

March 13, 2019

The Honorable Chair: Asw. Pam Hunter (NY)
The Honorable Vice Chair: Rep. Tom Oliverson, MD (TX)
Health Insurance and Long-Term Care Issues Committee
National Council of Insurance Legislators
2317 Route 34, Suite 2B,
Manasquan, New Jersey 08736

Dear Assemblywoman Hunter and Representative Oliverson:

On behalf of the American Medical Association (AMA) and our physician and medical student members, the AMA offers the following comments in general support of the National Council of Insurance Legislators' (NCOIL) proposed model act, "An Act Concerning Prescription Drug Costs" sponsored by Representative Tom Oliverson, MD (TX), and co-sponsored by Senator Dan "Blade" Morrish (LA). The AMA commends Representative Oliverson and Senator Morrish for the bill's focus on the three interrelated elements of rising drug costs to the nation's health care system and consumers: drug manufacturers, health insurance companies and pharmacy benefit management companies (PBMs). The proposed NCOIL model act wisely addresses ways to increase transparency by all three stakeholders.

NCOIL's proposed model act comes at a time when state-level opposition to similar bills by one or more of these three stakeholders has typically meant defeat. While all three stakeholders have strong views and employ uncompromising lobbying efforts, the defeat of this legislation demonstrates that mere finger pointing between stakeholders does not help legislators or the public understand the root causes of rising drug prices and their effects on patients.

As a guiding principle, the AMA encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs and health insurance companies. Specifically, the AMA supports:

1. Drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase;
2. Legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and
3. The expedited review of generic drug applications and prioritized review of such applications when there is a drug shortage, no available comparable generic drug or a price increase of 10 percent or more each year or per course of treatment.

The AMA offers the following suggestions to further improve the proposed model act:

Section 4(b)(1)

The AMA recommends an amendment to Section 4(b)(1) that will allow legislators and others greater insight into rising costs for a greater number of medications. As written, this provision could leave out more modest increases that would have considerable adverse effects on patients who may not require a 30-day supply or who would be severely challenged to maintain medication adherence by more than a 10 percent increase. The AMA, therefore, recommends amending this provision as follows:

(b)(1) Not ~~less more~~ than thirty days ~~before~~ ~~after~~ an increase in wholesale acquisition cost of ~~ten (10) fifty~~ percent or greater for ~~any a drug with a wholesale acquisition cost of one hundred dollars or more for a course of treatment or for the year, a thirty day supply,~~ a pharmaceutical drug manufacturer shall submit a report to the [COMMISSIONER OF INSURANCE]. The report shall contain the following information: . . .

Section 4(b)(1)(A-F)

The AMA supports the types of information proposed to be disclosed by manufacturers as a starting point toward helping understand what currently is in a pharmaceutical manufacturer's black box. The AMA further recommends, however, that the proposed model act go much further to require disclosure of additional information that would truly open the black box of how medications are priced by manufacturers.

The AMA suggests adding the following manufacturer disclosure requirements Section 4(b)(1)(A-F):

1. The total costs of any pre- or post-clinical studies of the medication;
2. The total costs of any clinical trials of the medication;
3. The total costs associated with the preparation and submission of any regulatory documents submitted to the FDA during this reporting period;
4. The total costs of any materials, manufacturing and administration attributable to the medication for the reporting period;
5. The total amount received, itemized, from any federal, state or other governmental program(s) or any other form of subsidies, grants or other support for this reporting period;
6. Any costs associated, if relevant, to acquire the medication, including costs for the purchase of patents, licensing or acquisition of any corporate entity owning any rights to the medication while in its development or manufacturing process;
7. Any costs associated with a settlement or other agreement between manufacturers to delay introduction of a generic drug or biosimilar biological product into the market;
8. The total administrative costs for the promotion, advertising, direct-to-consumer marketing, prescriber education, professional education and all other related costs to market the medication to consumers, prescribers, health insurers or PBMs;
9. Any costs or monies provided to or received by health insurers or PBMs or other third parties, such as group purchasing organizations or wholesalers, for rebates, discounts or other financial or other consideration;
10. The total amount of financial assistance the manufacturer provides through patient prescription assistance programs, including co-pay cards/coupons;

11. The total costs associated with sample doses, trial doses or other situations where the medication is provided to a prescriber or organization but not sold; and
12. The total revenue and net profit generated from qualifying medication under this section, both within the 12-month period, and since the medication was approved by the FDA.

The AMA notes that these types of disclosures have been bitterly opposed by the pharmaceutical industry for a variety of reasons, including that it is too difficult to figure out how to report the information, or that it is proprietary and would subject manufacturers to unfair competitive disadvantages. The AMA disputes these claims and further notes that in addition to outright opposition we have not seen manufacturers provide suggestions as to what they can disclose. The AMA urges NCOIL to include strong disclosure provisions in its model act.

