Child Genetic Screening Alliance

Establishing a Federal Anti-Kickback Statute (AKS) Safe Harbor for Genetic Testing

Frequently Asked Questions

1. **What is the federal Anti-Kickback Statute, and how does it affect genetic testing?**

   The federal Anti-Kickback Statute (AKS), enacted in 1972 and codified at 42 U.S.C. § 1320a-7b(b), makes it a crime to knowingly and willfully offer, pay, solicit, or receive any form of "remuneration" in order to induce referrals for items or services reimbursable by a federal health care program[i]. Because genetic and genomic tests are oftentimes billed to Medicare, Medicaid, or another federal program, nearly any arrangement in which a laboratory, manufacturer, or health system provides something of value connected to a genetic test (e.g. a free test, covered genetic counseling, or specimen-collection support) can technically trigger the application of the AKS statute, even when the arrangement exists purely to help patients access needed care. Starting in 1991, Congress authorized regulatory "safe harbors" to exempt from AKS liability specific, well-defined categories of low-risk arrangements. Additional safe harbors have been added over the next 30 years, but none currently addresses the sponsored testing, counseling, or specimen-support arrangements that have become common in modern genetic medicine.

2. **What would a federal AKS safe harbor for genetic testing actually provide?**

   A safe harbor would create clear, bright-line rules under which specific, tightly defined arrangements would not be treated as illegal remuneration under the AKS, provided the arrangement satisfies statutory conditions such as no billing of federal programs for the sponsored components, no conditioning on the use of a particular drug or provider, and defined clinical eligibility criteria[ii]. Today, absent such a safe harbor, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) can only tell a company whether a specific proposed arrangement is low-risk through a slow, resource-intensive, case-by-case advisory opinion process that legally binds only the requesting party and offers no protection to any other organization running a similar program[iii]. A safe harbor would replace the opinion-by-opinion approach with predictable, generally applicable rules that every similarly situated stakeholder could then rely upon.

3. **Would an AKS carve out for genetic testing legalize the marketing schemes and fraud that the U. S. Department of Justice has been prosecuting?**

   No. A properly drafted safe harbor would protect only arrangements that meet strict, affirmative conditions, such as defined clinical eligibility criteria, a prohibition on billing any federal or private payer for the sponsored components, and a bar on using the arrangement to steer prescriptions or drive marketing[iv]. A safe harbor would sharpen the legal line between legitimate patient-access programs and the referral-buying schemes the U.S. Department of Justice and OIG continue to prosecute aggressively.

4. **What safeguards would prevent the safe harbor from being exploited by bad actors?**

   The HHS/OIG's own advisory opinions on sponsored genetic testing offer a ready template for the safeguards a safe harbor should require: narrow clinical eligibility criteria tied to symptoms, family history, or confirmed risk factors; a prohibition on billing patients, Medicare, Medicaid, or private payers for any sponsored component; a requirement that the sponsored test not be conditioned on the prescription or purchase of a particular drug or service; and controls preventing the arrangement from being used as a marketing or patient-recruitment tool[v]. These are precisely the features that distinguish the arrangements OIG has approved from the illegal schemes it has prosecuted[vi]. Codifying such arrangements into a safe harbor's statutory conditions would give enforcement agencies an even clearer, more consistent standard against which to measure, and prosecute, noncompliant conduct.

5. **How would and AKS carve out for genetic testing help patients obtain more timely diagnoses and reduce healthcare costs?**

   Patients with a suspected rare or genetic condition currently endure a diagnostic odyssey that averages four to six years and multiple misdiagnoses before a correct diagnosis is reached, generating avoidable direct medical costs estimated at $86,000 to $517,000 per patient[vii]. A 2026 study of more than 8,000 pediatric patients with epilepsy, developmental delay, or intellectual disability found that exome and genome sequencing reduced average healthcare costs by roughly $80,000 per child, cutting hospitalizations from 3.5 to 0.6 per year and emergency room visits from 4.6 to 1.4 per year in the epilepsy cohort alone[viii]. These savings apply for Medicaid and commercially insured children alike[ix]. A safe harbor that removes the legal uncertainty around covering the cost of testing and counseling for eligible patients would make it easier for laboratories, health systems, and manufacturers to accelerate the diagnostic odyssey.

