



By the Center for Media and Democracy www.prwatch.org

# ALEC EXPOSE

"ALEC" has long been a secretive collaboration between Big Business and "conservative" politicians. Behind closed doors, they ghostwrite "model" bills to be introduced in state capitols across the country. This agenda-underwritten by global corporationsincludes major tax loopholes for big industries and the super rich, proposals to offshore U.S. jobs and gut minimum wage, and efforts to weaken public health, safety, and environmental protections. Although many of these bills have become law, until now, their origin has been largely unknown. With ALEC EXPOSED, the Center for Media and Democracy hopes more Americans will study the bills to understand the depth and breadth of how big corporations are changing the legal rules and undermining democracy across the nation.

**ALEC's Corporate Board** 

--in recent past or present

- AT&T Services, Inc.
- centerpoint360
- UPS
- Bayer Corporation
- GlaxoSmithKline
- Energy Future Holdings
- Johnson & Johnson • Coca-Cola Company
- PhRMA
- Kraft Foods, Inc.
- Coca-Cola Co.
- Pfizer Inc.
- Reed Elsevier, Inc.
- DIAGEO
- Peabody Energy • Intuit, Inc.
- Koch Industries, Inc.
- ExxonMobil Verizon
- Reynolds American Inc.
- Wal-Mart Stores, Inc.
- Salt River Project
- Altria Client Services, Inc.
- American Bail Coalition
- State Farm Insurance

For more on these corporations, search at www.SourceWatch.org.

DID YOU KNOW? Corporations VOTED to adopt this. Through ALEC, global companies work as "equals" in "unison" with politicians to write laws to govern your life. Big Business has "a VOICE and a VOTE," according to newly exposed documents. DO YOU?

Home → Model Legislation → Health and Human Services

Drug Utilization Review Board Act

Did you know that global pharmaceutical company Bayer Healthcare was the corporate co-chair in 2011?

#### **Model Legislation**

In accordance with the Federal Omnibus Budget Reconciliation Act of 1991, all states are required to establish a Drug Utilization Review Board for their Medicaid programs by January 1, 1993. Failure to create such a Board could result in the loss of funding for Medicaid programs. Despite this regulation, less than a dozen sates have DUR boards. Since the establishment of Boards is mandated, those states that do not legislate their creation will be subject to the regulatory creation of such a Board by the appropriate state agency. Alec's legislation creates the most fair and cost efficient DUR Boards, provides the duties of that Board, and provides guidelines for a drug approval program.

{Title, enacting clause, etc.}

**Section 1.** Definitions.

As used in this Act:

- (A) "Provider" means health professionals licensed to prescribe and/ or dispense medicine in this state.
- (B) "Board" means the Drug Utilization Review Board created in Section 2.
- (C) "Compendia" means resources widely accepted by the medical profession in the efficacious use of drugs, including "American Hospital Formulary Services Drug Information," "U.S. Pharmacopeia - Drug Information." "A.M.A. Drug Evaluations," and peer-re-viewed medical literature.
- (D) "Counseling" mans the activities conducted by a pharmacist to inform Medicaid recipients about the proper use of drugs, as required by the Board under this Act.
- (E) "Criteria" means those predetermined elements developed by health professionals used to measure drug use on an ongoing basis in order to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.
- (F) "Drug-disease contradictions" means that the therapeutic effect of a drug is adversely altered by the presence of another disease condition.
- (G) "Drug-interactions" means that the two or more drugs taken by the recipient lead to clinically significant toxicity that is characteristic of one of any of the drugs present, or leads to interference with the effectiveness of one or any of those
- (H) "Drug Utilization Review" or "DUR" means the program designed to measure and assess, on a retrospective and perspective basis, the use of outpatient drugs against predetermined criteria and standards.
- (I) "Intervention" means a form of communication utilized by the Board with a prescriber or pharmacist about optional drug use to maximize health care outcomes.
- (J) "Medically accepted indication" means any use for a covered outpatient drug that is approved under the federal Food, Drug and Cosmetic Act, that appears in peer-reviewed medical literature, and that is accepted by one or more of the following compendia: the American Hospital Formulary Service-Drug Information, American Medical Association-Drug Evaluations, and the U.S. Pharmacopeia-Drug Information.
- (K) "Overutilization" or "underutilization" means the use of a drug in such quantities that the desired therapeutic goal is not achieved.
- (L) "Pharmacist" means a person licensed in (insert state) to engage in the practice of pharmacy.
- (M) "Physician" means a person licensed in (insert state) to practice medicine and surgery.
- (N) "Prospective DUR" means that part of the drug utilization review program that

occurs before a drug in dispensed, and that is designed to screen for potential drug therapy problems based on explicit and predetermined criteria and standards.

