Category: Resource Management and Finance – Work in Progress

Financial Toxicity: Paying a Higher Price for Clinical Trials Participation

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1. Background

The National Coverage Decision ("NCD310.1"), enacted via executive memorandum in 2000, changed the clinical trials finance landscape, creating a path for Centers for Medicare & Medicaid Services beneficiaries to participate in qualifying clinical trials. NCD310.1, and a subsequent revision known as the Federal Clinical Trials Policy, enabled health care providers and organizations to seek reimbursement for routine costs associated with qualifying clinical trials (QCTs). Determination of what constitutes a routine cost in a QCT, and the downstream monitoring of financial activity associated with clinical trial and participant activity, is mired in the nuances of navigating specialty guidelines, Medicare coverage limitations, and historical billing precedent. Without careful consideration of third-party payer benefits, the clinical trial participant is caught in a maze of complex hospital billing, unaligned clinical trials industry sponsorship, and federal regulations – ultimately bearing a far greater financial burden for their contributions to advancing medicine.

2. Goals

This project evaluates the total financial burden associated with clinical trials participation comparing out-of-pocket payments at one NCI-Designated Cancer Center amongst straight-pay Medicare clinical trial participants versus non-participants (direct costs). Indirect costs of clinical trial participation will be derived and reported. The financial impact of current hospital billing regulations and practices will be identified and discussed to inform sensible federal policy change.

3. Solutions and Methods

Methods for calculating cost: De-identified outpatient charge data were pulled and aggregated excluding patients with non-Medicare plans in instances where patients had at least three encounters within Fiscal Year 2023 as a proxy for the diagnosis and active treatment phase of care. Charge data was joined and filtered with clinical trials management system trial and subject data. Straight-pay Medicare claims, excluding Medicare supplement plans, were analyzed and reported to attribute out-of-pocket expenses. Aggregate charges were compared between Medicare subjects enrolling in interventional treatment trials and those who did not enroll. Indirect costs were adopted from previous published findings, updated to 2024 dollars using an inflationary adjustment.

Methods for calculating information systems (IS) cost: Costs for information systems implementation and maintenance was reported from vendor contracts for subject payment tracking platform implementation and costs related to on-going maintenance. IS costs were included in the analysis to report institutional expense for maintaining IRS reporting requirements.

Applicable IRS tax regulation was reviewed, and a literature scan and summary of proposed legislative efforts was conducted.

4. Outcomes

Preliminary data indicate that Medicare subjects enrolled in clinical trials had a higher out-of-pocket payment burden several times greater than their counterparts. Information systems

infrastructure/support added institutional cost. Aggregate participant compensation qualifying for IRS-1099 reporting/issuance did not exceed nor come close to the median additional out-of-pocket costs associated with clinical trial participation.

5. Lessons Learned and Future Directions

Future data analyses are required to better refine out-of-pocket payments between clinical trial participants and their counterparts. A case-controlled analysis will be considered after evaluating diagnosis and stage characteristics within each arm. Out-of-pocket payments will be grouped and analyzed by participant race and ethnicity to determine if certain patient populations assume a higher financial burden. Immediate federal policy reform is needed.