Part D Changes for 2013 Will Put Pressure on P&T Committees

Drug Utilization Reviews and Medication Therapy Management Programs Under the Gun

Stephen Barlas

Starting next year, Medicare will be tightening the screws on formulary decision-makers and P&T committees for Part D drug plans. The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, is worried about abuse of controlled substances. This concern will result in a major change in operations for Medicare’s Part D drug program in 2013. Both stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage plans with a Part D component (MA–PD) will have to tighten up drug utilization reviews (DURs) for opioid analogs at a minimum and probably for all drugs. Part D plans will also have to galvanize medication therapy management (MTM) programs because the CMS will start publicizing the performance of MTM services next year.

In recent years, pharmacy professional groups have been putting increased pressure on the CMS to encourage Part D plans to expand MTM programs, with only modest success. Earlier this year, when the CMS first discussed potential changes to MTM requirements in its draft 2013 Call Letter, the CMS said it was concerned that Part D sponsors were restricting their MTM eligibility criteria to limit the number and percentage of beneficiaries who qualify for these programs and who are required to be offered comprehensive medication reviews (CMRs).

Part D plans are supposed to target beneficiaries who meet certain requirements for MTM services and then offer each beneficiary a CMR. The CMS said that sponsors should improve their targeting of beneficiaries who are most likely to benefit from access to MTM services. “The CMS requirements for targeting beneficiaries for the MTM program are the floor, and not the ceiling,” the CMS emphasized back in February.

The 2013 Call Letter touches on another hot-button issue: accountability care organizations (ACOs), which were authorized by the Patient Protection and Affordable Care Act (PPACA). ACOs are groups of physicians who take on all aspects of medical care for Medicare fee-for-service recipients, including responsibility for their hospitalizations. ACOs can earn incentive payments for keeping costs below certain thresholds. Medicare announced the names of the first 32 ACOs in December 2011. Additional physician groups will be added in the near future in a first category (Pioneer ACOs) and in a forthcoming second category (Shared Savings ACOs). Each category has slightly different ground rules. The Call Letter lists some areas in which Part D plans and ACOs can collaborate, but those suggestions are pretty weak, given the statutory prohibition that forbids ACOs from including Part D costs in their calculations.

Marissa Schlaifer, Director of Pharmacy Affairs at the Academy of Managed Care Pharmacy (AMCP), says:

In the Call Letter, CMS encourages ACOs to find Part D plan sponsor partners through a request for proposal process. I do believe that ACOs have an incentive to work with PDPs to control medical costs, including preventing readmissions. However, ACOs have no incentive to work to appropriately manage Part D utilization and may have incentives to increase Part D utilization to prevent the use of a Part B medication.

The final Call Letter was paired with a final rule—both issued in April—which suggested other changes to the Part D program in 2013. That final rule includes provisions such as a requirement that pharmacy benefit managers (PBMs) disclose certain transparency information and that Part D formularies include benzodiazepines and barbiturates. A third provision that the CMS had proposed earlier, requiring consultant pharmacists at long-term-care (LTC) facilities to be independent of LTC pharmacies, was dropped from the final rule.

The 180-page Call Letter will have a significant impact on Part D formulary policies and on P&T committee responsibilities. Almost 33 million Medicare recipients receive Part D coverage, most of them from PDPs. The largest stand-alone plans, according to the Kaiser Family Foundation, are AARP’s MedicareRx Preferred (UnitedHealthcare), Humana PDP Enhanced, CVS Caremark Value, First Health Premier, Humana Walmart Preferred, and Wellcare Classic.

None of the big players in Part D want to comment on the significance of the changes in either the Call Letter or the final rule. Sarah Bearce, spokeswoman for UnitedHealthcare Medicare and Retirement, said, “It’s difficult for us to talk specifically about 2013 plans before October 1, so we’ll have to pass.”

The most important changes for Part D pharmacy programs in 2013 are the new ground rules for DUR and MTM programs, which will require more P&T committee oversight. Medicare will raise the visibility of Part D MTM programs in 2013 by including a quality measure on its Part D Internet display page—the Pharmacy Quality Alliance (PQA)—designed Completion Rate for Comprehensive Medication Review (CMR). In 2014, the CMS will assign a star rating for each plan.

