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Details: Miscellaneous committee correspondence and documents

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WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

1995-96

(session year)

Assembly

(Assembly, Senate or Joint)

Committee on Insurance, Securities and Corporate Policy...

COMMITTEE NOTICES ...

- Committee Reports ... CR
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INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... Appt (w/Record of Comm. Proceedings)
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(**ab** = Assembly Bill)

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Miscellaneous ... Misc

OFF-LABEL DRUG USE MODEL ACT

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Drafting Note: Each state should determine where the provisions of this model act should be incorporated into its statutory or regulatory scheme. For example, it might be appropriate to include these provisions in a state's Unfair Trade Practices

Section 1. Purpose

In order to prevent unfair discrimination among insured persons in this state and to prohibit unfair competition among health carriers that include coverage for drugs as part of health benefit plans, standards for payment or reimbursement of costs associated with prescription drugs are required. Some health benefit plans deny payment for drugs that have been approved by the federal Food and Drug Administration (FDA) when the drugs are used for indications other than those stated in the labeling approved by the FDA (this use is hereinafter referred to as "off-label use") while other health benefit plans with similar drug coverage pay or reimburse for off-label use. Denial of payment or reimbursement for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for persons being treated for life-threatening illnesses. In addition, drugs for off-label use may provide efficacious treatment at a lower cost.

Drafting Note: States may want to consider utilizing the term "lawfully marketed to be prescribed for at least one indication" instead of the term "approved by the FDA" in this section and throughout this model. States that elect to utilize the term "lawfully marketed to be prescribed for at least one indication" may also want to define the term "prescribed" to be limited to the lawful prescriptive authority of the state.

Section 2. Scope

This Act applies to all health benefit plans that are issued, amended, delivered or renewed on or after the effective date of this Act and provide coverage for drugs, and to all persons making determinations regarding payment of reimbursement for prescription drugs under these health benefit plans.

Drafting Note: States that have appropriate statutory authority may wish to consider framing this model as a regulation rather than as an Act.

Section 3. Definitions

A. "Commissioner" means the commissioner of insurance.

Drafting Note: Insert the title of the chief insurance regulatory official wherever the term "commissioner" appears.

B. "Drug" or "drugs" means any substance prescribed by a licensed health care provider acting within the scope of the provider's license and that is intended for use in the diagnosis, mitigation, treatment or prevention of disease that is taken by mouth; injected into a muscle, the skin, a blood vessel or cavity of the body; applied to the skin; or otherwise assimilated by the body. The term includes only those substances that are approved by the FDA for at least one indication.

- C. "FDA" means the federal Food and Drug Administration.
- D. "Health benefit plan" means a risk transferring contract entered into to provide, deliver, arrange for, pay for or reimburse the cost of health care services.
- E. "Health carrier" means a person that contracts or offers to contract on a risk assuming basis to provide, deliver, arrange for, pay for, or reimburse any of the cost of health care services unless the person assuming the risk is accepting the risk from a duly licensed health carrier.
- F. "Peer-reviewed medical literature" means a published scientific study in a journal or other publication in which original manuscripts have been published only after having been critically reviewed for scientific accuracy, validity and reliability by unbiased independent experts, and that has been determined by the International Committee of Medical Journal Editors to have met the Uniform Requirements for Manuscripts submitted to biomedical journals. Peer-reviewed medical literature does not include publications or supplements to publications that are sponsored to a significant extent by a pharmaceutical manufacturing company or health carrier.
- G. "Standard reference compendia" means:
 - (1) The American Hospital Formulary Service-Drug Information;
 - (2) The American Medical Association Drug Evaluation; or
 - (3) The United States Pharmacopoeia-Drug Information.