- (O) "Retrospective DUR" means that part of the drug utilization review program that assess or measures drug use based on an historical review of drug use data against predetermined and explicit criteria and standards, on an ongoing basis with professional input.
- (P) "Standards" means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on the Medicaid recipient database.
- (Q) "SURS" means the Surveillance Utilization Review System of the Medicaid program.
- (R) "Therapeutic appropriateness" means drug prescribing and dispensing based on rational drug therapy that is consistent with criteria and standards.
- (S) "Therapeutic duplication" means prescribing and dispensation the same drug or two or more drugs form the same therapeutic class where periods of drug administration overlap and where that practice is not medically indicated.

#### Section 2. DUR Board - Creation and Membership.

- (A) There is created a 12 member Drug Utilization Review Board responsible for implementation of a retrospective and prospective DUR program.
- (B) The members of the DUR Board shall be appointed by the governor who shall appoint each member to a three year term. Persons appointed to the Board may be reappointed upon completion of their terms, but may not serve more than two consecutive terms. The membership shall be comprised of the following.
- 1) Four physicians who are actively engaged in the practice of allopathic or osteopathic medicine in this state, to be selected from a list of nominees provided by the (insert state) Medical Associations;
- 2) One physician who is actively engaged in academic medicine in this state, to be selected from a list of nominees provided by the (insert state) Medical Association;
- 3) Three pharmacists who are actively practicing in retail pharmacy in this state, to be selected from a list of nominees provided by the (insert state) Medical Association;
- 4) One pharmacist who is actively engaged in academic pharmacy in this state, to be selected from a list of nominees provided by the (insert state) Pharmaceutical Association;
- 5) One person who shall represent consumers in this state, to be selected from a list of nominees provided by the (insert state);
- 6) One dentist licensed to practice in this state, who is actively engaged in the practice of dentistry, nominated by the (insert state) Dental Association.
- (C) Physician and pharmacist members of the Board shall have expertise in clinically appropriate prescribing and dispensing of outpatient drugs.
- (D) Appointments to the Board shall be made so that the length of the terms are staggered. In making the appointments, the state shall provide for geographic balance in representation on the Board.
- (E) The Board shall elect a chair from among its members who shall serve a one year term, and may serve consecutive terms.

# **Section 3.** DUR Board - Responsibilities.

The Board shall:

- (A) Develop policies necessary to carry out its responsibilities as defined in this Act;
- (B) Oversee he implementation of a Medicaid retrospective and prospective DUR program in accordance with this Act, indulging responsibility for approving DUR provisions of contractual agreements between the Medicaid program and any other entity that would process and review Medicaid drug claims and profiles for the DUR program in accordance with this Act;
- (C) Develop and apply predetermined criteria and standards to be used in retrospective and prospective DUR, ensuring that the criteria and standards are developed with professional input, in a consensus fashion, with provisions for timely revision and assessment as necessary. The DUR standards developed by the Board shall reflect the local practices of physicians in order to monitor:
- 1) Therapeutic appropriateness;
- 2) Overutilization or underutilization;
- 3) Therapeutic duplication;



- 4) Drug-diseases contradictions;
- 5) Drug-drug interactions
- 6) Incorrect drug doses or duration of drug treatment; and
- 7) Clinical abuse and misuse
- (D) Develop, select, apply, and assess interventions and remedial strategies for physicians, pharmacists, and recipients that are educational and not punitive and nature, in order to improve the quality of care;
- (E) Disseminate information to physicians and pharmacists to ensure that they are aware of the Board's duties and powers;
- (F) Provide written, oral, or electronic reminders of patient-specific or drug specific information, designed to ensure recipient, physician, and pharmacist confidentiality, and suggest changes in prescribing or dispensing practices designed to improve the quality of care;
- (G) Utilize face to face discussions between the experts in drug therapy and a prescriber or pharmacist who has been targeted for educational interventions;
- (H) Conduct intensified reviews or monitoring of selected prescribers or pharmacists;
- (I) Create and educational program using data provided through DUR to provide active and ongoing education outreach programs to improve prescribing and dispensing practices, either directly or by contract with other governmental or private entities;
- (J) Provide a timely evaluation of intervention to determine if those interventions have improved the quality of care;
- (K) Publish an annual report, subject to public comment prior to its issuance, and submit that report to the United States Department of Health and Human Services by December 1 of each year. That report shall also be submitted to legislative leadership, the executive director, and the president of the (insert state) Medical Association by December 1 of each year. The report shall include:
- 1) An overview of the activities of the board and the DUR program;
- 2) A description of interventions used and their effectiveness, specifying whether the intervention was a result of underutilization or overutilization of drugs, without disclosing the identities of individual physicians, pharmacists or recipients;
- 3) The costs of administering the DUR program;
- 4) Any fiscal savings resulting from the DUR program;
- 5) An overview of the fiscal impact to the DUR program to other areas of the Medicaid program such as hospitalization or long term care costs;
- 6) A quantifiable assessment of whether DUR has improved the recipient's quality of care:
- 7) A review of the total number of prescriptions, by drug therapeutic class;
- 8) An assessment of the impact of educational programs or interventions on prescribing or dispensing practices; and
- 9) Recommendations for DUR program improvement;
- (L) Develop a working agreement with related boards or agencies, including the State Board of Pharmacy, Physicians' Licensing Board, and SURS staff within the division, in order to clarify areas of responsibility for each, where those areas may overlap:
- (M) Establish a grievance process for physicians and pharmacists under this act;
- (N) Publish and disseminate educational information to physicians and pharmacists concerning the board and the DUR program, including information regarding:
- 1) Fraud, abuse, gross overuse, inappropriate, medically unnecessary care among physicians, pharmacists, and recipients;
- 2) Potential and actual server adverse reaction to drugs;
- 3) Therapeutic appropriateness;
- 4) Overutilization or underutilization;
- 5) Appropriate use of generics;
- 6) Therapeutic duplications;