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based on its performance on CMR. Stars are awarded from 1 to 5 points, with 5 indicating excellent performance. Several Part D quality measures are currently rated. These individual ratings are converted to a total score and are used, in part, to determine bonus payments to each PDP.

Medicare clearly wants to give Part D plans a kick in the pants with regard to implementing MTM services. Plans have some flexibility in determining which members are eligible for MTM services. After this decision is made, the plan has 60 days to complete a CMR. The CMS has been unhappy with the rates at which CMRs are performed.

“The addition of CMR rates to the Medicare display page will force plans to increase the number of beneficiaries [who are] offered MTM services, which has been only 10% to 13%,” says Brad Tice, PharmD, Chief Clinical Officer of PharmMD in Brentwood, Tennessee. CMR rates are much lower, and about 1% of beneficiaries receive them.

As for new DUR requirements in 2013, the CMS wants Part D plans to inaugurate Level 3 retrospective DUR systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records.

“The approach is based on multifaceted beneficiary-level clinical assessment. Effectiveness will be highly dependent upon P&T committees and clinical case managers,” the CMS said in the Call Letter.

The CMS’ concerns about patient “doctor shopping” for controlled substances, verified in a Government Accountability Office (GAO) report in 2011, was the primary motivation for this forced expansion of DUR policies. The CMS expects Level Three controls to be applied to opiates in 2013, but the agency also thinks that PDPs need to expand DURs for all medications, and soon. (MA–PDs, of course, are in a better position to do that.) There will probably be more specific language to that effect in the 2014 Call Letter.

Of all the issues mentioned by the CMS in both the Call Letter and the final rule, the most controversial is the admonition about DURs. In the draft Call Letter published in February, the CMS angered the American Medical Association (AMA) by suggesting that DURs—even when performed to Medicare’s satisfaction—could result in the denial of medications to some Part D recipients if the “beneficiary’s prescription drug claims for opioid analgesics cannot be established as medically necessary to the plans’ satisfaction.”

The AMA hit the roof at the notion that pharmacists or nurses performing DURs at a PDP (in many cases lacking clinical data) could make a “medically necessary” decision. However, Medicare argued that PDPs have no contractual relationship with physicians like the Part D plans connected to Medicare Advantage plans. Too often the two sides go at it like the Hatfields and the McCoys.

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The agency also expects the P&T committee to develop an overall program to prevent opioid overutilization. Peter Carmel, MD, President of the AMA, says:

We are pleased that CMS listened and responded to our concerns. The AMA has made it clear that physicians, not health insurers, have the clinical knowledge and expertise to make decisions about which medications a patient should receive. The revised CMS policy will require health plan staff to communicate with physicians and resolve questions about potential overuse of medications before contemplating any changes to a patient’s prescription drug coverage.

Although the Level Three edits instituted by Medicare for 2013 are the big story and apply only to opioids, Medicare has expanded the requirements for controls in Levels One and Two; these new requirements apply to all drugs. The formal titles for those categories are:

- **Level One:** Improved Use of Concurrent Claim Edits (Safety Controls at the POS [point of service]).
- **Level Two:** Improved Use of Formulary Utilization Management Designs (QL [Quantity Limits] at POS [point of service]).

Point-of-service safety edits are limits based on such categories as therapeutic duplication, maximum dose exceeded, and refilled too soon. At Level Two, for example, the CMS emphasizes that Part D sponsors may apply quantity limits to drugs, as appropriate, for which there is no clearly defined maximum dose in the approved labeling (as with most opioids) to ensure safety; to promote cost-effectiveness through dose optimization; and to decrease fraud, waste, and abuse.

All of this technical verbiage related to DUR edits in the Call Letter skirts what many might argue is a bigger policy imperative—which the CMS might not have the authority to address: the sometimes thorny relationship between physicians who write prescriptions and Part D plan administrators who balk at filling the prescription for various reasons.

