AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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J. P. Wieske
Chair
Model #22 Subgroup
National Association of Insurance Commissioners
701 Hall of the States
444 North Capitol Street, NW
Washington, DC 20001-1509

Dear Mr. Wieske:

On behalf of the American Medical Association (AMA) and our physician and student members, thank you for the opportunity to comment on the current draft of the National Association of Insurance Commissioners' (NAIC) Health Carrier Prescription Drug Benefit Management Model Act (Model #22). As always, we appreciate the open process through which you and the Model #22 Subgroup (subgroup) have been revising Model #22 and the continuous opportunities you provide stakeholders to offer input. The effort to revise Model #22 is very timely, as patients are increasingly facing hurdles to timely care because of pharmacy benefit managers (PBMs) and health carrier practices such as utilization management programs. While we are strong advocates of addressing health care costs, especially pharmaceutical costs, the AMA believes that implementation of programs that have the impact of impeding patient access to medically necessary care is not an appropriate or effective way to achieve that goal. Unfortunately, that is often the basis of interaction between health carriers or PBMs and physicians.

As such, we think there is great opportunity with model legislation to improve transparency and right-size some of these PBM practices, while getting patients and their physician the information they need to make informed decisions about their health care. With that goal in mind, below are additional suggested changes to the current draft of Model #22.

Scope of Model #22

The AMA is disappointed that the subgroup has decided that PBMs will not be directly regulated under this model act. We appreciate that there may be oversight via health carriers with which PBMs have contracts. The scope of PBMs' work has significantly expanded over the last decade, however, with their "benefit management" now largely resembling the typical role of insurers including creating formularies, making coverage decisions, and determining medical necessity using utilization management tools or pharmaceutical benefit management procedures (PBMPs). As such, we feel that departments of insurance should have regulatory authority over PBMs directly, as they do over insurance companies and urge you to reconsider regulation of PBMs under Model #22.

Under Section 4, the applicability and scope of Model #22 should not be limited to just outpatient prescription drugs, but to prescription drugs that are physician-administered or provided in the inpatient setting. Therefore, we suggest removing the word "outpatient" in this section. Just as patients do not only access care in one setting, and because they are subject to PBM practices across all settings, we urge the subgroup to have the model bill apply to PBMs across all patient care settings.

Conflicts of interest in P&T committees

We appreciate that the subgroup spent a good deal of time debating the make-up of a pharmacy and therapeutics committee (P&T committee) with the goal of preventing conflicts of interest while ensuring the expertise and clinical independence of the members. While some positive changes have been made, the AMA still has concerns about the P&T committee guidelines in the draft of Model #22 and their ability to prevent conflicts of interest in the development of formulary and other utilization management programs. To address some of these concerns, the AMA suggests the following changes to Section 5:

- Under Section 5(B)(1), health care professionals who are developing and maintaining formularies and other PBMPs should not be employees of the health carrier or the PBM.
- Language in Section 5(B)(3) should clarify that conflicts of interest with respect to a health carrier include a conflict of interest with the PBM that manages the health carrier's pharmaceutical benefit. (e.g. "….address potential conflicts of interest that members of the P&T committee may have with the carriers *and its designee*, and any pharmaceutical developer or manufacturer…")
- At least 50 percent of the of the P&T members should have no conflict of interest with respect to the health carrier and its designees and any pharmaceutical developer or manufacturer, rather than only 20 percent as in the current draft.

The AMA urges the subgroup to make these changes to ensure that patients' interests are placed above any type of potential financial or other conflict of interest.

Mid-year formulary and PBMP changes

The AMA disagrees with the subgroup's decision not to include a prohibition on mid-year formulary and PBMP changes by the health carrier or the PBM, and we urge you to reconsider. We believe that holding health carriers and PBMs accountable for providing the coverage they promised at enrollment should be a critical protection included in Model #22. Currently, for patients and physician prescribers, it is a moving target throughout the year as to what drugs will be covered under the patient's plan and what restrictions around coverage will be in place. The system of rebates and the lack of transparency that makes up the PBM business model lead to regular, disruptive changes in formularies and PBMPs, and have direct and consequential effects on patient care. We again urge you to restrict mid-year formulary and PBMP changes under this model bill.

If the subgroup does not establish such protection in the version of final Model #22, we urge stronger notification requirements to both patients and prescribers of formulary changes and stronger continuity of care requirements. For example, under Section 6(C)(1), we think it is important that insurers and PBMs provide *both* a 60-day notice of a change in the formulary to patients and coverage of refill for the enrollee for at least 60-days once they are notified.

Moreover, we suggest that the 60-day notice should be provided to all enrollees of the health plan and contracted prescribers, rather than just those enrollees "impacted by the change." Many patients may not be currently taking the targeted medication when the change occurs, but are counting on its availability for future use (e.g. patients with seasonal allergy medication, psoriasis, sleep apnea, anxiety, migraines, severe allergic reactions, asthma, etc.) Additionally, we urge you to add a requirement under Section 6(C) that prohibits formulary changes when the notice requirements have not been met.

Transparency of formulary information

Although Section 6 of the current draft of Model #22 has been discussed at length by the subgroup and stakeholders, the AMA still feels that the current language does not capture the transparency sought by the subgroup. As drafted, we are concerned about patients' ability to select health plans based on their health care needs.

