Alliance for Regenerative Medicine

February 9, 2026

Tiana Korley
Office of Inspector General
U.S. Department of Health and Human Services
Attention: OIG–1125–N, Room 5628, Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Submitted electronically via http://www.regulations.gov

RE: Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts (OIG–1125–N)

Dear Ms. Korley:

The Alliance for Regenerative Medicine ("ARM") appreciates the opportunity to provide comments in response to the solicitation by the Office of Inspector General ("OIG") for proposals and recommendations for developing new, or modifying existing, safe harbor provisions under the Federal Anti-Kickback Statute, Section 1128B(b) of the Social Security Act (the "AKS"), as well as developing new OIG Special Fraud Alerts.

ARM is the leading international advocacy organization championing the benefits of engineered cell and gene therapies ("CGTs") for patients, healthcare systems, and society. As a community, ARM builds the future of medicine by convening the sector, facilitating influential exchanges on policies and practices, and advancing the narrative with data and analysis. We actively engage key stakeholders to enable the development of advanced therapies and to modernize healthcare systems so that patients benefit from durable, potentially curative treatments. As the global voice of the sector, we represent more than 400 members across 25 countries, including emerging and established biotechnology companies, academic and medical research institutions, and patient organizations.

As outlined below, we recommend that OIG adopt three new safe harbors to permit certain arrangements that seek to overcome the following significant barriers to access for patients considering CGTs: (1) the significant expense of travel, lodging, and associated expenses to specialized treatment facilities where CGTs can be administered; (2) the significant expense of diagnostic tests indicating a patient's eligibility for, or the success of, a CGT treatment; and (3) the loss of fertility associated with the administration of certain CGTs.

I. Background

CGTs hold enormous promise for patients with some of the most serious and historically difficult-to-treat diseases. As of January 2026, there were over 1,856 engineered cell therapy and genetic medicine developers worldwide with nearly 900

CGT clinical trials ongoing in the US and over 2,130 globally to test the next generation of therapies targeting dozens of indications, including rare monogenetic diseases, oncology, cardiovascular, central nervous system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.[1] To date, the Food and Drug Administration (FDA) has approved 48 cell and gene therapies.[2] This includes approvals for gene therapies treating Duchenne muscular dystrophy and hemophilia A, a cell therapy for type 1 diabetes, and two gene therapies treating sickle cell disease (SCD).[3] As the promise of CGTs continues to come into focus, the pipeline for both rare and prevalent diseases is accelerating. The FDA approved both a new cell therapy and a tissue engineered therapy in December 2025 and could issue approvals of up to three additional cell or gene therapies in the first few months of 2026.[4] Recent research projects approvals of between 75 and 96 new CGT product-indications by 2033,[5] with estimates of the number of patients receiving CGT treatments increasing approximately tenfold in a similar period.[6]

These advances have significant implications not only for patients but also for the Federal health care programs that serve them, representing a significant potential for cost savings to both the state and Federal governments. For example, Medicaid beneficiaries with SCD have five times more emergency department visits and nearly eight times more hospitalizations than Medicaid beneficiaries without SCD,[7] representing a significant cost to both the state and Federal governments. As CGTs can offer potentially curative and durable therapies, they have the potential to eliminate or replace the direct cost of chronic care and avert costs associated with downstream complications of disease progression,[8] in line with this administration's

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[1] *See* Sector Snapshot, Q4 2025, Alliance for Regenerative Medicine, December 2025, available at: https://alliancerm.org/wp-content/uploads/2026/01/ARM-Q4-2025-CGT-Sector-Data.pdf.

[2] Approved Cellular and Gene Therapy Products, FDA, December 9, 2025, available at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.

[3] *See* FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease, FDA, December 2023, available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease.

[4] *See* FDA Approves First Cellular Therapy to Treat Patients with Severe Aplastic Anemia, FDA, December 8, 2025, available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellular-therapy-treat-patients-severe-aplastic-anemia; FDA Approves Nerve Scaffold for the Treatment of Sensory Nerve Discontinuity, FDA, December 3, 2025, available at: https://www.fda.gov/news-events/press-announcements/fda-approves-nerve-scaffold-treatment-sensory-nerve-discontinuity; Sector Snapshot, Q3 2025, Alliance for Regenerative Medicine, December 2025, available at: https://alliancerm.org/wp-content/uploads/2025/11/Sector-Snapshot-Draft-Q3-2025_Published.pdf.