Section 4. Minimum Standards of Coverage

- A. A health benefit plan that provides coverage for drugs shall provide for any drug prescribed to treat a covered indication so long as the drug has been approved by the FDA for at least one indication, if the drug is recognized for treatment of the covered indication in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature.
- B. Coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.
- C. This section shall not be construed to require coverage for a drug when the FDA has determined its use to be contra-indicated for treatment of the current indication.
- D. A drug use that is covered by reason of Subsection A shall not be denied coverage based on a "medical necessity" requirement except for reasons that are unrelated to the legal status of the drug use.
- E. The following drugs or services shall not be subject to coverage under Subsection A:
 - (1) Drugs that are used in research trials sponsored by their manufacturers or a government entity; or
 - (2) Drugs or services furnished in a research trial, if the sponsor of the research trial furnishes the drugs or services without charge to any participant in the research trial.

Model Regulation Service—October 1995

Drafting Note: Some states may wish to authorize the commissioner to appoint a panel of medical experts to review specific indications and make written recommendations for approval by the commissioner as to what drugs are recognized for treatment in substantially accepted peer-reviewed medical literature. States choosing to authorize this procedure would need to add language to Section 4A to include drugs recognized and approved by the commissioner through this peer-review panel process. States may wish to ensure that members of such panels have training in assessing new drugs or new usage of existing drugs, follow scientifically sound and objective protocols, and have no financial or other conflicts of interest. A review panel would be subject to the state administrative procedures and open meetings laws.

Section 5. Effective Date

This Act is effective on [insert date].

Legislative History (all references are the <u>Proceedings of the NAIC</u>).

1995 Proc. 2nd Quarter (adopted).

Off-Label Drug Use Model Act



WISCONSIN STATE LEGISLATURE



STOP LOSS INSURANCE MODEL ACT

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Section 1. Purpose and Intent

This law shall be known as the Stop Loss Insurance Act. The purpose of this Act is to establish a standard for the determination of whether an insurance policy should be treated as a health insurance policy or a stop loss insurance policy for the purpose of state regulation of insurance. The laws regulating insurance in [insert state] impose distinctly different requirements upon health insurance policies and stop loss insurance policies. These include different licensing, reporting, policy form and solvency requirements for insurers issuing the policies. The Act applies only to insurers and the insurance policies sold to insured employer groups; the Act does not apply to employers or the self-funded health plans they establish for their employees.

Drafting Note: Due to the technical nature of the issues addressed in this model act, it is suggested that state legislatures wishing to adopt this Act retain this "Purpose and Intent" section.

Section 2. Definitions

- A. "Actuarial certification" means a written statement by a member of the American Academy of Actuaries, or other individual acceptable to the commissioner, that an insurer is in compliance with the provisions of this Act, based upon the individual's examination and including a review of the appropriate records and the actuarial assumptions and methods used by the insurer in establishing attachment points and other applicable determinations in conjunction with the provision of stop loss insurance coverage.
- B. "Attachment point" means the claims amount incurred by an insured group beyond which the insurer incurs a liability for payment.
- C. "Expected claims" means the amount of claims that, in the absence of a stop loss policy or other insurance, are projected to be incurred by an insured group through its health plan.

Drafting Note: This model act establishes criteria that determine whether a policy denominated as a stop loss insurance policy by the insurance carrier is subject to the state laws governing health insurance policies. The criteria apply regardless of how the stop loss insurance carrier calculates when the aggregate attachment point has been met for the purposes of triggering payment under the policy. The model act only requires an insurer to calculate the numerical value of the aggregate attachment point pursuant to the definitions and parameters of the model; it does not preclude a stop loss carrier from using different contractual definitions of "expected claims" and other terms in order to determine how that numerical value is to be reached under the terms of its contract with the insured employer group.

