

MEDICARE PART D

Compliance News

News and Compliance Strategies to Reduce the Risk of Penalties and Payments to CMS

Contents

- 3** Table: CMS Enforcement Actions Against Part D Sponsors
- 4** Medica, HealthSun Plans Cited for Multiple Part D Violations
- 5** Part D Bids Are Due June 2; Plans Urged to Enter Information Now
- 6** Part D Plan Sponsors Are Given Flexibility to Meet NPI Mandate
- 7** CMS Issues Additional Quality Checks for Plans On MPDPF Data
- 8** Enrollment, Membership Data Are Focus of '07 PDE Reconciliation
- 10** Timeline for 2009 Plan Year Data Submissions To MPDPF
- 11** Congress, Others Look Beyond CMS Rule; Some Seek State Enforcement
- 12** News Briefs



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

Managing Editor
Barbra Golub

Executive Editor
James Gutman

CMS Tries to Tighten Marketing Regs, Retool Pricing; Industry Fears Higher Fines, Bids

CMS in May issued new proposed rules designed to strengthen protections for Medicare beneficiaries, including tighter marketing standards for stand-alone Prescription Drug Plans (PDPs) and Medicare Advantage (MA) plans and new, potentially high-impact restrictions on how Part D plans calculate negotiated prices. And some industry experts fear that the proposed rules could allow federal regulators to impose hefty fines on plans and cause plans' bids to increase.

In announcing the new regs, CMS Acting Administrator Kerry Weems told a news briefing that the "large and comprehensive" rule would formalize a number of practices previously covered by operational guidance, and also introduce several new Part D requirements, "building on CMS's experience."

The rule would specifically prohibit cold-calling and expand CMS's current prohibition on door-to-door solicitation to cover other unsolicited circumstances, banning sales activities at such places as health information fairs and waiting rooms. It would put a \$15 limit on the value of promotional items offered by plans to potential enrollees, prohibit providing meals for potential enrollees regardless of the value, and limit any appointment to market products to the scope agreed to by the beneficiary in advance.

CMS said it also would require Part D plans to set commission structures for sales agents and brokers that are level across all plans and product types, in order to dis-

continued on p. 9

Plan Sponsors Face Difficult Options for Coverage, Administration of Part D Vaccines

When CMS decided to move coverage and administration of the majority of vaccines from Medicare Part B to Part D beginning in 2008, it caught many physicians off guard and sent Part D plan sponsors scrambling for a way to have these vaccine claims adjudicated. Now, one industry expert says some of CMS's recommended methods are causing hardship for beneficiaries by making them pay out-of-pocket and get reimbursed by their Part D plans.

All Part D formularies for contract year 2008 and later must contain all commercially available vaccines, unless they are available for reimbursement under Medicare Part B. Now, only three vaccines are covered under Medicare Part B — pneumococcal pneumonia, influenza virus, and hepatitis B vaccines. Another 27 vaccines are now covered under Part D.

For those 27 vaccines, the Part D program covers the cost of the vaccine and the administration costs associated with the Part D vaccines. According to CMS, the negotiated price for a Part D vaccine is comprised of the vaccine ingredient cost, a dispensing fee, sales tax, and a vaccine administration fee.

Recognizing that the change in coverage impacts beneficiaries' copayments and forces changes in standard physician billing procedures, CMS furnished sponsors with

multiple options in providing adequate access of vaccines to beneficiaries:

- ◆ **In-Network Access to Retail Pharmacies** — Enrollees could obtain a prescription from a physician and bring it to their local retail pharmacy for filling.
- ◆ **In-Network Pharmacy Distribution** — A Part D plan's local pharmacy or specialty pharmacy could provide vaccines directly to the physician offices.
- ◆ **Web-Assisted Out-of-Network Billing** — Physicians could electronically submit beneficiary out-of-network claims to Part D plans for vaccines dispensed and administered in the physician's office through a vendor.
- ◆ **Model Vaccine Notice for Physicians** — Part D plans could provide all enrollees with vaccine-specific notices that the enrollees could take to their physicians, provid-

Medicare Part D Compliance 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 © 2008 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 Compliance 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, James Gutman; Publisher, Richard Biehl; Marketing Director, Donna Lawton; Fulfillment Manager, Gwen Arnold; Associate Production Manager, Melissa Muko.

Call Barbra Golub at 800-521-4323 with story ideas for future issues.

Subscriptions to **Medicare Part D Compliance News** include this monthly newsletter in print and (optional) PDF formats, biweekly *Part D E-Letters*, and access to www.AISPartD.com, with regulations and CMS guidance. If you're not receiving E-Letters, call AIS at 800-521-4323 or email customerserv@aispub.com

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 Compliance 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 5.75% sales tax.

Call 800-521-4323 (or visit the Marketplace at www.AISHealth.com) to order **Medicare Part D Compliance News on CD**, a searchable CD with all issues of the newsletter published from March 2006 through December 2007. (\$89 for subscribers; \$389 for non-subscribers.)

ing information necessary for the physician to contact the Part D plan to receive authorization for coverage of a particular vaccine.

Industry Presents Turnkey Solutions

Judi A. Grupp, president and CEO of ActiveCare Network LLC, a company that aims to improve access to affordable chronic biological services, tells *PDN* that most physician practice management systems do not accommodate Part D billing, and most physicians are not able to administer these vaccines in their offices. Physicians can no longer bill for vaccines unless they have specialized systems. And doctors are willing to take an additional adjudication system only if they know they will get use out of it, she contends.

"Without access to a pharmacy billing system, physicians cannot validate benefit coverage, determine patient out-of-pocket responsibilities, or electronically submit claims for reimbursement," thus forcing beneficiaries to pay for their vaccinations in advance and then submit a claim for reimbursement, she says.

