



**Alberta Medical Association Recommendations
for a Provincial Pharmaceutical Strategy**

June 2008

CONTROLLING DRUG COSTS

RECOMMENDATION # 1

Alberta Health and Wellness should negotiate directly on a province-wide basis with wholesalers and drug manufacturers to secure the best prices for Alberta Blue Cross and regional health care facilities.

Rationale: Prescription drugs account for nearly 84% of all drug spending in Canada and represents the second largest share of health care expenditures next to hospital costs. Spending on prescription drugs has grown from \$3 billion in 1986 to \$21.1 billion in 2006, outpacing growth in the health care system overall (10.6% versus 6.5% per year since 1985) and in the Consumer Price Index (2.8% per year since 1985, Canadian Institute for Health Information). (British Columbia Medical Association. Policy Paper, *A Prescription for Quality: Improving Prescription Drug Policy in BC, A Policy Paper by BC's Physicians*, July 2007).

Such an exponential growth in expenditures in this area markedly hampers the health care system's ability to provide care in other areas – funding new physicians, nurses and other health care workers or building needed health care facilities.

Direct negotiations with wholesalers and drug manufacturers has been utilized in other jurisdictions and resulted in lower expenditures for prescription drugs. Limiting the growth of prescription drug costs will improve the sustainability of the delivery of quality health care. Higher drug costs also lead to higher out-of-pocket expenses for some of the more vulnerable segments of our population – seniors and low income Canadians. For example, a recent *Canadian Medical Association Journal (CMAJ)* article (Demers et al, *CMAJ* Feb. 12, 2008, 178: 405-9) compared costs to standardized patients across Canada on provincial drug plans.

A 65-year-old woman in Alberta with diabetes, hypertension and insomnia with an annual household income of \$23,315 would pay a little more than \$150 annually out-of-pocket for her medications, but would pay less in BC (about \$125), Ontario (about \$10), New Brunswick (about \$25), PEI (about \$80) and Newfoundland (about \$25).

Similarly, a 73-year-old senior in Alberta with heart failure and hyperlipidemia, and an annual household income of \$44, 806 would pay just above \$400 annually for his medications, while the same individual would pay less in Ontario (about \$150), New Brunswick (about \$50), Nova Scotia (about \$380) and PEI (about \$75).

RECOMMENDATION # 2

Alberta Health and Wellness should involve practicing physicians in the decision-making process in drug formulary decisions and behind policies to control prescription drug expenditures.

Rationale: Physicians are the one group with no vested financial interest in the decision-making process with regard to prescription drug policy. As such, they represent value towards what is best for patients and for the health care system overall.

Clinicians, with their intimate knowledge of the health care system and a broad focus on quality patient care can advise effectively in responsible, non-partisan and cost-effective ways towards a drug formulary process that will impact positively on health care delivery and effectiveness.

The voice of organized medicine and practicing physicians deserves to be heard in this forum.

RECOMMENDATION # 3

The Alberta Medical Association (AMA) is supportive of funding mechanisms and initiatives which promote improved educational materials to physicians on the efficacy and cost of prescription medications. Joint initiatives through the Toward Optimum Practice Program, the AMA and Alberta Health and Wellness should be ongoing, collaborative and continually funded.

The AMA recommends funding initiatives, which will utilize prescribing data to provide individual physician feedback and information on best practices in order to assist physicians in adopting optimal prescribing processes.

Rationale: Improved information on best practices for prescribing is an effective method of controlling rising drug costs and improving outcomes. Such improvements will often lead to further cost savings.

RECOMMENDATION # 4

Alberta Health and Wellness should work towards the integration and harmonization of hospital and out-patient formularies.

Rationale: Failure to integrate hospital and out-patient formularies will inevitably compromise patient care if patients' medications need to be changed after discharge.

Medications may become unaffordable to the patient on discharge if these are fully funded in hospital but are only partially funded on the out-patient formulary. Lack of harmonization of in-patient and out-patient formularies may lead to prolonged hospital stays and increased system costs.

RECOMMENDATION # 5

While the AMA recognizes there are limits on what a health care system can afford, issues of clinical effectiveness and value should be of primary concern in drug evaluations and in establishing budgets. Therefore, AHW should not implement a strict budget cap on public drug expenditures.

RECOMMENDATION # 6

The *Health Information Act* should be amended to specifically prohibit the disclosure and/or sale of health service provider individual prescribing information.

Rationale: Data on individual prescribing information is sold to pharmaceutical companies that use this information to target physicians. This allows them to tailor marketing strategies towards individual physicians in order to promote changes in prescribing patterns, usually towards more expensive medications. Such practices ultimately increase drug expenditures and will make it more difficult for the province to achieve its strategy of controlling drug costs.

