

MEDICARE PART D NEWS

Business and Compliance News and Strategies for the Medicare Drug Benefit

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Sponsors Must Increase Monitoring of Related Entities for Data Validation Audits

Part D plan sponsors may have to “delve down deeper” into the activities of their delegated entities when preparing 2010 data for 2011 data validation audits (DVAs). Dorothy DeAngelis, managing director at FTI Consulting, advised sponsors to start monitoring these entities immediately as they face a tight timeframe in which to do it. Sponsors with incomplete data that are not ready could face consequences ranging from being labeled an outlier, marketing and enrollment suspensions or contract termination.

In an effort to better understand whether data CMS relies on are accurate, complete and comparable among plans, the agency is requiring Part D and Medicare Advantage plans to hire independent third parties to perform DVAs. These audits will be performed in first-quarter 2011.

The external entity will review general standards and measure-specific criteria to determine whether the organization’s CMS-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.

For Part D plans, measure-specific criteria include medication therapy management programs, grievances, coverage determinations and exceptions, appeals, long-term care utilization and plan oversight of agents.

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As MTMPs Become More Robust, Plans Need To Compare Cost to Health Status

The health reform law has codified CMS medication therapy management program (MTMP) requirements, aiming to make the program more robust and providing incentives for some plans to provide programs that go beyond CMS requirement. Some industry insiders would like to see plans do more with their MTMPs but acknowledge a conflict between cost and beneficiary health status.

Under the health reform law, beginning in 2013, Part D plans must offer MTM services to targeted beneficiaries that include, at a minimum:

- ◆ *An annual comprehensive review of medications (CMR)*, either in person or telephone, by a licensed pharmacist or other qualified provider;
- ◆ *A process to assess, at least quarterly, the medication use* of individuals who are at risk but not enrolled in the MTMP, including individuals who have experienced a transition in care; and
- ◆ *Automatic enrollment of targeted beneficiaries* who qualify on a quarterly basis and provision for an opt-out.

For Medicare Advantage prescription drug (MA-PD) plans, beginning in 2012 there will be incentives in the form of bonus payments to establish MTMPs more robust than that required by CMS.

continued

Kristina Lunner, vice president of government affairs for the American Pharmacists Association (APhA), tells *PDN* that this is a good move. "It is always safer" if the requirements are included in statutes, she says. There is more assurance of compliance, she adds.

Lunner also says APhA supports recently introduced legislation to further shore up MTMPs. For example, Sen. Kay Hagan (D-N.C.) introduced the Medication Therapy Management Expanded Benefits Act, which would allow Medicare beneficiaries with a chronic condition to review all their medications in one-on-one sessions with pharmacists. The bill also would reimburse pharmacists to follow up and educate patients about their medication regimens.

Lunner also believes "very strongly that MTMPs would better serve beneficiaries if they were more robust." One of the problems she says she sees is that there is "a lot of variability in how plans implement" MTMPs. Programs should be focused on patient needs, she contends — but that's not always the case.

Moreover, plans tend to provide fewer of the core elements APhA likes to see in MTMPs, she maintains. APhA and the National Association of Chain Drug Stores issued "Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service," a document setting forth five core elements that every MTMP should have — CMRs, personal medication records, medication-related action plans, intervention and referral, and documentation and follow-up.

How MTMPs Are Shaping Up

James Owen, pharmacist and director of professional practice at APhA, tells *PDN* he was "pleased to see" more plans including some of the core elements in their MTMPs in 2010, such as targeted or comprehensive medication therapy reviews, patient lists and action plans.

CMS's overview of 2010 MTMPs released in June revealed that 100% of MTMPs offer annual comprehensive medication reviews and at least quarterly targeted medication reviews. Almost 100% (99.9%) of MTMPs perform interactive, person-to-person CMR consultations via telephone. A quarter (25.8%) offer face-to-face consultations.

The top five types of written summaries provided to beneficiaries by MTMPs in 2010 are recommendations (81.1%), personal medication lists (74.5%), action plans (59%), reconciled medication lists (29.4%) and educational materials (4.3%).

Owen is pleased plans are including follow-up methods. In the past, he says, "plans didn't have any follow-up. That part at least has been addressed."

