ConnectedHealthInitiative

August 24, 2026

The Honorable Thomas March Bell
Inspector General
Department of Health and Human Services
330 Independence Avenue SW
Washington, District of Columbia 20201

RE: Comments of the Connected Health Initiative regarding the *Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP* as Applied to Remuneration to Clinical Trial Participants (91 FR 37902)

Dear Mr. Bell:

The Connected Health Initiative (CHI) writes to respond to the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) request for information (RFI) on whether new or modified safe harbors under the Federal anti-kickback statute (AKS), or new exceptions to the definition of "remuneration" under the Beneficiary Inducements civil monetary penalty (CMP) provision, are needed to protect remuneration furnished to individuals who participate in clinical trials.[1] We appreciate OIG's decision to examine this question through rulemaking, and we note that HHS has identified this RFI as part of Operation TrialBlazer, the Department-wide effort announced in June to restore American leadership in clinical research and to remove unnecessary barriers to it.[2] CHI raised several of the issues addressed below in its comments on OIG's most recent annual solicitation of safe harbor proposals, and we appreciate the opportunity to develop them in the context of a proceeding devoted to clinical trials.[3]

I. Introduction and Statement of Interest

[1] *Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP*, 91 FR 37902 (June 24, 2026) (File Code OIG-2602-N; RIN 0936-AA16; Docket No. HHSIG-2026-0034) (RFI).

[2] HHS Press Release, *HHS Launches Unprecedented Department-Wide Effort to Restore American Leadership in Clinical Trials* (June 22, 2026) (announcing "Operation TrialBlazer" and describing this RFI as OIG's contribution to the initiative).

[3] Comments of the Connected Health Initiative regarding *Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts*, Docket No. HHSIG-2025-0001, Document ID HHSIG-2025-0001-0014 (Feb. 9, 2026), responding to 90 FR 57016 (Dec. 9, 2025) (urging OIG to clarify that providing patients with access to software platforms and devices at no or low cost does not violate the anti-kickback statute, to permit the use of multifunction devices, and to address the application of the statute to artificial intelligence used in clinical trials).

The Connected Health Initiative (CHI) is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations, and support an environment in which patients and consumers can see improvements in their health. We seek policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled healthcare system. For more information, see www.connectedhi.com.

CHI's members build and deploy the technologies that increasingly make it possible for a person to take part in a clinical trial without repeatedly traveling to a distant research site, including remote monitoring devices, sensors and wearables, connected diagnostics, mobile applications, telehealth platforms, and the analytics that support them. Those same technologies are also things of value furnished to Federal health care program beneficiaries, and their provision therefore sits within the conduct that OIG polices. Modern clinical trials increasingly depend on devices, connectivity, and technical support, and the remuneration question OIG has posed therefore should extend to the equipment and services that make remote participation possible, which are now routine in many protocols and, in some, a precondition of taking part at all. A safe harbor addressed only to cash and reimbursable out-of-pocket expenses would leave that category unprotected.

In developing these comments, CHI has been attentive to the professional obligations that govern clinical investigators and to the human subjects framework that FDA and the Office for Human Research Protections administer. Our recommendations are drafted to fit within that framework, and CHI believes that a safe harbor whose conditions can be satisfied and verified through the protocol, the informed consent document, and the IRB's existing review should prove more workable than one that operates on a separate track.

II. Remuneration to Clinical Trial Participants Addresses a Structural Access Problem

OIG asks first whether offering Federal health care program enrollees remuneration facilitates clinical trial participation, and what makes such remuneration effective or ineffective (Question 1). CHI believes that the constraint on trial enrollment is largely structural, and that remuneration works, where it works, because it relieves a practical burden on the participant.

Approximately 1.15 million Medicare fee-for-service beneficiaries are diagnosed with cancer in a single year, yet only 1.0 percent had any claim indicating enrollment in a clinical trial, with 1.9 percent among those receiving active treatment and those who did enroll were disproportionately drawn from higher-income areas.[4] Those figures are consistent with cost and distance keeping beneficiaries out of research.

[4] Green AK, Tabatabai SM, Aghajanian C, et al., *Clinical Trial Participation Among Older Adult Medicare Fee-for-Service Beneficiaries With Cancer*, 8 JAMA Oncology 1786 (2022) (of approximately 1.15 million Medicare fee-for-service beneficiaries diagnosed with cancer, 1.0 percent had a claim indicating trial enrollment, and 1.9 percent among those receiving active treatment, with participants disproportionately resident in higher-income areas).

A meta-analysis of 35 studies covering 9,759 patients found that 55.0 percent of patients agreed to enroll when a trial was actually offered to them.[5] However, a trial is frequently unavailable at the patient's own institution, eligibility criteria exclude many of those for whom one exists, and a substantial share of the patients who clear both hurdles cannot practically sustain the travel, the time away from work, and the caregiving arrangements that participation demands. Taken together, structural and clinical barriers make trial participation "unachievable for more than three of four cancer patients."[6]

Geography compounds the problem in a way that bears directly on the scope of any safe harbor OIG may write. Nearly 38 percent of the U.S. population over age 35 would have to drive more than 50 miles to obtain care at a National Cancer Institute-funded site, and nearly 17 percent more than 100 miles, with the gaps in access to NCI-funded sites concentrated in the South and Appalachia and with much of the West and Great Plains distant from any cancer facility.[7] Trial catchment areas are regional and in some cases national, which is a different geography from the one that routine local care occupies.

Where the burden has actually been relieved, enrollment has responded. A hospital-based program that reimbursed participants for travel and lodging was associated with an increase of nearly nineteen participants per month above the expected trend after accounting for trial availability and prior accrual, and the participants it added were disproportionately lower-income and lived farther from the site, with reimbursement of roughly $185 to $900 per month depending on distance.[8] A longitudinal follow-on study confirmed the mechanism, finding that targeted reimbursement measurably reduced participants' travel and lodging concerns even though it did not resolve financial hardship generally.[9] Remuneration is therefore most effective when it is matched to a specific participation cost that the participant would otherwise have to absorb, and it is least defensible when it bears no relationship to any such cost.

Roughly one in five adult cancer trials fails to complete, with nearly 48,000 participants having enrolled in trials that never produced an answer, and 18 percent of cooperative group phase II and

---

[5] Unger JM, Hershman DL, Till C, et al., *"When Offered to Participate": A Systematic Review and Meta-Analysis of Patient Agreement to Participate in Cancer Clinical Trials*, 113 J. Nat'l Cancer Inst. 244 (2021) (55.0 percent of patients agreed to enroll when offered, with no statistically significant difference by race).

[6] Unger JM, Vaidya R, Hershman DL, Minasian LM, Fleury ME, *Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation*, 111 J. Nat'l Cancer Inst. 245 (2019) (structural and clinical barriers make trial participation "unachievable for more than three of four cancer patients").

