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March 14, 2019

The Honorable Maggie Carlton, Chair
The Honorable David Santiago, Vice Chair
National Council of Insurance Legislators
Workers' Compensation Insurance Committee
National Council of Insurance Legislators
2317 Route 34, Suite 2B,
Manasquan, New Jersey 08736

Dear Assemblywoman Carlton and Representative Santiago:

On behalf of the American Medical Association (AMA) and its physician and student members, I am writing to state our concern with the National Council of Insurance Legislators' (NCOIL) current draft of the "Model Workers' Compensation Drug Formulary Act" (draft model act). Our primary concern is that the draft model act will impede access to needed treatment for patients and will establish unnecessary barriers to medically necessary care.

The AMA shares NCOIL's concerns about the rising cost of prescription drugs, including in the workers compensation program. However, we feel those issues are best addressed through more comprehensive and targeted legislative approaches. We are concerned that the draft model act, as written, may be too blunt of a tool to prevent patient harm.

As you move forward, we urge you to consider that medication costs are only part of the larger issue of health care costs. Limiting access to higher cost drugs is not necessarily a cost-saving strategy. Timely access to appropriate medication may allow individuals to return to work earlier after an injury, reduce emergency room visits or prevent continuous physician visits for conditions or symptoms that are exacerbated by poor medication adherence. As such, the AMA encourages NCOIL to incorporate more streamlined "N" drug request and appeals processes in this model act that will prevent delays in access. For example, five days, as outlined in the draft model act, is simply too long for a patient to wait for an employer's decision. As such, we ask that NCOIL consider establishing a maximum of 72 hours for non-urgent care and 24 hours for urgent care determinations.

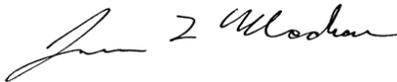
Finally, while we do not oppose the use of formularies, ultimately, health care decisions should be left to the patient and his or her physician. An employer's evaluation should never replace a

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physician's clinical judgment. To help physicians and patients make informed decisions, cost and formulary information should be available to physicians and patients at the point-of-care.

The AMA looks forward to working with NCOIL to improve this draft model act to ensure that patients have access to needed medications. If you have any questions, please contact Daniel Blaney-Koen, Senior Legislative Attorney at daniel.blaney-koen@ama-assn.org or (312) 464-4954 or Emily Carroll, Senior Legislative Attorney at emily.carroll@ama-assn.org or (312) 464-4967.

Sincerely,

A handwritten signature in black ink, appearing to read "Jim L. Madara".

James L. Madara, MD

Attachments: AMA policies on drug formularies

AMA formulary policies

Managed Care Cost Containment Involving Prescription Drugs H-285.965

(1) Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influence on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.

(2) Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

(3) Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Physician penalties for non-compliance with a managed care formulary in the form of deductions from withholds or direct charges are inappropriate and unduly coercive. Prescriptions should not be changed without physicians having a chance to discuss the change with the patient.

(4) Managed care plans should develop and implement educational programs on cost-effective prescribing practices. Such initiatives are preferable to financial incentives or pressures by HMOs or hospitals, which can be ethically problematic.

(5) Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient, so that the patient can decide whether to pay out-of-pocket.

(6) Research should be conducted to assess the impact of formulary constraints and other approaches to containing prescription drug costs on patient welfare.

(7) Our AMA urges pharmacists to contact the prescribing physician if a prescription written by the physician violates the managed care drug formulary under which the patient is covered, so that the physician has an opportunity to prescribe an alternative drug, which may be on the formulary.

(8) When pharmacists, insurance companies, or pharmaceutical benefit management companies communicate directly with physicians or patients regarding prescriptions, the reason for the intervention should be clearly identified as being either educational or economic in nature.

(9) Our AMA will develop model legislation which prohibits managed care entities, and other insurers, from retaliating against a physician by disciplining, or withholding otherwise allowable payment because they have prescribed drugs to patients which are not on the insurer's formulary, or have appealed a plan's denial of coverage for the prescribed drug.

(10) Our AMA urges health plans including managed care organizations to provide physicians and patients with their medication formularies through multiple media, including Internet posting.

(11) In the case where Internet posting of the formulary is not available and the formulary is changed, coverage should be maintained until a new formulary is distributed.

(12) For physicians who do not have electronic access, hard copies must be available.