Section 3. Health Insurance Coverage vs. Stop Loss Insurance Coverage

- A. An insurer shall issue an insurance policy that provides coverage to an insured employer group for health care expenses incurred under an employer-sponsored health plan provided to the employer's employees, retired employees or their dependents as a health insurance policy, rather than as a stop loss insurance policy, if the policy:
 - (1) Has an attachment point for claims incurred per individual which is lower than \$20,000; or
 - (2) (a) For insured employer groups with fifty (50) or fewer covered employees, has an aggregate attachment point which is lower than the greater of:
 - (i) \$4,000 times the number of employees;
 - (ii) 120 percent of expected claims; or
 - (iii) \$20,000; or
 - (b) For insured employer groups with fifty-one (51) or more covered employees, has an aggregate attachment point which is lower than 110 percent of expected claims.
 - (c) Insurers shall determine the number of covered employees of an employer, for the purposes of this subsection, on a consistent basis, (such as annually).
 - (3) For the purposes of determining the dollar amounts set forth in Paragraphs (1) and (2) above, and upon consideration of the medical components of the Consumer Price Index (CPI), the commissioner may amend these dollar amounts and shall publish any change in these dollar amounts at least six (6) months prior to their effective dates.

Drafting Note: States may wish to provide the commissioner with the authority to promulgate regulations relating to the establishment of the attachment points set forth in Paragraphs (1) and (2) above. This Act does not change the law applying to a stop loss policy that is not defined as a health insurance policy pursuant to Subsection A, for purposes of financial regulation or otherwise.

A state may wish to adjust the dollar amounts specified in Section 3A above to appropriately reflect medical costs in the particular state. Detailed discussions, including a statement of legislative intent, discussions concerning the actuarial assumptions underlying this model, and an actuarial study on issues relating to risk transference to stop loss insurance carriers, can be found in the minutes of the NAIC State and Federal Health Insurance Legislative Policy Task Force, and its ERISA Working Group, in 1994 and 1995.

- B. A policy issued by an insurer that provides direct coverage of health care expenses of an individual is a health insurance policy regardless of whether the policy is denominated as a stop loss policy.
- C. The commissioner may adopt rules that further prescribe when a policy issued to an insured employer group to cover health care expenses incurred under an employer-sponsored health plan is a health insurance policy.

Model Regulation Service—October 1995

D. An insurer that is required to issue a policy as a health insurance policy under this Act shall, even if the policy is denominated a stop loss policy by the insurer, comply with all the laws of this state that apply to a health insurance policy, including, but not limited to Sections [insert references to laws regulating health insurance].

Section 4. Actuarial Certification

An insurer shall file with the commissioner annually on or before March 15, an actuarial certification certifying that the insurer is in compliance with this Act. The certification shall be in a form and manner, and shall contain information, specified by the commissioner. A copy of the certification shall be retained by the insurer at its principal place of business.

Section 5. Effective Date

This Act shall become effective with respect to stop loss insurance policies issued or renewed six (6) months after [insert effective date].

Legislative History (all references are to the Proceedings of the NAIC).

1995 Proc. 2nd Quarter (adopted).

Stop Loss Insurance Model Act

WISCONSIN STATE LEGISLATURE



INSURANCE FRAUD PREVENTION MODEL ACT

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Section 1. Purpose

The [insert name for state's legislature] finds that the business of insurance involves many transactions that have potential for fraud, abuse and other illegal activities. This Act is intended to permit full utilization of the expertise of the commissioner to investigate and discover fraudulent insurance acts more effectively, halt fraudulent insurance acts and assist and receive assistance from state, local and federal law enforcement and regulatory agencies in enforcing laws prohibiting fraudulent insurance acts.

Section 2. Definitions

As used in this Act:

- A. "Business of insurance" means the writing of insurance or the reinsuring of risks by an insurer, including acts necessary or incidental to writing insurance or reinsuring risks and the activities of persons who act as or are officers, directors, agents or employees of insurers, or who are other persons authorized to act on their behalf.
- B. "Commissioner" means the commissioner of insurance, the commissioner's designees or the department of insurance.

Drafting Note: Use the title of the chief insurance regulatory official wherever the term "commissioner" appears.

