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 Act.

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.

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].

Chronological Summary of Action (all references are to the Proceedings of the NAIC)

1995 Proc. 2nd Quarter 2, 36, 552, 570, 573-574 (adopted).

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This chart is intended to provide readers with additional information to more easily access state statutes, regulations, bulletins or administrative rulings related to the NAIC model. Such guidance provides readers with a starting point from which they may review how each state has addressed the model and the topic being covered. The NAIC Legal Division has reviewed each state's activity in this area and has determined whether the citation most appropriately fits in the Model Adoption column or Related State Activity column based on the definitions listed below. The NAIC's interpretation may or may not be shared by the individual states or by interested readers.

This chart does not constitute a formal legal opinion by the NAIC staff on the provisions of state law and should not be relied upon as such. Nor does this state page reflect a determination as to whether a state meets any applicable accreditation standards. Every effort has been made to provide correct and accurate summaries to assist readers in locating useful information. Readers should consult state law for further details and for the most current information.

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KEY:

MODEL ADOPTION: States that have citations identified in this column adopted the most recent version of the NAIC model in a **substantially similar manner**. This requires states to adopt the model in its entirety but does allow for variations in style and format. States that have adopted portions of the current NAIC model will be included in this column with an explanatory note.

RELATED STATE ACTIVITY: Examples of Related State Activity include but are not limited to: older versions of the NAIC model, statutes or regulations addressing the same subject matter, or other administrative guidance such as bulletins and notices. States that have citations identified in this column **only** (and nothing listed in the Model Adoption column) have **not** adopted the most recent version of the NAIC model in a **substantially similar manner.**

NO CURRENT ACTIVITY: No state activity on the topic as of the date of the most recent update. This includes states that have repealed legislation as well as states that have never adopted legislation.

NAIC MEMBER	MODEL ADOPTION	RELATED STATE ACTIVITY
Alabama		ALA. CODE § 27-1-10.1 (1994).
Alaska	NO CURRENT ACTIVITY	
American Samoa	NO CURRENT ACTIVITY	
Arizona		ARIZ. REV. STAT. ANN. §§ 20-2326 (2000) (Accountable health plans) (Cancer drugs).
Arkansas		ARK. CODE ANN. § 23-79-147 (1995/1999) (Cancer drugs).
California		CAL. INS. CODE § 10123.195 (1992); CAL. HEALTH & SAFETY CODE § 1367.21 (1992) (Health care service plans).
Colorado	NO CURRENT ACTIVITY	
Connecticut		CONN. GEN. STAT. § 38a-492b; § 38a-518b (1994) (Cancer drugs).
Delaware	NO CURRENT ACTIVITY	
District of Columbia	NO CURRENT ACTIVITY	
Florida		FLA. STAT. § 627.4239 (1995) (Cancer drugs).

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NAIC MEMBER	MODEL ADOPTION	RELATED STATE ACTIVITY
Georgia		GA. CODE ANN. § 33-53-2 (1993) (Cancer drugs); § 33-24-59.11 (2003) (Drugs used for life-threatening illness); Directive 09-RS-1 (2009).
Guam	NO CURRENT ACTIVITY	
Hawaii	NO CURRENT ACTIVITY	
Idaho	NO CURRENT ACTIVITY	
Illinois		215 ILL. COMP. STAT. 5/370r (1992) (Cancer drugs for group policies).
Indiana		IND. CODE §§ 27-8-20-1 to 27-8-20-9 (1993).
Iowa	NO CURRENT ACTIVITY	
Kansas		KAN. STAT. ANN. §§ 40-2,167 to 40-2,170 (1999) (Cancer drugs).
Kentucky	NO CURRENT ACTIVITY	
Louisiana		LA. REV. STAT. ANN. § 22:215.18 (1997) (Cancer drugs).
Maine		ME. REV. STAT. ANN. tit.24, § 2320-F; § 2320-G (1999) (Nonprofits); ME. REV. STAT. ANN. tit. 24-A, § 2745-E; § 2745-F (1999) (Individual); § 2837-F, 2837-G (1999) (Group); § 4234-D; § 4234-E (1999) (HMOs) (Cancer and HIV drugs).
Maryland		MD. CODE ANN., INS. § 15-804 (1994/1997).
Massachusetts		MASS. GEN. LAWS ch. 175, §§ 47K to 47L (1992) (Cancer drugs); §§ 47O to 47P (1994) (AIDS drugs).