Other characteristics of 2010 MTMPs are:

- ◆ 68% of plans target beneficiaries at least quarterly during a plan year for enrollment in an MTMP, while 26.5% target them monthly.
- ◆ 99.9% of plans use pharmacists to provide MTMP services, 21.2% use registered nurses, 9.1% use physicians, and 53.5% use other methods.
- ◆ 80% of plans utilize outside personnel, such as pharmacy benefit managers (72.3%), MTM vendors (31.9%), disease management vendors (0.1%), community pharmacists (29.7%), or long-term care pharmacists (10.9%).
- ◆ 71.7% require a minimum of three chronic diseases.

Both Owen and Lunner acknowledge that there is an "inherent conflict" for plans between the cost of MTMPs versus the health benefits to enrollees. Because of this conflict, Owen says "some MA-PD plans may have more robust programs and follow-up [than stand-alone Prescription Drug Plans] because they are responsible for the beneficiary's health." MA plans have more of a stake in MTMPs, he says.

And now that stake is increasing, notes Lunner. Under the health reform law, MA plans can receive bonus

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payments if they provide certain services, such as more robust MTMPs than what is required by CMS.

She says in general Part D plans' MTMPs have improved since Part D was implemented, but "we want to see more."

Lunner maintains that some pharmacists tell APhA that many patients are not participating in the program. Owen attributes this to beneficiaries' lack of awareness of availability of MTMPs. There is not a lot of education on the programs, he argues.

Hopefully, Owen says, the requirement to automatically enroll beneficiaries and provide an opt-out will rectify this problem. The inclusion of automatic enrollment "speaks to the gaps in the program," says Lunner.

Contact Lunner at (202) 429-7507 and Owen at (202) 429-7540. ♦

New Marketing Guidelines Mean More Scrutiny in Enrollment Season

In light of CMS's recently updated Medicare marketing guidelines, Part D and Medicare Advantage plan sponsors should be prepared for intensified regulation of marketing efforts this upcoming enrollment season. Not only is CMS not giving sponsors any grace period from the June 4 release date of the guidelines, but according to some industry experts, the agency is going to be looking for tangible evidence of compliance.

CMS's final 2011 marketing guidelines focus mainly on incorporating recent policy clarifications and streamlining operational guidance (*PDN 7/10, p. 9*). However, there were some new provisions included, such as a mandate to include a summary of benefits in enrollment

Part D Sponsors Advised to Check Pricing, Pharmacy Files on Plan Finder	
CMS will perform quality assurance (QA) checks on contract year 2011-required pricing and pharmacy network files posted on the Medicare Prescription Drug Plan Finder (MPDPF) tool. Part D sponsors should perform QA checks to ensure that the files are complete and accurate or they risk having their pricing data suppressed on the MPDPF. The agency will review the following areas:	
Pharmacy Cost File	Change in network size — Determine if the retail pharmacy network size had a 10% or greater change compared to the last submission.
	High dispensing fees — Evaluate if the file contains dispensing fees greater than \$100.
	No file submitted
	Invalid pharmacy number format — Evaluate pharmacy numbers to ensure they are formatted correctly (12 digits; 10 digit National Provider Identifier with a leading one and zero), and check to see if the file contains National Council for Prescription Drug Programs numbers.
	Inconsistent duplicate record
	Missing file information
	No mail-order pharmacies in file
	No preferred pharmacies (retail)
	Exclusion of non-preferred network pharmacies (retail) — Check if a plan's network has preferred retail network pharmacies, then there must also be non-preferred retail network pharmacies.
	Inclusion of preferred pharmacies (retail) — Check if an organization's uploaded plan benefit package (PBP) indicates that there are only other network retail pharmacies but pharmacy cost file indicates preferred retail pharmacies.
	Pharmacies marked as neither retail nor mail order
	Vaccine administration fee outlier — Identify any vaccine administration fee filed that is populated with a zero or is left blank, and evaluate each contract/plan/segment/pharmacy number ID combination that is associated with a specific price file ID to ensure that each vaccine administration fee field associated with that price file ID has the same amount.
	Mail-order pricing not indicated in PBP
	Pricing File
Low unit cost — Identify NDC unit costs that are priced at 25 times less than lowest AWP and 25 times less than the median price for that NDC.	
Missing price file	
No active pricing file	
Pharmacy cost and pricing file mismatch — Identify pricing file IDs that are expected but have not been submitted.	
Pricing file unit cost discrepancy	
Potential brand priced at generic — Check products where the brand price is less than or equal to the generic price.	
Pricing file with duplicate NDC records (different unit costs)	
Pricing File and Formulary File	Pricing file and formulary file mismatch — Determine if the pricing file is missing pricing for reference NDCs found in the last approved formulary file.
Pricing File and Excluded Drug File	Pricing file and excluded drug file mismatch — Determine if the pricing file is missing pricing for NDCs identified in the submitted excluded drug file.
SOURCE: CMS, "Quality Assurance Checks for 2011 Data Submitted for Posting on Medicare Plan Finder Tool," June 30, 2010.	

