

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813
(I-15)

Introduced by: Academy of Physicians in Clinical Research

Subject: Removing Financial Barriers to Participation in Clinical Trials for Medicare Beneficiaries

Referred to: Reference Committee J
(Jeffrey P. Gold, MD, Chair)

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- 1 Whereas, Congress is currently considering legislation to modernize the US Food and Drug
2 Administration (FDA) approval process for medical devices and pharmaceuticals;¹ and
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4 Whereas, The proposed innovations will entail new types of clinical trials such as early
5 feasibility, prototype, and first in human clinical trials; and
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7 Whereas, After deductibles are satisfied, Medicare currently pays 80% of the Medicare
8 approved cost of routine care and care for complications leaving beneficiaries responsible for
9 the full amount of deductibles and, after those deductibles are satisfied, for the remaining 20%
10 of the cost of such care; and
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12 Whereas, Current law prohibits clinical trial sponsors from covering Medicare copays and
13 deductibles;² and
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15 Whereas, Medigap supplements may not cover some or all of the expenses that Medicare
16 approves, but does not pay; and
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18 Whereas, Disparities in coverage may arise when some Medigap insurers determine that a
19 particular procedure or treatment is experimental and therefore excluded from payment; and
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21 Whereas, Some Medicare beneficiaries do not have any Medigap insurance and thus bear the
22 full cost of expenses that Medicare approves, but does not pay; and
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24 Whereas, Medicare beneficiaries remain uncertain of their final financial obligation during the
25 course of a clinical trial; and
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27 Whereas, The fear of financial liability may reduce participation by Medicare beneficiaries in
28 clinical trials, particularly early feasibility, prototype and first in human clinical trials; and
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30 Whereas, Reduced participation in clinical trials may undermine the effectiveness of attempts to
31 modernize the FDA approval process; therefore be it

¹ H.R.6 - 21st Century Cures Act (<https://www.congress.gov/bill/114th-congress/house-bill/6/text>)

² <https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/clinicaltrialpolicies>

1 RESOLVED, That our American Medical Association advocate for legislation providing
2 Medicare beneficiaries with coverage for the full amount of Medicare approved expenses
3 incurred through participation in approved clinical trials by:

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5 a. Requiring Medicare to pay 100% of all of a beneficiary's Medicare approved costs of
6 routine care and care for complications associated with approved clinical trials and not
7 paid by Medicare or, if this proves unfeasible, a combination of b. and c. below;

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9 b. Removing Medicare provisions that prohibit clinical trial sponsors from covering
10 Medicare copays and deductibles; and/or

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12 c. Requiring all Medigap supplement insurance policies to pay all of a beneficiary's
13 Medicare approved costs of routine care and care for complications associated with
14 approved clinical trials³ and not paid by Medicare or clinical trials sponsors. (Directive
15 to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/12/15

RELEVANT AMA POLICY

H-460.965 Viability of Clinical Research Coverages and Reimbursement

Our AMA believes that: (1) third party payers should cover patient care costs of nationally approved (e.g., NIH, VA, ADAMHA, FDA), scientifically based research protocols or those scientifically based protocols approved by nationally recognized peer review mechanisms; (2) third party payers should formally integrate the concept of risk/benefit analysis and the criterion of availability of effective alternative therapies into their decision-making processes; (3) third party payers should be particularly sensitive to the difficulty and complexity of treatment decisions regarding the seriously ill and provide flexible, informed and expeditious case management when indicated; (4) its efforts to identify and evaluate promising new technologies and potentially obsolete technologies should be enhanced; (5) its current efforts to identify unproven or fraudulent technologies should be enhanced; (6) sponsors (e.g., NIH, pharmaceutical firms) of clinical research should finance fully the incremental costs added by research activities (e.g., data collection, investigators' salaries, data analysis) associated with the clinical trial. Investigators should help to identify such incremental costs of research; (7) supports monitoring present studies and demonstration projects, particularly as they relate to the magnitude (if any) of the differential costs of patient care associated with clinical trials and with general practice; (8) results of all trials should be communicated as soon as possible to the practicing medical community maintaining the peer reviewed process of publication in recognized medical journals as the preferred means of evaluation and communication of research results; (9) funding of biomedical research by the federal government should reflect the present opportunities and the proven benefits of such research to the health and economic well-being of the American people; and (10) the practicing medical community, the clinical research community, patient advocacy groups and third party payers should continue their ongoing dialogue regarding issues in payment for technologies that benefit seriously ill patients and evaluative efforts that will enhance the effectiveness and efficiency of our nation's health care system. (CSA Rep. F, I-89; Reaffirmed: Joint CMS/CSA Rep., I-92; Reaffirmed: BOT Rep.40, I-93; Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: CMS Rep. 4, A-02; Reaffirmed: CMS Rep. 4, A-12)

H-460.926 Funding of Biomedical, Translational, and Clinical Research

Our AMA: (1) reaffirms its long-standing support for ample federal funding of medical research, including basic biomedical research, translational research, clinical research and clinical trials, health services research, outcomes research, and prevention research; and (2) encourages the National Institutes of Health, the Agency for Healthcare Research and Quality and other appropriate bodies to develop a mechanism for the continued funding of translational research. (Sub. Res. 507, I-97; Reaffirmed: CSA Rep. 13, I-99; Modified: Res. 503, and Reaffirmation A-00; Modified: CSAPH Rep. 1, A-10)

³ Under Section 2709(d) of the Affordable Care Act, an approved clinical trial is a study being done for the prevention, detection, or treatment of cancer or another life-threatening illness. According to the law, the clinical trial must be federally funded, have an investigational new drug (IND) application, or be exempt from IND requirements.