

September 26, 2019

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

Dear Assemblywoman Carlton and Representative Santiago:

On behalf of the American Medical Association (AMA) and its physician and medical student members, thank you for the opportunity to comment on the Second Draft of the National Council of Insurance Legislators' (NCOIL) proposed "Model Workers' Compensation Drug Formulary Act" (draft model act). The AMA appreciated the opportunity to provide comments at this year's NCOIL Summer Meeting, and the comments below represent select recommendations to strengthen the draft model act.

The AMA's recommendations reflect three main priorities: (1) ensuring that treatment decisions are made between the patient and his or her physician; (2) conducting reviews of treatment decisions in a timely manner by a physician; and (3) ensuring that formularies provide clear and transparent information to help the physician make informed decisions. The AMA encourages NCOIL to take additional time to review these and other amendments offered by stakeholders. Multiple potential amendments were discussed at the NCOIL Summer Meeting that appeared to be favorably received from the Workers Compensation Insurance Committee. The AMA strongly believes having a second public hearing to further discuss specific language and amendments would be beneficial.

With respect to the draft model act under current consideration, as a threshold measure, the AMA seeks changes to the draft model act language that inserts the employer between the patient and physician relationship. Treatment decisions must be focused on the patient's medical history and diagnosis. Coverage decisions are inherently different. We understand and share NCOIL's goal in wanting to reduce health care costs, and we are sympathetic to an employer's role as a purchaser of health care insurance for its employees. Employers, however, do not have the medical training or other necessary information or background to make informed decisions about a patient's health care.

Similarly, accrediting organizations perform valuable services for states, but making individual treatment decisions is far outside of their area of expertise. Thus, the AMA has provided language below to streamline the formulary review and appeals process to provide a clear, medically-based structure to ensure expediency, fairness and patient safety.

Finally, a formulary must have sufficient choices for the patient—to ensure that patients have access to necessary medication. This includes ensuring the formulary is online and accessible by the patient and physician at the point of care and clearly identifying which medications are preferred or "N" drugs and

what utilization management controls may be present for each medication. This includes establishment or reliance on a **conflict-free** Pharmacy and Therapeutics Committee to evaluate the formulary. In addition, the AMA recommends additional information be provided to patients and physicians concerning the medications and any utilization management controls.

Therefore, we urge your consideration of the following revisions to Sections 3 and 4 of the proposed draft model act:

In Section 3, the AMA recommends addition of the following provisions:

- (A) It is the intent of the Legislature that the [insert appropriate state agency/department] select a nationally recognized, evidence-based drug formulary, for use in the workers' compensation system. Such formulary shall apply to prescription drugs that are prescribed and dispensed for outpatient use in connection with workers' compensation claims with a date of injury on or after [insert date]. The drug formulary shall not apply to care provided in an emergency department or inpatient setting.
- (1) The [insert appropriate state agency/department] shall have its Pharmacy and Therapeutics (P&T) committee or similar advisory committee conduct a quarterly review of the formulary as part of the selection process.
- (2) The P&T Committee or similar advisory committee or committees shall be comprised of practicing health care professionals who are not employees of the national formulary or the [insert appropriate state agency/department] and who, collectively, have current knowledge and expertise in: (a) clinically appropriate prescribing, dispensing and monitoring of outpatient prescription drugs; and (b) drug use review, evaluation and intervention.
- (E) The [insert appropriate state agency/department] shall [quarterly ~~annually~~] review updates issued by the formulary publisher to the selected formulary. At least sixty (60) days prior to the [insert appropriate state agency/department] implementing the updates, the [insert appropriate state agency/department] shall communicate the updates to the physicians treating patients in the [insert appropriate state agency/department] system as well as the patients receiving care through the [insert appropriate state agency/department]. Updates subject to this provision shall include:
- (1) Medications that have been added and/or removed from the formulary as well as the reasons for the addition and removal of the medications;
- (2) What, if any, changes to the utilization management controls have been placed on each medication in the formulary; and
- (3) Notice that the changes will not go into effect until sixty (60) days from the date that the [insert appropriate state agency/department] sent the required information.

