

MEDICARE PART D NEWS

Business and Compliance News and Strategies for the Medicare Drug Benefit

Contents

- 3** CMS Closes Potential Loophole in Draft Drug Maker Agreement
- 3** *Table:* Total Medicare Beneficiaries With Drug Coverage
- 5** Part D Sponsors Use Closed Formularies to Reduce Costs
- 6** *Table:* Effective Date of New Part D Reg Causes Confusion
- 7** OIG's Recommendations To Improve Bid Payment Process Not Followed
- 8** Enrollment Discrepancies Can Lead to Enforcement
- 11** *Table:* Sample Part D Data Validation Elements
- 12** *News Briefs*



Subscribers can access extensive primary documents and CMS guidance at www.AISPartD.com

Managing Editor

Barbra Golub
bgolub@aispub.com

Executive Editor

Jill Brown

As Part D Sponsors Prepare '11 Bids, CMS Adds Burden of Providing Discount in Gap

Part D plan sponsors already are struggling to create bids for contract year 2011 by the June 7 deadline taking into consideration the closing of the coverage gap. Now CMS has thrown another wrench into their plans by requiring sponsors to administer the 50% discount on brand-name drugs in the coverage gap. Although sponsors now use a similar method for processing claims, some industry experts contend that the new guidance will add burdens for plans and their pharmacy benefit managers, including changes to their prescription drug event (PDE) transaction edits.

Under recently enacted health care reform, beginning in 2011 beneficiaries will receive a 50% discount on brand-name drugs in the coverage gap from manufacturers. That year, CMS also will start phasing down the beneficiary coinsurance rate in the gap from 100% to 25% by 2020. This will be accomplished through the 50% manufacturers' discount, along with federal subsidies of the cost of brand-name and generic drugs beginning in 2013, an increase in the share paid by the Part D plan and a reduction in the out-of-pocket amount that qualifies beneficiaries to reach catastrophic coverage from 2014 through 2019. By 2020, manufacturers will pay 50%, plans will pay 25% and beneficiaries will pay 25% (*PDN 5/10, p. 3*).

In guidance finalized on May 21, CMS says Part D sponsors will be responsible for calculating the discount amount when claims are adjudicated at the pharmacy, and provide the discounted drug to beneficiaries through contracted pharmacies at the point of sale. Plans will then reimburse the pharmacy for the discount within a time-frame that is consistent with the 14-day prompt-payment requirements that are currently in place.

continued on p. 9

Health Plans Show Strong First-Quarter Results, But PDP Enrollment Decreases

While health plans posted strong overall first-quarter results, aided by enrollment gains, some of these organizations saw membership in their stand-alone Prescription Drug Plans drop from 2009 levels. In fact, year-to-date enrollment for PDPs as of April 9 was 17,592,875, a drop of almost 200,000 lives from its Feb. 5 level of 17,734,678 (see table, p. 3).

Humana Inc. saw a 19% increase in average membership in the company's Medicare Advantage plans, which it said was partially offset by losses in PDP and commercial fully-insured medical membership. Enrollment in the company's PDP was 1,917,100 on March 31, down from 2,078,900 on March 31, 2009, and 1,927,900 on Dec. 31, 2009. The organization warned investors in February about this drop when it announced that its January 2010 enrollment figures were down from December 2009 (*PDN 3/10, p. 1*). Again, it attributed the drop to a realignment, stating during its earnings call on April 26 that the decline "primarily resulted from the company's continued competitive positioning as it realigned stand-alone PDP premium and benefit designs to correspond with its pharmacy claims experience."

continued

PDP premiums in the first quarter decreased 3% compared with first-quarter 2009. "This reflects a 13% decline in average membership year over year, partially offset by an 11% increase in premiums per member per month (PMPM)," Humana said.

Despite reporting record first-quarter revenues and earnings (partly due to increased revenue in its PBM unit), *CVS Caremark Corp.* also saw a drop in PDP membership. Analysts were not surprised by the decrease, which CVS attributed to "the 2010 Medicare Part D competitive bidding process."

In October 2009, CVS announced that the number of low-income subsidy (LIS) members enrolled in its Silverscript and Accendo Part D plans would decline by approximately 30% to 35% in 2010. Those plans were qualified to receive automatically assigned LIS members in only 15 regions in 2010, compared with 30 regions in 2009. Based on those results, CVS estimated that the

decrease in LIS members could negatively affect 2010 earnings by 3 to 4 cents per share.

The organization did predict positive results for its PDPs in the future due to the repeal of the retiree drug subsidy tax exclusion. The RDS program furnishes plan sponsors with a tax-free subsidy payment if they continue to provide retiree drug coverage that is at least actuarially equivalent to the basic benefit under the Part D program. For 2010 and 2011, the subsidy is equal to 28% of the first \$6,300 the employer spends on a retiree's net drug costs, minus a \$310 deductible. Now the RDS will cease to be deductible, and this 28% subsidy will be subject to a corporate tax effective Jan. 1, 2013 (*PDN 4/10, p. 1*).

Some organizations and health care experts predict a steady flow of beneficiaries from employer-sponsored plans to employer group waiver plans (EGWPs) or stand-alone PDPs. Alternatively, some employers may choose to maintain retiree coverage and take the RDS despite its lower value.

CVS said it has already seen many clients taking advantage of EGWPs, "which will allow them to stay in the group product with less administrative burden and to continue to provide coverage to their retirees." EGWPs "provide a certain degree of flexibility and plan design, member cost sharing and premium contributions," it added. Moreover, the organization expressed confidence that if employers ultimately move their retirees to PDPs, it would benefit as its clients are "major players in this... space."

CMS Sanctions Impacted Some Plans

Both MA and PDP quarterly earnings figures for *WellCare Health Plans, Inc.* were below the level seen a year ago. But this was not unexpected and the organization attributed it to the loss of gross margin private fee-for-service plans, which WellCare exited at the end of 2009, as well as decreased premium revenue from MA coordinated care plans and PDPs. WellCare also was subject to CMS marketing and enrollment sanctions that did not end until after marketing for 2010 began last fall. PDP membership decreased 95,000 from March 31, 2009, due in large part to the CMS marketing sanction, it said.