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PDPs have no contractual relationship with physicians like the Part D plans connected to Medicare Advantage plans have. Too often the relationship looks from the physician side like these are the guys that say ‘no’ to me, switch my patients from off-formulary to on-formulary, making work for me, work I am not getting paid for.

We would expect the sponsor to notify the prescriber(s) and beneficiary in writing that the rejections will begin after a reasonable period of time. In other words, if despite multiple attempts, a sponsor has been unable to work with prescribers to adjust prescribing to a safe level of dosing, the sponsor may prevent the dispensing of unsafe level of drugs.

However, if a Part D plan takes that step, the CMS wants the plan’s P&T committee to document the basis for the opioid overutilization conclusion in every case.

P&T®  June 2012  Vol. 37 No. 6

continued on page 340
P&T®

continued from page 336

PDPs have their own complaints about physicians, of course, including the profession’s occasional refusal to hand over patient clinical data that would allow PDPs to better target beneficiaries for MTM services. Part D plans are supposed to target beneficiaries with at least three or more chronic diseases who are taking more than eight prescription medications and who have Part D costs of at least $3,000 per year. Plans have flexibility as to which diseases they use to qualify beneficiaries. All plans offer CMRs at least annually, and these can be performed by telephone or in a face-to-face meeting. Plans, however, apparently have some leeway as to who might be eligible for MTM and CMRs, and plan members can decline the CMR offer anyway. The problem is that PDPs are enrolling only 10% to 13% of members in MTM programs (according to the CMS), and only 1% of those members are getting CMRs.

The PPACA mandated three components of a standardized format for the written communication of the CMR to Medicare beneficiaries: (1) a cover letter, (2) a medication action plan, and (3) a personal medication list.

The effective date for implementing these PPACA-required improvements is January 1, 2013. As for the action plan, Part D plans are required to deliver a minimum level of service, such as discussing a beneficiary’s concerns about drug therapy; collecting the purpose and instructions for using their medications; and reviewing a beneficiary’s prescription drugs, nonprescription drugs, and supplements to aid in assessing medication therapy.

But the 2013 Call Letter pushes Part D plans beyond the PPACA requirements. It expands the minimum number of disease states that the plans must use to target MTM eligibles from three to five and widens the total pool of the diseases they can choose from by adding Alzheimer’s disease, end-stage renal disease requiring dialysis, and atrial fibrillation. Instead of reaching out via passive offers only, sponsors are expected to use more than one approach, when possible, to reach all eligible targeted beneficiaries so that they can receive MTM services and a CMR. Sponsors may increase beneficiary involvement by telephoning the beneficiary after the mailing.

Medicare is concerned about low CMR rates not only for their own sake; high rates lead to other benefits for beneficiaries such as increased member adherence to medications, reduced use of high-risk medications, and optimal diabetes treatment. These, too, are “plan-rating” categories and help dictate Part D plan bonus payments. Speaking of plan ratings, Medicare will adjust the high-risk medication list based on updates to the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults (the Beers List) by the Pharmacy Quality Alliance, the National Committee for Quality Assurance, and the American Geriatrics Society.

Of course, part of the reason for Part D’s low MTM and CMR rates is that stand-alone PDPs often do not have access to all the clinical data possessed by the health plan. Marcie Bough, Senior Director of Government Affairs at the American Pharmaceutical Association (APhA), says:

"We continue to be concerned with policies that target patients based on specific conditions absent diagnosis information, as stand-alone prescription drug plans often must do. We feel great opportunities exist for improving the public’s health through MTM, but eligibility and access to health records need to be addressed. Additionally, we believe that for pharmacists to provide comprehensive medication management, the pharmacist needs access to important clinical information, such as diagnosis and laboratory values, which can be provided, in many cases, only through the patient’s health record."