- C. "Fraudulent insurance act" means an act or omission committed by a person who, knowingly and with intent to defraud, commits, or conceals any material information concerning, one or more of the following:
 - (1) Presenting, causing to be presented or preparing with knowledge or belief that it will be presented to or by an insurer, a reinsurer, broker or its agent, false information as part of, in support of or concerning a fact material to one or more of the following:
 - (a) An application for the issuance or renewal of an insurance policy or reinsurance contract;

- (b) The rating of an insurance policy or reinsurance contract:
- (c) A claim for payment or benefit pursuant to an insurance policy or reinsurance contract;
- (d) Premiums paid on an insurance policy or reinsurance contract;
- (e) Payments made in accordance with the terms of an insurance policy or reinsurance contract;
- (f) A document filed with the commissioner or the chief insurance regulatory official of another jurisdiction:
- (g) The financial condition of an insurer or reinsurer;
- (h) The formation, acquisition, merger, reconsolidation, dissolution or withdrawal from one or more lines of insurance or reinsurance in all or part of this state by an insurer or reinsurer;
- (i) The issuance of written evidence of insurance; or
- (j) The reinstatement of an insurance policy;
- (2) Solicitation or acceptance of new or renewal insurance risks on behalf of an insurer reinsurer or other person engaged in the business of insurance by a person who knows or should know that the insurer or other person responsible for the risk is insolvent at the time of the transaction;
- (3) Removal, concealment, alteration or destruction of the assets or records of an insurer, reinsurer or other person engaged in the business of insurance:
- (4) Willful embezzlement, abstracting, purloining or conversion of monies, funds, premiums, credits or other property of an insurer, reinsurer or person engaged in the business of insurance;
- (5) Transaction of the business of insurance in violation of laws requiring a license, certificate of authority or other legal authority for the transaction of the business of insurance; or
- (6) Attempt to commit, aiding or abetting in the commission of, or conspiracy to commit the acts or omissions specified in this subsection.
- D. "Insurance" means a contract or arrangement in which one undertakes to:
 - Pay or indemnify another as to loss from certain contingencies called "risks," including through reinsurance;
 - (2) Pay or grant a specified amount or determinable benefit to another in connection with ascertainable risk contingencies;
 - (3) Pay an annuity to another; or
 - (4) Act as surety.

E. "Insurer" means a person entering into arrangements or contracts of insurance or reinsurance and who agrees to perform any of the acts set forth in Subsection D of this section. A person is an insurer regardless of whether the person is acting in violation of laws requiring a certificate of authority or regardless of whether the person denies being an insurer.

Drafting Note: A state may include other persons, such as fraternal benefit societies, medical and hospital service corporations, health maintenance organizations, certain types of self insurers, "county mutuals" or other types of insurance entities in the definition of insurer. In some cases, it may be necessary to amend other laws to bring these entities within the Act since the portions of state law applicable to these entities may provide that no other portion of the insurance code applies to these entities without a specific reference to the other provision.

- F. "NAIC" means the National Association of Insurance Commissioners.
- G. "Person" means an individual, a corporation, a partnership, an association, a joint stock company, a trust, an unincorporated organization, or any similar entity or any combination of the foregoing.
- H. "Policy" means an individual or group policy, group certificate, contract or arrangement of insurance or reinsurance affecting the rights of a resident of this state or bearing a reasonable relation to this state, regardless of whether delivered or issued for delivery in this state.
- I. "Reinsurance" means a contract, binder of coverage (including placement slip) or arrangement under which an insurer procures insurance for itself in another insurer as to all or part of an insurance risk of the originating insurer.

Section 3. Fraudulent Insurance Acts, Interference and Participation of Convicted Felons Prohibited

- A. A person shall not commit a fraudulent insurance act.
- B. A person shall not knowingly or intentionally interfere with the enforcement of the provisions of this Act or investigations of suspected or actual violations of this Act.
- C. (1) A person convicted of a felony involving dishonesty or breach of trust shall not participate in the business of insurance.
 - (2) A person in the business of insurance shall not knowingly or intentionally permit a person convicted of a felony involving dishonesty or breach of trust to participate in the business of insurance.

Section 4. Fraud Warning Required

A. Claim forms and applications for insurance, regardless of the form of transmission, shall contain the following statement or a substantially similar statement:

"Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison."