"Vaccines are very expensive, especially Zostavax for treating shingles," which could cost \$200 at a time, according to Grupp.

Moreover, Zostavax must be kept frozen, she explains. And not many physicians have freezers in their offices, she adds.

Grupp recommends a "turnkey solution" that would simplify the vaccination process for physicians. Under this solution, physicians unable to provide vaccines in their offices could fax prescriptions to a "national vaccination network" consisting of clinics that will administer the vaccine, validate beneficiary coverage, determine a beneficiary's out-of-pocket responsibilities, and electronically submit claims to Part D plans for reimbursements.

Sponsors Have Choices

According to Grupp, ActiveCare Network teams with NuFactor Specialty Pharmacy to provide its turnkey solution, VaxAmerica, to Part D plans and will sign up additional plans this year.

She indicates that there are other products or systems being used by plans, including informing beneficiaries where they can get vaccines and helping physicians adjudicate claims. Also, she acknowledges that some retail network pharmacies handle administration of vaccines.

Grupp clarifies that Part D plans do not have to contract with the individual clinics in the VaxAmerica network. Instead they need to just contract with VaxAmerica.

Other organizations also are offering vaccine-related systems. For example, Merck & Co, Inc. has developed a Web-based product that processes in-office Part D vaccines electronically. It provides patient-specific vaccine

coverage information and allows for online claims processing. However, it allows only Part D plans already participating in Merck's eDispensing network to participate.

According to Grupp, CMS is looking to move the other three vaccines over to Part D. She's not sure when

this will happen, but she says she appreciates the agency providing time to the industry to set up clinics to handle the vaccine coverage and billing issues.

Contact Grupp through Chempetitive Group at (312) 997-2436. ✧

CMS Enforcement Actions Against Part D Sponsors

CMS has updated its list of enforcement actions taken against stand-alone Prescription Drug Plan (PDPs) and Medicare Advantage prescription drug (MA-PD) plan sponsors to reflect action taken from January 2006 through May 2008. New for this update is a column indicating the status of the action against the sponsor.

Organization	Type of Plan	Date Action Taken	Basis for Action	Action Taken	Status
Health Net, Inc.	PDP	January 2008	Several contract actions	Suspension of enrollment and marketing	Sanction lifted in March 2008
SDM HealthCare Corp.	MA-PD	December 2008	Several contract actions	Suspension of enrollment and marketing	Under sanction
Humana Inc.	MA-PD, PDP	September 2007	Marketing violations	\$264 civil monetary penalty (CMP)	Resolved; paid in full
SunCoast Physicians Health Plan, Inc.	MA-PD	August 2007	Insolvency	Immediate termination	Termination
Torchmark Corp.-First United American Life Insurance	PDP	March 2007	Failure to issue Annual Notices of Change (ANOCs) in a timely manner	\$15,000 CMP	Resolved; paid in full
Florida Health Care Plans	MA-PD	March 2007	Failure to issue ANOC in a timely manner	\$10,000 CMP	Resolved; paid in full
Freedom Health Inc.	MA-PD	March 2007	Failure to issue ANOC in a timely manner	\$5,000 CMP	Resolved; paid in full
Vista Healthplan, Inc.	MA-PD	March 2007	Failure to issue ANOC in a timely manner	\$11,050 CMP	Resolved; paid in full
Health Net, Inc.	PDP	March 2007	Failure to issue ANOC in a timely manner	\$10,000 CMP	Resolved; paid in full
Health Net, Inc.	MA-PD	March 2007	Failure to issue ANOC in a timely manner	\$15,000 CMP	Resolved; paid in full
SunCoast Physicians Health Plan, Inc.	MA-PD	March 2007	Failure to issue ANOC in a timely manner	\$2,100 CMP	Resolved; paid in full
WellPoint, Inc.	PDP	March 2007	Failure to issue ANOC in a timely manner	\$20,000 CMP	Resolved; paid in full
United HealthCare	PDP	March 2007	Failure to issue ANOC in a timely manner	\$130,000 CMP	Resolved; paid in full
Humana Inc.	MA-PD	March 2007	Failure to issue ANOC in a timely manner	\$120,000 CMP	Resolved; paid in full
Elder Health, Inc.	PDP	March 2007	Failure to issue ANOC in a timely manner	\$4,000 CMP	Resolved; paid in full
Elder Health, Inc.	MA-PD	March 2007	Failure to issue ANOC in a timely manner	\$15,000 CMP	Resolved; paid in full
Universal Healthcare	MA-PD	February 2007	Financial insolvency concerns	Suspension of enrollment and marketing	Sanction lifted February 2008
Doctor Care, Inc.	MA-PD	December 2006	Financial insolvency concerns	Immediate termination	Termination
Doctor Care, Inc.	MA-PD	December 2006	Financial insolvency concerns	Suspension of enrollment marketing	Termination

SOURCE: CMS, Enforcement Actions Against Medicare Advantage Organizations and Prescription Drug Sponsors, January 2006–May 2008; http://www.cms.hhs.gov/MCRAAdvPartDENrolData/Downloads/Enforcement_Actions_Web.pdf

Medica, HealthSun Plans Cited For Multiple Part D Violations

Despite not agreeing with all of CMS's findings during a Part D audit of its Medicare Advantage prescription drug (MA-PD) plan, Medica HealthCare Plans, Inc. has submitted corrective action plans (CAPs) addressing all alleged deficiencies, Matthew Cruse, Medica's compliance officer, tells *PDN*.

According to the audit reports, Minnesota-based Medica allegedly did not meet CMS standards for timely notification of standard or expedited coverage determinations. CMS indicated it reviewed a sample of 10 requests for standard coverage determinations concerning drug benefits out of a universe of 520 and found six out of 10 samples were noncompliant.