[7] Shriver SP, Sahar L, Douangchai Wills VL, Adams D, Fleury ME, *Assessing populations with access to National Cancer Institute-funded sites using local distance-based service areas*, 9 J. Clinical & Translational Science e218 (2025) (nearly 38 percent of the U.S. population over age 35 would have to drive more than 50 miles to reach an NCI-funded site, and nearly 17 percent more than 100 miles).

[8] Nipp RD, Lee H, Powell E, et al., *Financial Burden of Cancer Clinical Trial Participation and the Impact of a Cancer Care Equity Program*, 21 The Oncologist 467 (2016) (participants in a travel and lodging reimbursement program received approximately $185 to $900 per month depending on distance, and enrollment increased by 18.97 participants per month above the expected trend following program implementation).

[9] Nipp RD, Lee H, Gorton E, et al., *Addressing the Financial Burden of Cancer Clinical Trial Participation: Longitudinal Effects of an Equity Intervention*, 24 The Oncologist 1048 (2019).

III trials close with low accrual or are still accruing below half of target three or more years after initiation.[10] Each such trial consumes Federal research dollars, exposes human subjects to risk, and returns nothing of scientific value. Where the rules make it hazardous to reimburse a participant's parking fee, some part of the resulting cost is borne by the Federal programs that funded the study.

III. The AKS and Beneficiary Inducements CMP Operate as Real Barriers, and No Existing Authority Closes the Gap

OIG asks whether the AKS and the Beneficiary Inducements CMP are barriers to offering appropriate remuneration (Question 2) and asks commenters to explain why existing safe harbors and exceptions do not already protect these arrangements (Question 12). CHI believes that AKS and the Beneficiary Inducements CMP are barriers to offering appropriate remuneration, and that each candidate authority fails for structural reasons.

The local transportation safe harbor. Section 1001.952(bb) protects only transportation, and it fails clinical trials on at least five independent grounds.[11] It excludes from eligibility entities that primarily supply health care items, which removes the sponsor, ordinarily the only party with both the resources and the protocol-wide vantage point to fund participant support consistently. Its established-patient limitation excludes the prospective participant who is screened at a distant academic center and has no prior relationship with it. Its 25-mile urban and 75-mile rural limits are calibrated to routine local care and not to the trial catchment areas described above. It requires that the transportation be for the purpose of obtaining medically necessary items and services, while many protocol-required visits, including screening visits, pharmacokinetic draws, protocol-mandated imaging, and quality-of-life assessments, are research procedures and not medically necessary treatment. And it forbids public marketing or advertising of the transportation, a condition fundamentally at odds with a recruitment process that is advertised by design and in which IRB-approved materials routinely disclose what participants will receive. Even if every one of these obstacles were surmounted, the safe harbor would still protect nothing beyond rides.

The Beneficiary Inducements CMP exceptions. The financial-need exception at section 1320a-7a(i)(6)(H) requires that the items or services not be offered as part of any advertisement or solicitation, that they not be tied to other reimbursed services, that there be a reasonable connection to the individual's medical care, and that the offeror make an individualized good-faith determination of financial need.[12] Trial recruitment is advertised, trial participation necessarily involves routine costs billed to Medicare, research is not doctrinally the participant's own medical

---

[10] Stensland KD, McBride RB, Latif A, et al., *Adult Cancer Clinical Trials That Fail to Complete: An Epidemic?*, 106 J. Nat'l Cancer Inst. dju229 (2014) (approximately 20 percent seven-year cumulative incidence of failure to complete among 7,776 phase II and III adult cancer trials, with nearly 48,000 participants enrolled in trials that never completed). *See also* Bennette CS, Ramsey SD, McDermott CL, et al., *Predicting Low Accrual in the National Cancer Institute's Cooperative Group Clinical Trials*, 108 J. Nat'l Cancer Inst. djv324 (2016) (18 percent of 787 phase II and III cooperative group trials closed with low accrual or were accruing below 50 percent of target three or more years after initiation).

[11] 42 CFR 1001.952(bb).

[12] 42 U.S.C. 1320a-7a(i)(6)(H). The separate exception for remuneration that promotes access to care and poses a low risk of harm appears at 42 U.S.C. 1320a-7a(i)(6)(F) and is implemented at 42 CFR 1003.110.

care, and means-testing every participant is administratively burdensome and in tension with the equitable-selection obligation that human subjects regulations place on IRBs. The regulatory exception for remuneration that promotes access to care fails on a more basic ground, because it protects items and services that improve a beneficiary's ability to obtain items and services *payable by Medicare or Medicaid*, and an investigational product is by definition not payable.[13] We note, however, that OIG's own explanation of that exception, which is that it exists to give beneficiaries the tools to overcome socioeconomic, educational, geographic, and mobility barriers, and which OIG illustrated with free childcare that enables a patient to attend a smoking-cessation program, supplies the logic that this RFI should extend. OIG has already accepted that removing a logistical barrier to attendance differs from paying a patient to choose a particular course of care, and the remaining obstacle is that the destination in this context is a trial visit and not a covered service.

The patient engagement and support safe harbor. Section 1001.952(hh) is the closest structural analogue, and its conditions are worth setting out.[14] It bars cash and cash equivalents outright, which forecloses stipends, per-visit payments, mileage, and parking. It excludes pharmaceutical manufacturers entirely and admits device and medical supply manufacturers only through a narrow carve-out for digital health technology. It requires a value-based enterprise, a value-based purpose, and a target patient population, none of which describes the relationship among a sponsor, a site, and a contract research organization. It requires a direct connection to the coordination and management of the patient's care, which research visits are not. It expressly forbids use of the tool for patient recruitment, which is the function at issue here. And its annual aggregate cap, which stands at $623 for calendar year 2026,[15] is an order of magnitude below the documented monthly need. The nominal-value policy statement is more remote still, setting $15 per item and $75 per patient per year, unadjusted since 2016 and unavailable for cash.[16]

The personal services and management contracts safe harbor. Section 1001.952(d) protects payment to an agent for services rendered. Recasting a research participant as a contractor performing services for the sponsor would be inaccurate as a description of the relationship, and it would also cut against a human subjects framework built on the premise that participants are autonomous subjects to be protected from undue influence and not vendors selling their time at fair market value. The one-year minimum term is also irreconcilable with a participant's absolute right to withdraw at any moment.

The advisory opinion process. OIG notes that it has issued approximately ten favorable advisory opinions over two decades permitting waiver or subsidization of Federal health care program cost-

[13] 42 CFR 1003.110. *See* 81 FR 88368, 88395 (Dec. 7, 2016). In the preamble, OIG explained that the exception is directed at giving beneficiaries the tools needed to overcome socioeconomic, educational, geographic, mobility, and other barriers to obtaining covered items and services, offering the example of free childcare that enables a patient to attend a smoking-cessation program.

[14] 42 CFR 1001.952(hh). *See* 85 FR 77684 (Dec. 2, 2020).

[15] OIG, *Annual Inflation Adjustments for Safe Harbor Regulations*, https://oig.hhs.gov/compliance/safe-harbor-regulations/annual-inflation-updates/ (the patient engagement and support annual aggregate cap is $623 for calendar year 2026).