B. The lack of a statement as required in Subsection A of this section does not constitute a defense in any prosecution for a fraudulent insurance act.

C. Policies issued by unauthorized insurers [use the term "unlicensed" or "nonadmitted" insurers in accordance with the terminology used in the state insurance code] shall contain a statement disclosing the status of the insurer to do business in the state where the policy is delivered or issued for delivery or the state where coverage is in force. The requirement of this subsection may be satisfied by a disclosure specifically required by [insert reference to insurance code provisions. Excess and surplus lines statutes and risk retention and purchasing group statutes are likely to be cited here in nearly every state].

Section 5. Investigative Authority of the Commissioner

The commissioner may investigate suspected fraudulent insurance acts and persons engaged in the business of insurance.

Section 6. Mandatory Reporting of Fraudulent Insurance Acts

- A. A person engaged in the business of insurance having knowledge or a reasonable belief that a fraudulent insurance act is being, will be or has been committed shall provide to the commissioner the information required by, and in a manner prescribed by, the commissioner.
- B. Any other person having knowledge or a reasonable belief that a fraudulent insurance act is being, will be or has been committed may provide to the commissioner the information required by, and in a manner prescribed by, the commissioner.

Section 7. Immunity from Liability

- A. There shall be no civil liability imposed on and no cause of action shall arise from a person's furnishing information concerning suspected, anticipated or completed fraudulent insurance acts, if the information is provided to or received from:
 - (1) The commissioner or the commissioner's employees, agents or representatives;
 - (2) Federal, state, or local law enforcement or regulatory officials or their employees, agents or representatives;
 - (3) A person involved in the prevention and detection of fraudulent insurance acts or that person's agents, employees or representatives; or
 - (4) The NAIC or its employees, agents or representatives.
- B. Subsection A of this section shall not apply to statements made with actual malice. In an action brought against a person for filing a report or furnishing other information concerning a fraudulent insurance act, the party bringing the action shall plead specifically any allegation that Subsection A of this section does not apply because the person filing the report or furnishing the information did so with actual malice.
- C. This section does not abrogate or modify common law or statutory privileges or immunities enjoyed by a person described in Subsection A of this section.

Section 8. Confidentiality

- A. The documents and evidence provided pursuant to Section 6 of this Act or obtained by the commissioner in an investigation of suspected or actual fraudulent insurance acts shall be privileged and confidential and shall not be a public record and shall not be subject to discovery or subpoena in a civil or criminal action.
- B. Subsection A of this section does not prohibit release by the commissioner of documents and evidence obtained by the insurance fraud unit in an investigation of suspected or actual fraudulent insurance acts:
 - (1) In administrative or judicial proceedings to enforce laws administered by the commissioner;
 - (2) To federal, state, or local law enforcement or regulatory agencies, to an organization established for the purpose of detecting and preventing fraudulent insurance acts or to the NAIC; or
 - (3) At the discretion of the commissioner, to a person in the business of insurance that is aggrieved by a fraudulent insurance act.
- C. Release of documents and evidence under Subsection B of this section does not abrogate or modify the privilege granted in Subsection A of this section.

Section 9. Creation and Purpose of the Insurance Fraud Unit

- A. The [insert name of state] insurance fraud unit is established within the [insert designation of organization, such as department of insurance]. The commissioner shall appoint the full-time supervisory and investigative personnel of the insurance fraud unit, who shall be qualified by training and experience to perform the duties of their positions. The commissioner shall also appoint clerical and other staff necessary for the insurance fraud unit to carry out its duties and responsibilities under this Act.
- B. It shall be the duty of the insurance fraud unit to:
 - (1) Initiate independent inquiries and conduct independent investigations when the insurance fraud unit has cause to believe that a fraudulent insurance act may be, is being or has been committed;
 - (2) Review reports or complaints of alleged fraudulent insurance activities from federal, state and local law enforcement and regulatory agencies, persons engaged in the business of insurance, and the public to determine whether the reports require further investigation and to conduct these investigations; and
 - (3) Conduct independent examinations of alleged fraudulent insurance acts and undertake independent studies to determine the extent of fraudulent insurance acts.
- C. The insurance fraud unit shall have the authority to:
 - Inspect, copy or collect records and evidence;
 - (2) Serve subpoenas;