kits, restrictions on the use of agent/broker telephone numbers without also including the plan's customer service number, limits on when to stop marketing non-renewing or reduced plans, and prohibition of mid-year benefit enhancements.

According to Camille Brown, CMS marketing lead, mid-year benefit changes may occur only when a national coverage determination takes effect mid-year and it is covered under the contract or it is covered on a fee-for-service basis outside the contract but the sponsor chooses to offer the coverage to the beneficiary.

Sponsors must notify CMS of allowable mid-year changes, she told listeners during a June 30 CMS webinar on the new marketing guidelines. Moreover, the change must be positive to beneficiaries, and plans must notify beneficiaries 30 days before the effective date of the change.

Effective Date is Firm

Probably the biggest impact that these guidelines will have on plans is their effective date. The effective date is June 4, the date the guidelines were released, and Brown said the date "is applicable to all materials that are submitted for review and approval after June 4."

"There's no grace period," she added. "Plan sponsors must comply with the requirements in the June 4, 2010, release as of June 4, 2010," Brown clarified.

Sponsors are expected to be in compliance effective immediately and "at all times," said Christine Williams, managing consultant, government programs and strategies, for Ingenix Consulting. She told listeners during a July 7 Ingenix-sponsored webinar on the guidelines that not only must sponsors be in compliance, but they "must be able to provide tangible evidence of compliance." For example, policies should address areas of compliance, restate guidance or regulations, and reference applicable guidance or regulations. These policies also should be supported by standard operating procedures, and the procedures should be cross-referenced in the policies, she said.

Williams recommended that plans establish the evidence needed by referencing and providing workflows, tables, audit results and meeting notes, among other documentation.

"It is not sufficient to just have policies and procedures and standard operating procedures," she said. "Plans must be able to demonstrate that these are operational every day of the plan year."

When formulating ways to comply with the final marketing guidelines, plans must also take into consideration the HIPAA privacy rule, the anti-kickback statute and the prohibition against beneficiary remuneration.

According to Kelli Back, an attorney with the law office of Mark S. Joffe in Washington, D.C., sponsors need to be aware of the HIPAA law when faced with new

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provisions in the marketing guidelines regarding obtaining prior authorization for certain non-health-related information. Back also spoke during Ingenix's webinar.

HIPAA compliance is "the floor," she said. It provides the basic requirements; the marketing guidelines can only add requirements, she explained. The guidelines clarify that only very general information can be included as part of a request for authorization, and non-health-related content cannot be included with plan-related materials, including in mailings and on a sponsor's website.

Reform Law Provides Kickback Exceptions

Anti-kickback issues may be raised, said Back, if a plan sponsor pays an individual or entity other than an agent for referrals where payment is based on volume or value or enrollments, she noted. Situations where a provider supplies something to a plan for free that would result in members using their services could also trigger the statute, she said.

In general, sponsors are prohibited from offering anything of value (remuneration) to a beneficiary that would be likely to influence the beneficiary to obtain coverage from a particular sponsor. For example, sponsors cannot offer discounts on other non-Medicare services in order to encourage beneficiaries to enroll in the sponsor's Medicare plan.

There are exceptions to the definition of remuneration that were added by the health reform law. Back said plans should be aware of these and coordinate with the marketing guidelines.