[5] *See* Cell and Gene therapy (CGT) pipeline deep dive, Center for Biomedical System Design, Tufts Medical Center, 2023, available at: https://newdigs.tuftsmedicalcenter.org/payingforcures/defining-disruption/cell-and-gene-therapy-products-and-%20pipeline/cgt-pipeline-deep-dive/#gsc.tab=0.

[6] *See* Phares S et al., The next decade in cell and gene therapy, Drug Discovery Today, January 2026; 31(1), available at: https://www.sciencedirect.com/science/article/pii/S1359644625002648.

[7] *See* Centers for Medicare and Medicaid Services. Sickle Cell Disease Report, March 2023, available at: https://www.medicaid.gov/sites/default/files/2023-03/scd-rpt-mar-2023.pdf.

[8] *See, e.g.,* Curative Regenerative Medicines: Preparing Health Care Systems for the Coming Wave, Alliance for

stated commitment to address chronic disease.

While CGTs offer great promise, and are often administered only once, they are complex to manufacture and administer, involving a number of steps that can take several months. First, for individualized treatments, patients must satisfy certain eligibility criteria, which may involve genetic testing. Then, for many CGTs, the patient's cells must be harvested, processed, purified, and then used to create the cell or gene therapy, which is subject to certain quality-control procedures. The patient then receives pre-conditioning treatments to prepare their immune system for administration, and the therapy is then infused at a specialized treatment center where ongoing monitoring occurs. Various consultations are also required in preparation for the administration of a CGT as clinicians ensure throughout the process that a patient remains an appropriate candidate. This may commence the initial requirement to travel to a treatment center, followed by traveling for the pre-conditioning treatments then again for administration.

Given the complexity of the manufacturing and administration processes for CGTs, the potential for CGTs to successfully improve care for patients and reduce the cost of chronic care for Federal health care programs ultimately depends upon reducing barriers to access. With a number of CGTs available to treat rare diseases, these barriers must themselves be understood within the context of the diagnostic odyssey that patients with rare diseases face. Some patients receive incomplete or inconclusive diagnostic results and must therefore undergo multiple rounds of genetic or biomarker testing, which delays their rare disease diagnosis. Improved access to testing would streamline the diagnostic process and potentially avoid unnecessary, and potentially harmful, interventions that are administered prior to obtaining an accurate diagnosis. Of those patients who are diagnosed—often only after multiple primary care and specialist visits—many face significant obstacles to obtaining appropriate CGT treatments, including needing to travel across state lines for extended stays near or at specialized treatment centers. Additional concerns related to access—such as issues with cross-state credentialing for Medicaid providers and inadequate payment models—have policy solutions outside the purview of OIG and the AKS. However, clear regulatory guidance from OIG can provide the certainty needed for CGT biotechnology companies, providers, and others to address common barriers to access. Further, we encourage OIG to coordinate with the Centers for Medicare and Medicaid Services and other Federal agencies, as appropriate, to address these additional barriers.

We greatly appreciate the focus that the various divisions of the U.S. Department of

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Regenerative Medicine, November 2016, *available at*: https://alliancerm.org/wpcontent/uploads/2018/04/IN_VIVO_ARM_WhitePaper_CurativeRegenMed.pdf; Regenerative Medicine is Here: New Payment Models Key to Patient Access, Alliance for Regenerative Medicine, August 2018, *available at*: https://alliancerm.org/wp-content/uploads/2018/07/ARM_WhitePaper3_IV1807_LRS.pdf; A Transformative Therapy Value Model for Rare Blood Diseases, Alliance for Regenerative Medicine, January 2020, available at: https://alliancerm.org/wp-content/uploads/2025/09/ARM-Marwood-White-Paper-FINAL.pdf.

Health and Human Services (HHS) has already brought to the promise of CGTs, including through the FDA's Cell and Gene Therapy Roundtable and the Center for Medicare and Medicaid Innovation (CMMI)'s commitment to its Cell and Gene Therapy Access Model. The CGT Access Model recognizes that gene therapies require innovative thinking about access, payment, and healthcare delivery and that patients with severe SCD should have timely access to life-changing gene therapies regardless of their income level, where they get their health coverage, or where they live. As of January 2026, two-thirds of the states, the District of Columbia, and Puerto Rico are participating in the CGT Access Model, seven of which plus the District of Columbia have received cooperative agreement funding to support with implementation costs.[9]