WellPoint, Inc. also attributed the loss of some Part D beneficiaries to CMS sanctions. However, despite a reduction in Part D LIS enrollment, WellPoint's "stand-alone Medicare Part D results... improved from the prior year quarter, which offset margin contraction in the Medicare Advantage program," the company reported last month.

WellPoint said the CMS marketing and enrollment sanctions imposed on it in 2009 "prohibited us from the marketing of, and enrollment into, all lines of our Medicare business from March [2009] until the sanction was

Medicare Part D News (ISSN: 1937-6642) is published 12 times a year by Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 202-775-9008, www.AISHealth.com.

Copyright © 2010 by Atlantic Information Services, Inc. All rights reserved. No part of this publication may be reproduced or transmitted by any means, electronic or mechanical, including photocopy, FAX or electronic delivery without the prior written permission of the publisher.

Medicare Part D News is published with the understanding that the publisher is not engaged in rendering legal, accounting or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

Managing Editor, Barbra Golub; Executive Editor, Jill Brown; Publisher, Richard Biehl; Marketing Director, Donna Lawton; Fulfillment Manager, Gwen Arnold; Production Director, Andrea Gudeon.

Contact Barbra Golub at bgolub@aispub.com with story ideas for future issues.

Subscriptions to **Medicare Part D News** include this monthly newsletter in print and (optional) PDF format, and access to www.AISPartD.com, with regulations and CMS guidance.

To sign up for free e-mail delivery of *PDN* in addition to the print copy, call AIS at 800-521-4323. E-mail recipients should whitelist aisalert@aispub.com to ensure delivery.

To order a subscription to **Medicare Part D News**:

- (1) Call 800-521-4323 (major credit cards accepted),
- (2) Order online at www.AISHealth.com, or
- (3) Staple your business card to this form and mail it to:
 AIS, 1100 17th St., NW, Suite 300, Wash., DC 20036.
 Payment Enclosed* \$437
 Bill Me \$467

*Make checks payable to Atlantic Information Services, Inc.
 D.C. residents add 6% sales tax.

Call 800-521-4323 (or visit the Marketplace at www.AISHealth.com) to order **Medicare Part D News on CD**, a searchable CD with all issues of the newsletter published from January 2007 to December 2008. (\$89 for subscribers; \$389 for non-subscribers.)

released in November [2009].” Although WellPoint did receive auto-assignments in subsequent months, “such assignments were at levels well below the level we typically experience in the month of January,” it said.

As of March 31, 2010, said WellPoint, its PDPs are in 49 states and the District of Columbia and below the LIS benchmark in 19 regions. The organization “exited the PDP program in Wisconsin at the end of 2009,” and its auto-assigned beneficiaries in that state were reassigned to other plans.

Some PDPs Increased Membership

Not all PDPs saw losses in enrollment. Christine Arnold, a securities analyst for Cowen & Co., tells *PDN* that Medicare Advantage enrollment, which includes Part D, increased overall. *HealthSpring, Inc.* reported PDP membership of 389,561, up from 286,810 one year earlier. Stand-alone PDP premium revenue was \$129.5 million for the 2010 first quarter, an increase of 40% compared with the same period in 2009. The increase in revenue was primarily the result of a 35.8% increase in membership. PDP premiums PMPM in the 2010 first quarter were \$111, compared with \$109 in the 2009 first quarter.

Universal American Corp. also reported better-than-expected results in its PDP and MA business. PDPs yielded \$644.2 million in operating income and a net loss of \$32 million in the first quarter, compared with \$615.7 million and a loss of \$35.9 million, respectively, in the year-ago period.

The first-quarter results for *Health Net, Inc.’s* Medicare operations were “stable” in a tough climate, CEO Jay Gellert said in the firm’s May 4 earnings call. Membership in the company’s Part D plans was 457,000 at the end of the first quarter, a 1.8% increase compared with the end of first-quarter 2009.

The Part D medical cost ratio was 96.9% in the first quarter of 2010 compared with 93.8% in first-quarter 2009. “The performance of both our Medicare Advantage and Medicare Part D businesses in the first quarter of 2010 is tracking with what our bids anticipated,” said Jim Woys, executive vice president and COO.

Health Net spokesperson Amy Sheyer tells *PDN* that the organization’s “2010 bid strategy helped us increase the number of regions that were under the LIS benchmark, which helped our net growth.”

UnitedHealth Group’s Ovation unit had first-quarter revenue of \$9.3 billion, a 10% increase from last year’s revenue. The company attributed the growth to “notable revenue advances in the Medicare Advantage, Medicare Supplement and Part D prescription drug businesses.” As of March 31, Ovations has 4.5 million beneficiaries in its stand-alone PDPs, an increase of 240,000 in the past year.

Coventry Health Care, Inc. also reported an increase in Medicare Part D membership. Enrollment as of March 31 was 1,600,000, an increase of 99,000 members from the same date last year.

Contact Sheyer at amy.l.sheyer@healthnet.com and Arnold at Christine.arnold@cowen.com. ✦

CMS Closes Potential Loophole In Draft Drug Maker Agreement

CMS on May 21 issued a draft drug manufacturer agreement for the Medicare Part D coverage gap discount program providing pharmaceutical companies with a model of the deal they must agree to if they want their drugs covered under Part D. In it, the agency clarifies its position on allowing discounts on Part D drugs not covered under manufacturer’s agreements, backtracking on its previous stance.

Beginning in 2011, beneficiaries will receive a 50% discount on brand-name drugs in the coverage gap from manufacturers (see story, p. 1). Specifically, the recently enacted health reform law requires manufacturers, effective Jan. 1, 2011, to provide a 50% discount for brand-name drugs in the coverage gap for enrollees who do not receive low-income subsidies and have incomes above \$85,000 per individual or \$170,000 per couple.