Commercial data collection services activities are not focused on best practice and quality. With the development of a PIN database, the government will have all of the information needed for educational purposes to promote optimal prescribing.

RECOMMENDATION # 7

The Alberta Medical Association recommends Alberta Health and Wellness advocate for transparency in federal drug-pricing decisions through the Patented Medicine Prices review board. The review process for “breakthrough” drugs should be modified so that undisclosed financial arrangements for drug prices in other countries, which are not reflected in published retail prices, must be revealed before making pricing decisions.

Setting prices for a “breakthrough” drug should include a review of research and development costs, manufacturing costs, and reasonable marketing and profit margins over the extent of the patent period for each particular drug. Similarly, rebates offered to pharmacies by generic drug manufacturers and any other financial incentives that contribute to higher drug costs should be made public to ensure transparency.

Rationale: Canadians should benefit from the best available price for prescription drugs. Current practices in price setting inflate drug prices in relation to that available to citizens of other countries. Practices such as pharmacy rebates by generic drug manufacturers inflate prices for generic drugs in Canada.

DRUG COVERAGE DECISIONS

RECOMMENDATION # 8

All Canadian Expert Drug Advisory Committee decisions should be brought forward to the Expert Advisory Committee (or its equivalent) for review.

Rationale: Currently, only some positive recommendations by the national Common Drug Review (CDR) are brought to the Expert Advisory Committee for review. In order to ensure that Albertans benefit optimally from formulary decisions, it is our view that all positive and negative recommendations from the CDR be brought before the Expert Advisory Committee.

There has been criticism that, because the CDR considers evidence from randomized controlled trials when assessing the efficacy of new drugs, some drugs with new indications or those for relatively rare disorders may not meet the criteria for approval simply because there is not enough world evidence or current clinical data to support their use.

In spite of this, the drug may be of significant therapeutic benefit to some patients. When assessing new drugs, only evidence from randomized controlled studies is considered, with a

focus on those utilizing clinical outcomes or a valid assessment of patient quality of life. However, new research often utilizes surrogate markers or clinical correlates. Thus, a drug may be rejected by the CDR in spite of having strong evidence of clinical efficacy based on data utilizing surrogate markers or clinical correlates.

In our view, this methodology by CDR merits review of negative decisions by the provincial committee. While we support the process of the CDR, we also feel that such concerns merit a provincial evaluation in each case (Tierney M, Mannas B. et al. "Optimizing the use of prescription drugs in Canada through the Common Drug Review." *CMAJ* 2008; 178: 432-5).

RECOMMENDATION # 9

The AMA recommends that there should be transparency in all research submitted by pharmaceutical companies to support a drug formulary decision.

Rationale: Recent literature has reported that while positive studies are published, often negative studies on the effectiveness of drugs are not published. Published studies may emphasize or overstate the effectiveness of a drug while minimizing aspects of the research that suggest limited effectiveness.

All studies involving human subjects for a particular drug should be made available to the national and provincial committees for consideration. Information on drugs being considered should be made public (Dhalla I, Laupacis A. "Moving from opacity to transparency in pharmaceutical policy." *CMAJ* 2008; 178: 428-31). Scientific truth should not be suppressed by commercial interests.

RECOMMENDATION # 10

There should be transparency of provincial drug formulary decisions and such decisions should be binding on the Alberta Government. Each decision should have a published rationale for the decision by the committee (or by the government if it decides not to accept binding decisions by the committee and contradicts a committee recommendation). It should outline in lay language why a drug was accepted or rejected. Decisions towards determining the therapeutic equivalence of drugs should include a thorough review of the relevant literature.

Rationale: Determining the cost-effectiveness of drug formulary decisions is a complex process requiring input from experts in many areas. Transparency helps to ensure fairness in the decision-making process and improves accountability. Making the expert committee's decisions binding ensures that clinical issues stay at the forefront of the decision-making process and that decisions are free of political considerations. Concerns regarding liability as a result of published decision rationales should not impede informing the public of a scientific and logical explanation for a formulary decision.

RECOMMENDATION # 11

There should be an appeal process outlined for drug formulary decisions, which is open to industry, professional groups such as physicians and to government. Outcomes of appeals should include a public rationale for each decision.

Rationale: The presence of an appeal process is important to ensure the quality of drug formulary decisions. It allows interested groups to bring to the fore aspects of the decision that may have not been fully considered in the initial committee process.

RECOMMENDATION # 12

The Expert Advisory Committee should abide by strict conflict of interest guidelines within an established code of conduct in determining membership and during the decision-making process.

Rationale: Some physicians have direct or indirect relationships with the pharmaceutical industry in the form of marketing endeavors and sponsorship of research activities. Similarly, pharmacy representatives may directly benefit from pharmaceutical industry incentives and reimbursements. Committee members should be screened to limit conflict of interest positions. Relationships with the industry should be made public for each member, to allow transparency in the decision-making process.

