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ASSEMBLY BILL 502

add F2 I2

(c) "Routine patient care costs" means the costs associated with the provision of health care services, ~~including drugs, items, devices,~~ and services that would otherwise be covered under the plan or contract if those drugs, items, devices, and services were not provided in connection with an approved clinical trial program, including:

a. Health care services typically provided absent a clinical trial.

b. Health care services required solely for the provision of the investigational drug, item, device or service.

c. Health care services required for the clinically appropriate monitoring of the investigational item or services.

d. Health care services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.

e. Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of complications.

add F I3

For the purposes of this section, "routine patient care costs" does not include the costs associated with the provision of any of the following:

~~a. Drugs or devices that have not been approved by the federal FDA and that are associated with the clinical trial.~~

b. Services other than health care services, such as travel, housing, companion expenses, and other non-clinical expenses, that an enrollee may require as a result of the treatment being provided for purposes of the clinical trial.

c. Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.

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d. Health care services that, except for the fact that they are not being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee's health plan.

e. Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Repeat in the appropriate sections of statute.

2-d

ASSEMBLY COMMERCE & LABOR
DATE: 4/11/03 ROOM: 4100 EXHIBIT J
SUBMITTED BY: DR. JOHN ELLERTON

3. The coverage for medical treatment required by this section includes routine patient care costs.

4. Health insurers may require copies of the approval or certification issued pursuant to 1.(b), patient consent documentation, protocols and other materials related to the scope of the clinical trial in order for services to be covered under this section.

6. Reimbursement under this section includes initial patient consultation to determine patient eligibility in the clinical trial study.

7. (a) Pursuant to the patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of a cancer clinical trial.

(b) The benefits under the policy shall not include any portion of the clinical trial that is customarily paid for by the government, biotechnical, pharmaceutical or medical device industry sources.

(c) This section does not create any private right or cause of action for or on behalf of any patient against the health insurer.

7. An insurer who delivers or issues for delivery a policy specified in subsection 1 shall:

(a) Include in the disclosure required pursuant to NRS 689A.390 notice to each policyholder and subscriber under the policy of the availability of the benefits required by this section.

(b) Provide the coverage required by this section subject to the same deductible, copayment, coinsurance and other such conditions for coverage that are required under the policy.

5. A policy of health insurance subject to the provisions of this chapter that is delivered, issued for delivery or renewed on or after January 1, 2004, has the legal effect of including the coverage required by this section, and any provision of the policy that conflicts with this section is void.

6. As used in this section:

(a) "Cooperative group" means a network of facilities that collaborate on research projects and has established a peer review program approved by the National Institutes of Health.

(b) "Provider of health care" means any physician, hospital or other person who is licensed or otherwise authorized in this state to furnish any health care service.