Section 5 Disclosure of pharmacy benefit management information

The AMA commends NCOIL for continuing its work to increase transparency and place reasonable legislative requirements on PBMs. Section 5 is a good starting point to begin to help ensure patient protections from PBM practices, but the AMA encourages NCOIL to go further. Specifically, the AMA encourages adding the following provisions, some of which also should apply to health insurers. The AMA has been dismayed by the lobbying doublespeak in other venues where the PBM says that it is simply doing the bidding of the health insurer and should therefore not be subject to reasonable oversight; and simultaneously, health insurers have claimed that they should not be held to account for actions taken by a PBM. Meanwhile, patients suffer the consequences of increased costs, medications removed from formularies without notice and considerable uncertainty that adversely affects medication adherence.

The AMA, therefore, recommends adding the following provisions in Section 5 as a matter of transparency and patient protection:

- A. Disclosure of health insurer and PBM utilization management rules:
 1. Each health insurer, PBM and their designee, if applicable, doing business in this state shall be required to provide consumers information about the required co-pays, cost-sharing, dose limits or restrictions and other information, including all applicable utilization management tools, for all prescription medication on each formulary for each health insurance product or coverage offered through the health plan, PBM and their designee.
 2. The health insurer, PBM and their designee shall be required to update this information at least once per month.
 3. The information shall be placed in a conspicuous location on the website of the health plan, PBM and their designee in a manner that is easily accessible and presented in plain language.
 4. The consumer shall not be required to create an account or enter a policy number or other contract-specific identifier to access the information.
 5. The health insurer, PBM or their designee shall include in a conspicuous place on its website a customer service email address and telephone number or electronic link that an enrollee or the general public may use to notify the health insurer, PBM or their designee of inaccurate information.

B. Notice and patient protections for changes to formularies

1. A health insurer, PBM or their designee shall be required to provide notice of at least 60 days to an enrollee prior to removing a medication from the formulary or moving a prescription medication to a different cost-sharing tier. The information shall include:
 - a. Specific changes to the cost-sharing requirements to the enrollee; and
 - b. Information on how to request an exception and the appeals process for the enrollee to remain on the same medication;
2. The requirements of this Section shall be in force for the duration of an enrollee's plan year or period of coverage, whichever is greater; and
3. A health insurer, PBM and their designee shall not adopt or implement a formulary or require co-pays or cost-sharing requirements that discriminate on the basis of health status, race, color, national origin, socioeconomic status, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health conditions. Health insurers, PBMs or their designees may be required to submit documentation explaining how they are compliant with this requirement.

The above suggestions are focused on transparency and disclosure requirements, but the AMA also wants to encourage NCOIL to take a deeper look at how health insurers and PBMs use formulary design in ways that harm patients.

For example, patients are often adversely impacted when a health insurer, PBM or their designee removes a covered prescription medication from its list of covered medications on a formulary during the enrollee's health plan year or reclassifies a medication to a higher tier. The AMA opposes this practice to move medications to a more restrictive tier or increase the amount that an enrollee must pay for a copayment, coinsurance or a deductible for prescription drug benefits, or move a drug to a higher cost-sharing tier during the enrollee's plan year. We urge NCOIL future action to address this practice.

In addition, we oppose practices by health insurers and PBMs that impose new utilization management requirements for a covered prescription medication during the enrollee's plan year. If an enrollee's health plan, PBM or their designee removes a covered prescription medication from its formulary during a plan year, or a covered prescription medication is moved to a higher cost-sharing tier during a plan year, the health plan, PBM or their designee should be required to ensure that the enrollee shall maintain access to the covered prescription medication at the same co-pay and cost-sharing obligations that the enrollee was required to pay on the date that the enrollee purchased the health plan or coverage.

This is not to suggest that new medications should not be added to a formulary, or that medication warnings from FDA should not be heeded. Rather, the AMA urges NCOIL to take additional steps beyond that of transparency to protect patients from inappropriate actions taken by health insurers and PBMs.

Section 6. Disclosure of health [CARRIER/INSURER] spending information.

The AMA generally supports the requirements in proposed Section 6 that would require disclosure by health insurers of the following:

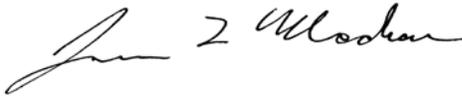
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1. The names of the twenty-five most frequently prescribed prescription drugs across all plans;
2. Percent increase in annual net spending for prescription drugs across all plans;
3. Percent increase in premiums that were attributable to prescription drugs across all plans;
4. Percentage of specialty prescription drugs with utilization management requirements across all plans; and
5. Premium reductions that were attributable to specialty drug utilization management.

We would further encourage that this information—as with all information required by the proposed model act—be audited by an independent certified public accountant who would then report the findings of the audit directly to the legislature and potentially also the state department of insurance.

The AMA appreciates the opportunity to provide these comments, and if you have any questions, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, AMA Advocacy Resource Center at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD

cc: Thomas B. Considine, NCOIL CEO
William Melofchik, NCOIL Legislative Director