As of Jan. 1, 2011, an applicable Part D drug will be covered under the program only if a manufacturer has a signed agreement to participate in the discount program and provide discounts on coverage gap claims for all of its applicable drugs. The agency clarifies in the draft model guidance that it may require *all* manufacturers to sign agreements in the future if it determines that access to applicable Part D drugs is being restricted. CMS also says it will “encourage manufacturers of non-applicable drugs to enter into an agreement if they intend to manufacture applicable Part D drugs in the future.” *continued*

Total Medicare Beneficiaries with Drug Coverage	
Type of Coverage	As of April 9, 2010
Medicare Stand-Alone Drug Coverage	17,592,875
Employ/Union Only Direct Contract PDP	153,650
All Other PDP	17,439,225
Medicare Advantage With Drug Coverage	9,865,671
Other Medicare Health Plans	223,987
Total	27,682,533
SOURCE: CMS data of enrollment figures as of the May 1 payment, reflecting enrollments accepted through April 9.	

The draft model defines “applicable drug” as a covered Part D drug that has been approved under a new drug application under the federal Food, Drug and Cosmetic Act, on the formulary of a stand-alone Prescription Drug Plan (PDP) or Medicare Advantage prescription drug (MA-PD) plan or not on a plan’s formulary but provided through an exception or appeal.

Agreements will be effective for two years and will be automatically renewed for a period of one year. CMS may terminate any agreement for knowing and willful violation of the requirements of the agreement or other good cause. Manufacturers may terminate for any reason. Such termination will be effective on the last day of the plan year if the termination is before Jan. 30 of a plan year, or the day after the end of the succeeding plan year if the termination is on or after Jan. 30.

Will Manufacturers Sign Up?

A potential loophole in CMS’s April 30 draft guidance on the discount raised concerns that some drug makers will not have to pay the discount at all. According to the draft guidance, Part D drugs would be covered only if the manufacturer has signed an agreement with CMS by Jan. 1, 2011, to provide the discount for drugs in the coverage gap. But because plan sponsors already submitted their 2011 formularies last month, they had no way of knowing which drug manufacturers would have agreements in effect for next year. AARP claims that

this language in the draft guidance creates a loophole for some manufacturers to not enter into an agreement for the 2011 plan year and wait until later to participate.

“By potentially giving drug manufacturers the option in 2011 of not participating in the program to close the doughnut hole, we risk confusing people in Medicare Part D and greatly raising their distrust of how the program will be implemented,” the association said May 4 in reaction to the draft guidance.

CMS acknowledged in a May 4 press release that exceptions would have to be made for next year because of timing conflicts, and added that it would allow coverage of Part D drugs next year, irrespective of manufacturer discount agreements.

Now, however, CMS says in the draft model agreement that it expects all manufacturers of applicable drugs to sign agreements. Therefore, it does not intend to allow coverage of drugs not covered under agreements, even if they are essential to the health of beneficiaries for 2011.

It further states in the final discount guidance that there will be no transition coverage for drugs that potentially become excluded from Part D due to the failure of a manufacturer to sign a discount agreement. Transition coverage is only available for drugs that can be covered under the Part D program, CMS says, and drugs not covered under an agreement cannot be covered under Part D. Thus, the agency contends, sponsors may not provide transition coverage for such drugs.

Preparing Your 2010 Data for Data Validation Audits

- Testing and reporting systems before data validation audits start;
- Conducting preliminary data validation audits to assess systems, reporting methodologies and controls, including the completion of the Organizational Assessment Instrument;
- Understanding recent changes to data validation tools, including the use of sample testing and the data collection form;
- Dealing with elements maintained by delegated administrative and clinical entities, such as PBMs;
- Understanding the organizational depth required to determine data validation audit readiness;
- Determining and correcting deficiencies found in the data assessment review; and
- Understanding the role of the data validation audit contractor.

Join **Dorothy DeAngelis** and **Richard Merino** of FTI Consulting
for a **June 22 Webinar**.

Visit www.AISHealth.com or call 800-521-4323

Margaret Nowak, director at Avalere Health LLC, tells *PDN* that CMS is probably right about all manufacturers entering into agreements. "From a PR standpoint, manufacturers would not look too good" if they didn't sign discount agreements, she says.

CMS tells *PDN* that interpreting the final guidance as a reversal on the issue of transition drugs is "reading too much into it." The guidance "simply conveys our belief that the issue will be moot because we expect all manufacturers of applicable drugs to sign agreements," CMS spokesman Peter Ashkenaz says.

In comments on the draft guidance, beneficiary advocacy groups asked CMS to go beyond providing transition drugs and ensure that these drugs are not moved to higher cost-sharing tiers than the ones they were on in 2010.

The groups also suggested that the agency:

- ◆ **Require sponsors to provide beneficiaries** with timely notice that the price of a drug has changed;
- ◆ **Provide beneficiaries with individualized notices** at the point of sale each time they fill a prescription explaining the amount they are paying for prescriptions, each party's cost responsibility and the process for requesting a coverage determination;
- ◆ **Include a statement in the Explanation of Benefits** that beneficiaries have the right to request coverage determinations and an explanation of cost if this is not provided at the point of sale; and
- ◆ **Allow for retroactive coverage** when a beneficiary receives a favorable coverage determination or favorable decision on appeal.

Party of Three

In its draft guidance, CMS stated that it considered using a third-party administrator to implement the program, but it would not institute such a model "for the foreseeable future."

Now, in the draft model agreement, the agency said it would contract with one or more third-party vendors to receive and transmit information between the various parties. This includes receiving, distributing or facilitating the distribution of funds from manufacturers to appropriate individuals; providing adequate and timely information to manufacturers to fulfill their obligations under the agreements; and allowing manufacturers to periodically audit the information used by the third-party contractor to determine discounts for applicable drugs.

Manufacturers' responsibilities listed in the draft model agreement include the following:

- ◆ **Reimburse all applicable discounts provided** by Part D sponsors for all of the manufacturers' applicable drugs based upon Prescription Drug Event (PDE) transaction information reported to CMS by sponsors;

- ◆ **Pay each sponsor within 14 days** of being invoiced by the third-party contractor the total quarterly applicable discounts provided by each sponsor during a previous specified quarter based upon PDE information used by CMS to calculate the applicable discounts;

- ◆ **Collect and have available** appropriate data, including data related to manufacturers' labeler codes, expiration dates of NDCs and utilization and pricing information relied on by the manufacturer to dispute discount calculations for no less than 10 years;

- ◆ **Pay all applicable discounts** provided by sponsors for applicable dates of service except for those dates of service after the marketing end date, which is the last lot expiration date, specified in the product labeling electronically submitted to the FDA;

- ◆ **Submit to periodic audits** of data and documentation; and

- ◆ **Make quarterly payments** directly to accounts established by sponsors via electronic funds transfer within specified time periods.

