found that the waiver procedure would be based upon "objective criteria" and therefore concluded that the waiver proposal would not be

¹⁰⁶ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 3, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹⁰⁷ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 3, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹⁰⁸ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 3, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹⁰⁹ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 4, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹¹⁰ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 4, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹¹¹ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 6, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹¹² OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 6, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹¹³ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), pp. 6-7, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

sanctioned under the AKS if implemented.¹¹⁴ The same limitations were contained in the AO as was AO 17-03 in 17-02.¹¹⁵

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¹¹⁴ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), p. 7, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.

¹¹⁵ OIG Advisory Opinion No. 17-02, U.S. Department of Health and Human Services: Office of Inspector General (Aug. 18, 2017), pp. 7-8, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf>.