The agency also reviewed a sample of four requests for expedited coverage determinations from a universe of four and found that in all the samples Medica did not demonstrate timely notification of the decision to the enrollee.

Cruse says Medica disputed the alleged deficiencies regarding both standard and expedited coverage determinations. He tells *PDN* that CMS's audit reports ignore the "fully compliant sample reviews" Medica provided. Medica and CMS had "different views of the same thing," he explains. However, after redispensing the alleged deficiencies, Medica on May 9 submitted CAPs "anyway," he says.

CMS also cited Medica for using 'non-model' documents for marketing and failing to require any person directly employed or contracted to market Part D plans on behalf of Medica to provide a written disclosure statement of the marketing compensation structure to all potential enrollees before enrollment or at the time of enrollment. Out of 10 sample contracts/compensation structures from a universe of 20 reviewed by CMS, the agency alleged that all 10 samples were noncompliant.

According to the audit report, Medica submitted notice templates that had been approved after the audit period and did not need to submit a CAP for that alleged deficiency. Cruse says that it did not dispute CMS's allegation regarding its failure to disclose the compensation structure of persons contracted to market its plans, and that it submitted a CAP to CMS.

HealthSun Also Cited for Multiple Violations

CMS has also posted multiple audit reports for Florida-based HealthSun Health Plans, Inc. MA-PD plans, citing the company for 28 separate, alleged violations, including failure to include in its policies and procedures the following provisions:

- ◆ HealthSun must notify enrollees within 72 hours of a determination of coverage after receipt of a payment request.
- ◆ If oral notice is provided for an adverse decision, the notices must state the specific reason for the denial and take into account the enrollee's presenting medical condition, disabilities, and special language requirements.
- ◆ If HealthSun requires a written statement from an enrollee's prescribing physician, it must request one immediately.
- ◆ All approved formulary drugs must be placed in existing cost-sharing tiers.
- ◆ HealthSun must provide for prompt and correct categorization of complaints as inquiries, grievances, or coverage determinations or appeals.
- ◆ All concerned parties must be notified of grievance disposition as expeditiously as the enrollee's case requires, based on the enrollee's health status, but not later than 30 days after HealthSun receives the oral or written grievance.

According to the audit reports, HealthSun also allegedly used 'non-model' documents in its marketing of its MA-PD plans and failed to include in its policies and procedures a requirement that any person directly employed or contracted to market on behalf of HealthSun provide a written disclosure statement regarding compensation structure to potential enrollees before enrollment or at the time of enrollment.

Moreover, CMS cited HealthSun for failing to provide standard contracting terms and conditions to any long-term care pharmacy in its service area that requests a contract and for not including in its policies and procedures requirements for addressing immediate needs of long-term care beneficiaries and time frames to ensure seamless transitions for long-term care facility residents.

According to the audit reports, the sponsor had until April 29 to revise its policies and procedures and submit

New Medicare Advantage and Part D Marketing Rules: Key Strategies for Health Plans

Join Jeff Fox and Mary Kaye Thibert of Gorman Health Group for a June 5 audioconference.

Visit www.AISHealth.com

a response and/or CAPs. However, the reports indicate that no CAPs have been submitted.

HealthSun did not respond to requests for comments by PDN press time.

Contact Cruse at mcruse@medicaplans.com. ✧

Part D Bids Are Due June 2; Plans Urged to Enter Information Now

The June 2 deadline for submitting Part D bids for contract year 2009 is rapidly approaching, and plans that did not get a head start creating 2009 plan structures in CMS's Health Plan Management System (HPMS) may be in a crunch. CMS has advised plans to start the upload process early and to ensure that all requirements are met and completed correctly.

On or after April 11, Part D and Medicare Advantage (MA) plans could begin creating 2009 plan structures in HPMS, Kristin Finch, a CMS analyst, told listeners during a recent CMS Webcast. This is a chance for plans to input plan IDs, select plan service areas, and indicate plan attributes other than plan-specific information, she said.

Before creating plans in HPMS, Finch recommended that sponsors review information that should have previously been entered into the HPMS Contract Management module to "ensure all organizational-level data entry is complete and correct." She advised plans to correct inaccurate information as soon as possible.

Only once a sponsor has created a plan and added organization and contact data in HPMS can it begin to download plan-specific data into its Plan Benefit Package (PBP), said Finch. Then the plan can open the PBP, which "will automatically generate appropriate BPT [bid pricing tool] spreadsheets for each plan defined," she explained.

After that, and after May 16, sponsors can start entering bid information into the BPT by completing the appropriate spreadsheet. Both stand-alone Prescription Drug Plans and MA prescription drug plans must complete the Part D BPT.

Finch noted that uploading the PBP will pre-populate only certain areas of the BPT with information from HPMS during the initial file creation. After that, the BPT will need to be updated manually with any changes to the general plan or organization information that is updated in HPMS, she said.

Greg Buglio, another analyst at CMS, told listeners that plans must "make sure to download and install the PBP/Summary of Benefits (SB) patch before attempting to upload their bids," or their submissions will be rejected.

To Bid or Not to Bid

He also clarified that for a bid upload to be considered complete, plans must do more than simply upload the bid and benefit packages. There are actually four critical steps that must be completed before a bid submission will be complete. "If one or more upload requirements are not completed by June 2," Buglio stressed, "the bid will not be reviewed timely."

Moreover, CMS's Office of the Actuary requires plans to submit actuarial certification and select BPT substantiation, he said.

First, plans must review their entire service areas and provide concurrence or non-concurrence. Non-concurrence may occur if one or more counties or regions that are part of a contract service area were not assigned to any plans, Buglio explained. In this case, a plan must non-concur and explain the issues.