Manufacturers that fail to pay applicable discounts may be subject to civil monetary penalties in the amount equal to the sum of the amount the manufacturer would have paid under the agreement, plus an additional 25% of that amount.

To view the draft model agreement, visit www.federalregister.gov/OFRUpload/OFRData/2010-12559_PI.pdf. ✧

Part D Plan Sponsors Use Closed Formularies to Reduce Rx Costs

Although more and more Part D plans are moving to "closed" formularies as a cost saving tool, they may want to exercise some caution based on CMS's recent sanctions against Aetna Inc. for failing to provide a transition process for beneficiaries when the sponsor moved from an open to a closed formulary (*PDN* 5/10, p. 1).

Formularies can be either closed — in which there is no coverage at all for nonformulary drugs — or open — in which nonformulary drugs are covered, but plans use incentives to encourage their enrollees to use the preferred drugs on the formulary.

According to CMS, after moving from an open formulary to a closed formulary, which resulted in the removal of certain drugs from coverage, Aetna's stand-alone Prescription Drug Plan (PDP) was "required to effectuate a meaningful transition for current enrollees from the old formulary to the new formulary prior to the start of the 2010 contract year." This includes receipt of a claim for an on-formulary drug or processing a drug formulary exception request, said CMS. Instead, in the first

two months of 2010, CMS said there were approximately 35,000 prescription denials due to the failure to properly effectuate the formulary transition.

Aetna spokesperson Fred Laberge told *PDN* that the organization switched its Part D coverage from an open formulary to a closed one that has payment tiers and in some cases favors generic drugs over brand names. The goal was to “provide beneficiaries with full access to a range of prescription drugs while ensuring an affordable, competitive product in the PDP marketplace.” Aetna declined *PDN*'s request for a more in-depth interview.

Closed Formularies Save Money

Plans use closed formularies “honestly to save money,” says Margaret Nowak, a director at Avalere Health LLC. With open formularies, beneficiaries may or may not incur additional expenses for using nonformulary drugs. These formularies typically have three tiers, she says, with the first tier being preferred generics and the second tier preferred brands. The third tier is usually non-preferred brands, with higher cost sharing.

Closed formularies, on the other hand, restrict access to drugs and do not reimburse beneficiaries who choose

nonformulary drugs. However, Nowak explains to *PDN* that beneficiaries may use the exceptions and appeals process if they need access to a nonformulary drug.

The rationale behind closed formularies is that sponsors can get “deeper discounts from manufacturers” whose drugs are listed on a closed formulary, Nowak says. Sponsors will try to drive beneficiaries towards certain drugs on their formularies in order to receive bigger rebates from manufacturers, she says.

Most plans in Medicare Part D have some closed formularies. For example, Anthem Blue Cross and Blue Shield's 2009 formulary for its Part D product is a closed generic premium drug formulary. It consists of the three tiers: nonspecialty generics, select covered brands and select covered specialty drugs. Drugs covered under this formulary are subject to specialty lock-down and NDC block. Anthem states that members may seek a necessity exception review process if coverage of a nonformulary drug is needed.

An NDC block is a point-of-sale edit at the pharmacy level to block the dispensing of any drugs that do not appear on the NDC match list. Effective Jan. 1, 2010, CMS began rejecting Prescription Drug Event (PDE) transac-

Effective Date of New Part D Reg Causes Confusion

CMS's final Medicare Advantage and Part D regulation setting forth policy and technical changes states that its provisions are effective on June 7 (*PDN* 5/10, p. 3). However, the agency explains in the regulation that because Part D and MA programs operate under contracts that are applicable on a calendar year basis, the provisions will not be applicable before Jan. 1, 2011, although some of the provisions will be enforced as of June 7. The agency issued a clarifying memo April 30 setting forth which specific provisions

involving activities performed in preparation for contract year 2011 would be applied as of June 7.

With regard to compliance deeming, Robert Slavkin and Lawrence Vernaglia, attorneys with law firm Foley & Lardner LLP, said in a client alert that Medicare providers will not have to wait until the next calendar year to demonstrate compliance under the regulations. This will significantly reduce the burden on providers who have struggled to demonstrate compliance with the fraud, waste and abuse requirements to plan sponsors, they said.

Provision	Effective Date
Contract Qualification Applications	On or after June 7, CMS will issue application determinations based on regulations in effect on that date, including those recently adopted by the agency. Specifically, applicants must demonstrate that they meet all Part C and Part D program requirements. CMS has the authority to deny applications based on an organization's past contract performance.
Bids	CMS will evaluate Part C and Part D bids submitted on June 7 according to the “meaningful differences” provisions included in the new regulation. The agency will specifically look at Part D plan bids to ensure that tiered cost sharing for non-defined standard benefit designs do not exceed annually determined levels.
Nonrenewal for Low-Enrollment Plans	CMS will evaluate Part C and Part D plan enrollments prior to bid submission on June 7 for the 2011 contract year and not renew plans with low enrollments.
Compliance Deeming	Beginning June 7, Medicare providers with valid Medicare provider agreements that contract with Part C and Part D sponsors will be deemed to be in compliance with the fraud, waste and abuse training and education requirements.

SOURCE: CMS memo, “Effective Date of Final Medicare Part C and D Policy and Technical Changes Regulation,” April 30. Visit www.cms.gov/PrescriptionDrugCovContra/Downloads/EffectiveDate2010Reg043010.pdf.

tion submissions with NDCs not listed with the FDA (*PDN 8/09, p. 1*).

Other plans, such as Medica Health Plans, offer both open and closed Part D formularies.