[16] OIG, *Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries* (Dec. 7, 2016) (retail value of no more than $15 per item or $75 in the aggregate per patient annually, and not cash or cash equivalents).

sharing for trial participants.[17] Those opinions have produced a stable and articulable set of safeguards, including protocol eligibility criteria and executed informed consent, IRB oversight, disclosure of the payment during the consent discussion and not in advertising, the absence of any seeding concern, and independent regulatory oversight of the study itself.[18] CHI regards that record as the strongest available evidence that a workable safe harbor can be written, because OIG has effectively written one ten times over on a case-by-case basis. An advisory opinion, however, binds OIG only as to the requester and may not be relied upon by anyone else,[19] so that every sponsor must fund and wait out its own. That is a problem rulemaking should solve.

OIG has recently issued favorable opinions permitting pharmaceutical and cell therapy manufacturers to furnish travel, lodging, meals, and associated expenses to patients and their caregivers receiving *commercially available* advanced therapies, in circumstances where the manufacturer has an immediate and direct financial stake in utilization.[20] We anticipate the response that these situations are not alike, in that those opinions involve patients who have already been prescribed a marketed product that is medically necessary for them, while a trial involves recruitment into research. CHI accepts that the risk profiles are not identical, but notes that in the commercial setting the manufacturer has a direct and continuing financial interest in the patient's utilization of a reimbursable product, and that OIG nonetheless concluded that the support could be furnished on appropriate terms. In the research setting, the sponsor has no reimbursement stream from the investigational article, eligibility is fixed by a protocol the sponsor cannot vary for an individual participant, and an IRB reviews the arrangement. The recruitment concern that distinguishes the two is addressed by the anti-steering, advertising, and anti-seeding conditions, each of which is directed at the mechanism by which recruitment could become improper. CHI submits that it is difficult to justify treating the research arrangement as categorically more suspect when the safeguards available to it are at least as strong.

Finally, CHI notes the structural gap on the coverage side that OIG should address. Medicare's Clinical Trial Policy addresses routine costs that are medical in nature, and says nothing about travel, lodging, parking, meals, childcare, connectivity, or devices.[21] The same is true of the parallel

---

[17] *See, e.g.*, OIG Advisory Op. No. 26-05 (Mar. 2026) (device manufacturer payment of Medicare cost-sharing for participants in an implantable cardiac device study); OIG Advisory Op. No. 23-11 (2023) (sponsor subsidy of up to $2,000 in cost-sharing for participants in a Category B IDE study); OIG Advisory Op. No. 22-05 (Mar. 11, 2022); OIG Advisory Op. No. 16-13 (Dec. 13, 2016) (cost-sharing waiver together with per-visit stipends of $100 and $25 to defray travel expenses, time off work, and inconvenience).

[18] OIG Advisory Op. No. 26-05, *supra* note 17 (relying on protocol eligibility criteria and execution of an informed consent document, IRB oversight and monitoring, a certification that the subsidy would not be advertised, first disclosure of the subsidy during the initial consent discussion, CMS approval of the study as a Category B IDE study, and the absence of any seeding concern).

[19] 42 CFR 1008.53; 42 U.S.C. 1320a-7d(b)(4). An advisory opinion binds OIG only with respect to the requesting party and may not be relied upon by any other individual or entity.

[20] *See, e.g.*, OIG Advisory Op. No. 25-06 (July 1, 2025) (pharmaceutical manufacturer provision of travel, lodging, and associated expenses to qualifying patients receiving its gene therapy product, and to their caregivers); OIG Advisory Op. No. 24-13 (Dec. 30, 2024) (cell therapy manufacturer provision of travel, lodging, meals, and associated expenses to qualifying patients).

[21] CMS, National Coverage Determination 310.1, *Routine Costs in Clinical Trials*. The determination reaches only items and services that are medical in nature, and it does not address travel, lodging, parking, meals, childcare, connectivity, or devices furnished to support participation. *See also* 42 U.S.C. 300gg-8 (defining

requirement applicable to group health plans, where no coverage authority defrays the costs that actually determine whether a beneficiary can enroll.

IV. CHI's Recommendations for a Clinical Trial Participant Remuneration Safe Harbor

Generally, CHI supports the creation of AKS safe harbors that responsibly facilitate greater acceptance and use of digital and connected health innovations (whether hardware, software, or a combination of the two) throughout the continuum of care and including in the research setting.

The protection CHI proposes would attach to the structure and purpose of the arrangement, and not to the identity of the party furnishing the remuneration or to the commercial value of the technology involved. CHI does not ask OIG to confer an advantage on any category of product, supplier, or industry segment, and requests that OIG protect research arrangements bounded by an IRB-approved protocol in which technology is one of the forms that participant remuneration may take.

a. The Object of the Remuneration Distinguishes Research Participation from Ordinary Beneficiary Inducement

Before turning to the specific questions, CHI notes that the anti-kickback statute reaches remuneration offered to induce or reward the referral of an individual for, or the purchase or ordering of, an item or service payable by a Federal health care program, and the Beneficiary Inducements CMP reaches remuneration likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier.[22] Both provisions are addressed to the same object, which is the beneficiary's selection or utilization of reimbursable health care goods and services.

Remuneration to a clinical trial participant is directed at a different object, which is the participant's willingness to undertake the burdens of an independently governed research protocol, including the visits, procedures, data collection, and travel that the protocol specifies. The investigational article is not payable by a Federal health care program, the protocol determines what is done and to whom, and the participant's eligibility is fixed by inclusion and exclusion criteria that the remuneration cannot alter. Where the payment is tied to protocol-required activities and documented participation costs, and where it is not conditioned on the participant's selection or use of anything outside the trial, the mechanism by which the statutes anticipate harm is largely absent.

Trial participation can generate reimbursable utilization, sites and sponsors may have commercial relationships that reach beyond the study, and a device furnished for a protocol may find its way into ordinary care. CHI acknowledges these concerns, and believes that the analysis should begin by asking what the remuneration is actually for. Framed that way, the safeguards described in these

---

"routine patient costs" for group health plans by reference to a parallel set of categories, with the same medical-in-nature limitation).

[22] 42 U.S.C. 1320a-7b(b) (reaching remuneration to induce or reward the referral of an individual for, or the purchase, lease, order, or arranging for or recommending of, any item or service for which payment may be made under a Federal health care program); 42 U.S.C. 1320a-7a(a)(5) (reaching remuneration likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier).

comments, including IRB review, informed consent disclosure, and the anti-steering conditions, provide evidence that an arrangement has the character we have described.

b. A Safe Harbor Should Protect Technology, Connectivity, and Technical Support Alongside Cash and Reimbursed Expenses

Question 3 asks what categories of remuneration are useful and at what levels. OIG's own examples, which include travel, lodging, parking, childcare, meals, stipends, compensation for time, and completion incentives, are all necessary and CHI supports protecting each of them. That list omits the category that our members supply and that FDA has already instructed sponsors to furnish.