Of particular note, the CGT Access Model aims to address access barriers facing Medicaid beneficiaries with SCD through the AKS safe harbor for CMS-sponsored model arrangements.[10] These flexibilities allow states to support travel, lodging, and other ancillary services to address other barriers to access. They also allow participating manufacturers to financially support a defined scope of fertility preservation services to address a significant access barrier—infertility resulting from CGT pre-conditioning and administration—that may otherwise lead patients in participating states to forego use of CGTs. The OIG has indicated its openness to evaluating data regarding payments for fertility preservation services in connection with use of CGTs, such as through the CGT Access Model, to assess whether such arrangements present sufficiently low risk of fraud and abuse as to warrant protection beyond the scope of the CGT Access Model.[11]

Unfortunately, the AKS's broad scope remains a core obstacle to patient access to CGTs. As OIG has repeatedly emphasized, the AKS may be violated where one purpose of remuneration provided to patients is to induce referrals for items or services reimbursable by a Federal health care program. However, OIG has likewise explained that certain remuneration to patients may serve the critical function of promoting access to care. Indeed, such arrangements may be permissible where the remuneration provided supports critical access, does not interfere with clinical decision-making, does not lead to over-utilization or inappropriate utilization, and does not raise safety or quality concerns.[12]

ARM believes that the Administration can help advance its Make America Healthy Again goals to confront chronic diseases by issuing new AKS safe harbors that address regulatory barriers to patients' timely access to transformative CGTs that address the root cause of disease and that pose minimal risk of fraud and abuse in Federal health care programs. Using this approach, we believe the three proposed

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[9] *See* CGT (Cell and Gene Therapy Access) Model, CMS, September 30, 2025, available at: https://www.cms.gov/priorities/innovation/innovation-models/cgt.

[10] *See* 42 C.F.R. § 1001.952(ii).

[11] *See* Advisory Opinion No. 24-05, OIG, July 17, 2025, available at: https://oig.hhs.gov/documents/advisory-opinions/9936/AO-24-05.pdf, p. 12-13; Advisory Opinion No. 24-06, OIG, July 18, 2024, available at: https://oig.hhs.gov/documents/advisory-opinions/9940/AO-24-06.pdf, p. 6-7.

[12] *See, e.g.*, Advisory Opinion No. 20-09, OIG, December 28, 2020, available at: https://oig.hhs.gov/documents/advisory-opinions/772/AO-20-09.pdf.

safe harbors set forth below facilitate common-sense, much-needed assistance to help patients to access CGTs in a manner consistent with the AKS and the above guardrails. We discuss each of the proposed safe harbors, in turn.

II. Proposed Safe Harbor for Travel, Lodging, and Associated Expenses Incurred While Receiving Treatment at Specialized Treatment Facilities

ARM first recommends that OIG establish a safe harbor for payments to certain patients and their caregivers for travel, lodging, and associated expenses incurred in connection with a patient's receipt of CGT treatment at specialized treatment facilities.[13] Specifically, OIG should establish a new safe harbor to permit a CGT biotechnology company or other entity to provide payments for travel, lodging, and associated expenses in the following circumstances:

- The patient seeks (i) initial visits to prepare for administration of a CGT treatment and/or (ii) the actual administration of a CGT treatment, each in a context in which there is a limited network of qualifying facilities available to perform such preparatory functions or administer the CGT treatment.
- The patient or his or her caregiver demonstrates financial need in association with lodging, travel, and similar costs to access the most appropriate specialized treatment facility.
- Payment is limited to reasonable costs for suitable lodging, travel, and associated costs incurred (each as verified by receipts) by the patient and/or his or her caregiver enabling them to stay comfortably within a reasonable distance of the facility administering the CGT treatment, including for the caregiver while the patient is hospitalized in connection with their receipt of the CGT treatment.
- With respect to lodging in particular, the patient or caregiver cannot otherwise be lodged at the facility at which the patient is receiving the treatment.
- The patient or caregiver does not have insurance, charitable, or similar assistance that can be applied to travel, lodging, and associated costs for CGT treatment.

The proposed safe harbor is justified by the on-the-ground realities of administering CGT treatments. It is common for the FDA in approving CGTs to require risk evaluation and mitigation strategies ("REMS") as well as elements to assure safe use ("ETASU") in the form of requirements that hospitals and clinics that provide CGTs be specially certified.[14] For some CGTs for which the FDA has not

[13] For purposes of this proposal, we are defining a "specialized treatment facility" as a facility that requests and agrees to become a treatment center for the administration of the CGT, meets certain objective criteria established by the CGT biotechnology company in accordance with the company's regulatory submissions to the FDA, and completes the company's training on the drug and its administration.