One consultant who asked not to be identified by name said closed formularies and particularly the use of NDC blocking are great cost-control mechanisms for sponsors because they drive the brand cost down.

In addition to using the NDC match list to establish new point-of-sale edits and pharmacy messaging, sponsors must evaluate the updated list with respect to their formularies and determine if it could negatively impact their enrollees. If sponsors find that the NDC match list contains NDCs for covered products on their formulary, CMS requires sponsors to manage their supply chain and take steps to get such products listed on the FDA NDC directory by reaching out to manufacturers, labelers, repackers or distributors.

Nowak says that the option of closed versus open formularies probably doesn't have much impact on beneficiaries' plan choices. Beneficiaries "don't usually know when they are looking at plans" if the formulary is open or closed. They are "just looking to see if their drugs are on the formulary," she says.

Contact Nowak at (202) 207-3684 and Laberge at labergear@aetna.com. ♦

OIG's Recommendations to Improve Bid Payment Process Not Followed

As Part D plans get ready to submit their bids for contract year 2011, the HHS Office of Inspector General (OIG) recently stated that CMS is not doing enough to hold sponsors accountable for inaccuracies in bids. It released its annual compendium of unimplemented recommendations, including priority recommendations involving accuracy of bids and prospective payments and safeguards to prevent and detect fraud and abuse.

In October 2007, OIG issued a report that estimated that Part D sponsors owed Medicare \$4.4 billion for the 2006 benefit year (*PDN 12/07, p. 5*). In its report, "Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2006," OIG found that CMS has no mechanisms in place to collect funds owed by sponsors until it completes reconciliation and no mechanism in place to adjust prospective payments before reconciliation.

Subsequently, OIG issued a report in September 2009 finding that sponsors owed \$18 million to CMS for 2007 reconciliation and continued to make large unexpected profits in addition to expected profits that were included in their bids (*PDN 10/09, p. 10*).

OIG recommended that CMS ensure that sponsors' bids more accurately reflect their costs of providing the benefit; hold sponsors more accountable for inaccuracies in bids; determine whether changes to risk corridors are appropriate; and determine whether alternative methodologies would better align payments with sponsors' costs for low-income cost sharing and reinsurance subsidies.

CMS said in response to OIG's September 2009 report that it did not believe changes to statutory risk corridors and risk-sharing percentages would be appropriate, that it had already incorporated plan-level experience in its bid desk reviews, that it has the authority to ensure sponsors' compliance with Part D operational requirements, and that it was evaluating whether to change the method for paying the low-income cost sharing subsidy.

OIG now says it will continue to monitor CMS's actions to further address OIG's previous recommendations, "including that CMS use its current authority to hold sponsors more accountable for inaccuracies in their bids." It contends that CMS may not have the authority to impose sanctions in all situations that lead to inaccuracies in bids.

Another recommendation that went unheeded by CMS, according to OIG, was to modify the bid audit process to hold sponsors more accountable for material findings identified in bid audits and conduct the required number of financial audits in a timely manner.

In a November 2008 report, "Centers for Medicare & Medicaid Services Audits of Medicare Part D Bids" (*PDN 12/08, p. 4*), OIG found that one-quarter of bid audits completed for 2006 and 2007 identified at least one material finding, with the largest number identifying nonpharmacy costs and methodology errors. Moreover, the report stated that CMS had not adjusted sponsors' bid amounts based on audit material findings, but used the bid audits to influence submission, review and audit of future bid amounts.

CMS responded to the November 2008 report that the Office of the Actuary will evaluate sponsors' and certifying actuaries' compliance with bid instructions to confirm that similar issues are not repeated in future bid submissions starting with contract year 2011.

OIG said it would continue to monitor CMS's implementation of this process.

More Drug Price Transparency

OIG also now states that it will continue to monitor CMS's verification of the accuracy of plans' drug prices on the Medicare Prescription Drug Plan Finder (MPDPF). In July 2009, OIG released a report, "Accuracy of Part D Plans' Drug Prices on the Medicare Prescription Drug Plan Finder." The report concluded that drug prices posted on the MPDPF exceeded ac-

tual drug costs for 92% of claims. OIG recommended that CMS ensure that plans' drug prices displayed on MPDPF accurately reflect actual drug costs on Part D claims and modify the disclaimer on the search results screen to indicate that drug cost estimates may differ more than "slightly" from actual drug costs.

CMS did not agree to modify the disclaimer, asserting that it "is sound" and the recommendation was "unwarranted." The agency also expressed concerns that OIG's methodology had serious limitations regarding the relationship between prices displayed and prices charged at the point of sale because OIG conducted a general search and not a pharmacy-specific search.

OIG now continues to recommend that CMS routinely ensure that prices on the MPDPF closely reflect

Prescription Drug Event transaction costs, and it encourages CMS to "raise beneficiaries' awareness of potential significant discrepancies between drug prices displayed on the website and actual drug costs."

OIG also continues to recommend that CMS:

- ◆ **Ensure marketing materials** for plans comply with program guidelines;
- ◆ **Support outreach and education** for beneficiaries before they enter the coverage gap;
- ◆ **Track beneficiaries'** true out-of-pocket costs;
- ◆ **Ensure adequacy of sponsors'** compliance plans; and
- ◆ **Implement safeguards** to prevent and detect fraud and abuse in plans.

View the complete report at www.oig.hhs.gov/publications/docs/compendium/compendium2010.pdf. ⇨

Enrollment Discrepancies Can Lead to Enforcement Actions

Plan sponsors that fail to provide accurate enrollment information may face CMS enforcement actions as well as financial risks. Just last month, CMS posted on its website an audit of Independence Blue Cross (IBC), alleging that the plan sponsor did not accurately submit to CMS all enrollments, disenrollments and Plan Benefit Package (PBPs) changes within seven days of receipt.

In addition to being required to submit the above transactions to CMS within seven days, plan sponsors must also reconcile enrollment transactions and provide attestations of the accuracy of enrollment information within 45 days of receiving membership data from CMS.

As part of the enrollment process, CMS sends sponsors a comprehensive report of all eligibility changes through a transaction reply report. The TRR covers the processing week while the monthly TRR or monthly membership report (MRR) covers the payment-processing month.

