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Joanne M. Chiedi, Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521 Cohen Building
330 Independence Avenue SW
Washington, DC 20201.

RE: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements
OIG-0936-AA10-P

Dear Ms. Chiedi:

Haystack Project appreciates the opportunity to comment on the Office of the Inspector General's (OIG's) proposed rule revising and clarifying safe harbors under the Anti-Kickback Statute (AKS) and civil money penalties (CMPs) for beneficiary inducements.

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease patient advocacy organizations to coordinate and focus efforts that highlight and address systemic reimbursement obstacles to patient access. Our core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality in care toward effective, accessible treatment options for all Americans. We strive to amplify the patient and caregiver voice in these disease states where unmet need is high and treatment inadequacies can be catastrophic.

The Rare Cancer Policy Coalition (RCPC) is a Haystack Project initiative that brings together rare cancer patient organizations. RCPC gives participants a platform for focusing specifically on systemic reimbursement barriers and emerging landscape changes that impact new product development and treatment access for rare cancer patients. It is the only rare cancer coalition developed just to focus attention on reimbursement, access and value issues across the rare cancer community. Working within the Haystack Project enables RCPC participants and rare and ultra-rare patient advocates to leverage synergies and common goals to optimize advocacy in disease states where unmet need is high and treatment inadequacies can be catastrophic.

While countless lives have been improved or saved by new therapies enabled by Congress' set of incentives for orphan drugs, 95% of the 7,000 rare diseases identified to date have no FDA-approved treatment option.

- Approximately 50% of the people affected by rare diseases are children;
- 30% of children affected by a rare disease will not live to see their 5th birthday; and
- Approximately half of identified rare diseases do not have a disease-specific advocacy network or organization supporting research and development.

Despite dramatically increased availability of novel treatment options, many patients with rare diseases still face hurdles accessing lifesaving and life-improving FDA-approved therapies. These hurdles are often related to reimbursement structures such as inadequate bundled payment rates, high cost-sharing and/or payer coverage delays and restrictions on what may be the only treatment available to reduce a patient's disease burden. Exceedingly small populations, long diagnostic journeys, and a limited natural history knowledge base for many rare diseases can also make the development and regulatory processes particularly challenging. Our sincere hope is that a greater understanding of our experiences will enable pragmatic solutions to existing problems and guide future health system refinements that take our unique needs into account.

While we understand that OIG has left the issue of expanded safe harbor protections for manufacturer inclusion in value-based arrangements for a future rulemaking, we urge it to consider the unique circumstances our patients face. Most patients with extremely rare disorders do not have the luxury of deciding which treatment best serves their needs. For our patients, the issue is whether or not any treatment is available and, if so, whether they can afford their share of its costs. The significant disease burden and potentially poor prognosis our patients live with day-to-day is more than enough incentive to seek treatment and choose an FDA-approved therapy; manufacturer assistance simply enables access to that treatment. We urge the OIG to devise safe harbors that address the realities patients with extremely rare disorders face so that the assistance many patients need to access treatment or undergo precision diagnostics to determine that a treatment path is appropriate is not mischaracterized as a prohibited inducement.

Haystack Project agrees that the OIG's proposed creation and/or clarification of safe harbors that facilitate care coordination, promote value for patients, and increase availability of lower-cost, high-quality products and services may serve to benefit both patients and the health care system. We are, however, concerned that without appropriate safeguards and sufficient government oversight, the proposed arrangements could have the unintended consequence of achieving savings or shifting incentives at the expense of patient safety, access, affordability, and/or quality of care. Complex patients with very rare conditions are at heightened risk of falling victim to the "cherry picking," "lemon dropping," and stinting on care that the OIG has identified as potential risk in the value-based payment models that would protected under the proposed safe harbors.

We focus our comments on ensuring that the Administration's final safe harbor revisions will adequately address the unique circumstances of patients with extremely rare conditions, including patients still within what can be a very long diagnostic journey.

First, we urge the OIG to refine the definitions of terms related to the three newly-proposed safe harbors to the AKS to reflect an appropriate balance between program integrity concerns, participant burden reduction, and protecting patient access to appropriate care as outlined below.

Value Based Enterprise (VBE). Haystack Project appreciates OIG's requirement that VBEs identify an "accountable body" that would be responsible for VBE financial and operational oversight, and urge it to further require that accountable bodies:

- Submit documentation and reports to the Department of Health and Human Services to demonstrate continuing compliance with safe harbor provisions and report on progress in improving outcomes at reduced costs;
- Implement and maintain a compliance program that includes processes through which patient concerns can be communicated and addressed in a timely manner;
- Incorporate oversight responsibilities that includes periodic peer-review of random samples of patient medical records to ensure care complies with clinical standards, including diagnosis and treatment of rare and very rare diseases;
- Ensure timely, periodic evaluation of VBE performance;
- Have a fiduciary duty to the VBE and its patients;
- Maintain a plan-English explanation of the VBE, its purpose, any impact on the patient experience, and procedures for patients to communicate and achieve resolution of any concern; and
- Ensure that VBE participants secure informed consent for each patient treated within the VBE.

Value-based purpose. Haystack Project strongly urges the OIG to require that VBEs identify at least one value-based purpose related to improvement in patient care and evaluate progress through one or more outcome measure. We are concerned that pursuing VBEs solely to reduce costs would unduly invite compromises in patient care, and are particularly concerned that those care compromises would fall disproportionately on patients with rare and extremely rare conditions.

Second, Haystack Project has significant concerns that VBE participants assuming downside risk present a heightened risk for cherry-picking patients, discharging highly complex, rare, and/or costly patients, and stinting on the care patients with high medical needs receive. To mitigate these risks, we recommend that the OIG:

- Ensure that all VBEs, including those with significant downside risk, be evaluated on outcome measures that reflect outcomes that are important to patients, including those with rare and very rare conditions;
- Prioritize transparency by requiring written documentation of all VBE arrangements, and informed consent processes that ensure clear understandings between participants and their patients;
- Protect the patient/provider decision making process by requiring that all VBEs operate in a manner that ensures non-interference with health care decisions;
- Include federal oversight to ensure that VBEs associated with downside risk do not stint on care and that remuneration does not induce limitations on or reductions of, medically necessary items or services furnished to any patient;
- Ensure that patients receiving care within a VBE are not disadvantaged by capitated rates or other risk arrangements when a new treatment option becomes available. The safe harbors should include protections for VBEs that implement "carve out" mechanisms

similar to those within Medicare Advantage and Medicaid managed care organizations to account for the costs of new technologies that were not incorporated into rate calculations.

Once again, we thank the OIG for the opportunity to provide comments on the Proposed Rule. Please do not hesitate to contact Saira Sultan if you or your staff would like to discuss these issues in greater detail.

Sincerely,

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