[14] *See, e.g.*, FDA Approves First Cell-Based Gene Therapy for Adult Patients with Relapsed or Refractory MCL, FDA, July 24, 2020, available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-cell-based-

required REMS or ETASU, the network of providers certified to administer the CGTs is similarly narrow due to the extensive training and expertise required for administration. Understandably, these requirements and certifications are intended to ensure safe administration of CGTs to patients but have the practical effect of restricting the number and distribution of providers at which CGTs are available. This results in patients being required to travel significant distances to reach an appropriate specialized treatment facility. In addition, as further discussed in the OIG Advisory Opinions ("AOs") detailed below, CGT administration frequently requires that a patient and their caregiver either make multiple visits to a facility, or remain at or near a facility for multiple days at a time (sometimes to receive the treatment and sometimes also to undergo post-treatment monitoring), or both.

The proposed safe harbor is highly consistent with OIG's long history of issuing favorable AOs regarding financial support for travel, lodging, and associated expenses related to CGT preparation and administration. Beginning with AO 20-02[15] and AO 20-09,[16] OIG favorably opined on arrangements where manufacturers covered travel, lodging, and associated expenses for patients to take one trip to undergo leukapheresis and a second trip to undergo drug administration and monitoring, each at facilities specially certified under the FDA's REMS/ETASU framework.[17] OIG did not impose administrative sanctions for several reasons—in particular, the arrangements:

- Helped indigent patients who would otherwise be "disproportionately impacted by significant health risks or even death if they cannot travel."[18]
- "[E]nable physicians to meet the FDA requirements in the Drug's prescribing information and to mitigate patient harm from potentially lethal Drug side effects."[19]
- Involved "a one-time, potentially curative treatment" that did not pose a risk of inducing the repeated ordering of the treatment and payment by a Federal health care program.[20]

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gene-therapy-adult-patients-relapsed-or-refractory-mcl#:~:text=Because%20of%20the%20risk%20of,CAR%2DT%20therapy%2C%20Yescarta; FDA Approval Brings First Gene Therapy to the United States, FDA, August 30, 2017, available at: https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states; FDA Approves New Treatment for Adults with Relapsed or Refractory Large-B-Cell Lymphoma, FDA, February 5, 2021, available at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-adults-relapsed-or-refractory-large-b-cell-lymphoma.

[15] *See* Notice of Modification of Advisory Opinion 20-02, OIG, May 26, 2022, available at: https://oig.hhs.gov/documents/advisory-opinions/1035/Modification-AO-20-02.pdf.

[16] *See* Advisory Opinion No. 20-09, OIG, December 28, 2020, available at: https://oig.hhs.gov/documents/advisory-opinions/772/AO-20-09.pdf.

[17] *See* AO 20-09, p. 10 ("Under the REMS with ETASU imposed by the FDA, only Centers that meet all REMS with ETASU requirements […] may administer the Drug; therefore, the number of Centers that can administer the Drug is limited.").

[18] AO 20-09, p. 9.

[19] AO 20-09, p. 9-10.

[20] AO 20-09, p. 10-11.

- Were limited to patients living far from a certified facility who could not be lodged at that facility (or who had other assistance available to pay for the lodging).[21]

More recently, OIG's framework for approving similar arrangements has evolved to be more flexible to keep pace with advances in CGTs and similar treatments. Since 2020, OIG has issued three favorable advisory opinions, AO 24-03,[22] AO 24-13,[23] and AO 25-06,[24] each of which involved payments for travel, lodging, and associated expenses for patients receiving gene therapy, T-cell immunotherapy, or autologous hematopoietic stem-cell based gene therapy, respectively, at approved "Treatment Centers" that did not necessarily meet all REMS and ETASU requirements. OIG reasoned that the arrangements still posed a low risk of fraud and abuse because each arrangement:

- "Removes a barrier to accessing medically necessary care that is furnished by Treatment Centers" that are selected using objective criteria resulting in only "a limited number of facilities" being qualified as Treatment Centers.
- Subsidizes travel, lodging, and meal expenses "the patients otherwise would not be able to afford," allowing patients to receive a one-time treatment that is "potentially curative" or that can "stop or slow [d]isease progression[,]" differentiating it from "problematic seeding arrangements."[25]
- "Facilitates compliance with" either "Drug Label instructions" or "instructions of the health care provider," in each case, for the patient and caregivers to remain at or near the Treatment Center for an extended period of time for monitoring of complications.[26]
- Includes "additional safeguards that mitigate the risk of fraud and abuse," such as requiring exhaustion of all other available sources of assistance prior to authorizing payment, refraining from advertising the arrangement, and not requiring that Treatment Centers exclusively use a specific product.[27]