Under the health reform law, effective as of March 23, the following types of remuneration are exempt from the definition under the Civil Monetary Penalties Law:

- ◆ *Other remuneration that promotes access to care* and poses a low risk of harm to patients and Medicare.
- ◆ *The transfer of items or services by a person consisting* of coupons, rebates, or other rewards from a retailer, offered or transferred on equal terms available to the general public regardless of insurance status, and not tied to the provision of other items or services reimbursed under Medicare.
- ◆ *The transfer of items or services by a person not offered* as part of an advertisement or solicitation; not tied to the provision of other items or services reimbursed under Medicare, for which there is a reasonable connection between the items or services and the medical care of the individual; and for which the person providing the items or services determines in good faith that the individual is in financial need.

Contact Brown at camille.brown@cms.hhs.gov, Williams at (312) 429-3927 and Back at (202) 457-6632. ✧

Group Waiver Plans May Be Viable Alternative to RDS for Employers

As employers evaluate whether to continue to provide actuarially equivalent prescription drug coverage to their retirees due to provisions in the health reform law, their options are taking shape. One particular option — Employer Group Waiver plans (EGWPs) — seems to be the frontrunner, with 43% of organizations surveyed by Hewitt Associates indicating this is the most favored alternative to the retiree drug subsidy (RDS).

According to Stuart Wohl, senior vice president and retirement health practice lead at The Segal Company, there are approximately 10 million beneficiaries enrolled in plans receiving the RDS. This is the "most common" option for employers, as it is a familiar program almost five years after implementation of Part D, he told an AIS-sponsored webinar July 28 on reform-driven changes in retiree health coverage. Many employers will continue to provide actuarially equivalent or better coverage to retirees and receive the RDS, contended Wohl.

RDS Is Predictable

In addition to familiarity, Wohl explained that under the RDS the subsidy amount is predictable (28%), sponsors maintain full control of the plan design and for-profit employers can take a tax deduction on the subsidy amount. However, the health reform law eliminates the tax deduction beginning in 2013. This loss of tax deductibility and enhancement of the Part D benefit through the manufacturers' discount in the coverage gap, said Wohl, are "causing sponsors to begin to revisit their options."

Although keeping the RDS is "essentially business as usual," employer plans that provide benefits actuarially equivalent or only a small margin better than benefits offered under the standard Part D benefit will need to review their benefit offerings. The standard benefit improves each year going forward, said George Bognar, lead pharmacy benefits consultant for The Segal Company, who also spoke at the webinar. "The hurdle to meet actuarial equivalency is going to be a little higher each year," he said.

According to the Hewitt survey, other options that employer plans are considering include a wrap-around approach (23%), where the sponsor would provide supplemental benefits on top of a Part D benefit, subsidizing their retirees' Part D premiums (24%) and providing defined contribution plans (35%). Twenty-nine percent of employers surveyed also indicated that they were considering eliminating retiree coverage altogether.

By far, the most popular alternative for employer plans is to contract with a stand-alone Prescription Drug Plan (PDP) for coverage equal to or greater than the

standard Part D benefit in an enhanced EGWP. In an EGWP, an employer receives a waiver from CMS to contract with an existing PDP to provide prescription drug benefits to retirees, explained Wohl.

The cost of providing retirees with an EGWP is lower than the RDS, maintained Bognar. Also, the premium charged by the PDP has the value of the subsidy built in. So there is no loss waiting for a prospective subsidy, he explained. Moreover, employers have the option under the EGWP to fully insure the benefit to a fixed premium rate. Although the PDP will build in a risk premium for that, Bognar said some employers find the fully insured PDP an attractive option.

EGWPs Don't Disturb Members

Another benefit of an EGWP as opposed to transitioning to a PDP is that there will be limited or moderate disruption to members. "Obviously if a plan continues to participate in RDS and makes no changes, there is no disruption to members," Bognar said. Under an EGWP there will be a degree of disruption, but the level will "depend on how much the benefit is

changing, as well as the number of beneficiaries affected by such things as changes in the formulary, utilization management programs and changes in the pharmacy network." The key to mitigating any amount of member disruption is to communicate with members at all points during the transition process, Bognar advised.