6. **Why does coverage for genetic counseling and testing present a barrier to a timely diagnosis, and how would an AKS safe harbor address it?**

   Genetic counselors are not recognized by the Centers for Medicare & Medicaid Services (CMS) as billable providers, so Medicare beneficiaries generally cannot consult a genetic counselor without an accompanying physician or nurse-practitioner visit[x]. Many Medicaid patients must pay out of pocket for counseling that private insurers would otherwise cover. Since the supply of practicing genetic counselors nationwide is not projected to meet

demand until after 2030, lower-income and rural communities are most impacted by the disparity[xi], i.e. they do not have access to genetic counselors and thus are not receiving timely diagnoses to inherited genetic conditions. By removing the AKS uncertainty that currently discourages laboratories and health systems from directly covering counseling costs for financially eligible patients, an AKS safe harbor would allow more sponsors to step in and help close this gap without waiting on separate Medicare reimbursement reform.

7. Wouldn't allowing labs and manufacturers to subsidize genetic testing create conflicts of interest?

Codifying an AKS safe harbor would protect only those arrangements that meet strict, independently verifiable conditions. OIG's existing advisory opinions already show how conflicts of interest can be managed. In Advisory Opinion 24-12, for example, the sponsor is required to let the treating clinician select from among several approved, independent tests, and the sponsor is barred from using test results to promote its own product[xii]. A Safe Harbor built around independent test selection, defined eligibility, no product-tying, and a bar on using the arrangements for marketing would preserve clinical independence while giving patient-access programs the legal certainty they currently lack.

8. Is there precedent for Congress or the HHS/OIG to create a safe harbor?

Yes. As healthcare delivery has evolved, the HHS/OIG has periodically added new safe harbors and solicits public proposals for new or modified safe harbors on an ongoing basis. In 2020, the HHS/OIG finalized permanent safe harbor protection for electronic health records donations[xiii]. Similarly to an AKS safe harbor for genetic testing, Congress has proposed legislation that sought to create an AKS safe harbor covering travel and lodging support for patients receiving cell and gene therapies, contending that a safe harbor would provide greater access for patients and eliminate the need for OIG to issue individual advisory opinions[xiv]. In June 2024, the HHS/OIG issued an advisory opinion approving a plan that would provide assistance with travel, lodging, meals, and other associated expenses for qualifying patients receiving a gene therapy product.

9. Would an AKS safe harbor for genetic testing reduce or increase costs to Medicare and Medicaid?

The evidence points toward a net savings for CMS. Beyond the roughly $80,000 in average per-child healthcare cost reductions found in the pediatric genomic sequencing study in the United States, data from a study in the United Kingdom (UK) shows that delayed rare-disease diagnoses have been estimated to cost the UK's National Health Service alone more than $4.3 billion over a ten-year period. These savings are driven largely by avoidable hospitalizations and repeated testing before an accurate diagnosis is reached[xv]. This dynamic plays out similarly across U.S. federal health care programs. By making it easier for eligible patients to access diagnostic testing and counseling earlier, a safe harbor is designed to accelerate exactly the kind of shift away from costly, reactive acute care that evidence shows generates savings for payers, including Medicare and Medicaid.

10. Would and AKS safe harbor for genetic testing apply only to rare disease testing?

While much of the cost-savings evidence to date comes from pediatric rare disease and

neurodevelopmental testing, OIG's existing advisory opinions already span a range of use cases including ultra-rare disease testing, oncology companion diagnostics, and disease-risk screening. This data suggests that a well-drafted safe harbor could be structured to apply wherever the same core safeguards can be met, regardless of the specific clinical indication.

11. Would an AKS carve out for genetic testing eliminate oversights provided by the Eliminating Kickbacks in Recovery Act (EKRA) or state anti-kickback laws?

Not automatically. EKRA (2018) separately prohibits kickbacks in exchange for referrals to medical testing laboratories[xvi]. But unlike the AKS, it is not limited to federally funded health care programs and applies even to referrals reimbursed by private payers. A safe harbor written into the AKS alone would not, by itself, protect an arrangement from EKRA liability or from separate state anti-kickback statutes.

12. What is the process for creating an AKS safe harbor?

A safe harbor can be created as a result of action by the legislative or executive branches. Congress can pass legislation directing the HHS/OIG to promulgate a new regulatory safe harbor, or the HHS/OIG can promulgate a new regulatory safe harbor directly through the OIG's existing rulemaking process. Note that changes made through the executive rulemaking process could be reversed by a future Administration, whereas legislation passed by Congress and signed into law by the President would be codified into statute and thus could not be changed without the passage of additional legislation.

Either path would allow the public the opportunity to provide comments, giving patient groups, providers, laboratories, and compliance experts a chance to help shape the specific eligibility and reporting conditions attached to the final safe harbor.