OIG believes that these safeguards "reduce the risk of inappropriate steering or inappropriate utilization of" CGTs and similar treatments.[28]

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[21] See AO 20-09, p. 11.
[22] *See* Advisory Opinion No. 24-03, OIG, June 12, 2024, available at: https://oig.hhs.gov/documents/advisory-opinions/9914/AO-24-03.pdf.
[23] *See* Advisory Opinion No. 24-13, OIG, December 26, 2024, available at: https://oig.hhs.gov/documents/advisory-opinions/10148/AO-24-13.pdf.
[24] *See* OIG, Advisory Opinion No. 25-06, June 27, 2025, available at: https://oig.hhs.gov/documents/advisory-opinions/10471/AO-25-06.pdf.
[25] AO 24-03, p. 8; AO 24-13, p. 6-7; AO 25-06, p. 8.
[26] AO 24-03, p. 8; AO 24-13, p. 7; AO 25-06, p. 8-9.
[27] AO 24-03, p. 8; AO 24-13, p. 7; AO 25-06, p. 9.
[28] AO 24-03, p. 8; AO 24-13, p. 7; AO 25-06, p. 9.

Thus, this more flexible framework espoused in OIG's recent AOs builds on prior guidance to provide a common-sense template on which OIG should base a new safe harbor, as we recommend. Creating a safe harbor that addresses the facts common to CGT treatments can provide greater certainty to biotechnology companies and other entities seeking to reduce barriers, as well as obviate the need for OIG to issue numerous AOs on factual scenarios driven by the common core of practical realities of CGT treatments. Moreover, the safeguards discussed above will appropriately limit the safe harbor to arrangements aimed at ensuring that out-of-pocket incidental costs associated with the highly specific CGT treatment infrastructure do not create a barrier to access. As OIG has already observed in this context, patients generally undergo CGTs for serious conditions for which curative, durable treatments are not otherwise available, and receive treatment within a very limited network of providers. These facts mitigate the risk that payment assistance for travel, lodging, and associated costs would either cause over-utilization or induce steering to particular providers or therapies.

III. Proposed Safe Harbor for Sponsored CGT Diagnostic Testing Services

Before preparation or administration of CGT treatments, the patient must often undergo certain diagnostic tests, including genetic or biomarker tests, to both confirm a diagnosis of a condition for which a CGT is indicated, as well as to confirm eligibility to receive the CGT treatment. Similarly, post-administration diagnostics are often required to track the progress of an administered CGT therapy. This diagnostic testing process can be a barrier to patients interested in receiving CGT treatments, particularly since some of the diagnostic tests can be quite costly and, thus, patients seeking CGT treatment can be faced with significant additional costs.

ARM believes addressing the unique barrier posed by lack of access to the requisite diagnostic testing is critical to improving access to and uptake of life-changing CGT treatments. As such, ARM recommends that OIG establish a new AKS safe harbor for payments to entities that provide a CGT patient with diagnostic services pre- or post-administration. Specifically, the safe harbor would permit a CGT biotechnology company or other entity to make payments to entities for CGT-related diagnostic services under the following circumstances:

- The patient is diagnosed with a disease, is suspected of having a disease based on objective clinical criteria, or a family member has a confirmed hereditary disease, for which a CGT is indicated.
- The patient requires genetic, biomarker, or other testing to confirm such a diagnosis, or the patient has been administered the applicable CGT and requires such testing to ensure safety and efficacy of the treatment.
- The test is ordered by a licensed physician in accordance with the standard of care.
- Payment for the test is fully funded by the CGT biotechnology company, limited to the costs of the applicable test and neither the provider nor the entity performing the test is permitted to charge associated fees to the patient or third-party payors.

- The use of the test is for an indication consistent with the test's designated purpose or label.
- The patient either has not previously received the test or additional testing or re-testing is necessary.[29]
- The prescribing provider is not required to prescribe, and does not receive benefit from prescribing, the sponsoring biotechnology company's CGT.
- Test results and identifying information of patients and their prescribing providers are not shared by the entity performing the testing with the sponsoring CGT biotechnology company or its affiliates or otherwise used for marketing or sales purposes by either entity.