RECOMMENDATION # 13

The Expert Advisory Committee should include physician representatives selected by the AMA, to ensure that the voice of practicing physicians is heard as part of formulary decisions. Committee membership by physicians should strive to strike a balance between rural and urban, academics and clinicians, and specialists and generalists. The committee will be further strengthened by the addition of public members.

Rationale: It is important that practicing physicians participate in this process. Physician membership in the committee will allow the voices of practicing physicians, who will be impacted by formulary decisions, to be heard during the decision-making process. Balanced representation by physicians is important to maximizing the quality of input into decisions. Public members have been valuable components of drug approval committees for the FDA, Common Drug Review and EMEA.

RECOMMENDATION # 14

The Expert Advisory Committee should seek input from AMA sections through their leaders in decisions which will affect their sections' areas of practice.

Rationale: While the Expert Advisory Committee has sought input from practicing physicians in the past, this has been limited and the process for seeking input has also not been transparent and has been ad hoc for physician input. The AMA should be informed in advance of drugs that will be considered in order to allow section leaders the opportunity for input.

RECOMMENDATION # 15

There should be a process for regular review of drugs on the formulary to ensure continued efficacy and continued cost-effectiveness.

Rationale: Advances in therapeutics will often lead to drugs previously indicated being superseded by others or to new contraindications and limitations on effectiveness. The committee needs to be supported in evaluating, at regular intervals, all formulary drugs.

RECOMMENDATION # 16

The Expert Advisory Committee should operate at arm's length from government to ensure the independence of its decisions. The Terms of Reference for the committee should be public and identify the criteria for the decision-making process, which is based with a primary focus on peer-reviewed literature, clinical effectiveness, safety and cost-effectiveness.

Rationale: It is important that drug formulary decisions be as free as possible from political and industry influence and based on clinical considerations.

RECOMMENDATION # 17

The AMA recognizes that reference-based drug pricing is being considered as a cost-containment mechanism. If such a program is introduced, it must be developed in a manner that will not demonstrate harm to patients. Ensuring that a reference-based program is transparent, utilizes physician input extensively into the decision-making process and provides ongoing review of formulary drugs are essential components towards achieving these ends.

Rationale: The AMA recognizes that control of prescription drug expenditures is a key component of maintaining sustainability of the health care system. Reference-based drug pricing is one initiative that has been shown to be effective in controlling drug costs without affecting health outcomes.

RECOMMENDATION # 18

If reference-based pricing is adopted, there must be a transparent process for evaluating the therapeutic equivalence of drugs in current and future reference drug categories. This process must be ongoing, include a thorough assessment of the peer-reviewed literature, and be conducted by a working group whose membership includes practicing physicians, some of whom are appointed by the AMA.

Decisions on therapeutic equivalence must be a medical decision. The medical profession must be satisfied that this decision will not harm patient care.

Rationale: Key to the effectiveness of a reference-based drug-pricing system is ensuring that drugs included in this process are truly therapeutically equivalent. This will require ongoing evaluation by a team of experts and clinicians who engage in a fair and transparent process.

RECOMMENDATION # 19

If reference-based pricing is adopted, there must be an assessment of the impact on health outcomes for all drug classes in the Alberta program on a short- and long-term basis. This process is necessary in order to detect any significant negative clinical outcomes that may be associated with reference-based pricing.

Rationale: A reference-based drug-pricing program must put the interests of Patients First®. The program must include ongoing monitoring of outcomes to ensure that efforts to control drug expenditures are not resulting in harm to patients.

RECOMMENDATION # 20

Physicians should be reimbursed for completion of special authorization forms. Forms should be regularly reviewed to ensure ease of completion by physicians and limited effect on physician workflows. The Expert Advisory Committee should make efforts to limit the number of special authorization forms physicians are required to complete on behalf of their patients.

Rationale: Completion of forms for special authorization limits the time available by physicians to attend to their patients. Many patients who are prescribed drugs requiring special authorization are seniors or on fixed incomes and are unable to afford paying for completion of their forms.

Some literature indicates that having a requirement for special authorization may decrease utilization of a drug indicated for optimal therapy (Sheehy O, LeLorier J. et al, "Restrictive access to clopidogrel and mortality following coronary stent implantation." *CMAJ* 2008; 178: 413-20).

PROMOTION OF PRESCRIPTION DRUGS

RECOMMENDATION # 21

The prohibition of direct-to-consumer advertising (DTCA) for prescription drugs should continue to be enforced in Canada. Restrictions on direct-to-consumer advertising should be strengthened to include restrictions on reminder ads. The Government of Alberta should publicly support such initiatives.