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NAIC MEMBER	MODEL ADOPTION	RELATED STATE ACTIVITY
Michigan		MICH. COMP. LAWS § 500.3406q; § 550.1416c (2002).
Minnesota		MINN. STAT. § 62Q. 525 (1999) (Cancer drugs).
Mississippi		MISS. CODE ANN. § 83-9-8 (1997) (Cancer drugs).
Missouri		MO. REV. STAT. § 376.429 (2002) (Cancer drugs as part of a clinical study).
Montana	NO CURRENT ACTIVITY	
Nebraska	NO CURRENT ACTIVITY	
Nevada		NEV. REV. STAT. § 689A.0404 (1999) (Cancer drugs).
New Hampshire		N.H. REV. STAT. ANN. § 415:6-g; § 415:18-j; § 420-A:2; § 420-B:20 (1999).
New Jersey		N.J. STAT. ANN. § 17:48-6h; § 17:48A-7g; § 17:48E-35.5; § 17B:26-2.1g; § 17B:27-46.1g (1994).
New Mexico	NO CURRENT ACTIVITY	
New York	NO CURRENT ACTIVITY	
North Carolina		N.C. GEN. STAT. § 58-51-59; § 58-65-94; § 58-67-78.
North Dakota		N.D. CENT. CODE § 26.1-36-06.1 (1997).
Northern Marianas	NO CURRENT ACTIVITY	
Ohio		OHIO REV. CODE ANN. § 3923.60; § 1738.30; § 1742.44 (1994/1996); § 1751.66; § 1753.23 (1997).

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NAIC MEMBER	MODEL ADOPTION	RELATED STATE ACTIVITY
Oklahoma	NO CURRENT ACTIVITY	
Oregon		OR. REV. STAT. §§ 743.695 to 743.697 (1997).
Pennsylvania	NO CURRENT ACTIVITY	
Puerto Rico	NO CURRENT ACTIVITY	
Rhode Island		R.I. GEN. LAWS §§ 27-55-1 to 27-55-3 (1994) (Cancer drugs).
South Carolina		S.C. CODE ANN. § 38-71-275 (1996) (Cancer drugs).
South Dakota		S.D. CODIFIED LAWS § 58-17-101 (2000) (Cancer or life threatening illness).
Tennessee		TENN. CODE ANN. § 56-7-2352 (1997).
Texas		TEX. INS. CODE ANN. §§ 1369.001 to 1369.005 (2005); 28 TEX. ADMIN. CODE §§ 21.3010 to 21.3011 (2000).
Utah	NO CURRENT ACTIVITY	
Vermont	NO CURRENT ACTIVITY	
Virgin Islands	NO CURRENT ACTIVITY	
Virginia		VA. CODE ANN. § 38.2-3407.5 (1995/1997).
Washington		WASH. ADMIN. CODE 284-30-450 (1994).
West Virginia	NO CURRENT ACTIVITY	
Wisconsin	NO CURRENT ACTIVITY	
Wyoming	NO CURRENT ACTIVITY	

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One Commissioner requested the NAIC staff to determine whether the model should be a statute or a regulation. **1994 Proc. 2nd Quarter Vol. I 591.**

The mission of the Accident and Health Insurance (B) Committee was to study and evaluate the necessity, if any, for minimum standards of insurance coverage for off-label drug use; develop and draft accordingly a model law or regulation setting appropriate minimum standards for coverage of off-label drug use. **1995 Proc. 1st Quarter Vol. I 42.**

There was some discussion about the appropriate place for the provisions of this model in the state statutory schemes. One Commissioner suggested that some states might want to consider adding provisions to their unfair trade practices acts. Another Commissioner indicated that she was not comfortable with directing that the provisions be added into the unfair trade practices act. Another Commissioner said that the terminology would have to be consistent not only with the unfair trade practices acts but also with the health care and reform model drafts now under development. Another Commissioner agreed and suggested that a drafting note should be added at the beginning to indicate that each state should determine the appropriate place in the state's statutory scheme. **1995 Proc. 1st Quarter Vol. I 506.**

The Experimental Treatments Working Group had been charged by the Accident and Health Insurance (B) Committee to investigate and develop as necessary, a model law establishing minimum standards for coverage of off-label prescription drug use by insurers. **1995 Proc. 2nd Quarter Vol. I 551.**

Section 1. Purpose

One Commissioner noted that the Nov. 30 draft of the purpose provision, Section 1, referred to "equity" among insureds, and stated that she did not believe it was appropriate to refer to "equity." She preferred the language of the Dec. 6 draft that addressed unfair discrimination among insureds and unfair competition among insurers. She noted that insurance and equity are not necessarily related, since the risk-spreading mechanism of insurance assumes that insureds are cross-subsidizing one another, either individually or collectively. The members decided to incorporate the Dec. 6 language concerning unfair discrimination in the place of the reference to "equity" in the Nov. 30 draft. **1995 Proc. 1st Quarter Vol. I 506.**

