

Mitigating Anti-Kickback Risks Of Health Tech Stock Warrants

By **Meenakshi Datta and Jon Zucker** (April 8, 2021)

There is no shortage of startup and established companies attempting to innovate and disrupt in the health technology space. From optimizing the functionality of electronic health records to utilizing artificial intelligence to identify patients at risk for major diseases, health tech innovators and disruptors have the potential to transform the patient experience.

However, it is generally difficult for health tech innovators and disruptors to create a new market, and they often need significant customer feedback or other services from the health care provider customers to move beyond a beta phase, or otherwise engage in continuous improvement.

Stock warrants are one way for technology companies to pay for such services, address their short-term liquidity shortages, and align the incentives of the customer to provide meaningful feedback or other services that allow for the continued growth and success of the health tech company.

Warrants are similar in many ways to stock options, allowing the holder to purchase stock at a set strike price and therefore potentially experience upside or downside financial risk depending on any changes in stock value over time.

However, warrants may present potential risk under the federal Anti-Kickback Statute^[1] if improperly structured to incentivize the referral of business by a recipient health care provider to the vendor.

The AKS is a broad criminal health care statute that prohibits any person from knowingly and willfully soliciting/receiving or offering-paying any remuneration — including any kickback or bribe — directly or indirectly, in return for making referrals or otherwise generating business for which payment may be made under federal or state health care programs.^[2]

To reduce risk under the AKS, organizations operating in the health care space should consider the elements of the recently reformed personal services and management contracts safe harbor,^[3] the safe harbor for discounts^[4] or other potentially applicable safe harbors, or incorporate appropriate risk mitigation factors, before finalizing an arrangement involving warrants in a health technology service provider.

Key risk mitigation steps include establishing and documenting the fair market value of the warrants, taking into account the optionality opportunity associated with the warrants — as the holder is not required to exercise the warrant and therefore able to limit downside risk — and accounting for any other remuneration between the parties.

Depending on the facts and circumstances, arrangements that fall outside of the personal services safe harbor or other applicable safe harbor may carry greater risk under the AKS, though they may nonetheless be entirely lawful.



Meenakshi Datta



Jon Zucker

Safe Harbors and Risk Mitigation

Arrangements with health care technology companies may become subject to the application of the AKS if, for example, a buyer such as a hospital seeks reimbursement on a cost report for the products from a federal or state health care program. Indirect reimbursement from federal or state health care programs through methods such as cost reports is sufficient to implicate the AKS.

Importantly, both the technology vendor and the health care provider can face potential AKS violation, as liability can result from both the offering/payment and solicitation/receipt of a kickback.

The personal services safe harbor may be relevant to a warrant arrangement where the health care organization receives the warrants as compensation for services to the technology vendor as part of a bilateral services arrangement, where each party to the transaction is providing services to the other.

This can occur where there are legitimate services that the vendor needs from its customer, such as feedback sessions on piloted software, and the vendor lacks the liquidity to pay cash for those services.

Parties seeking protection for warrant arrangements under the personal services safe harbor should consider the following safe harbor elements for a contemplated arrangement:

1. The agreement is set out in a signed writing that appropriately describes all of the services furnished between the parties.
2. The term of the agreement is not less than one year.
3. The methodology for determining the compensation paid to the agent — here, the health care organization — over the term of the agreement is set in advance, is consistent with the fair market value in arm's-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties reimbursed by a federal health care program.
4. The services do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
5. The amount of services contracted for are reasonably necessary to accomplish the commercially reasonable business purpose of the services.[5]

Prong 3 in particular is where the rubber meets the road, as there is a wide range of reasonable options that reflect normal-course business arrangements and negotiations, and result in arrangements consistent with fair market value.

Prior to the recent safe harbor reforms, total aggregate compensation was required to be set in advance. Effective Jan. 19, however, the Office of Inspector General for the U.S. Department of Health and Human Services requires only that the methodology for calculating the compensation amount be set in advance.

In finalizing these amendments, the OIG explained that the intent "is to provide enhanced

flexibility while mitigating the risk of parties periodically adjusting ... compensation to reward referrals." [6]

This change provides additional flexibility to organizations in structuring compensation methodologies that can satisfy the requirements of the personal services safe harbor.

Parties looking to value warrants should consider objective and recognized standards for valuation of such instruments with the assistance of a qualified expert. For example, the Black-Scholes model is a mathematical model for pricing in various options contracts, although additional adjustments to such models may be necessary for warrants — for example, accounting for illiquidity of warrants, as the underlying equity is not publicly traded, and potential dilution effects, as warrants typically relate to newly-issued rather than existing equity.

Other options include: (1) in-house benchmarking, such as a recent fundraising round; (2) issuing a request for proposals to allow for comparison between bids; and (3) arm's-length negotiation.

Regardless of the method utilized to determine fair market value, it is critical for safe harbor compliance to refrain from taking into account the volume or value of referrals, or other business generated, between the parties.

If the parties instead choose to treat warrants as discounts to the service fees charged, the ability to determine the value of the warrants is also important to facilitate compliance with disclosure obligations under the discount safe harbor.

Key Takeaways

Warrants are a practical business solution that can encourage innovative technology solutions in health care. Parties in the health care industry should be cognizant of potential AKS risk in entering into vendor arrangements involving warrants, and evaluate appropriate measures to address the potential risk.

To mitigate the risk, start early and identify the basis under the AKS under which warrants may be provided. This may include the personal services safe harbor, the discount safe harbor, other safe harbors, or prudential factors that demonstrate that the arrangement does not implicate the AKS.

Consider use of an independent and qualified valuation expert that can provide an objective view of the considerations for valuing warrants, including considerations around strike price and optionality value. An independent report may be particularly helpful in the case of large vendor deals where the customer may become a significant shareholder in the vendor should the customer exercise the warrants, or if the strike price of the warrants is set lower than the price paid in a recent financing round.

Meenakshi (Meena) Datta is a partner and Jon Zucker is an associate at Sidley Austin LLP .

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[1] 42 U.S.C. § 1320a-7b(b).

[2] 42 U.S.C. § 1320a-7b(b).

[3] 42 CFR 1001.952(d).

[4] 42 CFR 1001.952(h).

[5] 42 CFR 1001.952(d).

[6] OIG Final Rule, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77684, 77840 (Dec. 2, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf>.