For example, members should receive an opt-out letter explaining what is happening and receive a benefit guide and ID card. According to Bognar, EGWPs require certain step-therapy and clinical rules to be in place, while prohibiting other step-therapy rules and plan limits. It is important for sponsors to understand and know how many members will be affected and communicate with these members, he said. In most cases, formularies and retail pharmacy networks will also change, noted Bognar.

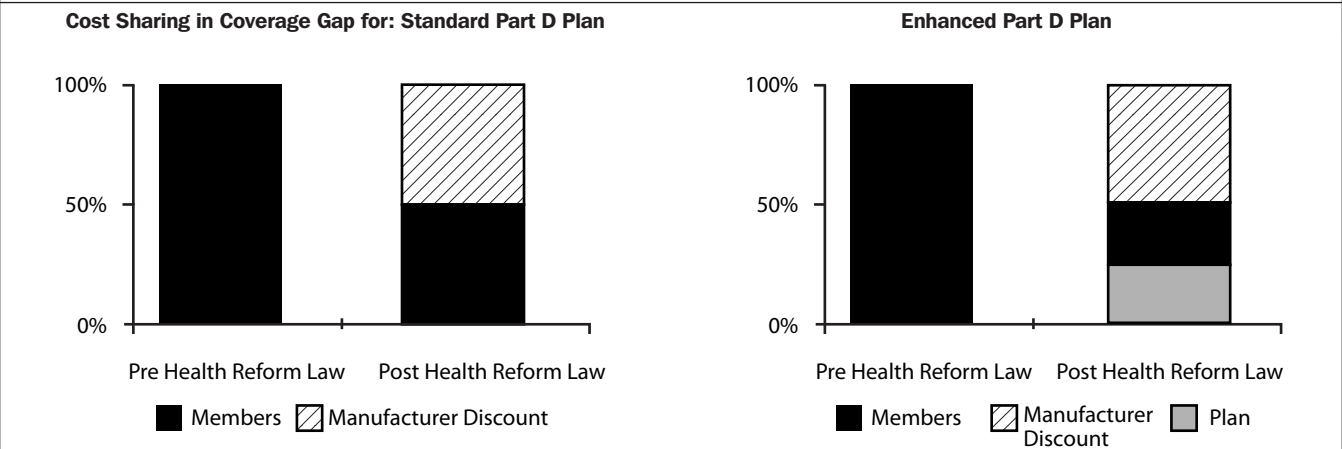
He did acknowledge some challenges associated with EGWPs, including a loss of some control in benefit and formulary design, and a more complex implementation process. Also, CMS asks for health insurance claim numbers to determine eligibility in EGWPs, he noted.

Manufacturer Discount Will Have Less Impact on Enhanced Part D Plans

The 50% manufacturer brand-name drug discount that will be provided to certain beneficiaries beginning in 2011 will apply only to an enrollee's out-of-pocket costs while that enrollee is in the Part D coverage gap. This has "interesting implications" for plans that provide some level of coverage in the gap now and plan on continuing to do so, said Stuart Wohl, senior vice president and retirement health practice lead at The Segal Company.

Speaking at a July 28 AIS-sponsored webinar on reform-driven changes on retiree health coverage, Wohl told listeners that Part D sponsors that offer enhanced benefits for brand-name drugs in the coverage gap will not see a reduction in costs as a result of manufacturers' discounts. Moreover, enrollees will receive a 50% manufacturer's discount only on their 50% share. For example, in the chart below illustrating an enhanced Part D plan, the manufacturers' discount is equal to 25% of the total drug costs. Essentially, said Wohl, the greater coverage provided for brand-name drugs in the gap, the less impact manufacturers' discounts will have on total drug costs. In contrast, in a standard plan where beneficiaries are responsible for 100% of the drug costs in the gap, they will pay only 50% of total drug costs.

By 2020, when the coverage gap will essentially be closed, Wohl said, the standard level of coverage will probably "be sufficient for many people and we may see significant reductions in the types of supplements and different structures that will be needed."



SOURCE: Analysis of Part D coverage gap, Stuart Wohl, senior vice president, and George Bognar, lead pharmacy benefits consultant, The Segal Company, July 2010.