The proposed safe harbor is rational as rigorous diagnostic testing is often necessary for determining appropriate treatment, but its cost can discourage potentially eligible patients from pursuing CGT treatments altogether. By establishing a new safe harbor to enable patient access to diagnostic tests that provide clarity at a time of great uncertainty and stress during a patient's diagnostic odyssey, the OIG can reduce a key barrier to CGT access and uptake while simultaneously safeguarding the integrity of Federal health care programs.

The proposed safe harbor is extremely consistent with OIG's guidance in similar contexts as described in AO 22-06,[30] AO 24-12,[31] and AO 25-07.[32] Each of these AOs involved manufacturer-sponsored payments for diagnostic testing necessary to confirm appropriate treatment—whether the manufacturer's CGT or another treatment—for a patient's confirmed or suspected rare disease. In AO 22-06 and AO 24-12, OIG concluded that it would not impose administrative sanctions for these arrangements due to various factors:

- The "nexus" between remuneration offered (the free test) and a patient's provider prescribing, ordering, or purchasing the CGT is "attenuated," meaning there was no certainty that a positive test result would lead to the use of a particular CGT over another treatment, and the test could just as easily rule out eligibility for a CGT.[33]
- Patients must satisfy "objective"[34] or "specific and narrow"[35] eligibility criteria, reducing the risk of improper or over-utilization of the test.

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[29] While OIG's guidance on sponsored testing arrangements has favorably cited the patient not having already received the sponsored test at issue as eligibility criteria, we believe a safe harbor should not preclude patients from receiving assistance in circumstances, for example, where they previously received the test and the results were inconclusive. Given the complexities of a patient's diagnostic odyssey, there are circumstances where additional testing or re-testing may be necessary.

[30] *See* Advisory Opinion No. 22-06, OIG, April 6, 2022, available at: https://oig.hhs.gov/documents/advisory-opinions/1028/AO-22-06.pdf.

[31] *See* Advisory Opinion No. 24-12, OIG, December 12, 2024, available at: https://oig.hhs.gov/documents/advisory-opinions/10117/AO-24-12.pdf.

[32] *See* Advisory Opinion No. 25-07, OIG, June 27, 2025, available at: https://oig.hhs.gov/documents/advisory-opinions/10472/AO-25-07.pdf.

[33] AO 22-06, p. 8; AO 24-12, p. 9.

[34] AO 22-06, p. 8.

[35] AO 24-12, p. 9.

- Neither the patient nor any payor can be billed for any component of the testing service, guarding against double payment.[36]
- The CGT biotechnology company "does not require or otherwise incentivize providers who order" tests through the arrangement "to recommend, prescribe, or administer any products manufactured by" the company.[37]
- The arrangements included "various safeguards in place to prevent use of the Arrangement as a marketing or sales tool to induce physicians to order additional items and services, including further testing or [CGT biotechnology company's] products, or to induce beneficiaries to purchase" their CGT,[38] such as restricting exchange of identifiable health information and prescribing provider information between the testing entity and the CGT biotechnology company to prevent targeted marketing.[39]

In 2025, OIG addressed a similar type of arrangement in AO 25-07 but in this case, there was a more direct nexus between the companion diagnostic test and the CGT, a positive result on which would be integral to a provider's decision to prescribe the CGT. Yet, even there OIG found the arrangement was "unlikely to result in overutilization or inappropriate utilization, skew clinical decision-making, or result in unfair competition," posing a low risk of fraud and abuse.[40] In particular, OIG noted the importance of safeguards against using the arrangement as a marketing or sales tool, echoing the language of AO 22-06 and favorably noting that under the arrangement:

- The CGT biotechnology company's "sales representatives do not distribute materials in a manner that takes into account a provider's usage of the Arrangement or the provider's history prescribing [the company's] products."[41]
- The CGT biotechnology company's "field personnel [cannot] access any data that [the CGT biotechnology company] receives from the [testing entity], and [the CGT biotechnology company] does not use data from the [testing entity] for sales and marketing activities, including sales targeting or incentives."[42]
- The terms of the CGT biotechnology company's contract with the testing entity prohibit, and the CGT biotechnology company does not "promote the Arrangement to providers or patients" or "proactively provide information about the arrangement directly to providers or patients."[43]

While each of the above AOs addressed tests required prior to CGT administration, the same concepts apply, albeit with a tighter "nexus," to post-administration diagnostic services that are similarly essential to appropriate treatment. Given OIG's favorable view of sponsored testing in the context of a direct nexus between test and CGT

[36] AO 22-06, p. 8; AO 24-12, p. 9.
[37] AO 24-12, p. 9. *See* AO 22-06, p. 8;
[38] AO 22-06, p. 9. *See* AO 24-12, p. 9.
[39] AO 22-06, p. 9; AO 24-12, p. 9.
[40] AO 25-07, p. 9.
[41] AO 25-07, p. 9.
[42] AO 25-07, p. 9.
[43] AO 25-07, p. 9. *See* AO 22-06, p. 9.

prescribing, it is logical to extend safe harbor protection to both pre-administration and post-administration diagnostic testing under the circumstances referenced above.