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[i] 42 U.S.C. § 1320a-7b(b); Social Security Amendments of 1972, Pub. L. No. 92-603, tit. II, § 242(c), 86 Stat. 1329, 1419 (1972); 42 C.F.R. § 1001.952. https://uscode.house.gov/view.xhtml?req=(title:42+section:1320a-7b+edition:prelim)

[ii] 42 C.F.R. § 1001.952; see also Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 680, 697 (codified at 42 U.S.C. § 1320a-7b(b)(3)). https://www.ecfr.gov/current/title-42/section-1001.952

[iii] 42 C.F.R. § 1008.53 (advisory opinions bind only the requestor); 42 U.S.C. § 1320a-7d(b) (advisory opinion authority). https://www.law.cornell.edu/cfr/text/42/1008.53

[iv] U.S. Dep't of Health & Human Servs., Office of Inspector Gen., Advisory Opinion No. 22-06 (Apr. 6, 2022); Advisory Opinion No. 24-12 (Dec. 12, 2024); 42 C.F.R. § 1001.952. https://oig.hhs.gov/documents/advisory-opinions/1028/AO-22-06.pdf
https://oig.hhs.gov/documents/advisory-opinions/10117/AO-24-12.pdf

[v] U.S. Dep't of Health & Human Servs., Office of Inspector Gen., Advisory Opinion No. 22-06 (issued Apr. 6, 2022; posted Apr. 11, 2022). https://oig.hhs.gov/documents/advisory-opinions/1028/AO-22-06.pdf

[vi] Press Release, U.S. Dep't of Justice, Pharmaceutical Company Ultragenyx Agrees to Pay $6 Million for Allegedly Paying Kickbacks to Induce Claims for Its Drug Crysvita (Dec. 21, 2023); Press Release, U.S. Attorney's Office, D. Mass., QOL Medical and Its CEO Agree To Pay $47 Million for Allegedly Paying Kickbacks To Induce Claims for QOL's Drug Sucraid (Nov. 15, 2024). https://www.justice.gov/archives/opa/pr/pharmaceutical-company-ultragenyx-agrees-pay-6-million-allegedly-paying-kickbacks-induce https://www.justice.gov/usao-ma/pr/qol-medical-and-its-ceo-agree-pay-47-million-allegedly-paying-kickbacks-induce

[vii] EveryLife Foundation for Rare Diseases, The Cost of Delayed Diagnosis in Rare Disease: A Health Economic Study (Sept. 2023). https://everylifefoundation.org/wp-content/uploads/2023/09/EveryLife-Cost-of-Delayed-Diagnosis-in-Rare-Disease_Final-Full-Study-Report_0914223.pdf

[viii] Colton Frazer et al., Reduction in Healthcare Costs for Children with Epilepsy Following Exome and Genome Sequencing: A SAVES-Kids Study (conference presentation, 2026 Annual Meeting of the American College of Medical Genetics and Genomics, Baltimore, MD, Mar. 13, 2026). https://ir.genedx.com/news-releases/news-release-details/genedx-present-18-abstracts-acmg-2026-showcasing-scale-genedx

[ix] Colton Frazer et al., SAVES-Kids Study, 2026 ACMG Annual Meeting, supra note 8. https://ir.genedx.com/news-releases/news-release-details/genedx-present-18-abstracts-acmg-2026-showcasing-scale-genedx

[x] 42 U.S.C. § 1395u(b)(18)(C); 42 U.S.C. § 1395x(s)(2); see also Access to Genetic Counselor Services Act of 2026, S. 3607, 119th Cong. (2026). https://uscode.house.gov/view.xhtml?req=(title:42+section:1395u+edition:prelim)

[xi] Julianne M. Hoskovec et al., Projecting the Supply and Demand for Certified Genetic Counselors: A Workforce Study, 27 J. Genetic Counseling 16 (2018). https://doi.org/10.1007/s10897-017-0158-8

[xii] U.S. Dep't of Health & Human Servs., Office of Inspector Gen., Advisory Opinion No. 24-12 (issued Dec. 12, 2024; posted Dec. 17, 2024). https://oig.hhs.gov/documents/advisory-opinions/10117/AO-24-12.pdf

[xiii] 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. 77,684 (Dec. 2, 2020) (codified at 42 C.F.R. § 1001.952(y)). https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

[xiv] Patient Access Act of 2024, H.R. 9184, 118th Cong. (2024) (not enacted). https://www.congress.gov/bill/118th-congress/house-bill/9184

[xv] Imperial College Health Partners, A Preliminary Assessment of the Potential Impact of Rare Diseases on the NHS: Mendelian — Report on Initial Findings (Nov. 2018). https://imperialcollegehealthpartners.com/wp-content/uploads/2019/05/ICHP-RD-Report-Nov-2018-APPROVED-002.pdf

[xvi] 18 U.S.C. § 220; SUPPORT Act, Pub. L. No. 115-271, tit. VIII, § 8122(a), 132 Stat. 3894, 4108 (2018). https://uscode.house.gov/view.xhtml?req=(title:18+section:220+edition:prelim)