Plan sponsors also may consider contracting directly with CMS. This is similar to an EGWP “except the employer becomes the PDP,” said Bognar. Sponsors that go this route will typically hire a pharmacy benefit manager to manage the PDP. They also could purchase reinsurance to mitigate some of the aggregate risk, he said.

This option is complex to manage and is probably unrealistic for smaller employer plans, contended Bognar. For companies with 20,000 or more retirees, however, it “may be an excellent choice.”

A secondary-wrap benefit is another option. Under this option, employer sponsors would group-enroll retirees into a PDP and supplement the plan with additional benefits. Retirees will receive the basic Part D benefit and the employer would provide supplemental coverage such as benefits in the gap or coverage of non-Part D drugs. Secondary-wrap benefits have complex implementations and moderate to significant member disruption, said Bognar.

Medicare Advantage prescription drug (MA-PD) plans are attractive to employer sponsors because they offer both drug and medical coverage and are usually fully insured. But Bognar cautioned that there is a lot of uncertainty with these plans in the future due to funding reductions, and they are less flexible for customized plan designs.

Plan sponsors also can consider just transitioning their members to a PDP. But this will cause the greatest disruption to members, he argued, because the plan gives up control of the benefit altogether except for its contribution to total drug costs.

RDS Versus EGWP

Before deciding whether to stay with RDS or transition to EGWP, Bognar recommended an “in-depth analysis.” Savings realized will vary depending on some key variables, he said, including member health status and underlying pricing, discounts and fees for the current RDS. For example, in general, EGWP savings will be higher for less healthy groups because of the value of the reinsurance provided in a direct subsidy, which is not provided in the RDS, said Bognar.

Another consideration is that the value of the direct subsidy will increase relative to RDS. This, Bognar explained, is because the value of a PDP subsidy is tied to the basic Part D benefit, “which becomes richer each year.” The subsidy under RDS is static at 28%. “The gap in subsidies between the PDP and RDS will grow wider over time, he maintained.

Employer sponsors that would be good candidate to transition from RDS to EGWP, said Bognar, include those that:

- ◆ *Want to reduce cost and can tolerate a degree of member disruption;*
- ◆ *Want to reduce long-term retiree liability;*
- ◆ *Would like to maintain their basic plan design, such as member copayments;*
- ◆ *Cannot meet the “actuarial equivalence test” either today or in the future; and*
- ◆ *Want to avoid the uncertainty surrounding Medicare Advantage plans.*

Contact Wohl at (202) 833-6431 and Bognar at (202) 833-6487. ✧

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Court Again Rules Part D Enrollees Are Not Entitled to Waiver Refund

A federal appeals court has ruled again that a group of 230,000 Medicare Part D beneficiaries who were erroneously mailed premium refunds by Part D plans do not have the right to apply for a waiver from repaying the money.

The court’s original decision led to CMS taking steps to shore up the premium withholding process, including barring plans from billing beneficiaries for premiums while a withholding request is being processed. The case stems from a lawsuit brought by the Center for Medicare Advocacy, Inc. on behalf of the advocacy groups the Action Alliance of Senior Citizens and the Gray Panthers (*Action Alliance of Senior Citizens v. Sebelius* (D.C. Cir. No. 09-5191, June 18, 2010)). The center argued that Medicare beneficiaries should not have to repay premium refunds erroneously sent to them in August 2006. According to the center, in certain circumstances a beneficiary may be entitled to a waiver of an overpaid refund, such as when a beneficiary was without fault in causing the overpayment and where repayment would be against equity and good conscience.

Premium withholding requests must be initiated by a beneficiary and then pass from the beneficiary to the plan, from the plan to CMS, and from CMS to the Social Security Agency. SSA data on premiums withheld must match the CMS data on the amount of premiums owed to the plans, or CMS will not pay the premiums to plans.

Due to a computer glitch in August 2006, these beneficiaries mistakenly received premium refund checks or had their premium deductions stopped without making a request. CMS informed the affected beneficiaries that they had to return any extra money to the agency.

In September 2006, a federal judge issued a preliminary injunction prohibiting CMS from collecting Part D

premium refunds erroneously sent to beneficiaries until those individuals were given the opportunity to seek a waiver of recovery. The letter sent to beneficiaries from CMS seeking recovery of these premiums did not include a statement that the Medicare statute requires recovery of incorrect payments such as these to be waived in specified circumstances. Thus, the court required CMS to send out new letters informing affected beneficiaries of this right and refunding any repayments that have already been made.