Therefore, our recommended safe harbor is consistent with current OIG guidance regarding sponsored testing arrangements. Establishing a safe harbor addressing circumstances common to CGT-related diagnostic services both mitigates existing barriers to effective, durable treatment of rare diseases and provides a more predictable landscape in which CGT biotechnology companies can further innovate to improve access to lifesaving treatments. With strict guardrails around the use and exchange of patients and prescriber information and clearly defined limits on acceptable marketing practices, OIG can mitigate risks that these arrangements would be used to inappropriately steer patients or prescribing providers towards a particular CGT.

IV. Proposed Safe Harbor for Fertility Preservation Services for CGT Patients

Prior to the infusion of some CGTs, the patient must travel to a treatment center to receive pre-conditioning treatments to prepare their immune system for CGT administration. These conditioning agents are used to remove diseased stem cells. This then allows the CGT treatment to stimulate the formation of healthy stem cells. While both the underlying conditions CGTs treat and current standard of care are known to impact fertility, conditioning agents utilized in some CGT approaches do have the potential to result in permanent sterility. As such, ARM also recommends that OIG establish an AKS safe harbor for payments to certain patients for fertility preservation. Specifically, the safe harbor should permit a CGT biotechnology company or other entity to make payments for fertility preservation under the following circumstances:

- The patient is prescribed a CGT treatment, the administration of which is known to have a significant impact on fertility, such as in the case of the gene therapies for SCD.
- The patient receives a fertility preservation treatment that is specifically intended to preserve fertility for the future—such as embryo or sperm cryopreservation—as opposed to treat other current fertility problems or utilize existing cryo-preserved embryos or sperm.
- Remuneration for such fertility preservation treatment is limited to patients (1) demonstrating financial need; and (2) who otherwise lack insurance or other assistance for fertility preservation.

Today, a patchwork of coverage for fertility preservation across states and insurers leads to uncertainty in access to and delivery of care. As of January 2026, only 21 states and the District of Columbia require coverage for fertility preservation for medically-induced infertility. Only six states—Illinois, Maryland, Montana, Oklahoma, and Utah—currently require that these costs be covered by Medicaid, creating access barriers for patients who do not have the financial means to pursue

these benefits on their own.[44] In addition, despite the high rate of state participation in the CGT Access Model, Medicaid patients in non-participating states continue to face significant barriers to receiving CGT treatments due to a lack of protection under AKS safe harbors for coverage of fertility preservation services, further contributing to inconsistencies in access faced by low-income patients.

The NIH has noted that infertility "is a high-risk and long-term side effect associated with […] gene therapy approaches to sickle cell disease," and that infertility "is a common reason people of reproductive age give for not pursuing these therapies,"[45] just as other researchers have noted that difficulties in "access to fertility preservation for girls and women with [sickle cell disease] […] is a meaningful barrier to optimizing [sickle cell disease] care."[46] In one survey of adult SCD patients considering an experimental treatment, about two-thirds of respondents were willing to accept a risk of mortality from the procedure, while only half were willing to run the risk of long-term infertility.[47] Although some CGTs are being developed with fewer implications on fertility, fertility preservation remains important to the long-term well-being of today's CGT patients, as studies have shown that even individuals receiving life-saving treatment commonly experience regret and depression as a result of treatment processes that permanently impair fertility.[48]

Although fertility preservation, unlike payments for travel and lodging and for sponsored diagnostic-testing services related to CGTs, is not currently the subject of OIG guidance in the form of favorable advisory opinions, many of the principles enunciated in OIG's advisory opinions on CGTs, especially those regarding travel and lodging assistance, are likewise applicable here:

- As with travel and lodging, costs associated with fertility preservation are a serious barrier to patient access that can be overcome with targeted financial assistance.[49]

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[44] *See* Resolve: The National Infertility Association. Insurance Coverage by State, 2025, available at: https://resolve.org/learn/financial-resources/insurance-coverage/insurance-coverage-by-state/.