- 7) Drug-disease contradictions;
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- 9) Incorrect drug dosage and duration of drug treatment;
- 10) Drug allergy interactions; and
- 11) Clinical abuse and misuse.
- (O) Develop and publish, with the input of the State Board of Pharmacy, guidelines and standards to be used by pharmacists in counseling Medicaid recipients in accordance with this part. The guidelines shall ensure that the recipient may refuse counseling and that the refusal is to be documented by the pharmacist. Items to be discussed as part of that counseling include:
- 1) The name and description of the medication;
- 2) The administration, form, duration of therapy;
- 3) Special direction and precautions for use;
- 4) Common severe side effects or interactions, and therapeutic interactions, and how to avoid those occurrences;
- 5) Techniques for self monitoring drug therapy;
- 6) Proper storage;
- 7) Prescription refill information; and
- 8) Action to be taken in the event of a missed dose.
- (P) Establish procedures in cooperation with the State Board of Pharmacy for pharmacists to record information to be collected under this Act. The recorded information shall include:
- 1) The name, address, age, and gender of the recipient;
- 2) Individual history of the recipient where significant including disease state, known allergies and drug reactions, and comprehensive list of medications and relevant devices;
- 3) The pharmacist's comments on the individual's drug therapy;
- 4) Name of prescriber; and
- 5) Name of drug, dose, duration of therapy, and direction for use.

#### Section 4. Confidentiality of records

- (A) Patient-related information obtained under this Act shall be treated as confidential or controlled information.
- (B) The Board shall establish procedures ensuring that the information described is held confidential by a pharmacist, being provided to patient's physician only upon request.
- (C) The Board shall adopt and implement procedures designed to ensure the confidentiality of all information collected, stored, retrieved, assessed, or analyzed by the Board, staff to the board, or contractors to the DUR program, that identifies individual physicians, pharmacists, or recipients. The Board may have access to identifying information for purposes of carrying out intervention activities, but that identifying information may not be released to anyone other than a member of the Board. The Board may release cumulative nonidentifying information for research purposes.

## Section 5. Drug Prior Approval Program.

Any drug prior approval program approved or implemented by the Board shall meet the following conditions:

- (A) No drug may be placed on prior approval for other than medical reasons;
- (B) The Board shall hold a public hearing at least 90 days prior to placing a drug on prior approval
- (C) The Board shall provide evidence that placing a drug class on prior approval will not impede quality of recipient car and that the drug class is subject to clinical abuse or misuse;
- (D) No later than nine months after any drug class is placed on prior approval, it shall be reconsidered:
- (E) The program shall provide either telephone or facsimile approval r denial at least Monday through Friday, within 24 hours after receipt of the prior approval request:



- (F) The program shall provide for the dispensing of at least a 72-hour supply of the drug in an emergency situation or on weekends;
- (G) The program may not be applied to prevent acceptable medical use for the appropriate off-label indications; and
- (H) Any drug class placed on prior approval shall receive a majority vote by the board for that placement, after meeting the requirements described in Subsections (A) through (G).

#### Section 6. Advisory committees.

The Board may establish advisory committees to assist it in carry out its duties under this Act.