Acquiring and maintaining accurate eligibility information is not only a requirement, but also it is important for the financial success of plans. Errors in beneficiary information can lead to costly mistakes, as discrepancies in the data kept by plans and by the agency can result in incorrect payments from CMS. That's because the agency uses these data to reimburse health plans for MA and Part D members, explains IBC spokesperson Ruth Stoolman.

Plan sponsors must provide monthly attestations of the accuracy of enrollment information for payment purposes within 45 days of the availability of the

MMR. This is an outer limit, according to the agency, which encourages plans to review and reconcile enrollment information as expeditiously as possible.

The agency requested that IBC submit a Corrective Action Plan (CAP) showing that all enrollments, disenrollments and PBP changes are submitted on time, the transaction reply report rejection rate is less than 1% of avoidable rejects, TRRs are reconciled within 45 days of receipt and the MMR is reconciled in a timely and accurate manner.

IBC Submits Timely CAP

According to the CAP report, IBC's response was due to CMS by March 29 and was accepted on April 1. Stoolman tells *PDN* that the CAP request was "not uncommon" and IBC is "cooperating fully with CMS" regarding its concerns on the plan's enrollment and disenrollment processes.

Stoolman says that IBC submitted the "detailed CAP" on March 5 and "is working closely with the local CMS representative to ensure all issues are fully resolved." The CAP included "controls and process changes to ensure timely and accurate communication of enrollment and disenrollment information to CMS, as well as additional training and communications for IBC's...enrollment staff," she explains. "Our members' benefits and access to care were unaffected by these compliance issues," Stoolman adds. She describes CMS's concerns as "primarily 'behind the scenes' transmittal of member data to CMS."

Visit www.cms.gov/MCRAdvPartDENrolData/CAP/list.asp#TopOfPage. Contact Stoolman at Ruth.stoolman@ibx.com.

Plans Add Discount to 2011 Bids

continued from p. 1

CMS says that plans are “the only entity capable of providing the discounts” because “no other entity will have all four pieces” of the information needed to efficiently execute payments to pharmacies. This includes information about the drug and the beneficiary’s eligibility for a discount, that the claim must be wholly or partially in the coverage gap and that the amount of the discount must take into consideration plan supplemental benefits that would be applied first.

CMS states in final guidance that the reason the agency cannot collect the discount payments directly from manufacturers is because the statute does not allow it. Further, it states that it did not believe “requiring manufacturers to pay the invoiced discount amounts directly to Part D sponsors would be overly burdensome.”

In the guidance, the agency clarifies that enrollees in employer group waiver plans (EGWPs) are considered “applicable beneficiaries” and included in the discount program. In the draft guidance, CMS raised questions about the level of the discount that would apply to EGWP claims. Now, it says that it will allow EGWPs to participate in the program in 2011 if they can attest or otherwise demonstrate that their beneficiaries have cost sharing between the plan initial coverage limit and the catastrophic threshold and that they will apply any supplemental benefits before determining the applicable discount that will be reported on PDEs.

CMS Allows Retroactive Changes

The guidance also allows for retroactive changes to applicable discounts when retroactive changes are made to claims or beneficiary eligibility. The agency says it was “concerned that allowing retroactive changes would complicate the application of the discount.” Now, it says it was convinced by comments that “such adjustments can be accurately applied.” It does warn sponsors that they should limit retroactive adjustments to pharmacies with claims in which pharmacy reimbursements change and not limit retroactive adjustments to distribution of sponsor, manufacturer and beneficiary liabilities.

One area that caused concern in the industry was whether multiple source products and authorized generics would be covered under the discount program. CMS clarifies in the final guidance that there is no distinction between multiple source drugs or authorized generics approved under new drug applications versus any other applicable drug. The agency defines “applicable drugs” as including all drugs approved under new drug applications, and all such drugs would be subject to the discount if covered under a manufacturer discount agreement.

CMS did remove a reference to authorized generics from the definition of “applicable drug,” however. The agency says that while most authorized generics are approved under new drug applications, others may be approved under abbreviated new drug applications. Only those authorized generics licensed by sponsors of new drug applications are applicable drugs subject to the discount, it says.

Discount Impacts Part D Bids

The results of the discount “are pretty substantial to pricing,” Susan Hayes, principal of Pharmacy Outcome Specialists, tells *PDN*, and will have significant implications for bids.

Bid amounts are sponsors’ per-member per-month estimated costs of providing the Part D benefit and are used to determine CMS’s payments to plan sponsors. To calculate bids, sponsors apply actuarial assumptions to actual data from a previous year of providing drug coverage.

CMS clarifies in its final guidance that sponsors must include administrative costs for the discount in the administrative expense components of their Part D bids. These costs should be reported in the bid in the same way as other administrative costs, the agency says. Moreover, sponsors must report these administrative costs separately for purposes of payment reconciliation, the guidance states. “These costs will be included in the determination of the administrative cost ratio.”

The agency declines to give manufacturers access to the estimates sponsors provide in their Part D bids, saying this information is “considered proprietary. We do not believe that this information would aid manufacturers in estimating the discounts for their specific brand drugs.” It further states that it will provide additional guidance regarding the data that will be available to manufacturers on invoices.

In comments received by CMS, some argued that the discount program would increase the drug costs projected in Part D bids because it would reduce the incentives for Part D beneficiaries to transition from brand name to generic drugs while in the coverage gap. The agency disagreed, saying, “Beneficiaries will continue to have strong incentives to use lower-cost drugs, including generics.”

According to Troy Filipek, principal and consulting actuary at Milliman, Part D sponsors are considering the “potential impacts on 2011 costs and Part D bid development” and coming up with a “range of conclusions.” He explains to *PDN* that these potential impacts include changes in utilization, cost per script and rebates. “To the extent that carriers build any of these impacts into their 2011 bids, they would [increase] costs and, therefore, increases to bid amounts and member premiums.”

continued

Sponsors should consider “if and how the reduced cost-share amounts on brand-name drugs may encourage people to switch from generic to brand drugs or simply be more compliant with their brand drug regimens,” he says.

