HHS Proposes Formulary Changes For Marketplace Health Plans

P&T Committees Would Take On a More Visible Role

Stephen Barlas

It isn’t often that federal officials shine a spotlight on P&T committees. But the glare bouncing off the proposed changes to the pharmacy benefit required for marketplace plans in 2016 is positively blinding. If finalized, it will require qualified topics inside the Beltway.

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Marketable Formularies Draw Complaints

Physicians, enrollees, and pharmaceutical sector players ranging from pharmacists to manufacturers to PBMs have complained about the somewhat arcane drug access rules the HHS imposed in 2014. "The CMS proposal to ensure that long-acting medications are adequately addressed is important for conditions such as chronic atrial fibrillation, hypertension, attention deficit disorder, and other chronic conditions," Dr. Hofford says. "This is important to improve patient compliance and outcomes.

Physicasts are one of 10 categories of essential health benefits (EHBs) that QHPs must provide. The HHS previously set up a rather unconventional formulary requirement compared with common practice. Plans could choose to cover whichever was greater: one drug per USP category or class, or the same number of drugs in each USP category and class as a state’s EHB benchmark plan.

That drug-count requirement was foreign to the way health plans and PBMs had been doing business. They depend on P&T committees solely in charge of QHP formularies would be "a step backward, leaving fewer protections for consumers when more are sorely needed."

Kris Haltmeyer, Vice President of Health Policy and Analysis for the Blue Cross Blue Shield Association, says the proposed conflict-of-interest standards would be difficult, if not impossible, to implement. "Instead, P&T committee standards should follow those that are already in place and working, such as NCQA or URAC standards," he adds.

Andy Behm, Vice President of Clinical Evaluation and Policy for Express Scripts, supports giving a P&T committee total freedom to develop a formulary; it is current industry practice in the commercial marketplace, he states. But he thinks that the conflict-of-interest requirements, which his national P&T committee essentially meets already, need to be made more specific, and perhaps tougher.
Express Scripts uses the USP methodology to create its health care reform formularies; however, it relies on its P&T committee alone to establish the national formularies that serve the vast majority of its members. “The greater of USP versus benchmark had never been in practice,” Behm explains. “HHS established the standard to put their stamp on the program. Realizing now how cumbersome the greater than rule is to administer, HHS appears to be looking to revisit the rule.”

**USP Versus AHFS**

Behm favors dropping any drug-count requirement, including the new drug-count option the HHS is considering tied to the AHFS, which is published by the American Society of Health-System Pharmacists. “We do fine with P&T committee only,” he states. If the HHS decides it wants to keep a drug-count option, he prefers the USP to the AHFS. Both formulary lists have shortcomings, however. The USP categories were developed with the Medicare population in mind, so they pose problems for nonseniors with nonsenior ailments. Obesity medications are statutorily excluded, for example. Moreover, the categories are updated only once every three years.

“When you look at the USP, there are 168 classes and categories; in AHFS, there are nearly 400,” explains Behm. “By continuing to require additional categories, the formulary process can become more of a quantitative than a qualitative exercise, meaning that more medications are required than are therapeutically necessary. We feel that clinical outcomes—as opposed to an arbitrary number of categories—should be the key focus.”

Oltmans wants the HHS to keep a drug-count standard and opposes a P&T-committee-only standard. However, he has problems with both the USP and AHFS methodologies. “In terms of which classification system to use, we urge HHS to establish a system specifically designed for this purpose and population, much like was done at the beginning of the Part D benefit with the creation of the USP Model Guidelines,” he says. “We believe creating a classification system specifically for this purpose will address the shortcomings of using either American Hospital Formulary Service (AHFS) or the Part D-focused USP classification system.”

**New P&T Committee Standards**

Whether it keeps a drug-count standard or not, the HHS is certain to elevate the stature of P&T committees, either by giving them sole responsibility for establishing a formulary, by shining a brighter light on their operations, or both. A couple of key elements of the HHS’s proposed changes are likely to become lightning rods. One would set categories of health professionals who would have to be represented on a committee. A majority of those sitting on the committee would have to be practicing physicians, practicing pharmacists, and other practicing health care professionals. The membership should include “experts in chronic diseases and in the care of individuals with disabilities.” The other standard would dictate conflict-of-interest requirements, including one related to the “independence” of some members. There, the HHS suggests that 20% of the members on a committee be totally free of financial ties to the health plan, drug companies, or any other supplier to the QHP.