The issue of collaboration also comes up in the context of Part D’s interaction with ACOs. However, the CMS seems to tiptoe around the topic. The problem, if one wants to call it that, is Congress’ statutory language in the PPACA with regard to ACOs. The ACOs are not measured by how they control Part D costs but by how they control Part A and Part B costs only. The Call Letter does nothing to change that, and it cannot. Congress would have to make a legislative adjustment; therefore, the CMS essentially has its hands tied behind its back and can offer only pablum along these lines: Medicare ACOs provide “a potential platform” for collaboration with Part D Sponsors. Because of congressional language constraints, the CMS can only “encourage” the ACOs and Part D plans to form “appropriate business arrangements” that support improved pharmacy care coordination “provided such arrangements comply with all laws and regulations.”

Jack Hoadley claims that ACOs can lower their patient costs generally by working with PDPs to improve medication adherence, especially for Part D participants with diseases such as asthma and diabetes. Better adherence means fewer visits to the emergency department, which go on the cost (savings) ledgers of the ACOs. As for the indirect benefits for the PDP, working more closely with a patient’s ACO physician, for example, by getting access to more clinical data, allows the PDP to improve its plan ratings in important areas, leading to the possibility of bonus payments.

However, the 2013 Collaboration Principles of the CMS emphasize that any data sharing must be contingent on adherence to all rules about beneficiary privacy and confidentiality, including HIPAA (the Health Insurance Portability and Accountability Act of 1996) and other applicable laws and regulations. It is not clear how large those stumbling blocks might be.

Perhaps the most surprising development for 2013 is that Medicare has ditched its proposal requiring pharmacists who consult at LTC facilities to be independent of the LTC pharmacies that provide pharmaceuticals to the nursing home or other facility. The problem is that these pharmacies provide consultant pharmacists to LTC facilities at below-cost rates and that those pharmacists, in exchange, advocate at the facilities for unnecessary and sometimes dangerous drug utilization, particularly antipsychotic agents. Medicare considered an “independence” standard for Part D plans for 2012 but then abandoned the effort, only to resurrect it in the draft 2013 Call Letter.

In the final rule, Medicare repeated what it has been saying for a number of years: “We share the grave concerns expressed by the commenters concerning the level of antipsychotic drug use in LTC facilities.”

But after again dropping an independence standard, the CMS bowed to LTC industry arguments that an independence standard would be counterproductive. Gregory S. continued on page 366
Weishar, PharMerica’s Chief Executive Officer, said the following last year:

PharMerica’s consultant pharmacists play an important role in ensuring safe and cost-effective outcomes for patients. We are concerned that the changes proposed by CMS could adversely affect customers, payers, and, ultimately, residents, resulting in a decrease of much-needed benefits and higher costs.

Omnicare and Managed Health Care Associates are the other major players; together the three control 90% of the nursing-home market, according to the CMS. Omnicare attempted a hostile takeover of PharMerica, but the Federal Trade Commission blocked the deal in 2012. The American Society of Consultant Pharmacists (ASCP) said it favored a standard but added that such a standard would not guarantee optimal patient outcomes and that it could be detrimental to patient care in some settings. After the final rule was issued, the ASCP stated that the independence issue wasn’t going away and that Medicare still had a big burr under its saddle. ASCP President Penny Shelton, PharmD, CGP, says that Medicare’s comments in the final rule about the value of consultant pharmacist services were “very strong and disconcerting.”

Medicare made it clear it was looking for the next opportunity to make a regulatory change. Until then, it wants the LTC industry to make voluntary changes in the way it uses consultant pharmacists (1) either by adopting voluntary transparency measures such as (a) separate contracting for LTC consulting services from dispensing and other pharmacy services; (b) payment by LTC facilities of a fair market rate for consultant pharmacist services; and (c) disclosure by consultant pharmacists to the LTC facility of any affiliations that would pose potential conflicts of interest; or by (2) executing an integrity agreement by the consultant pharmacists. The ASCP has already endorsed conflict-of-interest disclosures to nursing homes, payment to consultant pharmacists at market rates, and the issuance of integrity statements by LTC pharmacies.

The widespread adoption of these measures would probably cool Medicare’s regulatory ardor a bit; however, the agency’s drive to improve Part D effectiveness and reduce Part D costs will result in a few more turns of the regulatory screw—on formulary policies, P&T committees, and pharmacists—when the agency proposes the 2014 Call Letter and its associated proposed rule, probably sometime at the end of this year.