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In the News

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STATES ATTACK DRUG REIMBURSEMENT PROBLEMS

Legislation is being proposed in California and New York that would mandate payment for "experimental" drugs and the associated medical costs by third-party payors, including treatment IND agents, Group C agents, and/or off-label uses.

The organization, Life AIDS, is proposing amendments to the California Health and Safety Code and the Insurance Code that would prohibit health care service plans that provide prescription drug benefits from excluding coverage for 1) drugs approved by the FDA under a treatment IND, open protocol, or Group C designation, 2) drugs prescribed by a physician that are recommended by the NIH, the Centers for Disease Control, or any of the three compendia, and 3) the medical services associated with the use of such prescription drugs. The proposed legislation would also prohibit dollar limits in prescription drug coverage policies unless such provisions apply generally to all benefits paid under the policy.

The proposed amendments would also apply to group or individual disability insurance policies, and group or individual non-profit hospital service plans.

In New York, a proposed amendment to the state insurance law would require health insurance policies to provide coverage for the off-label use of antineoplastic drugs and their administration. At *Oncology Issues* deadline, the bill, sponsored by Assemblywoman Rhoda Jacobs and co-sponsored by 49 other Assembly representatives, was being reviewed in committee. A concurrent measure, introduced by Senator Michael Tully, is also being reviewed in committee.

ACCC staff is working closely with Life AIDS and reviewed the New York legislation to ensure that the language and intent of the amendments is clear, concise, and addresses all current and potential reimbursement difficulties.

NRC LIKELY TO RELAX PROPOSED QA RULES

Responding to an outcry from the medical community, the Nuclear Regulatory Commission has proposed amended quality assurance requirements for therapeutic radiology departments. The Commission is also considering changes to its reporting and recordkeeping requirements related to the medical uses of radioactive materials.

The revised rules require the establishment and implementation of a quality assurance program, but leave the details of the quality assurance procedures to licensees. The initial rules required specific quality assurance procedures that the medical community contended would interfere with the practice of medicine.

The new proposed rules require annual audits and management evaluation of the audits, and written policies and procedures designed to ensure the appropriate and safe use of radioactive materials. The rules also extend the reporting requirements to additional types of misadministration errors. In addition, information on the administration of radioactive materials will have to be kept on file for three years, even where no error was noted.

A draft regulatory guide for developing a quality assurance program that will meet the Commission's rules, "Basic Quality Assurance Program for the Medical Use of Byproduct Material," (Document No. DG-8001) is available by written request to the U.S. Nuclear Regulatory Commission, Division of Information Support Services, Washington, DC 20555. ■

CORRECTION

The list of ASCO Regional representatives in the Winter 1990 issue of *Oncology Issues* was incomplete and some names were incorrect. The following list includes all representatives available to assist with local reimbursement and coding problems:

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