[45] NIH researchers work to preserve fertility for people undergoing gene therapy, NIH, October 2023, available at: https://www.nih.gov/news-events/news-releases/nih-researchers-work-preserve-fertility-people-undergoing-gene-therapy.

[46] *See* Pecker L et al., Knowledge gaps in reproductive and sexual health in girls and women with sickle cell disease, Br J. Haematol., September 2021; 194(6), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8448913/.

[47] *See* Chakrabarti S et al., A survey on patient perception of reduced-intensity transplantation in adults with sickle cell disease, Bone Marrow Transplantation, March 2007; 39, available at: https://www.nature.com/articles/1705622.epdf?sharing_token=kW4SHXiXrHTGzXNlyn66htRgN0jAjWel9jnR3ZoTv0N_rUlkDixUVXtrzI1dQiQSFK22Kgxzx-xfJJ4kYcpTlyfF7pF_hiizwKUDy7bztHh0t3WNvtAjaNG_9J37MUi8vHNCbk5OJ12ZuCxwBVVKEx3_4dzcEi4QSBMLs4CetCRUNJPAP1EcRXTVGNqzZoKLDlDu9Iv98TCZ994TYR3ELA%3D%3D&tracking_referrer=www.statnews.com.

[48] *See, e.g.*, Loren, A et al., Fertility preservation in patients with hematologic malignancies and recipients of hematopoietic cell transplants, Blood, August 2019; 134(9), available at: https://www.sciencedirect.com/science/article/pii/S0006497120723256?ref=pdf_download&fr=RR-2&rr=8377b10abed84cf5.

[49] AO 20-09, p. 9.

- CGTs impacting fertility can offer "one-time, potentially curative treatment" that does not induce further "purchasing [of] the drug when it would be payable by a Federal health care program.[50]
- Assistance would be limited to patients with financial need and who did not otherwise have coverage for fertility preservation through other insurance or assistance.[51]

Moreover, fertility preservation can help to serve the AKS' ultimate goal of safeguarding the public and, particularly, the financial soundness of Federal health care programs. CGTs target some of the most expensive-to-treat chronic conditions, including SCD. As noted above, Medicaid is believed to cover the majority of emergency department visits and hospitalizations associated with SCD, which over a patient's non-elderly lifetime are estimated to average around $1.7 million per patient.[52] Now that CGT therapies exist in this therapeutic area, these chronic costs can be avoided. Removing barriers to Medicaid patients' receipt of durable CGT therapies for the treatment of SCD therefore has the potential to generate savings for the Medicaid program. Given current experience addressing access barriers related to Medicaid patients' use of CGTs under the CGT Access Model, it is essential that CMMI share data and lessons learned from the CGT Access Model with OIG on an ongoing basis and not wait until formal model evaluations. Such timely information sharing will only buttress the case for protecting fertility preservation coverage for Medicaid patients for whom a CGT is indicated under a new AKS safe harbor that extends beyond current protections offered under the CGT Access Model. This will enable improved access to essential treatments and achievement of additional savings beyond the current CGT Access Model participants, as well as creating a consistent national framework through which patients can more easily receive innovative, life-saving therapies.

V. Conclusion

ARM proposes that the above-described safe harbors can provide regulatory clarity as to arrangements addressing common barriers to accessing CGTs. CGTs differ in kind from other types of medical treatment, and those differences justify clear regulatory guidance that will enable patients, including beneficiaries of Federal health care programs, to benefit from innovations in regenerative medicine. CGTs also represent the future of medicine, necessitating a congruent regulatory structure to both encourage uptake and propel innovation.

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[50] AO 20-09, p. 10-11.

[51] A0 20-09, p. 11.

[52] *See* Johnson K et al., Lifetime medical costs attributable to sickle cell disease among nonelderly individuals with commercial insurance, Blood Adv, February 2023; 7(3), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9898623/. Although this study was based on commercial insurance data, the study notes that the previously-accepted estimate of around $1.2 million was based on a nearly-twenty year old study of a single state's Medicaid program; thus, although the data is somewhat incomplete, it is plain that, whichever estimate is used, the chronic care costs of treating sickle cell disease represent an enormous financial burden to Federal health care programs.

We thank you for your consideration of these comments, and we look forward to continuing engagement with OIG and other stakeholders to achieve better outcomes for patients with complex health conditions, for some of whom CGTs may be the only treatment option and have the potential to yield savings for Federal health care programs.

Please feel free to contact me at ddavenport@alliancerm.org with questions.

Sincerely,

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Alliance for Regenerative Medicine