However, he cautioned that the plan is not finished with reviewing its service area at this point. If a plan non-concurs, it must continue to try to resolve the issues with CMS and ultimately concur. "Many plans fell into this trap last year and ran into numerous problems later in getting their bids approved," Buglio contended. "The process is not complete until you concur," he said.

Next, plans must "crosswalk" formulary submissions to plans. Since most plans will have uploaded at

E-Mail Newsletters

Medicare Part D Compliance News transmitted biweekly e-mail newsletters on:

◆ **5/1/08** — Included stories on CMS's new outlier justification submission module, recommendations by the National Home Infusion Association regarding home infusion drugs that should be included on Part D plans' formularies, and a correction to CMS's new rule increasing the estimate of re-assigned beneficiaries.

◆ **5/15/08** — Contained information on coordinating Medicare Prescription Drug Plan Finder submissions with monthly formulary updates and a report by the Commonwealth Fund indicating that collaboration between the states and the federal government is a best practice in the Part D benefit.

If you aren't receiving your biweekly e-mail newsletter, call (800) 521-4323 or e-mail: customerserv@aispub.com.

least one formulary into HPMS, Buglio said they must link the formulary ID to the appropriate plan ID or IDs that offer Part D.

He noted that all Part D plans must have a formulary assigned to them, and all formularies submitted by a plan must be assigned to at least one plan ID.

All renewing organizations must crosswalk their contract year (CY) 2008 plans to their CY 2009 plans. Plans with contracts that operated in 2008 must "explain how your contract year 2008 plans will crosswalk to your contract year 2009 plans," Buglio explained.

Not only is this step critical to the bid-submission process, but Buglio contended that it is "critical to the enrollment process as well to understand how your existing beneficiaries are transitioning from one year to the next." The relationship between the plans will determine which beneficiary notifications need to be used, he said.

Sponsors Must Link Plans

According to Buglio, HPMS will display both sets of plans, and sponsors have the option of linking one CY 2009 plan to one CY 2008 plan, one CY 2009 plan to multiple CY 2008 plans, or multiple CY 2009 plans to one CY

2008 plan; not linking new CY 2009 plans to any CY 2008 plans; or terminating a CY 2008 plan.

Sponsors then must provide more specific statuses for each plan relationship. For example, obvious relationships are new, renewals, or terminations, he said. There are also consolidated renewals, renewals with service-area expansions of a county or region, renewals with service-area reductions, or renewals split based on provider groups. Buglio described the last one as "rare."

Only after the above three steps are completed can organizations upload their actual plan bids. This is done by validating PBP and BPT data using the PBP software. The software validates contract numbers, plan IDs, Part D indicators, and the type of Part D benefit offered.

Buglio recommended uploading more than one plan bid at a time to ensure that a plan meets the deadline, but bids can be uploaded one at a time.

Finch clarified that sponsors have until Oct. 1 to submit any 2009 PBP plan corrections. But she advised reviewing PBP data entry and SB language to "avoid corrections." This is the "common reason for PBP plan corrections," she said.

Contact Finch at kristin.finch@cms.hhs.gov and Buglio at gregory.buglio@cms.hhs.gov. ♦

Part D Plan Sponsors Are Given Flexibility to Meet NPI Mandate

All Medicare claims for services provided on or after May 23 must be submitted using the National Provider Identifier (NPI), or they will be rejected. While CMS has given Part D sponsors some flexibility in meeting this requirement, sponsors that did not submit an attestation for each contract stating that beneficiaries will not have their access to Part D drugs hindered as a result of missing prescriber NPIs on pharmacy claims transactions by May 9 may face unspecified consequences from CMS.

All Prescription Drug Event (PDE) data transactions must indicate prescriber IDs. And Part D sponsors must obtain prescriber IDs on all pharmacy claims, making reasonable efforts to obtain NPIs to put in the prescriber ID fields. However, CMS has issued guidance in the form of an FAQ, allowing flexibility in ensuring that "systems continue to accept non-NPI prescriber IDs," such as state license numbers and Drug Enforcement Administration numbers, on pharmacy claims transactions. The FAQ clarified that in cases when a prescriber doesn't have an NPI or a pharmacy can't obtain an NPI, non-NPI indi-

vidual identifiers may be substituted if allowed by the payer/plan.

The agency said that "Part D plans cannot justify putting enrollees at risk of service interruption by establishing point-of-sale edits that reject pharmacy claims that do not include the NPI in prescriber ID field." Thus, CMS advises Part D plans to establish alternative policies and procedures outside of the claims processing to address potential noncompliance with NPI prescriber ID requirements on pharmacy claims transactions.

To ensure acknowledgment and compliance with CMS's FAQ and memo, the agency required Part D sponsors to submit an attestation for each contract by May 9. Sponsors that could not attest "Yes" on the attestation had to provide an explanation as to why they were unable to attest to the requirement. And the agency said that it was planning on contacting each sponsor about failures to attest "Yes." Moreover, CMS sent each Part D plan compliance officer an e-mail with a link to the attestation at <https://vovici.com/wsb.dll/s/11dc4g3392c>.

CMS Issues Additional Quality Checks for Plans on MPDPF Data

In addition to the basic checks Part D sponsors must perform on data submitted for display on CMS's Medicare Prescription Drug Plan Finder (MPDPF) Web site, CMS has issued a detailed list of additional quality assurance (QA) checks that sponsors are expected to perform "to ensure that the information posted on the Medicare.gov Web site continues to be accurate and consistent."