“The biggest question for bid development,” asserts Filipek, is whether higher than expected accelerating average wholesale price trends that sponsors noticed in 2009 and early 2010 will continue. Alternatively, if this trend has been “fully captured in the 2009 experience already,” sponsors would not need to assume higher drug costs, thereby raising their bids. These increases may have been the “result of anticipating health care reform,” he says.

In addition, some sponsors have expressed concern that their existing rebate contracts may be renegotiated at lower rebates per brand-name drug terms, particularly in the coverage gap, explains Filipek.

The brunt of the burden for administering the discount is falling on plans and their PBMs, says Hayes. PBMs are currently “set with PDE records,” she tells PDN, adding that drug makers deny approximately 5% to 7% of rebate claims invoiced for payment. With the new system, they will have to change their PDE records and tell CMS each time a beneficiary falls into the doughnut hole, she explains. Furthermore, she contends, in general it is “hard for PBMs with experience to get rebates back from drug manufacturers.” What makes CMS think these discounts will be easy to recover, she asks.

More Business Newsletters From AIS

- ✓ **Health Plan Week**, the industry’s leading newsletter with weekly news, data and strategic information on business and regulatory issues affecting health plans.
- ✓ **Medicare Advantage News**, a biweekly newsletter with updates and business analysis on the Medicare and Medicaid managed care programs.
- ✓ **The AIS Report on Blue Cross/Blue Shield Plans**, monthly news and analysis of new products, strategies, alliances and market share of BC/BS plans. Not affiliated with BlueCross BlueShield Association or its member companies.
- ✓ **Drug Benefit News**, biweekly news, data and business strategies on the pharmacy benefit, for health plans, PBMs and pharmaceutical companies.
- ✓ **Specialty Pharmacy News**, monthly news and strategic information on managing high-cost biotech and injectable products.

Visit the AIS MarketPlace at
www.AISHealth.com

Aaron Eaton, vice president of strategic development at Gorman Health Group LLC, agrees that PBMs could have to deal with onerous cost and time burdens. “There are administrative costs associated with implementing these changes, as they’re going to be required to change their PDE layout,” he tells sister publication *Drug Benefit News*. “PBMs are doing similar calculations for drugs that they’re filling now, but they’re just not having to report that information like they will be required to moving forward.”

Plans Already Reconcile Payments

However, Eaton contends, the new rules shouldn’t be disruptive for plans from a payment standpoint. “This will function like the other incoming payments that they receive on a monthly basis that are subject to reconciliation at the end of the year,” he explains.

In the final guidance, CMS states that sponsors must submit their PDE records for the discount within the current PDE submission deadlines. “On average, Part D sponsors are expected to submit their PDE records within 30 days of claim receipt.”

In the guidance, CMS says it will give Part D sponsors monthly prospective payments for the discounts, which will be calculated based on the projections in the plan’s approved 2011 bid and current enrollment. To do this, the agency will subtract the projected costs for generic drugs used by beneficiaries in the doughnut hole from the total expected drug costs in the gap and then multiply the difference by 50%. On the other end, a contractor hired by CMS will be in charge of verifying the accuracy of all reported discounts and will then invoice each drug maker quarterly on behalf of plan sponsors. Drug makers will pay the plans directly.

Looking at the big picture, Hayes says this discount may actually “drive up costs.” While manufacturers might want the discounts to increase beneficiary utilization, she adds, there is no evidence “that beneficiaries will use more drugs with the discount.” In fact, it might be “sending the wrong message” to beneficiaries. Hayes thinks it might have been a better move for CMS to offer this discount only if a generic equivalent of the drug were not available.

Contact Hayes (708) 828-0797, Eaton at aeaton@gormanhealthgroup.com and Filipek at troy.filipek@milliman.com. Go to www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised%20Guidance%20052110.pdf to view CMS’s memo. ✦

Check out AIS’s Health Reform Week, which helps savvy business leaders in health care understand what the enormous changes mean to them...and what they can do about it. Go to www.aishealth.com/Products/NewsREF.html.

Sample Part D Data Validation Elements

Effective for contract year 2011, all Part C and Part D sponsors must undertake an independent data validation audit conducted by an external entity. CMS recently released guidance for the external auditors.

These entities will review general standards and measure-specific criteria to determine whether the organization’s reported data are accurate, valid and reliable. Each measure’s data validation standards include identical instructions relating to the types of information reviewed and a set of validation standards and

measure-specific criteria based on applicable Part C and Part D reporting requirements. Findings will address whether the organization has “adequate processes” in place to assure accurate and valid data results and whether the organization has reported “adequate results” (i.e., whether there are any data issues that might impact accurate reporting).

Below are listed each Part D data element to be audited and a sample of the standards to be reviewed in each element.

Data Element	Standard
Retail, Home Infusion and Long Term Care Pharmacy Access	Percentage of Medicare beneficiaries living within two miles of a retail network pharmacy in urban areas of a contract’s service area
	Percentage of Medicare beneficiaries living within five miles of a retail network pharmacy in suburban areas of a contract’s service area
	Number of prescriptions provided by all pharmacies owned and operated by the plan
	Number of prescriptions provided by all pharmacies contracted by the plan
Medication Therapy Management Programs (MTMPs)	The total number of beneficiaries identified to be eligible for, and automatically enrolled in, the MTMP during the specified time period
	The total number of beneficiaries who opted out of enrollment in the MTMP during the time period
	The number of beneficiaries who opted out of enrollment in the MTMP due to disenrollment from the plan at any time during the specified time period
	For beneficiaries enrolled in the MTMP at any time during the specified time period, provide the prescription cost of all covered Part D medications on a per-MTMP-beneficiary per-month basis
Grievances	Number of low-income subsidy beneficiaries who filed grievances
	Number of grievances filed by LIS beneficiaries
	Number of enrollment, plan benefits or pharmacy access grievances
	Number of customer service grievances
Coverage Determinations and Exceptions	The total number of pharmacy transactions in the time period
	The total number of prior authorizations requested in the time period
	The number of tier exceptions requested in the time period
Appeals	The total number of redeterminations in the time period
	Of the total number reported above, the number resulting in full reversal of original coverage determination
	Of the total number reported above, the number resulting in partial reversal of original coverage determination
Long-Term Care Utilization	The total number of LTC pharmacies in the service area
	The total number of network retail pharmacies in the service area
	The total number of beneficiaries in LTC facilities for whom Part D drugs have been provided under the contract
Employer/Union-Sponsored Group Health Plan Sponsors	Employer legal name
	Employer address
	Type of group sponsor
	Employer plan year start date
Plan Oversight of Agents	Total number of agents
	Number of agents investigated based on complaints
	Number of agents receiving disciplinary actions from the sponsor based on complaints
	Number of agents whose selling privileges were revoked by the plan based on conduct or discipline