- (F) The [insert appropriate state agency/department] shall ensure that the current nationally recognized, evidence-based prescription drug formulary is available through its publicly accessible Internet website for reference by physician and the general public.
- (1) The formulary shall be updated on a monthly basis and contain an accurate, up-to-date and searchable list of all drugs. A written copy of this information shall be available upon request.
 - (2) The formulary shall state, in plain language, for each specific drug, any financial or utilization management controls required by the [insert appropriate state agency/department].
 - (3) The formulary shall include in both its electronic and print information a customer service email address and telephone number or electronic link that patients, health care professionals, and the general public may use to notify the [insert appropriate state agency/department] of inaccurate formulary information.

In Section 4, the AMA recommends the following edits:

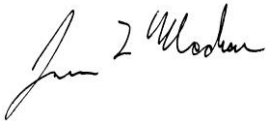
- (B) If a prescribing physician recommends that a patient receive ~~submits to an employer a request to permit use of~~ a drug or other treatment that is included but not recommended in the formulary including the prescribing physician's reason for requesting use of such drug, such request shall be reviewed by a health care professional with experience treating the same or similar condition, and if approved, the employer approves the request, the reviewing physician shall notify the medical director of the [insert appropriate state agency/department] and the prescribing physician may prescribe such drug or other treatment as approved for use by the injured employee.
- (C) If the reviewing physician ~~employer~~ does not approve the prescribing physician's request under subsection (B) to permit use of a drug that is included but not recommended in the formulary, the reviewing physician shall notify the medical director [insert appropriate state agency/department] ~~employer~~ who shall:
- (1) Notify the patient's physician that medical necessity is being questioned. Prior to issuing an adverse determination, the enrollee's physician must have the opportunity to discuss the medical necessity of the health care service on the telephone with the reviewing physician; and
 - ~~(1) Send the request to a third party that is certified by the [Utilization Review Accreditation Commission (URAC) or another Accreditation Organization] to make a determination concerning the request; and~~
 - (2) In non-urgent circumstances, the medical director must make his or her determination of coverage and notify the physician and patient within 48 hours of obtaining all necessary information to make the determination. In urgent health care circumstances, the medical director must make his or her determination of coverage and notify the physician and patient of that determination not later than twenty-four (24) hours after receiving all information needed to complete the review of the requested health care services. In emergency situations, the medical director may not deny coverage for the provision of emergency health care services

- ~~(2) — notify the prescribing physician and the injured employee of the third party's determination not more than [five (5)] business days after receiving the request.~~
- (D) If an employer fails to provide the notice required by subsection (C)(2), the prescribing physician's request under subsection (B) is considered approved, and reimbursement of the drug that is included but not recommended and prescribed for use by the injured employee is authorized.
- (E) If the medical director's ~~third party's~~ determination under subsection (C) is to deny the prescribing physician's request to permit the use of the drug that is included but not recommended on the formulary or not included in the formulary:
- (1) Prior to issuing an adverse determination, the patient's physician must have the opportunity to discuss the medical necessity of the health care service on the telephone with the physician who will be responsible for determining authorization of the health care service under review.
 - (2) Any reviewer making an adverse determination must be a physician who:
 - a) possess a current and valid non-restricted license to practice medicine in the state in which the proposed services would be provided if authorized;
 - b) be currently in active practice in the same or similar specialty as a physician who typically manages the medical condition or disease for at least five (5) consecutive years;
 - c) be knowledgeable of, and have experience providing, the health care services under review;
 - d) not be employed by the [insert appropriate state agency/department] other than to participate in the care of workers compensation patients or to perform reviews of appeals, or otherwise have any financial interest in the outcome of the appeal;
 - f) consider all known clinical aspects of the health care service under review, including but not limited to, a review of all pertinent medical records provided to the [insert appropriate state agency/department] by the patient's health care provider, any relevant records provided to the workers compensation agency by a health care facility, and any medical literature provided to the workers compensation agency by the health care provider.
- ~~(1) — the employer shall notify the prescribing physician and the injured employee; and (2) the injured employee may apply to [workers' compensation board] for a final determination concerning the third party's determination under subsection (C)~~
- (F) Notwithstanding subsections (A) through (E), during a medical emergency, an employee shall receive a drug prescribed for the employee even if the drug is a drug that is included but not recommended on the formulary

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Thank you for your consideration of these amendments to the draft model act. If you have any questions, please contact Daniel Blaney-Koen, Senior Legislative Attorney, AMA Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jim L Madara".

James L. Madara, MD