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Recent Legislative Activity

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Off-Label Uses of FDA-Approved Drugs May Help Contain Health-Care Costs in New Jersey

New Jersey recently enacted a new statute requiring insurers to cover certain "off-label" uses of drugs. Off-label usage means that Food and Drug Administration (FDA) approved drugs are prescribed for treatments other than those stated on the label.

The legislature's extensive findings revealed that most people rely on health insurance to pay for health care. Insurers denying payment for off-label drug use can interrupt or effectively deny access to necessary and appropriate treatment for a person with a life-threatening illness. In addition, passage of the Omnibus Budget Reconciliation Act of 1990 required Medicaid agencies to pay for the off-label use of drugs prescribed for Medicaid patients if the use is stated in specific compendia or in peer-reviewed literature.

The legislature emphasized that offlabel use of an FDA-approved drug is legal when prescribed by a doctor and is often necessary to provide the appropriate medical care. For example, the legislature found approximately 50 percent of cancer patients receive some type of off-label use of FDA-approved drugs in their treatment.

The legislature also recognized the fact that off-label usage provides effective treatments at a lower cost. To require that every use of a drug undergo FDA approval could substantially increase the cost of drugs and delay or even deny patients' ability to obtain medically effective treatment.

Under the new law, most insurers will not be allowed to deliver, issue, execute, or renew contracts to provide benefits in New Jersey unless the contract allows medically appropriate uses of off-label drugs. In order to qualify as a medically appropriate use, the treatment must have been recognized in the American Medical Association Drug Evaluations, the American Hospital Formulary Service Drug Information, or the United States Pharmacopeia Drug Information. In addition, an off-label use is medically appropriate if it has been recommended by a clinical study or review article in a major peer-reviewed professional journal.

The law requires coverage of any medically necessary services associated with the administration of the drug. The new law makes clear, however, that coverage is not required for any experimental or investigational drug. 1993 N. J. Sess. Law Serv. Ch. 321 (West).

Recent Legislative Activity is prepared by the Research Editor, Kristin Moran. A limited number of statutes appearing here are available for a \$5 copying charge. Please be specific (include volume number, issue number, and statute cite) when ordering. Send requests to: Research Editor, Loyola Consumer Law Reporter, One East Pearson Street, Chicago, Illinois 60611.

Florida Limits Cancellation of Insurance Due To Risk of Hurricanes

To protect homeowners, the Florida Legislature placed restrictions on insurers who cancel or do not renew residential property insurance to guard against future hurricane claims. The law provides that in any twelve month period, an insurer may not cancel or fail to renew more than five percent of its homeowners' policies in the state for the purpose of reducing the insurer's exposure to hurricane claims. Further, insurers may not cancel or fail to renew ten percent of its homeowner's policies in any county.

Any insurer proposing to cancel or not renew more policies than allowed under the law must file a phaseout plan with the state at least ninety days prior to the effective date of the plan. The insurer's plan must demonstrate that the insurer is protecting market stability and the interests of its policyholders. In developing the plan, the insurer must consider policyholder longevity, the use of voluntary incentives to accomplish the reduction, and geographic distribution.

If an insurer considers the number of cancellations and nonrenewals provided for under the law insufficient, it may apply for approval of additional cancellations or nonrenewals on the basis of an unreasonable risk of insolvency. In evaluating such a request, the state will consider the insurer's size, market concentration, general financial condition, and the portion of the business in the state represented by personal lines residential property insurance. In addition, the state will consider the reasonableness of the insurer's assumptions with respect to size, frequency, severity, and path of hurricanes, reinsurance available to the insurer, potential recoveries from the Florida Hurricane Catastrophe Fund, and the extent to which the insurer's assets have been voluntarily transferred by dividend or otherwise from the insurer to its stockholders, parent companies, or affiliate companies. 1993 Fla. Sess. Law Serv. Ch. 93-411 (West). *

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Congress Considers Bill Requiring Enhanced Disclosure of Risks Associated with High Cost Mortgages

In order to protect the thousands of homeowners who are taken advantage of every year by unscrupulous lenders, Congress is considering a bill that would boost disclosure requirements for high cost mortgages, restrict the use of certain terms and prepayment penalties, prohibit unfair and deceptive trade practices, and hold buyers of such loans responsible for violations by the original lender.

A high cost mortgage is defined as a consumer credit transaction, other than a residential mortgage transaction, that is secured by a consumer's principal dwelling and that (1) has an annual percentage rate at consummation that will exceed by more than ten points the interest rate on any U.S. obligation with a maturity greater than one year or (2) has points and fees payable by the consumer at or before closing that will exceed 8% of the amount financed (less fees and points) or \$400.

In addition to disclosures required under current law, the loan document must contain the following in clear, conspicuous type "if you obtain this loan, the lender will have a mortgages on your home. You could lose your home, and any money you have put into it, if you do not meet your obligations under this loan."

Further, the loan documents must contain information such as the initial APR, the consumer's gross monthly income, the total initial monthly payment, and the amount of funds remaining to meet the consumer's other obligations. The loan must also include the statement "under federal law, this is a high cost mortgage. You may be able to obtain a less expensive loan."

Any person who purchases or is assigned a high cost mortgage is sub-

ject to all claims and defenses with respect to the mortgage that the consumer could assert against the original lender. In addition to any damages presently imposed under the Truth-In-Lending Act, damages may include an offset of all remaining indebtedness and the total amount paid by the consumer in connection with the transactions.

