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Beware Fraud And Abuse Pitfalls In Precision Medicine

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Precision medicine has the potential to transform health care but also presents significant challenges from a regulatory perspective. In this article, we explore the federal fraud and abuse pitfalls inherent in certain precision medicine arrangements, particularly those affecting health systems and hospitals and clinical laboratories with which they routinely partner to perform genomic testing.

Precision medicine, sometimes referred to as personalized medicine, is the future of patient care, and has increasingly become a focal point for hospitals and health systems across the U.S. While the concept of accurate and precise medicine is not new,[1] advances in the fields of regenerative medicine, genomic sequencing and medical imaging have transformed the delivery of care. With countless technological advancements, patients are treated and monitored more precisely and effectively to better meet their individual needs.

Precision medicine uses information about a person's genes or proteins to prevent, diagnose or treat a particular disease.[2] The critical difference between a traditional diagnosis and precision medicine is the degree of reliance on data — especially genomic data — to aid providers in their decision-making about specific treatment paths for a particular patient.

Collaborative arrangements among providers and clinical laboratories have become more common, as they align with the trend towards value-based reimbursement and population health management initiatives. Throughout the health care industry, precision medicine is changing the role of clinical laboratories.

When considering the shift from fee-for-service reimbursement to value-based care, labs are positioned to help providers eliminate unnecessary tests and identify the most effective treatment. With access to data highlighting a patient's genetics, comorbidities, and medical history, labs can provide even more value to health care providers by presenting results compared against those of others with a similar profile, and by drawing high-level insights about populations of patients with a similar profile.[3] Other labs are looking for increased access to data, which may drive relationships with providers.

Collaboration in the provision of precision medicine may offer myriad benefits to patients; however, common arrangements among labs and providers present regulatory issues — particularly in the fraud and abuse space - that must be carefully navigated. Entities exploring such arrangements should be aware of the complex laws that implicate these arrangements at the outset.

Fraud and Abuse Laws

Federal Anti-Kickback Statute

A hospital or health system[4] or genomics lab interested in exploring a precision medicine arrangement must evaluate whether the arrangement implicates the federal Anti-Kickback Statute. The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.[5]

For purposes of the AKS, remuneration includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.[6] The U.S. Department of Health and Human Services' Office of Inspector General has stated that, "[w]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business."[7] Certain complicating factors common in precision medicine arrangements are discussed in more detail below.

It is important that payments from the health system to the lab for tests reflect fair market value. If a payment from the health system to the lab is less than fair market value, it could be deemed remuneration for referrals. This relationship is especially complex if the laboratory is in a position to refer business to the health system or if the lab and health system do business outside of the precision medicine arrangement.

Some health systems believe that carving out Medicare/Medicaid patients from the arrangement reduces the risk that the arrangement would run afoul of the AKS. However, even if such patients are not included, health systems and genomics labs must be wary of state AKS equivalents[8] and consider their contracts with private payors.

Moreover, the OIG has cautioned that carving out federal health care beneficiaries does not completely eliminate the AKS risks.[9] Where possible, a precision medicine arrangement should be structured to fit within one of the AKS regulatory safe harbors in Title 42 of the Code of Federal Regulations Section 1001.952.

Some precision medicine arrangements may be structured to fit within the personal services and management contracts safe

harbor.[10]

To do so, the agreement between the health system and the genomics lab must: (1) be set out in writing signed by the parties; (2) cover all of the services provided during the term of the agreement with specificity; (3) specify the exact schedule of the relevant intervals if the agreement is intended to provide for services on a periodic, sporadic or part-time basis; (4) include a term of not less than one year; (5) include aggregate compensation that is set in advance, consistent with fair market value in arms-length transactions not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under a federal health care program; (6) not involve the counselling or promotion of a business arrangement or other activity that violates any state or federal law; and (7) not include aggregate services that exceed those reasonably necessary to accomplish the commercially reasonable business purposes of the services.

Although an arrangement need not fit into a safe harbor to be considered legal, arrangements that fit within an AKS safe harbor are exempt from the purview of the statute.

Eliminating Kickbacks in Recovery Act of 2018

In addition to the AKS, an entity engaging in a precision medicine arrangement should consider the Eliminating Kickbacks in Recovery Act of 2018.[11] EKRA, part of the larger Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,[12] prohibits a broader scope of conduct, specifically "knowingly and willfully (1) solicit[ing] or receiv[ing] any remuneration … directly or indirectly, overtly or covertly, in cash or in-kind, in return for referring a patient or patronage to … a laboratory, or (2) pay[ing] or offer[ing] any remuneration … directly or indirectly, overtly or covertly, in cash or in-kind (A) to induce a referral of an individual to a … laboratory or (B) in exchange for an individual using the services of that … laboratory."[13]

EKRA applies to services covered by a health care benefit program, which is defined as "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."[14] Thus, the law is not limited to federal health care programs (as with AKS), and also covers private insurance plans and, potentially, self-pay patients.

