SENATE AMENDMENTS TO SENATE BILL 316

By COMMITTEE ON HEALTH CARE AND VETERANS' AFFAIRS

April 15

On page 1 of the printed bill, line 6, after "patients" insert "enrolled in and".

Delete lines 8 through 31.

On page 2, delete lines 1 through 13 and insert:

"(a) Means medically necessary conventional care, items or services covered by the health benefit plan if typically provided absent a clinical trial.

"(b) Does not include:

"(A) The drug, device or service being tested in the clinical trial unless the drug, device or service would be covered for that indication by the health benefit plan if provided outside of a clinical trial;

"(B) Items or services required solely for the provision of the drug device or service being tested in the clinical trial;

"(C) Items or services required solely for the clinically appropriate monitoring of the drug, device or service being tested in the clinical trial;

"(D) Items or services required solely for the prevention, diagnosis or treatment of complications arising from the provision of the drug, device or service being tested in the clinical trial;

"(E) Items or services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient;

"(F) Items or services customarily provided by a clinical trial sponsor free of charge to any participant in the clinical trial; or

"(G) Items or services that are not covered by the health plan if provided outside of the clinical trial.

"(3) As used in subsection (1) of this section, 'qualifying clinical trial' means a clinical trial that is:

"(a) Funded by the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the United States Department of Defense or the United States Department of Veterans Affairs;

"(b) Supported by a center or cooperative group that is funded by the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the United States Department of Defense or the United States Department of Veterans Affairs;

"(c) Conducted as an investigational new drug application, an investigational device exemption or a biologics license application subject to approval by the United States Food and Drug Administration; or

"(d) Exempt by federal law from the requirement to submit an investigational new drug appli-

cation to the United States Food and Drug Administration.

"(4) The coverage required by this section may be subject to provisions of the health benefit plan that apply to other benefits within the same category, including but not limited to copayments, deductibles and coinsurance.

"(5) An insurer that provides coverage required by this section is not, based upon that coverage, liable for any adverse effects of the clinical trial.".