Drug Formularies and Therapeutic Interchange H-125.991

It is the policy of the AMA:

(1) That the following terms be defined as indicated:

(a) Formulary: a compilation of drugs or drug products in a drug inventory list; open (unrestricted) formularies place no limits on which drugs are included whereas closed (restrictive) formularies allow only certain drugs on the list;

(b) Formulary system: a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care;

(c) Pharmacy & Therapeutics (P&T) Committee: an advisory committee of the medical staff that represents the official, organizational line of communication and liaison between the medical staff and the pharmacy department; its recommendations are subject to medical staff approval;

(d) Therapeutic alternates: drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;

(e) Therapeutic interchange: authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system; and

(f) Therapeutic substitution: the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber.

(2) That our AMA reaffirms its opposition to therapeutic substitution (dispensing a therapeutic alternate without prior authorization) in any patient care setting.

(3) That drug formulary systems, including the practice of therapeutic interchange, are acceptable in inpatient hospital and other institutional settings that have an organized medical staff and a functioning Pharmacy and Therapeutics (P&T) Committee, provided they satisfy the following standards:

(a) The formulary system must:

(i) have the concurrence of the organized medical staff;

(ii) openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;

(iii) have policies for the development, maintenance, approval and dissemination of the drug formulary and for continuous and comprehensive review of formulary drugs;

(iv) provide protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;

(v) provide active surveillance mechanisms to regularly monitor both compliance with these standards and clinical outcomes where substitution has occurred, and to intercede where indicated;

(vi) have enough qualified medical staff, pharmacists, and other professionals to carry out these activities;

(vii) provide a mechanism to inform the prescriber in a timely manner of any substitutions, and that allows the prescriber to override the system when necessary for an individual patient without inappropriate administrative burden;

(viii) provide a mechanism to assure that patients/guardians are informed of any change from an existing outpatient prescription to a formulary substitute while hospitalized, and whether the prior medication or the substitute should be continued upon discharge from the hospital;

(ix) include policies that state that practitioners will not be penalized for prescribing non-formulary drug products that are medically necessary; and

(x) be in compliance with applicable state and federal statutes and/or state medical board requirements.

(b) The P&T Committee must:

(i) objectively evaluate the medical usefulness and cost of all available pharmaceuticals (reliance on practice guidelines developed by physician organizations is encouraged);

(ii) recommend for the formulary those drug products which are the most useful and cost-effective in patient care;

(iii) conduct drug utilization review (DUR) activities;

(iv) provide pharmaceutical information and education to the organization's (e.g., hospital) staff;

(v) analyze adverse results of drug therapy;

(vi) make recommendations to ensure safe drug use and storage; and
(vii) provide protocols for the timely procurement of non-formulary drug products when prescribed by a physician for the individualized care of a specific patient, when that decision is based on sound scientific evidence or expert medical judgment.

(c) The P&T Committee's recommendations must be approved by the medical staff;

(d) Within the drug formulary system, the P & T Committee shall recommend, and the medical staff must approve, all drugs that are subject to therapeutic interchange, as well as all processes or protocols for informing individual prescribing physicians; and

(e) The act of providing a therapeutic alternate that has not been recommended by the P&T Committee and approved by the medical staff is considered unauthorized therapeutic substitution and requires immediate prior consent by the prescriber; i.e., authorization for a new prescription.

(4) That drug formulary systems in any outpatient setting shall operate under a P&T Committee whose recommendations must have the approval of the medical staff or equivalent body, and must meet standards comparable to those listed above. In addition:

(a) That our AMA continues to insist that managed care and other health plans identify participating physicians as their "medical staff" and that they use such staff to oversee and approve plan formularies, as well as to oversee and participate on properly elected P&T Committees that develop and maintain plan formularies;

(b) That our AMA continues to insist that managed care and other health plans have well-defined processes for physicians to prescribe non-formulary drugs when medically indicated, that this process impose minimal administrative burdens, and that it include access to a formal appeals process for physicians and their patients; and

(c) That our AMA strongly recommends that the switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen be discouraged.

(5) That our AMA encourages mechanisms, such as incentive-based formularies with tiered co-pays, to allow greater choice and economic responsibility in drug selection, but urges managed care plans and other third party payers to not excessively shift costs to patients so they cannot afford necessary drug therapies.