EKRA provides for certain exceptions to the prohibition. Most notably for providers engaged in a precision medicine arrangement, EKRA does not apply to financial arrangements that fit within the AKS' personal services and management safe harbor.[15]

Accordingly, where health systems and laboratories enter into precision medicine arrangements, even where federal health care beneficiaries are excluded from the program, the parties should attempt to structure such arrangements to fit within the personal services and management contracts safe harbor. Where an arrangement cannot be structured to satisfy an AKS safe harbor, the arrangement should be scrutinized under EKRA on a facts and circumstances basis to determine the risk.

Medicare Beneficiary Inducements Pursuant to Civil Monetary Penalties Law

Any individual or entity (such as a clinical laboratory) that offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the individual or entity knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties for each violation of the CMP and damages of up to three times the amount of remuneration at issue.[16]

The CMP law defines "remuneration" to include waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. As noted above, some precision medicine arrangements seek to offer a reduced or waived fee for the laboratory testing. The CMP law and its implementing regulations contain a limited number of exceptions to the term "remuneration."

One exception permits the offer or transfer of items for free or less than fair market value if there is a good faith determination of the individual's financial need, among the satisfaction of other requirements.[17] Thus, providers partnering with clinical laboratories to offer discounted genetic or other types of clinical testing should be especially wary of violating the CMP Law when federal health care beneficiaries are included.

Conclusion

Federal government enforcement action involving genetic laboratories sharply increased in late 2019 and the first ever EKRA enforcement action occurred against a Kentucky woman, Theresa Merced, in early 2020. It is clear that the U.S. Department of Justice is focusing on genomics laboratories, and the trend will likely continue as federal agencies turn their attention to schemes involving increasingly popular genetic testing.

As such, now more than ever, health systems and genomics laboratories involved in precision medicine initiatives should carefully review their existing arrangements for legal compliance. Further, health systems and genomics laboratories should engage competent health care legal counsel to review any proposed arrangement.

While this article only addresses some of the federal fraud and abuse laws that are implicated in such arrangements, there are a number of other legal issues that should be evaluated, including but not limited to, federal and state privacy and security laws, anti-mark-up laws and self-referral laws.

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[1] Paving the way for Personalized Medicine: FDA's Role in a new era of medical product development. U.S. Department of Health and Human Services – U.S. Food and Drug Administration, October 2013. Available at: http://wayback.archive-it.org/7993/20180125110554/https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PrecisionMedicine/UCM372421.pdf. Accessed February 25, 2020.

[2] NCI dictionary of cancer terms [online]. Bethesda, Md: National Cancer Institute, 2017. Available at: www.cancer.gov/publications/dictionaries/cancer-terms. Accessed February 25, 2020.

[3] Kate Torchilin, Clinical Labs and the Rise of Precision Medicine. CLP Magazine, 2017. Available at: http://www.clpmag.com/2017/07/clinical-labs-rise-precision-medicine/. Accessed February 24, 2020.

[4] We refer to a hospital or health system as a health system for the purposes of this article.

[5] 42 U.S.C. § 1320A-7b(a)(1), (2).

[6] 42 U.S.C. § 1320A-7b(b)(1).

[7] Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), reprinted at 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

[8] Most states have their own state anti-kickback statutes - some of which are modeled after the federal AKS and others which have broader applicability and take different variations. Although outside the scope of this article, state fraud and abuse laws should evaluated in any arrangement.

[9] See OIG Advisory Opinion 12-05.

[10] 42 CFR § 1001.952(d).

[11] 18 U.S.C. §220.

[12] EKRA has limited legislative history and no regulations have been implemented. While its legislative background suggests an emphasis on substance abuse treatment, labs under EKRA are defined by reference to the CLIA statute, 42 U.S.C. § 263a. This broad definition means that all laboratories, not just laboratories that perform toxicology screenings, are subject to EKRA.

[13] 18 U.S.C. §220(a).

[14] 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).

[15] 18 U.S.C. § 220(b)(4).

[16] 42 U.S.C. §1320a-7a.

[17] 42 U.S.C. §1320a-7a(i)(6)(H).