June 30, 2026

The Honorable Jake Auchincloss
U.S. House of Representatives
1524 Longworth House Office Building
Washington, DC 20515

Dear Congressman Auchincloss:

Thank you for the opportunity to comment on the Cures in Care Initiative (CCI). As health economics and policy researchers, we share your interests in modernizing the clinical development of innovative biomedical products.[*] The CCI represents an important and timely recognition that the fragmented structure of U.S. clinical development is itself a barrier to biomedical progress. The legislation appropriately emphasizes embedding clinical research into routine care and expanding the use of real-world evidence (RWE) in regulatory decision-making. As we work toward these important goals, it will be important to establish reliable mechanisms to identify clinical trial participation in administrative data and to support the longitudinal follow-up needed for robust real-world evidence generation. We write to offer practical recommendations that draw from our recent viewpoint piece on clinical trial reporting, published in JAMA Health Forum (Haye & Jacobson, "Improving Clinical Trials Reporting in Medicare Claims," June 2026).

Supporting real-world evidence generation

The legislation's near-term goal of aligning regulatory requirements for real-world clinical research data with CMS/ONC interoperability standards (Provision 3) is well-conceived and presents an opportunity to address an important implementation challenge: the inaccurate and inconsistent reporting of National Clinical Trial (NCT) identifiers in Medicare claims.

Since 2014, CMS has required an 8-digit NCT identifier on Medicare claims for routine care delivered as part of clinical trials. In practice, however, these identifiers are not validated and quality is poor. In our work on the Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study, we found widespread inaccuracies: NCT codes appeared on claims for beneficiaries who lacked a PET scan (a condition of study participation) and on claims filed years after the study concluded. Evidence from cancer trials suggest NCT reporting may be more accurate in specific disease contexts and institutions, but false positives and false negatives remain a systemic concern.

Accurately reported NCT identifiers would substantially amplify the legislation's impact in the follow specific ways:

Real-world evidence generation. The legislation envisions integrating routine RWE into product approvals and labeling. Accurate NCT identifier reporting in claims data is an important part of the infrastructure that will support this goal. Reliable tracking of trial participation in claims

[*] The opinions expressed herein represent those of the authors and do not represent the positions of any of their affiliated organizations, including the University of Southern California or USC Schaeffer.

would facilitate downstream surveillance studies, coverage analyses, and post-market outcome tracking. More broadly, it would strengthen the infrastructure underlying CMS's Coverage with Evidence Development (CED) program, potentially accelerating evidence generation and enabling more timely reconsideration of coverage decisions, thereby expanding patient access to promising therapies.

Expanding access for providers serving high-risk patient populations. The legislation emphasizes involvement of non-academic health care providers and providers serving high-risk patient populations (Provision 4). Medicare claims, when paired with reliable NCT identifiers, offer a practical mechanism for evaluating whether these goals are being met. Measures already available in Medicare claims, include zip code of the performing provider, dual Medicare-Medicaid enrollment as a proxy for low-income status, and race and ethnicity data would allow rigorous assessment of participation across geographic, socioeconomic, and demographic groups and help determine whether the legislation is broadening access to clinical research among historically underrepresented populations.

In addition, the unique coverage arrangements for Medicare Advantage beneficiaries participating in clinical trials may create administrative complexity for patients and providers. Reliable identification of trial participants in Medicare claims data would allow Congress, CMS, and FDA to assess whether these arrangements are associated with lower participation rates among Medicare Advantage enrollees and whether they create barriers to equitable access to clinical research.

Specific recommendations

First, the legislation should direct CMS, as part of its data modernization mandate under Provision 3, to develop and evaluate payment or quality-reporting incentives for accurate NCT identifier submission. Current reporting requirements impose administrative burden without providing meaningful incentives or validation mechanisms to ensure accuracy. A modest payment tied to accurate reporting and verified through linkage to ClinicalTrials.gov enrollment data or other quality-reporting incentives could improve data quality without adding friction to the trial process.

The legislation should also encourage simplification of current reporting requirements. Current guidelines require clinicians to report not only the NCT identifier but also ICD-10 code Z00.6 and HCPCS modifiers Q0 or Q1. Streamlining these requirements, while prioritizing NCT identifier accuracy, would reduce administrative burden and improve the reliability of claims-based measures of trial participation.

Second, the legislation should direct HHS, in coordination with CMS, FDA, and NIH, to establish a mechanism for secure submission of participant-level identifiers that would allow validation of NCT identifier reporting and linkage of trial participation records to Medicare claims data where applicable. Such a system would support post-market surveillance, evaluation of trial representativeness, and the integration of real-world evidence into regulatory and coverage decision-making.

Additional ideas for consideration

Beyond the reporting and data-infrastructure recommendations above, we offer three complementary ideas that build on the Schaeffer Center's broader work, much of it conducted through its Clinical Trial Recruitment Lab (CTRL). We would welcome the chance to develop any of them further with you.

First, the legislation could test reimbursement for clinician time spent discussing trial participation with patients. Much of the work of identifying and referring eligible patients falls on front-line clinicians, yet that time is rarely compensated. Our researchers have shown that financial incentives are among the most effective levers for improving the speed and representativeness of trials, and that current arrangements do too little to offset the real costs participation imposes (Goldman, Perez, and del Rio, "Lack of Diversity in Clinical Trials Costs Billions of Dollars. Incentives Can Spur Innovation," 2022, drawing on the National Academies report Improving Representation in Clinical Trials and Research). A modest, point-of-care reimbursement for trial-related counseling would align clinician incentives with the legislation's goal of embedding research into routine care (Provisions 2 through 4).

Second, the data-modernization mandate (Provision 3) could go further by enabling interoperability across electronic medical record (EMR), claims, and research data when participants consent. Realizing this would require capturing key steps in the clinical workflow as structured EMR data rather than free text. Cognitive assessments performed as part of the Medicare Annual Wellness Visit are one example: when recorded in structured fields, they can support trial identification, eligibility screening, and longitudinal follow-up. This extends the same logic behind our recommendations on NCT identifier reporting, making trial-relevant care legible across the systems that govern coverage and evidence generation.

Third, the legislation could recognize clinical trial participation as a form of public service and support protected paid time off for participants, comparable to existing protections for blood donation, organ donation, and jury duty. Research participation produces broad social value by generating the evidence base on which future patients depend, but its time costs fall on individual volunteers and contribute to slow, unrepresentative enrollment. Treating participation as a public good, and lowering the personal burden it imposes, is consistent with our finding that reducing participant burden is essential to faster and more representative trials.

We would be glad to work with you and your staff to flesh out any of these ideas.

Conclusion

The Cures in Care Initiative has the potential to make clinical trials a genuine function of U.S. health care rather than a parallel system. Realizing that potential requires investing in the data infrastructure that makes trial participation legible in routine administrative data. With relatively targeted changes to reporting requirements and payment policy, existing Medicare claims could be transformed into a powerful resource for generating robust evidence on the impact of clinical trials, supporting equitable access, and informing coverage decisions — all objectives this legislation shares.

Respectfully,

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