FDA's guidance on digital health technologies for remote data acquisition instructs sponsors that sponsor-provided technologies "should be available as an option to ensure that participants who do not bring their own are not excluded from the clinical investigation for that reason," and states further that "[s]ponsor-provided telecommunication services should also be made available as needed so that participants who have no or limited access to these services are not excluded from the clinical investigation."[23] FDA's guidance on decentralized elements is to the same effect, directing that digital health technologies be "available and suitable for use by all trial participants" so that participants who cannot afford a protocol-specified device are not excluded on that basis.[24] FDA further directs sponsors to develop a plan for technical assistance to participants for all such technologies used during the trial.[25]

A smartphone, tablet, cellular data plan, connected blood pressure cuff, continuous glucose monitor, or wearable sensor furnished to a Medicare beneficiary is unambiguously a transfer of an item of value to a Federal health care program beneficiary, as is a year of connectivity and, arguably, an ongoing technical support service. FDA has advised sponsors that these should be available as an option so that participants are not excluded, the AKS and CMP framework offers no assurance that furnishing them is protected, and nothing in the current regulatory structure resolves the resulting tension. While FDA's guidance is a recommendation about trial design and does not require a sponsor to supply hardware in every circumstance and OIG has not asserted that furnishing a study device is unlawful, the difficulty is that a sponsor following FDA's recommendation receives no corresponding assurance under the fraud and abuse rules. Reducing that uncertainty falls within the harmonization objective that Operation TrialBlazer announced, and CHI respectfully submits that a final rule should address it.

Federal survey data show that 12 percent of people lived in households without any internet connection as recently as 2023, that fixed terrestrial broadband at the current benchmark speed has not been deployed to approximately 7 percent of Americans and to roughly 28 percent of people in

[23] FDA, *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations: Guidance for Industry, Investigators, and Other Stakeholders*, at § IV.A.4 (Dec. 2023). *See* 88 FR 88629 (Dec. 22, 2023).

[24] FDA, *Conducting Clinical Trials With Decentralized Elements: Guidance for Industry, Investigators, and Other Interested Parties*, at § III.C (Sept. 2024). *See* 89 FR 76481 (Sept. 18, 2024). The guidance responds to section 3606(a)(2) of the Consolidated Appropriations Act, 2023.

[25] FDA, *Digital Health Technologies for Remote Data Acquisition in Clinical Investigations*, *supra* note 23, at § IV.H.1 (directing sponsors to "[d]evelop a plan for technical assistance to trial participants or trial personnel for all DHTs used during the trial").

rural areas, and that the use of a computer or tablet varies substantially across demographic groups.[26] A protocol that presumes reliable home connectivity and a suitable personal device therefore excludes a meaningful share of the population before enrollment begins, and it excludes that share unevenly. Federal research programs have already acted on this recognition, and the National Institutes of Health *All of Us* Research Program conducted a device distribution effort that furnished wearable devices at no cost to more than 25,000 invited participants.[27] Congress has likewise concluded that furnishing technology to beneficiaries so that care can occur at home is a benefit and not an inducement, creating a statutory exception for telehealth technologies furnished to individuals receiving home dialysis.[28]

OIG should also consider that technology often reduces the underlying participation expense instead of adding to it. FDA has concluded that reimbursement for travel to and from a trial site, including airfare, parking, and lodging, does not raise issues of undue influence.[29] In many protocols, a remote visit substitutes for a trip whose reimbursement would already be unobjectionable, and the substitute may cost less than the travel it displaces.

Depending on the item and the participant, a smartphone, a tablet, a continuous glucose monitor, or a year of connectivity may be valued a great deal, and OIG may reasonably conclude that some items warrant more attention than others. The influence of in-kind technology can be bounded in ways that a cash payment cannot, and an item specified in the protocol, furnished because the protocol requires its functionality, configured for protocol use, and returned or deactivated at the end of the study is limited in its value to the participant by design. Those limits are verifiable from the protocol and the sponsor's records, and a rule that protects travel reimbursement while leaving the device or connectivity needed for remote participation uncertain would fail to account for an important substitute for travel.

CHI therefore recommends that any safe harbor expressly protect the following categories:

---

[26] National Telecommunications and Information Administration, *New NTIA Data Show 13 Million More Internet Users in the U.S. in 2023 than 2021* (June 6, 2024) (reporting that 12 percent of people lived in households without any internet connection in 2023, and documenting substantial disparities in the use of a desktop, laptop, or tablet across demographic groups). *See also* U.S. Census Bureau, *Computer and Internet Use in the United States: 2021*, Report No. ACS-56 (June 18, 2024) (90 percent of households had a broadband subscription nationally, and 84 percent in tribal areas); Federal Communications Commission, *2024 Section 706 Report*, FCC 24-27 (Mar. 18, 2024) (fixed terrestrial broadband at 100/20 Mbps has not been deployed to approximately 7 percent of Americans, including approximately 28 percent of people in rural areas).

[27] Patten T, et al., *The All of Us Research Program's wearables dataset*, 32 Nature Medicine 2302 (2026) (describing the Wearables Enhancing All of Us Research study, "a device distribution effort that provided [wearable] devices to invited participants from across the USA at no cost," which enrolled 25,072 participants).

[28] Section 50302(c) of the Bipartisan Budget Act of 2018, Pub. L. No. 115-123, implemented at 42 CFR 1003.110 (excepting from the definition of remuneration certain telehealth technologies furnished to individuals with end-stage renal disease receiving home dialysis).

[29] FDA, *Payment and Reimbursement to Research Subjects*, Information Sheet Guidance for Institutional Review Boards and Clinical Investigators (Jan. 2018).

- Digital health technologies, including hardware, software, and services that electronically capture, transmit, aggregate, or analyze data, furnished for use in connection with a clinical trial protocol.
- General-purpose computing devices such as smartphones and tablets, where the protocol requires their functionality and the participant does not otherwise have a suitable device.
- Telecommunication and connectivity services necessary to transmit protocol-required data, including reimbursement of a participant's existing data plan.
- The training, technical assistance, and support services necessary to make the foregoing usable, consistent with the technical assistance plan that FDA already directs sponsors to develop.

Protection should be available on the same terms whichever configuration a protocol adopts. FDA does not direct sponsors to supply hardware in every case, and instead provides that sponsor-provided technologies and telecommunication services should be available as an option so that participants are not excluded. A safe harbor drafted around sponsor-furnished hardware alone would leave unprotected the support that a sponsor provides to a participant using a device the participant already owns, including reimbursement of a data plan, provision of an accessory or application subscription, and access to a technical help desk. That result would penalize the bring-your-own-device model that a substantial part of the research community relies on, and the alliance of sponsors, sites, and technology companies working on decentralized research has asked FDA to address that model expressly.[30] CHI recommends that OIG state that protection extends equally to sponsor-furnished, participant-owned, and hybrid configurations.

