Drug Companies and Physicians Push For Tighter P&T Committee Standards

Changes to NAIC Model Act Would Restrict Formularies, Too

Stephen Barlas

Drug manufacturers and the American Medical Association (AMA) are attempting to limit running room for P&T committees and formularies as part of their efforts to affect a revamping of the influential model act published by the National Association of Insurance Commissioners (NAIC). The NAIC’s Health Carrier Prescription Drug Benefit Management Model Act was last revised in 2003, and the NAIC asked for and has received a wide range of comments on how to modernize that act given the major changes in pharmacy benefits over the past 13 years. The NAIC model acts (on formularies, network access, etc.) sometimes serve as a kind of talisman for the Centers for Medicare and Medicaid Services (CMS), which cites them as a rationale for decisions it makes on federal pharmacy access requirements. The model acts can also serve as a cap that limits how far the CMS can go.

The NAIC subgroup responsible for sifting through already-submitted comments and moving the recommendations up the NAIC line met for the first time on February 29. Prior to that meeting, an insurance industry policy expert labeled the Pharmaceutical Research and Manufacturers of America (PhRMA) lobbying efforts as “particularly pernicious.” A PhRMA representative declined to make any comments prior to the meeting.

The CMS has frequently referred to the NAIC model act when issuing recent annual rules and call letters on the Patient Protection and Affordable Care Act (PPACA) exchange and Medicare Part D. Alluding to the 2016 final rule-setting requirements for individual and small

continued on page 260
PRESCRIPTION: WASHINGTON

continued from page 206

group plans offered on the federally facilitated exchanges, Candy Gallaher, Senior Vice President of State Policy at America’s Health Insurance Plans (AHIP), says, “We note that many of the provisions in that final rule reflect language that exists in the NAIC model act, indicating that the NAIC model act standards for prescription drug benefit management were recognized.”

However, the CMS is now undertaking what it calls an “outlier” analysis of exchange plan policies to determine whether the use of formulary techniques, such as step therapy and tiers, discriminates against certain populations. The PhRMA, whose members want formularies to offer more drugs at affordable prices, tiers be damned, has rallied patient advocacy groups, who have the same objective. Both are lobbying the NAIC to modernize its formulary model act to reflect those objectives, thinking that the CMS would then follow suit.

P&T committee membership policies are part of their focus. The PhRMA would go further by limiting to 20% the members of a P&T committee who could have any conflict of interest. The AMA thinks the 2003 model act sets the bar too low. The current language just says the members must be employees of the health carrier. The AMA wants the majority of P&T committee members to be network health care professionals who are not employees of the health carrier. So that would be a big change. The current act also says insurers must have policies that address conflicts of interest on P&T committees. The AMA-revised language would require those policies to prevent conflicts of interest and to be publicly disclosed.

Then the PhRMA sets out a long list of steps a P&T committee would have to take, including some that go far beyond what P&T committees generally do today. A headliner there would be to require coverage for each drug newly approved by the FDA until such time as the P&T committee reviews that drug for formulary inclusion. In this era of expensive specialty pharmaceuticals, that would hardly go over well with health insurers. “PCMA [Pharmaceutical Care Management Association] believes that the model act is sufficiently comprehensive in its current form. Suggesting additional regulation in the commercial marketplace, which is already feeling the strain of rising drug prices, would lead to reduced access and increased costs for consumers,” says Scott J. Kipper, Vice President of State Affairs at PCMA.

Moreover, the P&T committee would have to ensure that the formulary covers a range of drugs across a broad distribution of therapeutic categories and classes, does not discourage enrollment by any group of covered persons, and provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices. The “does not discourage enrollment …” language calls to mind the current CMS effort to institute “nondiscrimination” provisions of the PPACA where formulary policies have come to the fore.

The PhRMA would establish a whole new section in the model act dedicated only to qualified health plans offered in the federal exchange marketplace. Medical management techniques would be outlawed unless they are based on accepted best medical practice for treating any disease, condition, or category of patients, and unless they are published in peer-reviewed medical journals or adopted as standards of care by medical specialty societies.

Not only would PhRMA dictate when medical management techniques could be used, it would also include language in the model act that required a state insurance commissioner to develop standards related to the plan’s formulary, such as the number of drugs available in each category or class and the availability of appropriate drug classes to treat certain diseases.

It normally takes the NAIC a year or so to finalize changes to a model act, so the race is on.

REFERENCES
