

Focus Arrangements Transaction Reviews: The Curling of Compliance Work Plans?



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Originating in 16th century, Scotland and popular primarily in northern hemisphere countries where Scots have emigrated, curling is one of those winter sports the majority of the general public do not think about between quadrennial Olympic Games.¹ Often referred to as chess or shuffleboard on ice, success in the team sport of curling requires mastering skills, rules, and terminology that aren't intuitive.

Similarly, for healthcare compliance professionals, establishing a scalable and effective system for tracking and periodically auditing focus arrangement transactions can seem akin to curling for the uninitiated. The legalistic terminology, combined with lack of transparency when sensitive business details such as physician remuneration are involved, often translates into lack of awareness even at the compliance officer level regarding their own organization's risk level. Responsibility for arrangements compliance, if formally assigned at all, is often siloed within the internal legal department, or delegated to outside counsel. Whereas navigating the legal implications of Anti-Kickback Statutes (AKS) and Stark should absolutely be reserved for health law attorneys with AKS expertise, overseeing operational compliance with AKS and Stark should ideally be a team sport.

THROWING STONES TOWARD HOUSES

Any agreement between a health care entity and any actual or potential source of health care business or referrals to the entity, or any actual or potential recipient of health care business or referrals from the entity that may implicate AKS, or Stark is considered a focus arrangement. Health care entities with agreements implicating AKS or Stark should ideally also have some form of an Arrangements Compliance Program to mitigate the organization's risk exposure.² For compliance officers with a lower degree of familiarity with AKS and

Stark, or with under-resourced programs, the prospect of adding arrangements oversight or transactions auditing to an already long list of work plan items seems aspirational at best.

Olympic curling is played on an ice surface called a sheet, roughly the size of a hockey rink. At opposite ends of the sheet are what in curling parlance are referred to as “houses,” 12 ft. round bullseyes with centers called buttons.³ During each round or “end,” the curling teams take turns aiming and sweeping carefully to guide their 42 pound stones at the houses. Unlike other ice sports like hockey where a smooth surface is preferred, prior to the start of matches, the ice is sprinkled to create a surface with the friction necessary to make the rocks curl.

Fortunately, if an organization’s internal compliance risk assessment has identified AKS and Stark compliance is a significant risk, implementing an appropriately scaled program that includes periodic transactions level review doesn’t require throwing stones or creating friction with internal stakeholders. Nor does it require a compliance officer to become an expert in conducting or designing Arrangements Reviews. The publicly available Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) Corporate Integrity Agreement (CIA) documents with Arrangements Review obligations provide detailed expectations for how Independent Review Organizations (IROs) are expected to conduct Arrangements Systems and Transactions Reviews.⁴

IROs typically employ a team of former compliance officers, attorneys with AKS expertise, as well as valuation experts. Healthcare organizations of any size or specialty can leverage the same publicly available instructions within CIAs that IROs use. With planning, creativity and perhaps some initial outside coaching, recruiting a team of internal stakeholders to participate in designing tracking

systems and assisting compliance with conducting periodic reviews makes measuring effectiveness more feasible for resource constrained programs.

ON THE BROOM

The most desirable curling shot results in a stone that leaves the thrower’s hand on the target line from the hack to the broom. Olympic caliber curlers make this shot look easy. Finding a CIA document with an Arrangements Review appendix is not easy because the HHS-OIG CIA Web site is organized alphabetically by CIA party name. Luckily, with the exception of vendors, the content of CIAs with Arrangement Transaction Review requirement does not substantively vary by organization type or specialty. Recent CIAs with Arrangements Review obligations are listed in Figure 1.

Whereas the body of the CIA provides a significant trove of detail and citations, including sections describing *Focus Arrangements Procedures* and *Focus Arrangements Requirements* providing salient guidance for developing a program, more practical tips for structuring a transactions review are found in Appendix B (or C).⁵ Figure 2 includes each of the elements an IRO is required to assess compliance of randomly selected transactions. Given the objective of auditing transactions is to measure internal compliance with the systems, processes, policies, and procedures an organization has formally established, if an element such as maintaining service and activity logs, is not applicable to any Focus Arrangement types the organization engages in, for the purposes of fulfilling a compliance work plan item, omitting non-applicable review items is advisable.

