Child Genetic Screening Alliance

VIA ELECTRONIC SUBMISSION

August 20, 2026

The Honorable T. March Bell
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, D.C. 20201

Attention: OIG-2602-N

RE: Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP[1]

Inspector General Bell,

On behalf of the Child Genetic Screening Alliance (CGSA), a nonprofit coalition advocating for policies that improve the health outcomes of children through timely diagnoses of rare, inherited childhood genetic diseases, I appreciate the opportunity to comment on the Request for Information (RFI) issued by the Office of Inspector General (OIG). These comments respond specifically to Question 13 of the RFI and support the reasoning that the broader-impacts analysis OIG has requested applies with equal, if not greater, force to manufacturer-sponsored genetic testing and counseling programs for children with rare genetic diseases.

Question 13 asks the OIG to weigh the broader impacts of remuneration-based arrangements against the criteria set forth in section 1128D(a)(2) of the Social Security Act. OIG has already determined, in advisory opinions addressing manufacturer-sponsored genetic testing programs, that arrangements built around three key safeguards: (1) defined eligibility criteria, (2) independence from product promotion, and (3) deidentified data use, do not violate the Anti-

[1] Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP, 91 Fed. Reg. 37902 (June 24, 2026) (RIN 0936-AA16), https://www.federalregister.gov/documents/2026/06/24/2026-12676/medicare-and-state-health-care-programs-fraud-and-abuse-request-for-information-regarding-the.

Kickback Statute (AKS) or the Beneficiary Inducements Civil Monetary Penalties Law (BICMPLs). These three safeguards map directly to section 1128D(a)(2) factors that Question 13 directs OIG to consider and they demonstrate that manufacturer-sponsored genetic testing programs increase the access to care and the quality of care without creating the risks of overutilization, impaired competition, or improper steering that the AKS is designed to prevent.

Just as Question 13 asks whether higher clinical trial participation could lead to improved health care for Federal health care program enrollees, the same logic supports the conclusion that facilitating earlier genetic diagnosis through manufacturer-sponsored testing programs improves outcomes and reduces costs to Federal health care programs -- particularly for children with progressive, treatable genetic conditions. Thus, the CGSA urges OIG to use this rulemaking as a basis for supporting the decision to adopt a parallel safe harbor for manufacturer-sponsored genetic testing and counseling programs.

I. Question 13's Broader-Impacts Framework Applies With Equal Force to Manufacturer-Sponsored Genetic Testing Programs

Question 13 asks commenters to address the "broader impacts or implications" of remuneration arrangements and related safe harbors "as they relate to the criteria set forth in section 1128D(a)(2) of the Act," including changes in access to health care services, quality of health care services, and costs to Federal health care programs[2]. OIG poses this question in the context of clinical trial participant remuneration, but the underlying analytical framework is not unique to clinical trials. Rather, it applies whenever OIG considers whether an arrangement that confers value on a Federal health care program beneficiary, or a beneficiary's family, should be protected because the public health benefits of the arrangement outweigh its fraud and abuse risk.

Manufacturer-sponsored genetic testing and counseling programs present that same benefit. Like clinical trial remuneration, these programs provide valuable genetic testing and associated counseling to individuals who could not otherwise readily access these programs. In addition, access to these programs oftentimes advances early and accurate diagnosis of a genetic condition rather than generation of clinical evidence. Just as OIG has recognized that appropriately structured clinical trial remuneration need not run afoul of the AKS, OIG has already recognized in advisory opinions that appropriately structured genetic testing programs do not[3] break existing laws.

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[2] 91 Fed. Reg. at 37905 (Request for Information Question 13); see also 42 U.S.C. § 1320a-7d(a)(2).

[3] See OIG, HHS, Advisory Opinion No. 22-06 (Apr. 6, 2022), https://oig.hhs.gov/documents/advisory-opinions/1028/AO-22-06.pdf.
OIG, HHS, Advisory Opinion No. 24-12 (Dec. 17, 2024), https://oig.hhs.gov/documents/advisory-opinions/10117/AO-24-12.pdf.