Rationale: Direct-to-consumer ads have been shown to increase utilization of drugs without improvement in patient outcomes. Governments should not promote activities that increase health care costs without demonstrated benefits. Current restrictions on DTCA are poorly monitored and enforced.

RECOMMENDATION # 22

Health Canada should appoint a watchdog to oversee and regulate drug manufacturers' promotional activities to the public, to prescribers and to all other health care providers.

Rationale: Drug promotion to health professionals in Canada is currently weakly regulated, with few incentives for compliance and a low risk for prosecution when violated. The Pharmaceutical Advertising Advisory Board (PAAB) provides voluntary pre-screening of prescription drug advertisements but this body lacks real authority. Its activities are often not transparent and enforcement of its guidelines is felt to be limited. A new public agency to replace the activities of PAAB would greatly improve this process.

RECOMMENDATION # 23

The AMA supports Canadian Medical Association (CMA) guidelines on appropriate relationships between physicians and the pharmaceutical industry and encourages other health care providers to adopt similar guidelines.

Rationale: The CMA recently revised its guidelines for relationships between physicians and the pharmaceutical industry. The AMA supports the principles enshrined within this document for physicians. With other health care professions becoming involved in prescribing, it is essential that they adopt similar guidelines to provide leadership to their members in prescribing activities.

RECOMMENDATION # 24

AHW, in conjunction with the AMA and other health professional organizations including, but not limited to, the College and Association of Registered Nurses of Alberta, the Alberta College of Pharmacists, the Canadian Association of Chain Drug Stores and the College of Physicians and Surgeons of Alberta, should develop and provide accurate, unbiased prescription drug information to patients.

Rationale: Currently, there is no common, independent source of drug information readily available to prescribers and patients to assist in making informed drug decisions. Developing a source of reputable, unbiased information to assist physicians and patients will require government support and the assistance of professional bodies and aid in informing best practices in prescribing.

PROFESSIONAL ROLES IN PRESCRIBING

RECOMMENDATION # 25

The right to prescribe medications independently for medical conditions must be reserved for qualified practitioners who are adequately trained to take a medical history, perform a medical examination, order and interpret appropriate investigations and arrive at a working diagnosis. Expansions in prescribing scopes of practice by health care professionals outside of traditional physician prescribing should be evaluated to ensure that outcomes demonstrate the safety of such practices and improved system efficiency.

Rationale: The AMA supports the rights of all professions to determine their own scopes of practice. However, multiple expansions of prescribing privileges can contribute to fragmentation of care, confusion as to who is managing a patient's ongoing care and a resultant increased risk to patient safety. Proposed expansions to prescribing privileges must be carefully considered and evaluated to ensure the best outcomes for our patients.

RECOMMENDATION # 26

Delegated professional prescribing is acceptable provided that:

- It is part of a multidisciplinary practice (i.e., takes place in the physician's office or as part of a virtual team), and
- The multidisciplinary practice is led by a clinical team leader with independent prescribing authority who has ultimate responsibility for patient care and is the best-trained generalist

Rationale: Delegated prescribing is acceptable but should follow the guidelines for collaborative practice outlined in the CMA document, approved in August 2007. There must be clear lines of communication, and roles and responsibilities within the team must be understood by all.

NATIONAL PHARMACEUTICALS STRATEGY)

RECOMMENDATION # 27

The National Pharmaceuticals Strategy (NPS) Ministerial Task Force must honor its 2004 commitment to include meaningful physician input in the development of its policies and recommendations. Should the task force not come forward with any meaningful timetable for moving forward with its mandate, the Alberta government should take steps to proceed with a provincial catastrophic drug coverage policy for the citizens of Alberta.

This policy should also address issues of coverage for high-cost drugs (as is currently funded through Province Wide Services). Such a program should be developed with input and dialogue from physicians, other health professionals and public representatives.

Rationale: Since the NPS task force was struck in 2004, there has been little progress in its mandate to develop a national pharmaceutical strategy. Similarly, there has been little effort to date to involve organized medicine in meaningful consultation towards meeting its objectives. With little evidence that this process is moving forward, the government should move forward to ensure that Albertans are protected from the burdens of catastrophic drug costs.

RECOMMENDATION # 28

The National Pharmaceuticals Strategy (NPS) Ministerial Task Force must expediently develop positions on the remaining four focus areas: physician prescribing behavior and optimal drug therapy, e-prescribing, generic drugs, and improving analytic capability.

Rationale: The first progress report of the NPS task force released in September 2006 addressed only five of the original action areas in its mandate. It is imperative that the task force move forward towards addressing all of the actions set forward for a national pharmaceutical strategy. Improvements in the above areas will facilitate better care and assist in addressing rising drug costs.

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