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Model Legislation

The Prescription Project promotes appropriate prescribing, free of conflicts of interest caused by pharmaceutical marketing and based on the best available medical evidence.

It is promoting policy change by working with

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.

Model Act to Create an Evidence-Based Prescriber Education Serviceⁱ

Bill Summary

This act establishes an evidence-based educational outreach service for health care professionals licensed to prescribe prescription drugs. It will support clinician-educators to provide physicians and other health care professionals with balanced, clinically relevant, evidence-based materials on the comparative efficacy, safety, and cost-effectiveness of treatments for a particular condition, to assist them in making the most appropriate prescribing decisions for their patients.

Section 1. Purposes.

It is the intent of the legislature to ensure that health care professionals have balanced and unbiased evidence-based information readily available in order to ensure the highest quality prescribing decisions are made for the citizens of this state, which will improve health outcomes and reduce unnecessary costs.ⁱⁱ

Section 2. Definitions.

(1) "Prescribed product" includes a drug or device as defined in section 201 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 and a biological product as defined in section 351 of the Public Health Service Act, 42 U.S.C. §262 .

(2) "State health care program" means a program for which the state purchases prescribed products, including, but not limited to, the state medical assistance program (Medicaid), a state pharmaceutical assistance program, or a program for state employees and their dependants, individuals under the supervision of corrections, or state retirees and their dependants.

Section 3. Education Service.

(a) The commissioner of [agencyⁱⁱⁱ] shall develop an evidence-based prescription education service designed to provide health care professionals who are licensed to prescribe or dispense^{iv} prescribed products with information and education on the comparative efficacy, safety, and cost-effectiveness of commonly used prescribed products. In designing the service, the commissioner shall consult with appropriate health care professionals or organizations knowledgeable about the practice of

medicine and continuing medical education.^v

(b)(1) The service shall conduct in-person outreach and education sessions made available to health care professionals in their place of work and will be facilitated by qualified and appropriately trained clinician-educators. The sessions will be conducted on a one-to-one basis, whenever practicable. This service shall be made available to health care professionals who participate in, contract with, or are reimbursed by state-funded health care programs . The service may also provide education to other health care professionals as funding permits or for a fee.

(2) The educational materials used by the service shall be based on a balanced and comprehensive review of evidence that is accepted within the practice of medicine, including scientific research which conforms to the generally accepted standards of experimental design, data collection, analysis, and interpretation ^{vi} with the purpose of providing unbiased continuing education on the comparative efficacy, safety, and cost-effectiveness of medications. ^{vii} The service may use materials that meet this criterion developed by a medical school, an academic medical center, ^{viii} a school of pharmacy, a medical society, a research institute, or another publicly-sponsored prescriber education service.^{ix}

(c) The service shall create by rule:

(1) minimum clinical and educational qualifications for prescriber educators employed by or under contract with the service,^x

(2) required training for educators,^{xi} and

(3) a code of conduct governing the behavior of educators in their interactions with health care professionals and establishing conflict of interest guidelines for educators and others involved in advising, developing and administering the service.^{xii}

(d) The commissioner may seek grants and financial gifts from non-profit charitable foundations to cover planning, development, and the on-going operation of this service.^{xiii}

(e) The commissioner shall present an annual report on the development of the service to the [appropriate legislative committees] by [date].

Section 4. Rulemaking.

The [agency] may adopt rules as necessary to implement this chapter.

ⁱ Prescriber education services are also known as “academic detailing programs.”

ⁱⁱ It may be appropriate to make specific findings in the legislation, although many state legislatures do not do so as a matter of bill drafting policy in that state.

ⁱⁱⁱ The agency developing the service will vary from state to state. In Vermont, the Department of Health was charged to work with an existing academic detailing program run through the University of Vermont, College of Medicine and the Area Health Education Centers Program. The Maine Department of Health and Human Services is the agency establishing a prescriber education service. In South Carolina, the Medicaid agency

granted money to the South Carolina College of Pharmacy to create the service. The Department of Aging Pharmaceutical Assistance Contract for the Elderly (PACE) program in PA was the agency that began the Independent Drug Information Service (IDIS).

^{iv} The model act does not include a definition of which health care professionals are licensed to prescribe or dispense products, because that is governed by state law. The intent is to cover all health care professionals who are licensed to prescribe or dispense products in the state.

^v This consultation provision could be amended to include groups or organizations in that state with whom the agency should consult. The following organizations provide examples of groups that have been involved in state-sponsored prescriber education services: Area Health Education Centers (AHEC), medical schools, schools of pharmacy, state medical associations and societies, existing prescriber education services in other states, health plans, hospitals, pharmacy benefits managers, consumers, and Medicaid or Medicaid drug utilization review committees.

^{vi} This standard complies with the expectations created by the Accreditation Council for Continuing Medical Education. See “Validation of the Clinical Content of CME: The ACCME Expectations of Providers and of the Accreditation Process” available at: http://www.med.cornell.edu/education/programs/pdf/accme_content_val.pdf

^{vii} Pharmaceutical manufacturers or their trade association may suggest that language be included which references the Federal Drug Administration's regulations about labeling. Approved product labeling is a detailed technical document produced by the product manufacturer and approved by FDA, and is not suited to effective communication about risks, benefits and comparative effectiveness across drug classes. If necessary, academic detailing materials could be required to carry the following statement: “Additional information about specific drugs is available on official product labeling.”

^{viii} A team of physicians and drug researchers at Harvard Medical School, working under the direction of Dr. Jerry Avorn through the Independent Drug Information Service, has developed materials used in Pennsylvania’s prescriber education service. These materials are available to other prescriber education services for non-commercial use at www.rxfacts.org.

^{ix} The model bill does not define “publically-sponsored,” however, an individual state may wish to be more specific as to what this terms refers to. Several states have developed or are developing prescriber education services, including Pennsylvania [<http://www.rxfacts.org>], South Carolina [803-767-6299], Vermont [<http://www.med.uvm.edu/ahec>], Maine [under development], New Hampshire [under development], New York [under development], and the District of Columbia [under development]. Not all of these services include every aspect of a model service as

described in this model legislation. In particular, some do not include rigorous conflict of interest policies.

^x At minimum, the criteria should include a bachelor's degree in a relevant field such as a biological or chemical science, nursing, pharmacy, or public health.

^{xi} Some states provide prescriber educators with training in communication methods drawn from behavioral science, educational theory and where appropriate, pharmaceutical industry outreach techniques.

^{xii} A conflict of interest policy for the funding of the service may also be important to include.

^{xiii} A state may wish to provide a specific appropriation for the service, or may wish to fund the service from an alternative source than general revenue. Existing services have been funded through: state lottery proceeds (Pennsylvania), licensing fees for pharmaceutical sales representatives (District of Columbia), a flat fee paid by pharmaceutical manufacturers (Maine), a fee paid by pharmaceutical manufacturers based on the percentage of spending in the Medicaid program on that manufacturer's products (Vermont), or a grant from the Medicaid program (South Carolina).

The model legislation was prepared for the Prescription Project
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