SOURCE: CMS, Medicare Part C and Part D Measure Instructions for Findings Data Collection Form for Data Validation Contractors, April 19 Visit www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoPartCDReportingPRA_05.10.10.pdf.

Join AIS on June 22 for the *Preparing Your 2010 Data For Data Validation Audits* webinar. Hear from two experts, Dorothy DeAngelis and Richard Merino of FTI Consulting, how to examine and test your reporting systems and correct and deficiencies to make sure your 2010 datasets are ready. To register, go to www.aishealth.com/Products/COA22_062210.html.

NEWS BRIEFS

◆ **Humana Inc. said April 30 that it arranged for eHealth Inc. to distribute the insurer's Part D, Medicare Advantage and Medicare supplement products through eHealth's Medicare website.**

The company's eHealthMedicare.com site will direct Medicare-eligible members through the online plan selection and purchasing process by providing premium quotes, side-by-side benefit comparisons and online applications for Humana Medicare products, according to eHealth. The website will offer an interactive product recommendation tool, an out-of-pocket cost calculator, a formulary tool and a physician finder tool. This is the second MA/Part D product distribution deal within a month for Humana. On April 16, the company announced that CIGNA Corp. would market its MA and MA prescription drug products to its employer group customers (*PDN 5/10, p. 12*). Visit www.humana.com or www.eHealthMedicare.com.

◆ **CMS on May 17 issued two notices of intent to imposed intermediate sanctions and a civil monetary penalty (CMP) on Quality Health Plan (QHP) for alleged billing deficiencies and denying or delaying getting beneficiaries their Part D medications.** The first notice would suspend marketing and enrollment of new members into QHP's two Medicare Advantage plans and a stand-alone Prescription Drug Plan. The second notice would impose a CMP of \$586,800 "based on the adverse impact or substantial likelihood of adverse impact that QHP's premium billing violations had on" its enrollees. CMS said it discovered that QHP had not been billing beneficiaries for their premiums since January 2008 and recently sent enrollees a lump sum bill for the entire amount of back premiums with no payment options. QHP released a statement saying that it takes compliance very seriously and is cooperating fully with CMS on its review and is working to resolve the issues raised. It further assured members that the notification of sanctions will not affect QHP's ability to continue to provide service to its current enrollees. Go to www.cms.gov/MCRADVPartDENrollData/EA/list.asp.

◆ **CMS regional offices are warning beneficiaries about potential health care reform scams.** According to John Hammarlund, regional administrator for CMS in Seattle, some beneficiaries are being approached by individuals claiming to be with "Obamacare." They tell beneficiaries they are eli-

gible for the \$250 Part D rebate because they either have or will reach the coverage gap and must provide their credit card and Social Security number to receive a check in the mail, he says. Hammarlund says the agency will send out printed materials and hold public meetings with local agencies in the next few months explaining the new health reform law. Contact Hammarlund at rosea_ora2@cms.hhs.gov.

◆ **HHS said it expects the first of the \$250 rebate checks for Medicare beneficiaries who have reached the Part D "doughnut hole" to be mailed on June 15.**

Additional checks will be mailed roughly every six weeks thereafter until the end of the year, it said. The agency projects that 4 million beneficiaries will receive a check in 2010, with 80,000 of them receiving checks in the June 15 initial mailing, followed by larger mailings throughout the summer and fall. Go to www.hhs.gov.

◆ **CMS on May 17 sent a letter to Fox Insurance Co., which had its Part D contracts terminated in March (*PDN 4/10, p. 1*), reminding the insurer of its obligation to pay pharmacy prescription drug claims.**

This action came after the National Community Pharmacists Association (NCPA) submitted to CMS numerous complaints from pharmacies about delinquent payments. The agency terminated Fox's Part D contracts March 9 for failure to provide access to prescription drugs by imposing unauthorized step-therapy and prior-authorization criteria, among other alleged violations. It told Fox that the insurer was in direct violation of regulatory requirements and the terms of its prior contract with CMS for failing to promptly pay claims. According to CMS, between beneficiary premiums and monthly capitated payments Fox received from the agency, the insurer was paid more than \$30 million for February and \$33 million for March to provide coverage to its enrollees. ProCare Pharmacy Benefit Manager, Inc., the PBM that administered claims for Fox, filed a request for a temporary restraining order as a result of Fox's nonpayment, said NCPA. The order sought "the segregation of the funds that Fox received from CMS in an effort to assure funding for pharmacy reimbursement." Fox did not respond to a request for comments before press time, and a CMS spokesperson tells *PDN* the agency cannot comment due to pending litigation. Go to www.ncpanet.org/pdf/leg/foxrxclaims.pdf.

**IF YOU DON'T ALREADY SUBSCRIBE TO THE NEWSLETTER,
HERE ARE THREE EASY WAYS TO SIGN UP:**

1. Return to any Web page that linked you to this issue
2. Go to the MarketPlace at www.AISHealth.com and click on “newsletters.”
3. Call Customer Service at 800-521-4323

**IF YOU ARE A SUBSCRIBER AND WANT TO
ROUTINELY FORWARD THIS PDF EDITION OF
THE NEWSLETTER TO OTHERS IN YOUR ORGANIZATION:**

Call Customer Service at **800-521-4323** to discuss AIS's very reasonable rates for your on-site distribution of each issue. (Please don't forward these PDF editions without prior authorization from AIS, since strict copyright restrictions apply.)