On definitions, OIG already maintains a workable formulation of digital health technology, which reaches hardware, software, and services that electronically capture, transmit, aggregate, or analyze data, and which expressly includes any internet or other connectivity service necessary to enable the operation of the item.[31] CHI recommends that OIG borrow that formulation with one adjustment. The existing purpose clause limits the definition to technology used for coordinating and managing care, and a trial device serves protocol data capture. OIG should substitute a purpose clause covering technology used to conduct a clinical investigation or to enable a participant's participation in one, including the collection of protocol-specified data, and should retain the connectivity sentence without change.

CHI also asks OIG to state expressly that the annual aggregate cap applicable to the patient engagement and support safe harbor does not carry over to this context. That cap is calibrated to care-delivery engagement tools furnished by a value-based enterprise participant to its own patient population, where the risk of concern is steering toward reimbursable services. A trial device is a

[30] Decentralized Trials & Research Alliance, *Response to FDA Draft Guidance on Decentralized Clinical Trials* (Aug. 2023) (stating that the alliance is "strongly supportive of the FDA for recognizing the appropriate role of the sponsor in providing DHTs to participants," and urging FDA to address bring-your-own-device approaches expressly in the final guidance).

[31] 42 CFR 1001.952(ee)(14)(ii) (defining digital health technology as "hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care," and providing that the term "includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose").

scientific instrument specified in an IRB-approved protocol and furnished to generate data, and it is frequently returned at the conclusion of the study. Where appropriate limits are needed, we suggest that the item be protocol-specified, that its value be reasonable in relation to what the protocol requires, and that it be returned or deactivated at the conclusion of the study where the protocol so provides.

A device with multiple functions, such as a smartphone or tablet, should be protected where it is furnished for and primarily used to conduct the trial or to enable the participant's participation in it, including scheduling, transportation, communication with the study team, and the protocol-specified health-related functions the study requires. Multifunction devices allow identity verification of trial participants, and they integrate study tasks into the digital life a participant already leads while giving investigators real-time information about a participant's status. Restricting protection to single-purpose research hardware would in many cases raise costs and exclude the participants least likely to own a suitable device already. Conditions requiring return of the device at study completion, a documented protocol requirement, and valuation at the sponsor's cost can address residual risk.

We are aware of OIG's recent oversight work identifying concerning billing patterns in remote patient monitoring, and we share OIG's commitment to protecting the Medicare program from fraud, waste, and abuse.[32] A safe harbor with clear terms assists enforcement, because it distinguishes arrangements that satisfy stated conditions from those that do not. Where no protection is available, compliant sponsors and technology companies tend to stay out of participant support altogether, while arrangements structured without regard to the statute proceed unremarked. Conditions that can be audited, including a documented protocol requirement, IRB approval, disclosure in the consent document, return of loaned equipment, and the absence of any linkage to outside utilization, give OIG something concrete to enforce against.

c. *Eligibility to Furnish Remuneration Should Turn on Conduct and Safeguards, and Investigators Should Retain Clinical Authority*

Question 5 asks whether trials currently limit who may provide remuneration, and Question 11 asks what conditions a safe harbor should carry. CHI's longstanding position, which we have urged on OIG in prior comments in the value-based context, is that OIG's rules should address the behavior that represents fraud and abuse and should not turn on organizational categorization.

OIG has accepted this principle before, and the cybersecurity technology and services safe harbor that OIG adopted in the 2020 rulemaking places no restriction on the category of donor.[33] OIG also created a carve-out permitting certain device manufacturers to participate in care coordination arrangements involving digital health technology, which is existing regulatory precedent both for

[32] OIG, *Billing for Remote Patient Monitoring in Medicare*, OEI-02-23-00261 (Aug. 2025); OIG, *Additional Oversight of Remote Patient Monitoring in Medicare Is Needed*, OEI-02-23-00260 (Sept. 19, 2024).

[33] 42 CFR 1001.952(jj); *see* 85 FR 77684 (Dec. 2, 2020) (adopting a cybersecurity technology and services safe harbor that imposes no restriction on the category of donor, in contrast to the electronic health records safe harbor). CMS reached the parallel result under the Physician Self-Referral Law exception, declining to limit the types of protected donors.

treating digital health technology as a distinct and protectable category and for calibrating eligibility to conduct.

The digital and connected health market is characterized by rapidly melding categories. Many CHI members find themselves potentially classified as medical device manufacturers, DMEPOS suppliers, and software vendors at the same time, depending on which product line is examined. Under safe harbors that exclude entire industry segments, the availability of protection turns on a labeling exercise that bears little relationship to the risk actually presented. That approach is inconsistent with the conduct-focused design of the statute, and in this context it produces a result that undercuts the rule's purpose, because the trial sponsor designs the protocol, bears the cost, and answers to both FDA and the IRB, and it is often the entity that categorical exclusions would disqualify.

CHI accordingly recommends that eligibility turn on the character of the arrangement and not on the status of the party. Protection should be available to a sponsor, contract research organization, investigator, site, or technology vendor that furnishes remuneration pursuant to a written, protocol-based arrangement and that satisfies the applicable conditions. A party that does not furnish remuneration on those terms gains nothing from the safe harbor, whatever its role in the trial. Where OIG retains concern about a particular category of entity, the appropriate response in our view is a condition addressed to that concern, and not exclusion of the category from the safe harbor altogether.

CHI also recommends that OIG distinguish, in terms, between eligibility to furnish logistical and technological support and authority over clinical and enrollment decisions. Consistent with the settled principle that entities not licensed to practice medicine should not exercise control over clinical decisions, any safe harbor should condition protection on the furnishing entity having no role in determining participant eligibility, no role in the informed consent conversation, no contact initiating enrollment, and no influence over the investigator's clinical judgment. Support should be furnished pursuant to an IRB-approved protocol and not at the independent discretion of a vendor. Authority over who is approached, who is enrolled, and what a participant is told should remain with the principal investigator and the IRB, and we think a safe harbor is easier to enforce if it says so.

d. Caps Should Be Objective and Indexed, and Protection Should Not Depend on Individualized Means-Testing

Question 4 asks whether trials currently impose value caps or require demonstrated financial need. CHI recommends against conditioning protection on an individualized financial-need determination, for reasons grounded in the ethical framework that governs human subjects research. The foundational statement of that framework provides that where research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these "not provide advantages only to those who can afford them" and that such research "should not unduly involve persons from groups unlikely to be among the beneficiaries" of its later application.[34] That principle operates in both directions, and a means test satisfies neither half of it.