- (3) Administer oaths and affirmations;
- (4) Share records and evidence with federal, state or local law enforcement or regulatory agencies;
- (5) Execute search warrants and arrest warrants for criminal violations of this Act;
- (6) Arrest upon probable cause without warrant a person found in the act of violating or attempting to violate a provision of this Act;

Drafting Note: If the insurance fraud unit has only civil authority, the state should omit Paragraphs (5) and (6) from Subsection C.

- (7) Make criminal referrals to prosecuting authorities; and
- (8) Conduct investigations outside of this state. If the information the insurance fraud unit seeks to obtain is located outside this state, the person from whom the information is sought may make the information available to the insurance fraud unit to examine at the place where the information is located. The insurance fraud unit may designate representatives, including officials of the state in which the matter is located, to inspect the information on behalf of the insurance fraud unit, and the insurance fraud unit may respond to similar requests from officials of other states.

Section 10. Other Law Enforcement or Regulatory Authority

This Act shall not:

- A. Preempt the authority or relieve the duty of other law enforcement or regulatory agencies to investigate, examine and prosecute suspected violations of law;
- B. Prevent or prohibit a person from disclosing voluntarily information concerning insurance fraud to a law enforcement or regulatory agency other than the insurance fraud unit; or
- C. Limit the powers granted elsewhere by the laws of this state to the commissioner or the insurance fraud unit to investigate and examine possible violations of law and to take appropriate action against wrongdoers.

Section 11. Insurer Antifraud Initiatives

Insurers shall have antifraud initiatives reasonably calculated to detect, prosecute and prevent fraudulent insurance acts. Antifraud initiatives may include:

- A. Fraud investigators, who may be insurer employees or independent contractors; or
- B. An antifraud plan submitted to the commissioner. Antifraud plans submitted to the commissioner shall be privileged and confidential and shall not be a public record and shall not be subject to discovery or subpoena in a civil or criminal action.

Section 12. Regulations

The commissioner may promulgate regulations deemed necessary by the commissioner for the administration of this Act.

Section 13. Penalties

A person who violates this Act is subject to the following:

- A. Suspension or revocation of license or certificate of authority, civil penalties of up to \$[insert amount] per violation, or both. Suspension or revocation of license or certificate of authority and imposition of civil penalties shall be pursuant to an order of the commissioner issued under [insert reference to statutes relating to hearings conducted by the commissioner]. The commissioner's order may require a person found to be in violation of this Act to make restitution to persons aggrieved by violations of this Act; or
- B. A person convicted of a violation of Section 3 of this Act by a court of competent jurisdiction [states should insert here classifications for misdemeanor and felony penalties which match provisions in their penal codes for theft offenses]. A person convicted of a violation of Section 3 of this Act shall be ordered to pay restitution to persons aggrieved by the violation of this Act. Restitution shall be ordered in addition to a fine or imprisonment, but not in lieu of a fine or imprisonment; and
- C. A person convicted of a felony violation of this Act pursuant to Subsection B of this section shall be disqualified from engaging in the business of insurance.

Legislative History (all references are to the Proceedings of the NAIC).

1995 Proc. 2nd Quarter (adopted).

This model replaces and incorporates three earlier models:

Model Insurance Fraud Statute

1980 Proc. II 22, 25, 176, 181 (adopted).

Model Legislation Creating a Fraud Unit in a State Department of Insurance

1980 Proc. II 22, 25, 176, 179-180 (adopted).

Model Immunity Act

1983 Proc. II 16, 22, 25, 30 (adopted).

1990 Proc. I 6, 30, 840, 872, 891-893 (amended and reprinted).