The agency broke up the QA checks into two types — checks on pricing files and technical specifications. Checks on pricing files consist of the following:

Plan Benefit Package Information:

- ◆ High coinsurance greater than 100% of the drug cost.
- ◆ Low copayment less than \$1 when the cost-sharing preference is copayment, or less than 5% of the drug cost when the cost-sharing preference is coinsurance.
- ◆ Overspecified coinsurance in dollars.
- ◆ Extreme tier copay amounts.
- ◆ Failure to list a cost-sharing preference for either retail or mail order.
- ◆ Low non-preferred copay less than the amount for preferred retail pharmacies.
- ◆ Invalid copay constraints.
- ◆ Records that are not unique by plan, days supply, coverage level, and tier.

Excluded Formulary File (EFF):

- ◆ EFF submitted incorrectly.
- ◆ EFF expected but not submitted.
- ◆ EFF National Drug Codes (NDCs) added since last resubmission.
- ◆ EFF NDCs deleted since last resubmission.
- ◆ EFF with reference NDCs.

Formulary File (FF):

- ◆ FF size has decreased by greater than 25%.
- ◆ Missing formulary.
- ◆ Tier combinations found in beneficiary cost record but not in FF.

Pharmacy Cost File (PC):

- ◆ Change in PC network size of 10% or greater compared to last submission.
- ◆ High dispensing fees greater than \$100.

- ◆ No in-area preferred pharmacy.
- ◆ No PC file submitted.
- ◆ Invalid pharmacy number format.
- ◆ Inconsistent duplicate PC record.
- ◆ Missing PC information.
- ◆ Pharmacies marked as neither retail nor mail.

Pricing File (PF):

- ◆ High unit cost 25 times greater than the highest average wholesale price (AWP) and 25 times greater than the median price for that NDC.
- ◆ Low unit cost 25 times less than the lowest AWP and 25 times less than the median price for that NDC.
- ◆ Missing mail or retail unit cost.
- ◆ Inaccurate pricing display.
- ◆ Missing PF.
- ◆ No active PF.
- ◆ Potential brand priced at the generic price.
- ◆ Potential low unit cost for NDC.

Reference Pricing (RP) File:

- ◆ NDCs not in formularies.
- ◆ No RP file submitted.
- ◆ No unit cost provided.
- ◆ NDCs not found in CMS reference NDC list.
- ◆ Target prices less than reference prices.
- ◆ Target NDCs with multiple reference NDCs.
- ◆ NDCs with a copay reference type contain a reference amount less than or equal to \$1 or NDCs with a coinsurance reference type that contains a reference amount greater than 100%.

QA checks for technical specifications consist of looking at beneficiary cost, pharmacy cost, pricing, and reference pricing files.

To view CMS's complete memo, go to www.AISPartD.com. Under "Part D Sponsors" click on "Contract Information" and "HPMS Guidance History."

Enrollment, Membership Data Are Focus of '07 PDE Reconciliation

Now that CMS has extended until July 30 the deadline for Medicare Part D sponsors to resubmit their 2007 rejected Prescription Drug Event (PDE) data transactions, plans must move quickly in order to potentially recoup money from CMS.

As such, any summer vacations Part D plan sponsors were planning on taking are pretty much canceled, said Aaron Eaton, director of strategic development for Gorman Health Group, LLC. In a recent Internet presentation, Eaton explained what sponsors need to do to reconcile membership and PDE data to reduce their financial exposure.

There are two types of plans facing PDE reconciliation in 2007, said Eaton — those that finished 2006 PDE reconciliation but expended more energy and resources to do so than they had, and those that didn't finish the process or didn't do it right. For 2007, "plans need to be more efficient, more data driven, and more automated," he contended.

One of the biggest challenges, according to Eaton, who is a former CMS Medicare Part D official, is that the rejections are "not about PDEs most of the time." He explained that "90 plus percent rejections are coming from enrollment and membership issues."

Since data are constantly being exchanged between plans, CMS, and pharmacy benefit managers, the first place to look when PDE data are rejected is "membership data," Eaton said. It is "so important to start with membership cleanup and avoid bad data in and bad data out," he asserted.

Enrollment Departments Reign Supreme

As a result of the emphasis on membership data, Eaton maintained that enrollment departments have become major drivers within Medicare organizations. It is now a "24-7, 365-day-a-year job," he said.

Enrollment departments are faced with two jobs. Current maintenance consists of reviewing membership data on a daily basis and keeping the membership system in sync with CMS. These departments must also "examine snapshots of the membership system" on a monthly basis for reconciliation purposes, Eaton said. These snapshots must be compared with CMS data to make sure nobody "has fallen through the cracks," he added.

Eaton suggested that many plans wind up "chasing their tails," using rejected PDEs to inform them of discrepancies in membership data. This "lack of tools to link membership and PDE data" is a cause of many problems, he said.

The keys to successful 2007 PDE reconciliation, said Eaton, are processes, tools, and resources. "None can stand alone," he contended, and "all three must work in unison."

All groups or departments in the organization must fall under the "big picture" and reconciliation processes, Eaton said. He recommended making sure new hires are fully trained in the reconciliation processes because they usually lack the necessary experience.

Having reconciliation tools allows organizations to be "proactive" in identifying discrepancies, said Eaton. Plans need to use tools designed by those working in the industry on a daily basis, he suggested.

Eaton described the evolution of reconciliation tools from 2006 PDE reconciliation to 2007 PDE reconciliation as from passive, where organizations just looked at data and counted errors, to proactive. First, in early 2007, plans started incorporating more knowledge into their reconciliation tools, he said, with "interactive prioritization of cleanup."

Plans Should Wisen Up

Now, plans need to enter into an intelligence phase, Eaton recommended, by using an integrated identification and research tool that will put the right data in the right place at the right time. The best reconciliation tool will combine the ability to identify and research discrepancies and include an Internet search engine that retrieves and presents relevant information to address the pertinent questions, he said.