A 2013 report from the HHS Office of Inspector General (OIG) suggested new requirements on independence for the P&T committees at Part D drug plans, which the HHS has so far declined to make. So it is notable that the HHS picked up the thread of that OIG recommendation and wants to weave it into marketplace plans in 2016.

The remaining 80% of members of the P&T committee who would not have to be independent, according to the HHS preliminary proposal, could have commercial links to the QHP and its suppliers. They could not vote in committee meetings when those conflicts came into play. The P&T committee would be responsible for defining a reasonable definition of conflict of interest and for managing the conflicts of interest of its committee members. Members of the committee would have to disclose financial arrangements with the health plan and any drug manufacturer.

Greg Low, RPh, PhD, Program Director of MGPO Pharmacy Quality and Utilization Program Performance Analysis and Improvement at Partners HealthCare, sits on two P&T committees. The first was established by Massachusetts General Hospital, one of the seven hospitals that make up Partners. The second is the P&T committee for the health plan offered to all employees at those seven hospitals. Partners did not offer a marketplace plan until it recently bought Neighborhood Health Plan of Massachusetts, which has a marketplace plan, but Dr. Low is not involved with that enterprise.

Dr. Low runs the employee health plan P&T committee, where members must disclose financial information, including honoraria they receive and stock they hold. He says he cannot remember a time when any physician had a conflict of interest on any vote. The employee committee has seven voting physicians and three voting pharmacists, plus three additional nonvoting pharmacists who provide content and staff support. Lack of conflicts may have something to do with the fact that primary care physicians are much less likely to have financial ties resulting from drug development. Partners’ policy allows a conflicted member to participate in the discussion as long as he or she doesn’t vote, the conflict was disclosed, and the member has expertise beneficial to the decision.

Partners’ P&T committee calls in specialists to talk about whether a new oncology, psychiatric, or other chronic-condition drug should be placed on the formulary, and if so on what tier. These specialists must disclose potential conflicts, too, whether they appear before the committee in person or provide comments via email. “Sometimes you have to repeat a request to a specialist for financial information but I have never had one refuse to provide financial information,” he says.

Not everyone agrees with Partners’ exclusion of specialists from its P&T committee. Dr. Low justifies it by saying: “You need people who know the right questions to ask… It’s usually not a good use of a urologist’s time to review a cardiology drug and vice versa. The primary care physicians, pharmacists, and nurses (they serve only on the Massachusetts General Hospital P&T committee) who have experience with the committee have learned the questions to ask: about a drug’s role in therapy, how it will be used, how it will be supplied, what the side effects are, if there is abuse potential, whether prescribing should be limited to selected groups, and so on.”

Express Scripts has specialists on its committee. Behm says...
the company’s model has worked well because all members are fully engaged—not just in their areas—and are willing to pick at the evidence base. “I think we are best in class,” he says. But he thinks it is important to have voting specialists because of the predominance of specialty drugs among those newly approved each year by the FDA, a significant percentage of which are orphan drugs. Still, he doesn’t think there is anything wrong with a committee like Partners’ that uses only primary care doctors, as long as it has access to outside specialists.

None of the 16 members of the Express Scripts committee is an employee of Express Scripts and none has a conflict of interest with Express Scripts, so they are independent. Prior to every meeting, the 16 committee members present up-to-date financial data to a three-person subcommittee about potential conflicts of interest they may have with pharmaceutical manufacturers. Members are asked to disclose payments for speaking at a meeting, serving on an advisory board, any honorarium gift over $50, stock holdings, etc. The subcommittee then decides whether any member is too conflicted to vote on a particular issue. “The subcommittee interprets ‘conflicts’ very conservatively, so that almost all relationships, even something minor like a $50 gift card, constitute a conflict in our eyes,” says David Whitrap, an Express Scripts spokesman. “If the subcommittee confirms that the conflict does exist, they disqualify that P&T member from voting, or even from being present during the final discussion and vote.”

The Express Scripts requirements for its P&T committee members appear to go beyond what the HHS is proposing. Behm believes there may be a bit too much latitude in the proposed conflict standards. “As the guy who has to answer questions that arise with regard to the bias of our P&T committee, I think some additional detail wouldn’t be harmful. A little more transparency could be good for the industry as a whole.”