MIND THE HOG LINE

Similar to a foul line in baseball, in curling the placement of a stone within the boundaries of the hog line determines whether a stone is in play. Likewise, CIA documents provide definitions that can

Figure 1: CIAs with Arrangements Review Obligations

Organization	Type/Specialty	Effective Date
Arthrex Inc.	Vendor/Surgical Devices	11/8/2021
Flower Mound Hospital Partners, LLC	Provider/Acute Care Hospital	11/30/2021
UCI Medical Affiliates of South Carolina, Inc.	Provider/Urgent Care Center	4/6/2021
Southwest Orthopaedic Specialists, PLLC	Provider/Physician Specialty	7/7/2020
Oklahoma Center for Orthopaedic and Multi-Specialty Surgery	Provider/Surgery Center	7/7/2020
Vascular Access Centers, LP	Provider/ Specialty Outpatient	10/9/2018
Greenway Health, LLC	Vendor/Health IT Software	2/5/2019
Sweet Dreams Nurse Anesthesia, LLC	Provider/Anesthesia Services	8/5/2016
Integrated Oncology Network, LLC	Provider/Outpatient Oncology & IMRT	3/19/2018
Homebound Healthcare Inc.	Provider/Home Health & Hospice	10/11/2016

Figure 2: Sample Arrangements Transaction Review Template

Transaction Type		Reviewer Initials	
Transaction Date		Date Reviewed	
Date of Original Contract/Agreement		Findings/Observations? [Y/N]	
Customer/Parties to Agreement		Final Review Status	
Transaction Value		Recommendation(s) Y/N?	
Review Step	Internal P&P Reference(s)	Compliant w/ P&P(s)? Y/N/NA	Observations/Notes
Documentation provided indicates selected transaction details were tracked in Organization's 'centralized system'?			
Documentation provided includes parties, covered person(s), terms, performance details as applicable to the Focus Arrangement and transaction type.			
Transaction was reviewed by legal or met criteria to bypass review per applicable Organization policy/procedure for Arrangement type?			
Transaction was reviewed by business units or met criteria to bypass review per applicable Organization policy/procedure for Arrangement type?			
Legal and Business unit approvals are clearly documented, including dates and identity of approver(s) and any additional approver documentation requirements were completed (if applicable per Organization policy)?			
Remuneration associated with transaction is in compliance with FMV established per Organization policy/procedure for Focus Arrangement type?			
Business need/rationale is documented in transaction record?			
Business need/rationale is in alignment with applicable Organization policy/procedure for Focus Arrangement type?			
If Focus Arrangement type requires a service/activity log, log is complete and compliant with applicable Organization policy/procedure?			
Organization/Parties to Arrangement authenticated agreement date is prior to date remuneration released/received for selected transaction [if applicable to Type]			
Record of transaction supports review/approvals occurred prior to date remuneration released/received.			

be applied to inform and customize the scope of an AKS compliance program, as well as provide a guide to constructing a simple, credible transactions review to assess Arrangements Program effectiveness. How an organization defines these key ideas also establishes the foundation for creating policies and procedures, as well as an AKS friendly, sustainable contract management process that includes assessing risks of new agreements and determining which types of arrangements transactions the compliance team should consider auditing (if any!). Involving an attorney with AKS expertise to work with compliance during the initial phase of designing the Arrangements Compliance Program is arguably non-negotiable; however, performing the deliberate exercise of defining terms such Arrangements,

Focus Arrangements, and Covered Persons within the unique business and operational context of the organization is crucial to establishing the boundaries and stakeholders of an internal program or transactions review.

Endnotes

1. <https://www.rulesofsport.com/sports/curling.html>.
2. Focus Arrangements CIAs: A Good Model for Stark/Anti-kickback Statute Compliance Programs? *Journal of Health Care Compliance*, 21(5), 23–42, September–October 2019.
3. <https://thegrandslamofcurling.com/beginners-guide-to-the-rules-of-olympic-curling/>.
4. <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>.
5. https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.aspxhttps://oig.hhs.gov/fraud/cia/agreements/Flower_Mound_Hospital_Partners_LLC_DBA_Texas_Health_Presbyterian_Hospital_Flower_Mound_11302021.pdf.

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