[34] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 44 FR 23192 (Apr. 18, 1979), Part B.3 ("whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those

Individualized financial-need screening conditions access to participation on a disclosure of personal finances, it imposes a stigmatizing burden on the participant, and it creates a threshold at which a participant just above the line still cannot afford to travel. It also inverts the ethical analysis, in that the concern the human subjects framework identifies is the possibility of undue influence on economically disadvantaged persons, and a rule that channels payment exclusively toward the financially needy would concentrate that concern instead of reducing it. The Secretary's Advisory Committee on Human Research Protections has made the same observation, cautioning that where payment is restricted out of concern about enrollment by individuals of lower socioeconomic status, those individuals "may still be encouraged by lower payments," which leads to justice concerns of its own, and observing that reimbursement "can make participation more widely accessible, and therefore more diverse."[35]

A structure that distinguishes among the kinds of payment would serve OIG's purposes better, and the taxonomy that the Secretary's Advisory Committee on Human Research Protections has developed, which separates reimbursement of out-of-pocket costs, compensation for time and burden, appreciation, and incentive, supplies a workable framework.[36] Reimbursement of documented and actually-incurred participation costs, together with provision of in-kind technology, should not be capped, because both are bounded by the cost they defray and by protocol requirements, and documentation is the safeguard. Compensation for time and burden should be permitted at a level set in advance in the protocol and approved by the IRB, without an arbitrary ceiling that would fall hardest on the longest and most demanding protocols. If OIG concludes that a fixed cap is necessary for any category, CHI urges that it be indexed for inflation, as the patient engagement cap is. We note in this connection that an indexed cap of $623 in one provision sits alongside a figure of $75 in another that has remained unchanged since 2016.[37]

In place of means-testing, CHI recommends the following conditions, each of which responds to the concern about undue influence that OIG and the human subjects framework have both identified:

---

who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research").

[35] Secretary's Advisory Committee on Human Research Protections, *Attachment A: Addressing Ethical Concerns Regarding Offers of Payment to Research Participants* (approved Sept. 30, 2019) ("[o]ffering reimbursement can make participation more widely accessible, and therefore more diverse," and "participants should not be required to bear financial burdens in order to contribute to socially valuable knowledge," and cautioning that where IRBs bar higher payments out of concern for enrollment by individuals of lower socioeconomic status, "such individuals may still be encouraged by lower payments … leading to justice concerns").

[36] Secretary's Advisory Committee on Human Research Protections, *supra* note 35 ("[g]enuine offers of payment do not satisfy the definition of coercion," and distinguishing reimbursement, compensation, appreciation, and incentive).

[37] *Compare* OIG, *Annual Inflation Adjustments for Safe Harbor Regulations*, *supra* note 15 (patient engagement and support annual aggregate cap of $623 for calendar year 2026), *with* OIG, *Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries*, *supra* note 16 ($15 per item and $75 in the aggregate per patient annually, unchanged since 2016).

- Remuneration should be calibrated to the burden and expense of participation, including visit frequency, travel distance, time commitment, and the procedures involved, and should not be calibrated to the value of the participant's enrollment to the sponsor.
- Remuneration should be uniform within a protocol, so that all participants at a site receive the same terms, which is itself a safeguard against selective steering.
- Escalating completion bonuses that operate to penalize withdrawal should be prohibited. FDA guidance already provides that credit for payment should accrue as the study progresses and should not be contingent on the participant completing the entire study, while permitting a small proportion to be paid as a non-coercive completion incentive.[38] That approach is also the one consistent with the participant's regulatory right to discontinue participation at any time without penalty or loss of benefits.[39]
- The amount, form, and timing of remuneration should be reviewed and approved by the IRB and documented in the protocol.
- The remuneration and its source should be disclosed in the informed consent document.

e. OIG Should Build on Existing IRB Oversight Instead of Duplicating It

Question 6 asks whether IRB review of the type, amount, frequency, and advertising of remuneration is a meaningful safeguard against fraud and abuse. CHI agrees that it is meaningful and should be a primary safeguard for participant remuneration, while acknowledging that it should not be the only condition a safe harbor imposes. We suggest that OIG can build on a review that already occurs, and that duplicating it would add cost without adding protection.

IRBs are already assigned both halves of the balance about which OIG is concerned. They must find that selection of subjects is equitable and must be particularly cognizant of the special problems of research involving economically or educationally disadvantaged persons,[40] and they must ensure that consent is sought under circumstances that minimize the possibility of coercion or undue influence.[41] FDA guidance directs IRBs to review the amount, method, and timing of payment specifically to assure that none of these is coercive, and it recommends that all payment

[38] FDA, *Payment and Reimbursement to Research Subjects*, *supra* note 29 ("Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study," while "payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive"). *See also* National Institutes of Health, *IRB Member Tip Sheet: Payment for Research Participation* (June 2023) (payment "should be prorated for the time of the subjects' participation in the study rather than delayed until study completion").

[39] 45 CFR 46.116(b)(8); 21 CFR 50.25(a)(8) (requiring a statement that participation is voluntary and that the subject "may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled").

[40] 45 CFR 46.111(a)(3); 21 CFR 56.111(a)(3). Both require that selection of subjects be equitable and direct the IRB to be "particularly cognizant of the special problems of research" involving "economically or educationally disadvantaged persons."

[41] 45 CFR 46.116(a)(2); 21 CFR 50.20 (consent must be sought under circumstances that minimize the possibility of coercion or undue influence); 21 CFR 50.25(b)(3) (disclosure of additional costs to the subject resulting from participation).

information, including the amount and schedule of payments, be set forth in the informed consent document.[42] The equitable-selection obligation is properly read in both directions, because an IRB must guard against over-recruiting economically disadvantaged persons and must equally guard against a study design that systematically excludes people who cannot afford to participate. Federal guidance describes the objective as ensuring that both the benefits and the burdens of research are distributed fairly, and that no group is targeted or excluded absent a sound scientific or ethical rationale.[43]

CHI recognizes that IRBs are constituted to protect human subjects and are not fraud and abuse bodies. FDA's own regulations reflect a related structure in that the investigator bears a freestanding responsibility for conducting the study in accordance with the protocol and applicable regulations and for protecting the rights, safety, and welfare of subjects under the investigator's care, and that responsibility sits alongside the separate obligation to ensure IRB review.[44] CHI recommends a layered structure under which IRB review is supplemented by conditions addressed to the risks that IRBs do not evaluate. Specifically, a safe harbor could require a written remuneration plan within the IRB-approved protocol specifying the categories, amounts, and method of payment, should limit remuneration to individuals who are enrolled in or being screened for that protocol, should prohibit any linkage to the participant's use of federally reimbursable items or services outside the trial, should prohibit use of the arrangement to market the furnishing party's other products, and should require records retention and availability to OIG.

CHI also urges OIG to keep the administrative burden of these conditions as low as the fraud and abuse objective permits, and to build the conditions on documentation that regulated trials already generate. The protocol, the IRB approval, the informed consent document, and the sponsor's financial records exist in every trial subject to FDA oversight, and conditions expressed in terms of those documents can be verified without creating a parallel reporting regime. Minimizing incremental burden matters for reasons that bear directly on the access problem this rulemaking addresses. Reporting obligations fall disproportionately on small and mid-sized sponsors, community-based and rural sites, and the smaller technology companies that supply much of the innovation in this field, and those are the participants in the research ecosystem whose involvement most directly determines whether trials reach beneficiaries outside major academic centers. Every hour that site staff spend on duplicative compliance documentation is an hour not spent on recruitment and retention. CHI accordingly recommends that OIG avoid periodic certifications, standalone attestations, and separate compliance program requirements of the kind that commenters opposed in the 2020 rulemaking, and that OIG instead rely on the documents the trial already produces.