The AMA suggests the following edits to improve the transparency of the formulary information under Model #22:

- Under Section 6(A)(1)(c), it is still unclear as to how formulary information will be made available to patients in a clear, meaningful way. At a minimum, we think there needs to be greater clarity as to how the patient can access the documents outlining the formulary information and how a patient can access any documents containing PBMP requirements. We also think it is critical that such documents be linked to one another and that each clearly states that additional documents have information regarding their prescription drug coverage.
- We also feel that it is going to be very difficult for patients to determine the scope of prescription drug coverage under a certain plan without being able to search for the type(s) of drugs they may need. Simply being able to search for a drug by name is insufficient for the purposes of helping patients select the best plan for their needs.
- Under Section 6(A)(4)(a), we suggest that there be more specificity about what information must be available to consumers. Specifically, the Model #22 should require that the *amount* of the prescription drug copayment; the *amount* of the prescription drug coinsurance; and the *amount* of any cost sharing difference between the days' supply of the prescription drug be available.
- Under Section 6, current language leaves the health carrier essentially in charge of monitoring whether it is in compliance with the transparency requirements. In addition to this self-monitoring provision, we suggest that audits by the departments of insurance be required to help determine if health carriers are meeting these standards.
- The AMA feels that Section 6(D) of the draft Model #22 is repetitive and does not lend itself to greater transparency for patients. Therefore, we suggest removing it.

Utilization management or pharmaceutical benefit management programs (PBMPs)

Utilization management programs, or PBMPs, applied to prescription drugs by health carriers and benefit managers often threaten access to timely care for patients and create significant administrative burdens on physician practices. The AMA feels there are still a number of changes to be made to the draft of Model #22 that could be made to ensure patient access to care:

- In order to comprehensively address utilization management tools used by health insurers and PBMs, the definition of PBMP should include "quantity limits," "pharmacy restrictions," and "any other utilization management tools identified by the commissioner."
- Under the current Section 5(F)(2), we ask that the subgroup reconsider allowing health carriers and their designees to charge covered persons different cost-sharing amounts based on the distribution method used to obtain a prescription drug. We believe that without this change, patients may be unfairly penalized for accessing a covered drug in a manner most accessible and beneficial to them, including at a brick and mortar pharmacy where they have access to pharmacists with whom they can discuss questions about their prescription.
- Under Section 7, we suggest identifying a restriction on "dose strength" as a PBMP that allows for an exception process under and throughout this Section.
- Under Section 7(A)(2), we think that patients should have the opportunity to appeal for not just continued coverage, but coverage "at the same cost-sharing level," and urge the subgroup to clarify that.
- Under the same section, we have concerns about formulary and PBMP changes in the name of "safety." It is not clear what the result would be, for example, if the U.S. Food and Drug Administration issued a black box warning for a particular drug but did not remove it from the market. While the warning indicates greater safety precautions are necessary, the drug remains available. Would this constitute sufficient grounds for a health carrier or PBM to remove the drug from the formulary? We think there are many instances where safety concerns may arise for certain populations, but removing a drug from the formulary or restricting access for all enrollees would be unjustified.
- In order to allow a prescriber to submit information that he/she deems relevant to establishing medical necessity without allowing health carriers to require more than is intended in this section, we suggest removing Section 7(B)(2)(b)(vi) and adding a Section 7(B)(2)(c) that states: "A prescriber may submit additional information he/she deems necessary to establishing medical necessity for the purposes of the request."
- Under Section (7)(C), we urge the subgroup to consider the importance of having a health care professional with the same training and within the same specialty as the prescriber to review the request. The current language indicating it must be reviewed by an "appropriate health care professional" allows health carriers and PBMs far too much leeway and could truly result in patients being inappropriately denied needed care.

Oversight and disclosure

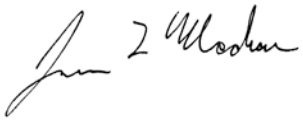
The AMA sees a number of missed opportunities in the bill to require greater oversight of the requirements in Model #22, or at least allow for commissioners to exercise greater oversight authority when appropriate:

- While we are glad to see nondiscrimination language included in Model #22, we are concerned that Section 8 does not have the teeth necessary to prevent discrimination in prescription drug benefits. At a minimum, we would urge the subgroup to include language to allow regulators to regularly review P&T committee decisions/information to determine compliance with the requirements of this section.

- Under Section 9, we also suggest a provision to allow commissioners to collect information from plans on formulary and PDMP changes throughout the year, to help departments of insurance better assess the frequency and patient impact of these changes.
- Under Section 11(A)(1), it is important that disclosure include the actual formulary and PBMP information, and therefore we suggest removing the language "existence of the" and "that there may be" in order provide the patient with the most useful information.
- Under Section 11(A)(2), disclosure should include any PBMP requirement that is subject to the medical exception process, not just dose restrictions or step-therapy requirements.
- Under Section 11(B)(1), required language of the health carrier should clarify where a patient can access benefit information electronically and in print, and should also require that a health carrier provide a toll-free number for patients to contact them.

Thank you again for giving the AMA the opportunity to share its thoughts concerning the subgroup's discussions on this Model Act. Please contact Emily Carroll, Senior Legislative Attorney, at (312) 464-4967 or emily.carroll@ama-assn.org, or Daniel Blaney-Koen, Senior Legislative Attorney, (312) 464-4954 or daniel.blaney-koen@ama-assn.org, if you have any questions or comments.

Sincerely,



James L. Madara, MD