II. The Safeguards That Justify a Genetic Testing Safe Harbor Directly Track the Section 1128D(a)(2) Factors Cited in Question 13

OIG's advisory opinions establish that manufacturer-sponsored genetic testing and counseling programs avoid AKS and Beneficiary Inducements CMP liability when they include three safeguards: defined eligibility criteria; independence from product promotion; and deidentified data use[4]. Each of these safeguards corresponds directly to one or more of the section1128D(a)(2) factors that Question 13 asks OIG to weigh:

- **Defined eligibility criteria.** Limiting testing to patients who present with relevant symptoms, or who have a biological relative with a confirmed diagnosis or known genetic profile, ensures that the program increases access to medically necessary diagnostic services for a clinically defined population rather than creating a generalized inducement. This directly addresses the section 1128D(a)(2) factors concerning increases in access to and quality of health care services, and it forecloses any risk of overutilization as testing is tied to medical necessity rather than beneficiary status alone.

- **Independence from product promotion.** Conditioning the program on a prohibition against tying testing or its results to the use of any particular manufacturer's product and prohibiting use of test results to promote such products eliminates the risk that the arrangement could induce or reward referrals or purchasing decisions. This directly addresses section 1128D(a)(2) concerning patient freedom of choice among providers, competition among health care providers, and the absence of any financial benefit to a health care professional tied to ordering decisions.

- **Deidentified data use.** Restricting a manufacturer's use of program data to deidentified aggregate information rather than beneficiary-specific data prevents the arrangement from being used to identify, target, or steer specific beneficiaries or referral sources. This addresses the residual "other factors" prong of section 1128D(a)(2), which permits OIG to weigh any consideration relevant to preventing fraud and abuse.

Because these safeguards align so closely onto the statutory factors Question 13 identifies, OIG's existing advisory opinion analysis of manufacturer-sponsored genetic testing programs provides a ready template for both the broader-impacts analysis Question 13 requests and for codifying that analysis in a safe harbor, rather than relying solely on discretionary, case-by-case guidance.

III. Facilitating Earlier Genetic Diagnosis Produces the Same Kind of Broader Benefit Question 13 Identifies for Clinical Trial Participation

[4] See OIG, HHS, Advisory Opinion No. 22-06, supra note 4; OIG, HHS, Advisory Opinion No. 24-12, supra note 4.

Question 13 asks whether higher participation rates among Federal health care program enrollees, facilitated by remuneration, "could lead to improved health care for individuals in those programs."[5] The evidence concerning manufacturer-sponsored genetic testing programs answers affirmatively with respect to children with progressive genetic disorders for whom the cost of delayed diagnosis is measured in irreversible harm.

The Recommended Uniform Screening Panel (RUSP) currently includes only 40 core conditions, and states often take years to implement newly added conditions, if they do so at all[6]. The 2019 statutory expiration and subsequent termination of the Advisory Committee on Heritable Conditions in Newborns and Children has further stalled expansion of newborn screening[7]. As a result, children with progressive genetic disorders that have FDA-approved therapies like CLN2 Batten disease, Duchenne muscular dystrophy, Fabry disease, Friedreich's ataxia, Gaucher disease, Niemann-Pick disease, Morquio A syndrome (MPS IVA), Maroteaux-Lamy syndrome (MPS VI), and Sly syndrome (MPS VII), are often not diagnosed until irreversible damage has occurred[8].

Manufacturer-sponsored genetic testing programs, such as "FA Identified," "Behind the Seizure," "The Lantern Project," and "Discover Dysplasias," have emerged specifically to close this gap, enabling earlier diagnosis for children with rare diseases that are not currently screened at birth.[9] Earlier diagnosis through these programs directly reduces costs to Federal health care programs by avoiding the higher-cost acute and long-term care associated with late-stage disease progression, and it increases access to and quality of care by connecting patients to treatment during the window in which FDA-approved therapies are most effective. Improved health care outcomes and reduced program costs are the precise kinds of broader impacts that Question 13 asks OIG to consider. These impacts support extending safe harbor protection to this category of

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[5] 91 Fed. Reg. at 37905 (Request for Information Question 13); see supra note 3.