**Section 7.** Retrospective and prospective DUR.

- (A) The board, in cooperation with the division, shall include in its state plan the creation and implementation of a retrospective and prospective DUR program for Medicaid outpatient drugs to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.
- (B) The retrospective and prospective DUR program shall be operated under guidelines established by the board under Subsections (D) and (E).
- (C) The retrospective DUR program shall be based on guidelines established by the Board, using the mechanized drug claims processing and information retrieval system to analyze claims date in order to: Identify patters of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care; and
- 1) Assess data on drug use against explicit predetermined standards that are based on the compendia and other sources for the purpose of monitoring:
- a) Therapeutic appropriateness;
- b) Overutilization or underutilization;
- c) Therapeutic duplications;
- d) Drug-disease contradictions;
- e) Drug-drug interactions;
- f) Incorrect drug dosage and duration of drug treatment; and
- g) Clinical abuse and misuse.
- (D) The prospective DUR program shall be based on guidelines established by the Board and shall provide that, before a prescription is filled or delivered, a review will be conducted by the pharmacist at the point of sale to screen for potential drug therapy problems resulting from
- 1) Therapeutic duplication;
- 2) Drug-drug interactions;
- 3) Incorrect dosage or duration of treatment;
- 4) Drug-allergy interactions; and
- 5) Clinical abuse or misuse.
- (E) In conducting the prospective DUR, a pharmacist may not alter the prescribed outpatient drug therapy without the consent of the  $\,$

## **Drug Utilization Review Board Act**

## **Model Legislation**

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- 7) A review of the total number of prescriptions, by drug therapeutic class;
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- 9) Recommendations for DUR program improvement;
- (L) Develop a working agreement with related boards or agencies, including the State Board of Pharmacy, Physicians' Licensing Board, and SURS staff within the division, in order to clarify areas of responsibility for each, where those areas may overlap;
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- (O) Develop and publish, with the input of the State Board of Pharmacy, guidelines and standards to be used by pharmacists in counseling Medicaid recipients in accordance with this part. The guidelines shall ensure that the recipient may refuse counseling and that the refusal is to be documented by the pharmacist. Items to be discussed as part of that counseling include:
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- (C) The Board shall adopt and implement procedures designed to ensure the confidentiality of all information collected, stored, retrieved, assessed, or analyzed by the Board, staff to the board, or contractors to the DUR program, that identifies individual physicians, pharmacists, or recipients. The Board may have access to identifying information for purposes of carrying out intervention activities, but that identifying information may not be released to anyone other than a member of the Board. The Board may release cumulative nonidentifying information for research purposes.

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- (A) No drug may be placed on prior approval for other than medical reasons;
- (B) The Board shall hold a public hearing at least 90 days prior to placing a drug on prior approval
- (C) The Board shall provide evidence that placing a drug class on prior approval will not impede quality of recipient car and that the drug class is subject to clinical abuse or misuse:
- (D) No later than nine months after any drug class is placed on prior approval, it shall be reconsidered;
- (E) The program shall provide either telephone or facsimile approval r denial at least Monday through Friday, within 24 hours after receipt of the prior approval request:
- (F) The program shall provide for the dispensing of at least a 72-hour supply of the drug in an emergency situation or on weekends;
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## Section 6. Advisory committees.

The Board may establish advisory committees to assist it in carry out its duties under this Act.

### **Section 7.** Retrospective and prospective DUR.

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- (B) The retrospective and prospective DUR program shall be operated under guidelines established by the board under Subsections (D) and (E).
- (C) The retrospective DUR program shall be based on guidelines established by the Board, using the mechanized drug claims processing and information retrieval system to analyze claims date in order to: Identify patters of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care; and
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- e) Drug-drug interactions;



- f) Incorrect drug dosage and duration of drug treatment; and
- g) Clinical abuse and misuse.
- (D) The prospective DUR program shall be based on guidelines established by the Board and shall provide that, before a prescription is filled or delivered, a review will be conducted by the pharmacist at the point of sale to screen for potential drug therapy problems resulting from
- 1) Therapeutic duplication;
- 2) Drug-drug interactions;
- 3) Incorrect dosage or duration of treatment;
- 4) Drug-allergy interactions; and
- 5) Clinical abuse or misuse.
- (E) In conducting the prospective DUR, a pharmacist may not alter the prescribed outpatient drug therapy without the consent of the prescribing physician. This section does not effect the ability of a pharmacist to substitute a generic equivalent.

#### Section 8. Penalties.

Any person who violates the confidentiality provisions of this  ${\sf Act}$  is guilty of a class  ${\sf B}$  misdemeanor.

#### Section 9. Immunity.

There is no liability on the part of and no cause of action of any nature arises against any member or the board, its agents, or employees for any action or omission by them in effecting the provisions of this part.

Section 10. {Severability clause}

Section 11. {Repealer clause}

Section 12. {Effective date}

Adopted by the Health and Human Services Task Force in 1992.

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Were *your* laws repealed?

Section 12. {Effective date}

Adopted by the Health and Human Services Task Force in 1992.

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