There was considerable discussion among the members regarding the reference to approval by the Food and Drug Administration (FDA) for at least one indication. One Commissioner suggested that states be provided an alternative to approval by the FDA for at least one indication and suggested that states may want to consider utilizing the term "lawfully marketed to be prescribed for at least one indication." Two other Commissioners expressed concern that this alternative was too broad and should be geographically limited at the least. It was further stated that the broad language also would not take into consideration the varying prescriptive practices in the states. It was suggested that the prescriptive practice be limited to the practice in the principle state. It was also suggested that a drafting note have some language to limit the prescriptive authority. There was no objection to such a drafting note. **1995 Proc. 1st Quarter Vol. I 506.**

The members agreed that the reference to "insurers" in Section 1 was also an error. The reference should be to "health carriers" since that term is defined in the draft. **1995 Proc. 2nd Quarter Vol. I 572.**

Section 2. Scope

Under the scope provision, Section 2, the members elected to utilize the language of the Dec. 6 draft with some additional revisions to make the language consistent with other NAIC models. One Commissioner noted that this provision includes adjusters and third-party administrators by reference to persons making determinations regarding payment of reimbursement for prescription drugs under such health benefits plans. The members agreed that these persons should be included in the scope of this model. **1995 Proc. 1st Quarter Vol. I 506.**

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Section 3. Definitions

The chair also recommended that the term "peer reviewed medical articles" be used to replace the term "medical articles." **1994 Proc. 2nd Quarter Vol. I 591.**

Some terminology was changed to achieve consistency with other NAIC health insurance related models, the reference to the insurance commissioner and the Secretary of Health and Human Services was deleted, and the definition of "standard reference compendia was revised." **1995 Proc. 1st Quarter Vol. I 504.**

One Commissioner noted that the terms in this model should be consistent with the terms in the health care and reform models under development by other NAIC committees and task force. For example, the term "health benefit plan" should be used instead of health contract or some other term. Also, the term "health carrier" should be used instead of health insurer. The members agreed. **1995 Proc. 1st Quarter Vol. I 506.**

One Commissioner suggested that the definition of "drug" or "drugs," Section 3, be revised to include substances, rather than "articles." The definition would also include approval by the FDA for at least one indication. The members agreed. **1995 Proc. 1st Quarter Vol. I 506.**

One Commissioner suggested that the term "health carrier" be defined in this model draft and that the definition be consistent with that in the Dec. 6, 1994, draft Complaint Procedure Model Regulation. The members agreed to add this definition as a new definition in the Nov. 30, 1994, draft model for coverage of off-label drug use. **1995 Proc. 1st Quarter Vol. I 506.**

One Commissioner recommended that the definition of "peer-reviewed medical literature" from the Dec. 6 draft be used because it was narrower and more clearly defined what is deemed peer-reviewed. Another Commissioner noted that this provision was probably one of the more controversial provisions of this model draft. She added that the Dec. 6 definition would likely be more acceptable than the previous definitions because it was more narrow in scope. The members agreed. **1995 Proc. 1st Quarter Vol. I 506.**

Under the definition of "standard reference compendia," the reference to other recognized medical compendia was deleted because the three items listed under the definition were inclusive of the known compendia. One Commissioner suggested that a drafting note could be added to advise states to make sure they have the current compendia listed in the statute. The members did not believe such a drafting note would be necessary since additions to the list were infrequent. **1995 Proc. 1st Quarter Vol. I 506.**

Also in Section 3, under the definitions, the term "health plan" was replaced by "health benefit plan" for consistency with other NAIC models. The definition of "health benefit plan" was proposed to be defined as: "any risk transferring contract entered into to provide, deliver, arrange for, pay for or reimburse the cost of health care services; a 'health benefit plan' does not include: (a) a contract that accepts risks from an entity licensed under [insert reference to appropriate licensing statutes for health maintenance organizations, indemnity carriers, nonprofit health services corporations, etc.] and (b) [insert other exclusions such as automobile insurance policies and workers' compensation programs]." This definition is consistent with the definition in the Dec. 6, 1994, draft Complaint Procedure Model Regulation developed by the State and Federal Health Insurance Legislative Policy (B) Task Force. The members agreed to use this definition. **1995 Proc. 1st Quarter Vol. I 506.**