[6] See Health Res. & Servs. Admin. (HRSA), Recommended Uniform Screening Panel Core Conditions (as of July 2024), https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/rusp/rusp-july-2024.pdf.
EveryLife Found. for Rare Diseases, Pioneering the New Era of Newborn Screening: Collaborative Insights and Recommendations for Modernizing NBS Systems (2023), https://everylifefoundation.org/wp-content/uploads/2023/09/ELF-NBS-WhitePaper_Final.pdf.

[7] See Spreeha Choudhury & Richard Hughes IV, Newborn Screening At Risk: Implications Of Disbanding The Advisory Committee On Heritable Disorders In Newborns And Children, Health Affairs (May 1, 2025), https://www.healthaffairs.org/content/forefront/newborn-screening-risk-implications-disbanding-advisory-committee-heritable-disorders.

[8] See, e.g., Anna Bryzik et al., Case Report: The Window that Closed Too Soon: Lessons from a Late CLN2 Diagnosis and Death of a 9-year-old Boy, 16 Frontiers in Genetics, https://pmc.ncbi.nlm.nih.gov/articles/PMC12270889/pdf/fgene-16-1622185.pdf.

[9] See ThinkFA, FA Identified Genetic Testing Program (Biogen-sponsored program administered by PreventionGenetics), https://www.thinkfa.com/fa-genetic-testing.html.
Invitae, Behind the Seizure® Program (Labcorp-sponsored genetic testing for pediatric epilepsy), https://www.invitae.com/us/sponsored-testing/behind-the-seizure.
Revvity, The Lantern Project (Sanofi Genzyme-sponsored testing for lysosomal storage disorders), https://www.revvity.com/revvity-omics-ordering-resources-the-lantern-project.
Blueprint Genetics, Blueprint Genetics and BioMarin Collaborate to Launch Discover Dysplasias Program (skeletal dysplasia testing), https://www.blueprintgenetics.com/news/blueprint-genetics-and-biomarin-collaborate-to-launch-discover-dysplasias-program/.

arrangement.

IV. Recommendation: OIG Should Use This Rulemaking to Adopt a Parallel Safe Harbor for Manufacturer-Sponsored Genetic Testing and Counseling Programs

For the reasons above, CGSA urges OIG to treat this RFI, and its Question 13 broader-impacts inquiry, as an opportunity to create a safe harbor for manufacturer-sponsored genetic testing and counseling programs. CGSA proposes that OIG should amend 42 C.F.R. § 1001.952 to add a new paragraph protecting a "Pharmaceutical Manufacturer-Sponsored Genetic Testing and Counseling Arrangement" that satisfies conditions requiring: (1) that the test address a disease or condition for which the patient was not adequately screened at birth or for which testing is otherwise medically necessary; (2) that a licensed health care professional determine the test is medically necessary based on presenting symptoms or family history; (3) that results be provided directly to the patient and the ordering professional; (4) that the program not be conditioned on, or used to promote, any prescription product or service; and (5) that the program include safeguards to protect patient privacy consistent with the Health Insurance Portability and Accountability Act and other applicable law.

Codifying these conditions in a safe harbor, rather than addressing them only through case-by-case advisory opinions would provide manufacturers, providers, and patient organizations durable certainty to continue and expand programs that OIG's own analysis, and the section 1128D(a)(2) factors, confirm serve a vital public health function.

On behalf of the CGSA, I appreciate your attention to this matter and welcome the opportunity to provide additional information as OIG considers the questions raised in this RFI.

Respectfully submitted,

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Board Secretary
Child Genetic Screening Alliance