Researching with the proper tools should consist of identifying rejected PDEs by member and code, linking

Health Reform & the 2008 Elections

July 10-11, 2008

Capitol Hill, Washington, D.C.

Senators Rockefeller, Hatch and Wyden

Congressmen Rangel, Stark, Waxman and Camp

Speakers from Washington think tanks

Health care association leaders

Health policy experts from Calif., Indiana,
Mass., Minn. & Vermont

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

rejected PDEs with the correct members, researching the rejections, and viewing all historical member information.

Reconciliation resources are also important, said Eaton, and organizations should focus on how many teams in the enrollment department are dedicated to the various enrollment functions — current, maintenance, cleanup, and open enrollment.

Although the industry will “never get to a point when reconciliation is not needed,” Eaton said that by being proactive in identifying discrepancies, using technology, and identifying the root causes of PDE rejects, plans can ease the pain of reconciliation.

Contact Eaton at aeaton@gormanhealthgroup.com. ✧

New Regs Call for Level Commissions

continued from p. 1

courage “churning” of beneficiaries from plan to plan each year based on where commissions are highest. This means that while commissions can be different for MA plans versus PDP products, “the MA or Part D plan may not vary the fixed-fee commission on the premium or any other measure,” within the MA or PDP product groups, says Jean LeMasurier, director of the employer group practice at health care consultant Gorman Health Group, LLC.

The rule does not specify actual amounts of commission that plans are allowed to offer. And according to Abby Block, director of the Center for Beneficiary Choices at CMS, there is a reason. A specific amount is not included because CMS formulated the rules to “create...stability in the marketplace” so that there is no incentive for agents to move beneficiaries from plan to plan, she said.

The regulations would give CMS greater flexibility in deciding penalties against PDPs whose violation of Medicare rules adversely affects beneficiaries. Under the proposal, CMS would have authority to levy a penalty of up to \$25,000 for each enrollee affected, or likely to be affected, by such a violation.

Industry Fears Big Fines

“I’m scared to death about the level of [proposed] fines...which is seemingly limitless,” says Stephen Wood, a principal in the Chicago office of actuarial consulting firm Reden & Anders, Ltd. “If your call center is doing something wrong, that could add up to millions and millions” of dollars’ worth of fines. For Medicare plans, “\$100 million fines are unusual, but they’re not unprecedented,” he says.

“We all know what CMS is doing. They’re trying to pre-empt Congress...and tell Congress, ‘Not to worry.

We’re all over it,’” Wood says. In fact, he describes the alternative of Congress passing legislation on MA marketing as “far, far worse.” He says Congress, for example, might “prohibit independent agents from selling MA products, period,” allowing only salaried employees of the plan to sell its products.

However, beneficiary advocacy groups are urging Congress to follow through and “enact laws that prohibit cold-calling, rein in agent commissions and take other steps to stop abusive marketing,” according to the Medicare Rights Center.

The center expressed concerns that CMS may “weaken its proposal in the final rule” and questioned whether the final rule will “still prohibit plan agents from making harassing phone calls to solicit new enrollees, or will it create the loophole desired by insurance companies and allow cold calls that follow a mailing?”

Moreover, the center said that “CMS does not have the personnel or the expertise to enforce marketing rules at the local level.” This, it added, should be left up to

Compliance Resources From AIS

- ✓ *Report on Medicare Compliance*, the industry’s leading compliance newsletter, with weekly news and insightful analysis of the key compliance problems that lie ahead for the industry.
- ✓ *Report on Research Compliance*, a monthly newsletter, weekly e-letters and subscriber-only Web site on conflict of interest, human subjects, scientific misconduct, tech transfer and much more; copublished by NCURA.
- ✓ *The HCCA-AIS Medicaid Compliance News*, monthly news and valuable how-to strategies for identifying and reducing the top Medicaid compliance risks. Co-published by the Health Care Compliance Association (HCCA) and AIS.
- ✓ *A Guide to Complying With Stark Physician Self-Referral Rules*, a comprehensive looseleaf (plus quarterly updates) with practical summaries of the federal rules and separate analyses for hospitals, physician groups and other stakeholders.
- ✓ *49 Steps to Implement Sarbanes-Oxley Best Practices in Private & Nonprofit Health Care Entities*, a highly practical book that identifies and describes steps for adopting consensus best practice standards (includes a free CD with templates).

Visit the AIS MarketPlace at
www.AISHealth.com

state insurance departments, and Congress should “find a role for states to hold both agents and plans to account for marketing misconduct.”

Just Passing Through

Under the new rule, Part D sponsors would also face new restrictions on how they calculate “negotiated prices” for pharmaceuticals under their plans, using “pass-through” pricing.

The agency said the change in calculating negotiated prices would lower the cost-sharing burden on beneficiaries, while increasing Part D sponsors’ bids that are used to calculate premiums.

The new definition of negotiated prices in the proposed rule would be based on the price “ultimately received” by the pharmacy or other dispensing provider. The change would be effective for contract year 2010, according to the rule.

Timeline for 2009 Plan Year Data Submissions to MPDPF

All stand-alone Prescription Drug Plans and Medicare Advantage prescription drug plans must submit plan data to CMS’s Medicare Prescription Drug Plan Finder (MPDPF) Web site on a biweekly basis during a contract year. Before the data are publicly released on Oct. 9 for contract year 2009, CMS will conduct three test-pricing data submissions. These data submissions are required for all existing plans as well as any plans that are new for contract year 2009. Part D plan sponsors will need to submit complete pricing files, pharmacy cost files, and, if applicable, a reference pricing file. Reference pricing files must be submitted only by plans using reference pricing as indicated in the plans’ plan benefit packages.