Others argue the HHS proposal goes too far. “HHS has already deemed NCQA, URAC, and AAAHC as qualified accrediting bodies for QHP issuers operating on the exchanges,” states Daniel T. Durham, Executive Vice President of Policy and Regulatory Affairs for America’s Health Insurance Plans. “These organizations currently have standards in place that address P&T committees. Therefore we recommend HHS defer to these accrediting body standards to avoid inconsistencies across markets. This would support a flexible approach to P&T committees that would allow for issuers to make formulary changes in a timely manner to address up-to-date evidence on drug safety and efficacy.” NCQA is the National Committee for Quality Assurance, URAC is a health accreditation body, and the AAAHC is the Accreditation Association for Ambulatory Health Care.

Exceptions Policy

The changes the HHS appears ready to make go beyond mandates on P&T committees and formulary construction. Another hotly debated topic in 2012, when the department was putting together the first iteration of pharmaceutical category rules, was the “exception” process. The issue: What should plan members and their physicians have to do to get a drug that is not on the QHP’s formulary? The HHS final rule was rather vague.

Now the HHS wants to inject clearer, more uniform standards into its exceptions policy. Current rules require plans to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. The physician has to file a request for prior authorization with the health plan. Under the current exceptions policy, an enrollee or his or her physician can request an expedited review based on exigent circumstances. Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee’s life, health, or ability to regain maximum function or when an enrollee is undergoing a course of treatment using a nonformulary drug. A health plan must answer that request within 24 hours.

The HHS wants to revamp the exceptions policy in two ways. First, it would apply the exceptions policy to standard requests for drugs not on the plan formulary, not just requests stemming from exigent circumstances. The plan would have to reply within 72 hours to a “standard” request. Then it would establish a secondary external review process available to enrollees if their plan rejected their first request—standard or exigent—for a nonformulary drug. That secondary review would be done by an independent organization accredited by a nationally recognized private accrediting organization, to be named later.

These changes don’t really address difficulties some practicing physicians face when a patient really needs an off-formulary drug immediately, as opposed to in 24 hours. This can happen in two situations. In the first, the patient changes health plans and the new plan’s formulary doesn’t carry a drug the patient received on the formulary of the prior plan. In the second, the current health plan offers one version of a drug but not a second version, typically a longer-lasting form of the drug, which is more expensive.

Dr. Hofford at the Carilion Clinic frequently encounters both situations. His patients are members of about 30 plans, whether marketplace, Medicare Part C (Medicare Advantage) or Part D, or Medicaid. In one recent instance, a new insurance plan did not provide on its formulary for long-acting amphetamine/dextroamphetamine (Adderall XR, Shire), which a patient had been taking with good results on his old plan. Dr. Hofford called the new health plan to get prior authorization. It was not forthcoming for seven days. “The plan only wanted to pay for short-acting generic Adderall,” he explains. Because it is a Schedule II controlled substance, Adderall must be kept under lock and key at school. The child must be called out of class to receive it, and the short-acting dose (given twice a day) can wear off before the next dose is due. The difference in cost between short- and long-acting Adderall is about $75 a month versus $150 a month, depending on the health plan. Pediatric and child psychiatric organizations and others recommend not using the short-acting version at school to get the most benefit.

Another incident involved an insurance company’s refusal to allow the clinic to prescribe enoxaparin sodium injection (Lovenox, Sanofi-Aventis), which was off formulary, to a patient with blood clots in his legs, and administer it in the office. The practice sent this patient to the hospital. “I imagine it might cost the health plan several thousand dollars a day for that in-patient care,” Dr. Hofford states.

Dr. Hofford uses EPIC electronic health record software,
so when he sees a patient, the patient’s health plan pops up on
Dr. Hofford’s computer screen, along with its formulary. But the
formulary drug listings are often inaccurate. “Because generic
prices have increased so much lately, formularies can change
on a monthly basis and it is difficult to keep the databases up
to date,” he states. “It is a mess.” The HHS proposal includes
a potential solution to that problem. The URL link to a QHP’s
formulary drug list would have to be up to date, which the
HHS would define as meaning the URL must accurately list
all of the health plan’s covered drugs at that time.

The number of questions raised about the HHS proposals
on formularies underlines the variety of concerns among a
broad group of interested parties about marketplace plan
drug access. Specific disease group advocates have their
own, insular concerns. For example, the American Diabetes
Association, backed by manufacturers such as Novo Nordisk,
want formularies to provide better access to insulin pens as
opposed to traditional vial-based delivery mechanisms. The
American Society of Clinical Oncology wants formularies to
have to use the National Comprehensive Cancer Network Drug
& Biologics Compendium. The list goes on. Reconciling the
varied and sometimes conflicting demands will take a Solomon.

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