AMENDMENT TO SENATE BILL 475

AMENDMENT NO. _____. Amend Senate Bill 475 on page 3 by replacing lines 7 through 32 with the following:

"Sec. 356z.4. Clinical trials; routine patient care costs.

(a) This Section applies to:

(1) insurers and nonprofit health service plans that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups on an expense-incurred basis under a health insurance policy or contract issued or delivered in this State;

(2) health maintenance or managed care organizations that provide hospital, medical, surgical, or pharmaceutical benefits to individuals or groups health insurance policy or contract issued or delivered in this State; and

(3) the State Medical Assistance Program, and its contracted insurers, that provide hospital, medical, surgical, or pharmaceutical benefits to individuals enrolled in the Medical Assistance program.

(b) This Section does not apply to a policy, plan, or contract paid for under Title XVIII or Title XIX of the Social Security Act.

(c) Coverage.

(1) In general. If a group health plan or health insurance issuer that is providing health insurance coverage provides coverage to a qualified individual (as defined in subsection (d), the plan or issuer:

(A) may not deny the individual participation in the clinical trial referred to in subdivision (d)(2);

(B) subject to subsection (e) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

(2) Coverage of routine patient care costs. For purposes of paragraph (1), subject to paragraph (3), routine patient costs include all items and services provided in either the experimental or the control arms of a clinical trial that would be otherwise covered if not provided in the context of a clinical trial and are generally available to the qualified individual.

Routine patient care costs include:

(A) Conventional care. Items or services that are typically provided absent a clinical trial;

(B) Administrative items. Items or services required solely for the provision of the investigational item or service (such as the administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

(C) Reasonable and necessary care. Items or services needed for reasonable and necessary care

arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

(3) Exclusion. For the purposes of paragraph (1), routine patient care costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

(4) Use of in-network providers. If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that, if a qualified individual is enrolling on the same clinical trial, the qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in that same trial. If the patient is to enroll on a trial and no acceptable in-network provider is participating or if a participating provider cannot accept new enrollees, then the patient may enroll through an out-of-network provider.

(d) Qualified individual defined. For purposes of subsection (c), the term "qualified individual" means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:

(1) (A) the individual is eligible to participate in an approved clinical trial protocol as defined in subsection (f) of this Section;

(B) the clinical trial is undertaken for the purposes of the prevention, early detection, or treatment of cancer or for the treatment of a serious or life threatening illness; and

(C) the treating facility and personnel have the expertise and training to provide the treatment

and treat a sufficient volume of patients to maintain expertise; and

(2) either:

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(e) Payment.

(1) In general. Under this Section a group health plan or health insurance issuer shall provide for payment for routine patient costs described in subdivision (a)(2) but is not required to pay for costs of items and services that are customarily provided by the sponsors of an approved clinical trial.

(2) Payment rate. In the case of covered items and services provided by:

(A) a participating provider, the payment rate shall be at the agreed upon rate; or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable services under subparagraph (A).

(f) Approved clinical trial defined.

(1) (A) In general. In this Section, the term "approved clinical trial" means a trial approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(i) the National Institutes of Health;

(ii) the Centers for Disease Control and Prevention;

(iii) the Agency for Health Care Research and Quality;

(iv) the Centers for Medicare and Medicaid Services;

(v) a cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense, Veterans Affairs, or Energy, including a qualified nongovernmental research entity to which the National Cancer Institute (NCI) has issued a center support grant. In the case of the NIH, cooperative groups must have an established NIH-approved Peer Review Program operating within the group. This includes the NCI Clinical Trials Cooperative Group Program and the NCI Community Clinical Oncology Program; or

(vi) Any of the following if the conditions described in paragraph (2) are met:

(I) the Department of Defense (DoD);

(II) the Department of Veterans Affairs (VA);

(III) the Department of Energy (DoE); or

(B) conducted by a qualified nongovernmental research entity where the study or investigation is approved by an institutional review board (IRB) that is registered with the Department of Health and Human Services and is associated with an institution that has a federal-wide assurance approved by the Department of Health and Human Services specifying compliance with 45 CFR 46; or

(C) a study or investigation conducted under an investigational new drug application reviewed by the Food and Drug Administration (FDA); or

(D) a study or investigation that is exempt from having such an investigational new drug application.

(2) Conditions for departments. The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the appropriate Secretary determines:

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and

(B) assures unbiased review of the highest ethical standards by an institutional review board (IRB) or other body that meets the standards laid out by 45 CFR 46 or 21 CFR 50 and 21 CFR 56.

(g) Coverage for approved and non-approved drugs and devices. Coverage by this Section shall include coverage for patient cost incurred for drugs and devices that have been approved by the Food and Drug Administration (FDA) whether or not the FDA has approved the drug or device for use in treating the patient's particular condition, to the extent that the drugs or devices are not paid for by the manufacturer, distributor, or provider of that drug or device. This shall include coverage for reasonable and medically necessary services needed to administer the drug or device under evaluation in the clinical trial.

(h) Construction. Nothing in this Section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

(i) An entity seeking coverage for treatment,

prevention, or early detection in a clinical trial approved by an institutional review board under subdivision (f)(1)(B) of this Section shall maintain and post electronically a list of the clinical trials meeting the requirements of subsections (b) and (c) of this Section. This list shall include: the phase for which the clinical trial is approved; the entity approving the trial; whether the trial is for the treatment of cancer or other serious or life threatening disease, and if not cancer, the particular disease; and the number of participants in the trial. If the electronic posting is not practical, the entity seeking coverage shall periodically provide payers and providers in the state with a written list of trials providing the information required in this Section.

(j) On or before June 1 of each year, each insurer, nonprofit health service plan, health maintenance and managed care organization subject to the requirements of this Section shall submit to the Director, in a form the Director requires, a report on its coverage of clinical trials during the previous year. The Director shall compile an annual summary report based on the information provided under this subsection and provide copies to the Speaker of the House and President of the Senate. The Director shall make copies of the report available to members of the general public upon request and at a reasonable charge for copying and postage.";

and

by deleting all of page 4; and

on page 5 by deleting lines 1 through 27.