◆ **July 17–18** — Part D plans must submit initial 2009 plan year pricing and pharmacy network data electronically to CMS.

◆ **Aug. 14–15** — Part D plans must submit corrected 2009 plan year pricing and pharmacy network data to CMS.

◆ **Aug. 26–28** — Part D plans may preview 2009 plan year pricing data, based on data submitted Aug. 14–15.

◆ **Sept. 4–5** — Part D plans must submit corrected 2009 plan year pricing and pharmacy network data to CMS for final testing.

SOURCE: CMS memo, 2009 Plan Year Pricing Data Requirements, May 6, 2008

CMS said that it had initially intended the definition to be consistent with the meaning of “pass-through prices,” an industry term for prices negotiated with and paid to the pharmacy. But this earlier definition was interpreted by pharmacy benefit managers (PBMs) and others to include the term “lock-in pricing,” a contract method by which the plan sponsor agrees to pay the PBM a set price for a particular drug that may vary from the price that the PBM negotiates with each pharmacy, CMS explained.

Under the lock-in pricing arrangement, on any given drug purchase, the PBM may pay the pharmacy a higher or lower price than it will bill the plan sponsor, CMS said. “However, we assume that the prices billed to the plan sponsor are generally higher than the prices paid to pharmacies, resulting in an overall net profit to the PBM that is marketed as a ‘risk premium’ earned for shielding the sponsor from price variability,” it added.

PDPs use the negotiated price to calculate beneficiary cost sharing and the reporting of drug costs to CMS, among other things, CMS said. The agency explained that continuing to allow lock-in prices to be used for Part D drug-cost calculations and reporting could have several undesirable results, including:

- ◆ *continued and probably increased cost shifting from the government to the beneficiaries in the form of higher beneficiary out-of-pocket costs;*
- ◆ *interference with market competition among Part D sponsors; and*
- ◆ *beneficiary confusion over actual drug prices.*

On the other hand, CMS continued, when the PBM spread is included in the administrative costs component of the Part D sponsor’s bid — as opposed to being treated as a drug cost — the plan sponsor’s bid would be increased by that amount. “Consequently, all other things being equal, the sponsor’s bid must be higher with pass-through prices than with lock-in prices,” the agency said. This will increase premiums for beneficiaries and the direct-subsidy costs for the government, CMS noted.

However, it explained that for the vast majority of Part D beneficiaries, total out-of-pocket costs, including both monthly premiums and cost sharing, would go down under pass-through pricing because: (1) cost sharing per prescription is lower; (2) the lower drug costs advance the beneficiary through the benefit toward the coverage gap more slowly; and (3) increased premium costs are principally borne by the government.

Plans Will Adjust, Expert Says

Margaret Nowak, senior manager of Avalere Health LLC’s Medicare practice, contends that Part D sponsors and PBMs will adjust to any financial squeezing under the new rule. “They’re going to shift what prices go into that

pass-through definition," she says. "Plans may not pass as much [price savings] back to the beneficiaries at the point of sale, because they now need to account for this administrative-cost line item that they didn't necessarily have before."

Nowak says that some stakeholders who use lock-in pricing will oppose the proposed definition. As such, "there definitely is a potential for this to change," she says of language that might appear in CMS's final rule.

The proposed rule would also extend these pass-through pricing changes to the Retiree Drug Subsidy program.

And the proposed rule would codify the following additional provisions:

◆ **Streamline eligibility determinations for Medicare's low-income subsidy (LIS) and limit beneficiary liability.**

◆ **Limit plans' option to disenroll beneficiaries for failure to pay premiums only if they pay premiums directly to plans.**

◆ **Prohibit Part D plans from directly billing enrollees when premium withholding is selected.**

◆ **Modify the definition of "other prescribers" to allow non-physician prescribers to perform coverage determinations and appeals processes.**

The agency will accept public comments on its proposed rule until 5 p.m. Eastern Time July 15 and expects to have a final rule out before open enrollment for contract year 2009. Visit www.cms.hhs.gov/HealthPlans-GenInfo/Downloads/PDP-MA_Proposed_Rule.pdf. ◇

AIS is sponsoring an audioconference June 5 on the proposed new Part D and MA rules. To register or for more information, please call (800) 521-4323 or visit www.AISHealth.com.

Congress, Others Look Beyond CMS Rule; Some Seek Legislation, State Enforcement

Federal lawmakers and lobbying groups seem anxious to move beyond CMS's newly proposed rule (see story, p. 1) — and seek a legislative fix, more aggressive enforcement, and more input from state regulators to tighten marketing standards for Part D and Medicare Advantage (MA) plans. In recent remarks:

◆ **Sen. Max Baucus, (D-Mont.),** chairman of the Senate Finance Committee, issued a statement on May 8 — the day that CMS released the proposed rule — voicing his strong support of provisions in the rule that would ban cold-calling and door-to-door marketing by agents, prohibit plans from offering free meals to beneficiaries, and require plans to increase training for agents. Baucus then said that he "intends to strengthen these policies by writing them into federal law."

◆ On the House side, **Rep. Pete Stark (D-Calif.),** chairman of the House Ways and Means health subcommittee, responded by stating that at first glance the proposed rule "offers an improvement over the status quo, particularly the level commission structure requirement." But he says that in order for the CMS rule to be effective, it "must be accompanied by a commitment to aggressive enforcement from CMS as well as the states. Secret shopping won't cut it."

◆ **National Association of Insurance Commissioners President Sandy Praeger,** who also is the Kansas insurance commissioner, issued a statement May 8 noting that CMS had incorporated some of the previous NAIC recommendations to CMS into the rule. Specifi-

cally, she cited CMS's prohibition on cross-selling of insurance products, and a proposal requiring plans to adhere to state agent-appointment laws.