---

[42] *Supra* note 29.

[43] National Institutes of Health, *IRB Member Tip Sheet: Equitable Selection of Subjects* (Feb. 2022) ("No one group should be targeted or excluded from research without sound scientific or ethical rationale," and the goal is "to ensure that both benefits and burdens of research are distributed fairly").

[44] 21 CFR 312.60 (an investigator "is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations," and "for protecting the rights, safety, and welfare of subjects under the investigator's care"); 21 CFR 812.100 (parallel provision for device investigations); *see also* 21 CFR 312.53(c)(1)(vi) (separate written commitments by the investigator to conduct the study in accordance with the protocol, to personally conduct or supervise the investigation, and to ensure that the informed consent and IRB requirements are met).

f. Anti-Steering Safeguards Should Be Targeted and Auditable

Question 7 asks what safeguards should prevent participants who receive remuneration from being inappropriately steered to items or services offered by the remunerating party outside the trial. CHI shares this concern, and it is a concern that grows more salient as vertically integrated organizations that combine technology, care delivery, and pharmacy operations participate in research. We believe it can be addressed with conditions that are specific enough to enforce:

- Remuneration should be tied to protocol-required activities and documented participation costs, and should not vary with the participant's use of any item or service outside the trial.
- Remuneration should not be conditioned on the participant's selection of any particular provider, practitioner, supplier, pharmacy, or product outside the trial, and it should not be conditioned on the participant's use of any other item or service furnished by the remunerating party or an affiliate of that party.
- In-kind technology should be furnished for the duration of the protocol and either returned or, where retention is clinically appropriate, disclosed and valued. It should not be configured to promote the sponsor's other products or to route the participant to the sponsor's commercial services.
- Remuneration should be furnished directly to the participant or, where appropriate, to the participant's caregiver, and should not be routed through a referring practitioner in a manner that rewards referral volume.
- The arrangement should be set out in writing in advance in the protocol and the informed consent document, so that any deviation is detectable on audit.

These conditions track the safeguards OIG has found sufficient in its advisory opinions, and each can be verified from documents that exist in every regulated trial.

g. Trial Phase and Trial Type Should Inform IRB Review and Should Not Drive Categorical Exclusions

Questions 8 and 9 ask whether remuneration varies across development phases and whether particular types or categories of trials should be excluded. Remuneration does vary in practice, in that early-phase studies typically involve more frequent visits, longer confinement, and greater burden, so that compensation for time and inconvenience is correspondingly more significant, while later-phase studies more often turn on travel, logistics, and retention over long follow-up periods. CHI recommends that OIG accommodate that variation by protecting remuneration set in advance in the protocol and approved by the IRB, and by declining to fix phase-specific dollar amounts that would be obsolete on publication.

CHI cautions against categorical exclusions by trial type, because the categories that might intuitively seem to present the greatest risk, such as studies of products with an existing reimbursed analogue or studies conducted at sites with a commercial relationship to the sponsor, are better addressed through the anti-steering and anti-seeding conditions described above, which reach the mechanism of concern. A categorical exclusion would deny protection to legitimate studies within

the excluded category while doing nothing about an abusive arrangement in a category that remains protected.

h. Recruitment Advertising Should Be Governed by the Existing FDA and IRB Standard

Question 10 asks whether there should be advertising limitations. At the outset, CHI wishes to be clear about the scope of this comment. CHI urges OIG not to import the flat advertising prohibitions that appear in the local transportation safe harbor and in the financial-need exception. Those prohibitions are the single condition most responsible for the current gap, because recruitment materials are advertising by definition and honest disclosure of what a participant will receive is an ethical requirement of the consent process.

A workable standard already exists and has been applied by IRBs for nearly three decades. FDA guidance provides that advertisements "may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type," and that they should not use misleading terms such as "free medical treatment."[45] CHI supports substantive limits of this kind and recommends that OIG incorporate the FDA standard by reference, conditioning protection on review and approval of the recruitment materials by the IRB and on the materials not emphasizing the remuneration relative to the study's purpose, procedures, and risks. Recruitment materials should also refrain from stating or implying that the investigational article is safe or effective. This approach gives OIG an enforceable limit without layering a second and potentially inconsistent advertising regime on top of the one FDA and IRBs already administer, and without suppressing the trial-awareness communication that reaches the underrepresented populations the Department is trying to serve.

i. OIG Should Clarify the Application of the Anti-Kickback Statute to Artificial Intelligence Used in Trial Identification and Conduct

Although the RFI is directed at remuneration to participants, the arrangements necessary to offer and provide that remuneration, which Question 11 expressly places within scope, increasingly involve artificial intelligence (AI). CHI believes that AI tools should support and extend the judgment of the care team.

CHI asks OIG to confirm two narrow propositions in this area. The first of these is that a sponsor's or contract research organization's use of AI tools to screen for and identify potentially eligible participants does not constitute remuneration intended to induce referrals, because the output of such a tool is a determination of trial eligibility and not a referral for a federally reimbursable item or service. The second is that a sponsor's provision of such a screening tool to a trial site for protocol-specific use, at fair market value and on a fixed-fee, subscription, or per-record-screened basis, is likewise outside the statute.

CHI notes that it does not seek protection for any arrangement in which compensation to a physician, a practice, a health system, or a vendor varies with the number of participants identified, referred, enrolled, or retained. Compensation that tracks enrollment volume is the paradigm case

[45] FDA, *Recruiting Study Subjects*, Information Sheet Guidance (Jan. 1998) (advertisements "may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type," and should not use misleading terms such as "free medical treatment").

the anti-kickback statute was enacted to reach, and it has long been understood to be inconsistent with the professional standards that govern investigators, under which payment for conducting a trial should reflect fair market value for work actually performed and should not vary with the number of subjects a physician enrolls. CHI likewise does not seek protection for incentives offered to enrolled participants in exchange for recruiting other participants. The arrangements CHI is asking OIG to protect are readily distinguishable from them on the face of the contract.

CHI further recommends that any clarification carry conditions drawn from our community's established positions on the responsible use of these technologies. The treating clinician should retain authority over whether to raise a trial with a patient, so that an eligibility signal generated by such a tool operates as a suggestion to a member of the care team and not as a communication to a patient. Where a participant interacts directly with such a tool, that use should be disclosed to the participant at the outset, consistent with the transparency recommendations CHI has developed with the broader healthcare community. Tools used for this purpose should be validated for the population in which they are deployed, and sponsors should evaluate and document their performance across the populations a protocol is intended to reach. These conditions reflect the allocation of roles and responsibilities that CHI has proposed across the health AI value chain, under which the party best positioned to manage a given risk is the party accountable for it.