The members agreed to change the definition of "drug" or "drugs" in Section 3B to add reference to substances prescribed by a licensed health care provider acting within the scope of such provider's license. **1995 Proc. 2nd Quarter Vol. I 572.**

The members agreed that reference to a "health plan" at the end of Section 3F should be changed to a reference to a "health carrier" since the latter term is defined in the draft while the former is not defined. **1995 Proc. 2nd Quarter Vol. I 572.**

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Section 4. Standards of Coverage

After an extensive debate on whether to maintain the term "insurance commissioner" in Section 4a, the group voted to maintain it. **1994 Proc. 2nd Quarter Vol. I 591.**

One Commissioner informed the group that another Commissioner had suggested that the listing under the provision for Minimum Standards of Coverage, Section 4, be rewritten so that it reads affirmatively rather than negatively. One Commissioner also suggested redrafting the first subsection under this provision to provide for coverage for a drug prescribed to treat a covered indication as long as the drug has been approved by the FDA for at least one indication, and if the drug is recognized for treatment of the covered indication in one of the substantially accepted peer-reviewed medical literature. She added that the provisions calling for approval by the Secretary of Health and Human Services or the insurance commissioner were very problematic. Another Commissioner agreed, adding that there is some opposition to the inclusion of the Secretary of Health and Human Services and the insurance commissioner. Another Commissioner also noted that some commissioners oppose having the insurance commissioner involved in this determination because of the potential for liability and the difficulty of the issues. The reference in this subsection to the Secretary of Health and Human Services and the insurance commissioner was deleted. **1995 Proc. 1st Quarter Vol. I 506-507.**

One Commissioner noted that the language in the subsection that referred to a medical necessity requirement was provided by the American Society of Clinical Oncologists. This language would prevent denial of coverage by an insurer by stating that the off-label drug use was not medically necessary and that an alternative, less expensive treatment was medically necessary. One Commissioner noted that most states have some definition of "medically necessary" in existing statutes or regulations. The members agreed with the language of this subsection. **1995 Proc. 1st Quarter Vol. I 507.**

Under the last subsection of the Minimum Standards of Coverage provision, it was noted that the reference to legal requirements to be marketed should be deleted for consistency and that the definition of drug includes approval by the FDA; accordingly, an additional reference to approval by the FDA was not necessary. It was also decided to revise the second part of this subsection to include reference to a drug or a service, rather than reference only to a service. **1995 Proc. 1st Quarter Vol. I 507.**

The members agreed that a review panel provision should not be included in the model, but agreed that a drafting note with an explanation and an optional provision for the selection of a review panel by the commissioner was appropriate. One Commissioner noted that deletion of the reference to the insurance commissioner in an earlier provision (under the Minimum Standards of Coverage) might be inconsistent with inclusion of this optional provision. One Commissioner noted that the drafting note explained the purpose of the optional provision, providing the latitude to include a review panel provision as well as some guidance in the event a state elected to have a review panel provision. **1995 Proc. 1st Quarter Vol. I 507.**

One Commissioner noted the provision from the Dec. 6 draft dealing with accountability of the health benefit plan. She referred to the requirement in that provision for filing with the commissioner policies, procedures and schedules which describe the review standards. Another Commissioner stated that he was concerned about the provisions for coverage of off-label drug use being transparent to insureds and health care providers. This provision would permit the insureds and providers the opportunity to determine which insurers afford such coverage and standards. The members expressed some concern about increasing the filing requirements to insureds and the recordkeeping responsibilities of the insurance departments. Another Commissioner also noted that this was an area which goes beyond coverage for off-label drugs into other areas of insurance. She said the issue should probably be discussed in more detail, but added that she did not believe the provision was appropriate for this model. The members agreed and the provision was not incorporated into the revised draft. **1995 Proc. 1st Quarter Vol. I 507.**

The Committee adopted the working group report, including an amendment deleting the last sentence of Section 4. **1995 Proc. 2nd Quarter Vol. I 552.**

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Section 4 (cont.)

One representative requested that his continuing objection to the inclusion of the optional provision for a review panel in the model be noted for the record; however, he did not object to the entire model. **1995 Proc. 2nd Quarter Vol. I 570.**

The members agreed that there was an error in the March 13, 1995, draft in Section 4A. It was the intent of the members that a health benefit plan that provides coverage for drugs shall provide for any drug prescribed to treat a covered indication as long as the drug has been approved by the Federal Drug Administration (FDA) for "at least one" indication, rather than for "that" indication. **1995 Proc. 2nd Quarter Vol. I 572.**

Section 5. Effective Date

Chronological Summary of Action

June 1995: Model Adopted