Any loan contract with provisions prohibited by the proposed new law will not be enforceable. 1993 H.B. 3153 (proposed). ❖

Ohio Health Insurance Applicants Not Required To Undergo Genetic Testing

Effective February 9, 1994, the Ohio Legislature passed a law prohibiting the use of genetic screening or testing in connection with contracts for health care insurance. Genetic testing includes laboratory testing of a person's genes or chromosomes for abnormalities, defects, or deficiencies that are linked to physical or mental disorders or that indicate a susceptibility to illness or disease constitutes genetic testing. After being passed in the House by a 91-1 vote, the bill's chief sponsor, Rep. Wayne M. Jones said, "I believe Ohio will become a national leader in respecting that people's genes are private."

When processing an application for coverage for health care services, insurers may not (1) require an individual to undergo genetic screening or testing; (2) take into consideration the results of genetic screening or testing except when voluntarily submitted by the applicant; (3) make any inquiry to determine the results of genetic screening or testing; or (4) make a decision adverse to the applicant based on entries in medical records or other reports of genetic screening or testing.

Insurers who violate the new law are guilty of an unfair and deceptive act or practice in the business of insurance and are subject to the jurisdiction of the Ohio Superintendent of Insurance. 1993 Ohio Laws File 75. ❖

Information Regarding Public Hazards Cannot Be Concealed in Washington State

In Washington, a new law provides that agreements, contracts, and court orders may not conceal a public hazard or any information relevant to the public's knowledge or understanding of a public hazard. A public hazard is defined as a single incident, such as an oil spill, which affects or is likely to affect many people. A public hazard can also be an instrumentality that presents a real and substantial potential for repetition of harm, such as asbestos.

The law provides that any agreement or contract that conceals a public hazard or relevant information regarding the public hazard is void, contrary to public policy, and may not be enforced. Further, no court may enter an order or judgment that conceals a public hazard or relevant information about a public hazard.

Parties to an agreement or contract may bring a declaratory judgment action to determine whether an agreement or contract conceals a public hazard and is void. Any third party, such as the news media, has standing to contest a motion, order, judgment, agreement, or contract that allegedly conceals a public hazard. To prevail, the third party must (1) establish the existence of a public hazard; (2) establish that the public hazard was a subject within the agreement, contract, order, or judgment; and (3) establish a basis for a reasonable belief by the third party that the agreement,

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contract, order, or judgment concealed a public hazard in violation of the new law. The court is entitled to award reasonable attorneys' fees and actual costs to the prevailing party in such an action.

Any party that (1) attempts to condition an agreement or contract upon another party's agreement to conceal a public hazard or (2) enters into an agreement or contract concealing a public hazard that the party knows or reasonably should have known is a public hazard will be in violation of the state consumer protection act. 1993 Wash. Legis. Serv. Ch. 17 (West). ❖

Local Businesses To "Adopt Schools" in New Jersey

The New Jersey Legislature enacted the "Adopt A School Program" on December 23, 1993, to provide for business partnerships with public school districts. Similar programs exist in communities throughout the United States to bring resources to schools, including money, expertise, and job opportunities.

Under the New Jersey program, each county school superintendent will create a business advisory board to involve local businesses that wish to assist students enrolled in a program involving vocational or technical training. The board will encourage and coordinate local business participation in "Adopt A School Programs," which may be instituted at public secondary schools. The business partnership programs may include: supplying materials and funding; offering work-based learning opportunities to students, including apprenticeships; and providing volunteers for the classroom. Businesses involved in the "Adopt a School Program" may not seek reimbursement for any donation of time, money, materials, or personnel from the state or a local school district.

The board is responsible for preparing a rating of the effectiveness of the programs. The business advisory board will also suggest to the local school board any changes which need to be made to the curriculum or programs designed to prepare students for employment in a vocation or technical field. 1993 N. J. Sess. Law Serv. Ch. 314 (West). &

Announcements

EPA Issues Health Warning about Well Water

The Environmental Protection Agency (EPA) has issued a public health warning about possible lead contamination from drinking water from private wells. The EPA urged people who drink from private wells with pumps installed within the past year to switch temporarily to bottled water and to test for possible lead contamination.

Households with older pumps should continue to use well water, but also have tests conducted.

Studies and laboratory analyses conducted by two prominent national environmental organizations, the Environmental Defense Fund and the Natural Resources Defense Council, indicate that some wells are equipped with submersible pumps that contain components made of lead alloys. Scientists warn that most of the 450,000 submersible pumps sold last year contained lead components. Newer pumps are more likely to cause pollution because their brass parts tend to release larger amounts of lead into the water during the first year or two of

People who use a public water system are not affected. Public water systems are already tested as required by law.

The EPA's safe drinking water hotline (1-800-426-4791) can provide information about how to have home water tested and answer any other questions.

Lawyers Look to Alternative Research Sources

With the proliferation of new electronic research alternatives, attorneys are relying less on the expensive online services provided by Lexis and Westlaw. The new on-line and CD-ROM products are usually cheaper than Lexis and Westlaw, which can cost up to \$240 an hour. For example, a month of unlimited research on a CD-ROM database costs about \$60.

While the new products can fill specialized needs, most law librarians argue a law firm cannot survive without the vast resources of Lexis and Westlaw. "You can't live without them yet," said one law-library computer consultant. However, the alternative products are popular at small firms, whose clients cannot afford to pay the hefty prices of the on-line services.

Nutritional Content of School Lunches May Get Boost

The Agriculture Department has recommended that its school lunch program be revised to improve the nutritional content of foods served daily to 25 million children. The new guidelines will attempt to reduce the amount of fat, sodium, and cholesterol in the foods currently served to children. Instead of featuring foods such as french fries, fried chicken, and hot dogs, the school lunches will have more emphasis on low-fat alternatives such as fruits, vegetables, and grain products.

The school lunch program, which cost the federal government \$4.3 billion this year, was started in 1946 as a way to reduce malnutrition among children. But now the Agriculture Department says that the problem is not malnutrition, but "excesses in consumption." The public has three months to comment on the new guidelines before they become final.