CHI has worked with the broader community to develop healthcare ecosystem-wide consensus recommendations on the use of AI in healthcare, which generally encourage OIG to align with:

- CHI's *Health AI Policy Principles*, a comprehensive set of recommendations on the areas that should be addressed by policymakers examining AI's use in healthcare, and how they should be addressed (https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf).
- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf).
- CHI's *Health AI Roles & Interdependency Framework*, which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use, and which suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept (https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf).

j. Participant Control, Privacy, and Cybersecurity Safeguards Should Accompany Protected Trial Technology

If OIG protects the provision of connected devices and connectivity to trial participants, it should condition that protection on safeguards governing what the technology collects, what the participant is told, and how the data may be used. We frame these in terms of transparency and limits on use, because a sponsor commonly owns and administers a loaned study device and the participant's interest is better described in those terms than as ownership or control. Specifically, protection should be conditioned on the following:

- The participant is informed, in the informed consent document, of what the device collects, how and to whom the data are transmitted, how long they are retained, what device-management capabilities the furnishing party will exercise, and what becomes of the device and the data if the participant withdraws.
- Collection is limited to what the IRB-approved protocol and the participant's informed consent authorize, including any separately consented optional modules, long-term follow-up, and re-contact components.
- Consent for optional or secondary data uses is sought separately from consent to the trial itself, and withdrawal of that consent does not affect the participant's continued participation, except where the data collection at issue is integral to the investigational intervention or to participant safety, in which case that dependency is disclosed in advance.
- Device-management capabilities are exercised only for purposes disclosed in the informed consent document and necessary to the conduct of the study, including data integrity, security, and safety monitoring, and are not used to access data outside the protocol.
- Data collected through protected technology are not used for advertising or marketing, are not sold to data brokers, and are not used for any secondary commercial purpose of the furnishing party.
- The participant may request deletion of data that the protocol and applicable law do not require to be retained, and the furnishing party discloses in advance which categories must be retained and why.

Security deserves parallel treatment, and devices in participants' homes transmitting protocol data create an attack surface, and the party best positioned to secure it is the sponsor or technology vendor that furnished the device. OIG has already recognized this logic in the cybersecurity technology and services safe harbor.[46] CHI recommends that a clinical trial safe harbor expressly include cybersecurity technology, threat monitoring, and security training furnished in connection with protected trial technology, and that OIG confirm that such provision does not itself constitute separately problematic remuneration. As to the standard, CHI recommends that OIG require encryption in transit and at rest together with documented practices mapped to a recognized framework such as the Department's own Health Industry Cybersecurity Practices or the National Institute of Standards and Technology Cybersecurity Framework,[47] and that OIG encourage but not mandate end-to-end encryption. A mandate would disqualify much of the installed base of research-grade and consumer devices without a corresponding gain in participant protection, while a documented-practices standard is achievable across the market and is consistent with the approach OIG has already taken.

k. Broader Impacts Under Section 1128D(a)(2)

[46] 42 CFR 1001.952(jj).

[47] HHS, *Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients* (405(d) Program); National Institute of Standards and Technology, *Framework for Improving Critical Infrastructure Cybersecurity*.

Question 13 asks about broader impacts under the criteria in section 1128D(a)(2), including effects on access to health care services and on costs to Federal health care programs.[48] CHI's assessment is that a well-conditioned safe harbor would advance each of the relevant criteria:

- On access, because trial participation is, for many Medicare beneficiaries with advanced or rare disease, the only route to a therapy that does not yet exist outside the study, and a participation rate of 1.0 percent among Medicare fee-for-service cancer patients that skews toward higher-income areas is an access finding.[49]
- On underserved areas, protecting technology-enabled participation is among the most powerful levers available, because it substitutes bandwidth for distance in the regions where distance is the binding constraint.[50]
- On quality of care, trials that complete produce evidence and trials that fail for want of accrual produce none, and the resulting evidence base underrepresents the older adults who make up the majority of the patients to whom a therapy will ultimately be given.[51]
- On cost, the analysis turns on who ultimately bears the expense. Where a sponsor or another private party bears a participation expense without shifting it to a Federal health care program, direct Federal expenditure is reduced or avoided, and faster and more complete trials shorten the period during which Federal programs pay for less effective standard care.

The remaining questions are indirect ones, including whether the remuneration affects utilization of reimbursable items and services, whether trial participation changes what is billed, and whether a device furnished for a protocol is later used in ordinary care. Those questions are the reason CHI proposes the conditions set out above on protocol-tied valuation, return or deactivation of loaned equipment, and the absence of any linkage to outside utilization.

l. Guidance Would Help in the Near Term, and Rulemaking Is Necessary

Question 14 asks whether a Special Advisory Bulletin, an FAQ, or other guidance could offer sufficient protection. CHI's view is that guidance would be valuable and that it would be insufficient on its own, for a reason particular to this subject matter.

The parties that must make the decision are frequently small and medium-sized technology and biotechnology companies for which a single enforcement exposure would be existential. Those companies cannot capitalize a program on a document that expressly confers no protection, and they cannot readily absorb the cost and delay of an individual advisory opinion. In our experience, sub-regulatory guidance does not change the risk assessment that counsel and investors make in these circumstances, and conduct follows that assessment. The likely result is that participant

[48] 42 U.S.C. 1320a-7d(a)(2) (section 1128D(a)(2) of the Act).

[49] *Supra* note 4.

[50] *Supra* note 7.

[51] American Cancer Society Cancer Action Network, *Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer: A Landscape Report* (Apr. 2018) (patients with household income less than $50,000 per year are approximately 30 percent less likely to participate, and adults 65 and older are roughly two-thirds of cancer patients but historically only 25 to 30 percent of trial participants).

support continues to be funded mainly by the largest sponsors, in whatever form their counsel will approve, which would leave much of the problem Operation TrialBlazer identified in place.

CHI accordingly recommends that OIG proceed to notice-and-comment rulemaking on a clinical trial participant remuneration safe harbor, together with a corresponding exception to the definition of remuneration under the Beneficiary Inducements CMP where a safe harbor alone would not reach. Because remuneration protected by an AKS safe harbor is already excepted from the CMP definition of remuneration by statute, a single well-drafted safe harbor can resolve most of the problem in one instrument. In the interim, CHI would welcome guidance, including a Special Advisory Bulletin consolidating the safeguards OIG has relied upon in its advisory opinions, as a bridge to that rulemaking.

We would also encourage OIG to coordinate with FDA, CMS, and the Office for Human Research Protections as it develops this rule, so that the resulting conditions align with the IRB review, informed consent, and decentralized trial frameworks those agencies administer. Divergent Federal standards governing the same payment schedule would reintroduce, in a new form, the uncertainty this rulemaking is meant to eliminate, and they would multiply the administrative burden on the sites and sponsors that must satisfy all of them at once.

V. Conclusion

We appreciate the opportunity to provide input as OIG considers new safe harbors and exceptions for remuneration to clinical trial participants, and we welcome the chance to discuss these recommendations further or to provide additional detail on the technology-related issues described above. CHI stands ready to serve as a resource to OIG as this rulemaking proceeds.

Sincerely,

Brian Scarpelli
Executive Director

Chapin Gregor
Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005