Praeger contends that despite positive changes proposed in the rule, a significant issue was left unaddressed: States lack sufficient regulatory authority to ensure proper enforcement in MA and Part D marketing and sales. "Although CMS has made a number of attempts over the past year to tighten their rules, we have continued to see problems in the marketplace because the federal government is unable to provide adequate enforcement," she asserts. "The proposed rule fails to ensure that the states have the ability to properly oversee the marketing activities of these plans."

◆ **America's Health Insurance Plans (AHIP) spokesman Mohit Ghose** says the industry has pushed for marketing reforms since problems first were identified last year, asserting that the industry has "zero tolerance" for marketing abuses. He says AHIP members met with about 10 senators from the Senate Finance Committee in March, after the panel held two hearings on MA marketing in February, to address issues such as improving agent training, and AHIP continues working with CMS, Congress and representatives of the agent and broker community. "We need to have a system in place that puts an end to unscrupulous [marketing] practices," he adds.

Contact Robert Zirkelbach at (202) 778-8493 for more information on AHIP's position.

NEWS BRIEFS

◆ **CMS on May 16 launched a 2008 spring low-income subsidy campaign in an effort to increase the number of applications submitted to the Social Security Administration for the Part D low-income subsidy (LIS).** The campaign will run through July and will focus on targeted areas where new data indicate “a high level of potentially eligible beneficiaries,” CMS said. The agency said it “will work with other federal agencies and partners to conduct a nationally-organized, locally-implemented outreach effort,” one of the goals being to increase the number of applications for extra help by beneficiaries who may qualify and increase the number of beneficiaries receiving Part D coverage. The agency said it will use a multi-pronged approach consisting of informed outreach based on data and research, key products, stronger partnerships in the community, and leveraging coverage in the media. During a hearing on May 16, CMS Acting Administrator Kerry Weems said that he will hold regional CMS officials accountable for enrollment by establishing and publicizing goals for enrollment in each region. Go to www.AISPartD.com. Under “Low-Income Subsidy Program” click on “General Information” and “2008 LIS Outreach Toolkit.”

◆ **CMS has renewed its contract with Maximus Federal Services for three years in a pact valued at approximately \$14 million.** Under the contract, Maximus will continue to process appeals related to Part D as a qualified independent contractor (QIC) to CMS. As a QIC, Maximus receives and impartially adjudicates appeals from Medicare beneficiaries resulting from a claims denial made by a Part D plan.

◆ **In response to an article appearing in last month's issue (PDN 5/08, p. 5) regarding an audit of Samaritan Advantage Health Plan that alleged violations, Jim Kelly, operations manager for Samaritan, tells PDN that “we were issued the findings from our Part D audit on Feb 4, 2008, and submitted our response to the findings on March 14, 2008, in compliance with CMS time frames.”** Samaritan worked with “CMS on the identified areas for improvement,” he added. Contact Kelly at jkelly@samhealth.org.

◆ **CMS has excluded “hundreds of marketed unapproved drugs from its 2008 Formulary Reference File (FRF), according to a recent report by Avalere Health LLC.** The report shows that CMS dropped more than 1,500 drug codes from the contract year 2008 FRF, which led to commercial health plans

dropping many of these drugs from their Medicare offerings in 2008. This resulted in significantly smaller Part D formularies in 2008 compared to 2007, the report says. Avalere also found that CMS dropped drug codes from the FRF that were connected to discontinued drugs, Part A or Part B products; products with redundant codes; and products not reimbursable under statute (such as nonprescription medications, and agents used for anorexia, weight loss, or weight gain). These changes to the FRF “had significant ripple effects to plans, patients, physicians, and pharmacists,” says Avalere. For patients, changes in the formularies could result in their need to pay out-of-pocket for non-covered drugs, or transition to a comparable drug. Plans have the authority to decide whether to pay for the deleted drugs. Information on all products — approved or unapproved, repackaged or marketed directly — should be readily accessible to Part D plans and CMS through FDA databases and other resources, states the report. Visit http://www.avalerehealth.net/research/docs/05142008_Part_D_2008_Formularies.pdf.

◆ **Manufacturer prices of 185 widely used generic drugs in Medicare Part D decreased by an average of 9.6% in 2007, according to a May 18 report released by AARP.** Taken together with a previous AARP report showing that manufacturer prices of 220 of the most commonly used brand-name drugs by Part D enrollees increased by more than 7% during the same period, AARP has concluded that Americans who are not taking advantage of lower-cost generic prescriptions are wasting their hard-earned money. Of the 185 generic drugs AARP studied in 2007, there were no price changes for 133 generic drugs; 43 generics drugs had price reductions up to 69.5%; and nine generic drugs had price increases. “More needs to be done to speed generic drugs to market and protect against loopholes that allow pharmaceutical companies to block or delay entry of these lower priced alternatives,” said John Rother, director of public policy at AARP. Go to http://www.aarp.org/research/health/drugs/rx_watchdog.html.

◆ **CORRECTION:** Part D plans may begin submitting 2009 marketing materials June 16 for CMS review. If CMS approves the materials, they can be used during the 2009 marketing season beginning Oct. 1. Separately, Part D plans have until June 30 to submit any changes to their 2008 marketing materials. A story in PDN's May issue incorrectly stated that plans have only a two-week period starting June 16 to submit marketing materials for 2009 Part D products to CMS for review.

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



(1) Call us at **800-521-4323**



(2) Fax the order form on page 2 to **202-331-9542**



(3) Visit the MarketPlace at **www.AISHealth.com**

**IF YOU ARE A SUBSCRIBER
AND WANT TO ROUTINELY FORWARD THIS
E-MAIL EDITION 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 e-mail editions without prior authorization from AIS, since strict copyright restrictions apply.)