However, in April 2007, the U.S. Court of Appeals for the Circuit Court of D.C. held that the plaintiffs had not met the "presentment" requirement by not presenting the claim to the government for payment, and the district court lacked jurisdiction to consider its contentions. The appeals court vacated the preliminary injunction. The court also held that the beneficiaries were not entitled to apply for a waiver under the Medicare law because the right applies only to providers of services for items or services furnished to individuals, and it has nothing to do with erroneous refunds of premiums. The court acknowledged the government's "monumental gaffe" in mistakenly refunding the premiums originally.

Beneficiaries Argue Hardship

The beneficiaries corrected the jurisdictional defect and refiled an appeal, arguing that they were entitled to a refund under the Social Security law because repayment would be a hardship. The court disagreed and upheld its original decision. It found that the law cited by the plaintiffs provides a right to waiver from recovery only for overpayments covered by the Social Security law — only for overpayments of Social Security benefits, not for "any government overpayment that happens to come through the Social Security Administration".

The court further said that the plaintiffs' argument makes "little sense," since it would allow waivers from recovery for Medicare prescription drug beneficiaries who pay their premiums through Social Security deductions but not for those beneficiaries who pay premiums through bank account deductions. "We see no evidence that Congress intended such a half-baked waiver regime for recovery of mistaken Medicare prescription drug premium refunds."

Gill Deford, the director of litigation for the Center for Medicare Advocacy, tells *PDN* that the center is "disappointed by the decision and feels that the court has misread the law." He says it is "especially egregious" because this is the only category of federal beneficiaries who are not entitled to request waiver of recovery when the government makes an erroneous payment.

"It is difficult to imagine that Congress intended this result when it created the Medicare Part D program,"

contends Deford. "If the Court had applied the correct analytical standard, it would have had to confront that fact, and the fact that Part A and B beneficiaries are entitled to waiver. In our view, the outcome makes no sense and punishes Part D beneficiaries for the mistakes of CMS and SSA," he argues.

Contact Deford at gdeford@medicareadvocacy.org. ✧

CMS Focuses on Policies and Procedures in Latest Audit Reports

A recent audit report posted on CMS's website indicates that the agency appears to be focusing on the details of Part D plans' policies and procedures and proper training of staff on the revised policies and procedures.

According to the audit report posted in July for LifeCircles, the plan did not submit and certify monthly enrollment and payment data to CMS in a timely manner. The agency asked the sponsor to develop a fraud, waste and abuse plan and submit a copy to CMS. The document should include:

- ◆ *Internal auditing tools,*
- ◆ *Procedures and reports,*
- ◆ *An auditing and monitoring work plan,*
- ◆ *A compliance reporting tracking log,*
- ◆ *Any responses to detected offenses* and correction plans, and
- ◆ *Training and education materials.*

The agency also required LifeCircles to develop and implement policies and procedures that contain language ensuring the sponsor is submitting and certifying monthly enrollment and payment attestation forms in a timely manner. It must provide evidence to CMS that the reports are being submitted to CMS on time and must conduct training of appropriate staff on these policies and procedures and submit documentation to CMS setting forth the details of the training, including the material used in the training, the individuals conducting the training and the individuals being trained.

LifeCircles did not respond to a request for comments on the audit report by *PDN* press time.

Johns Hopkins Health System, Inc. was also required to submit revised policies and procedures regarding confirmation of enrollment into its employer group/union coverage. According to CMS's audit report, Johns Hopkins did submit the requested document outside of the audit period. Since it contained the two provisions the agency asked for, CMS accepted it.

But the agency did require Johns Hopkins to conduct training of appropriate staff on the revised policies

and procedures and submit documentation detailing the nature of the training to ensure proper implementation. This included the materials used in the training, the individuals conducting the training and the individuals being trained.

Johns Hopkins did confirm to *PDN* that it submitted revised policies and procedures to CMS, but it did not respond to a request for information about its training.

Plans Do Their Bidding

Part D sponsor Arcadian Management also was cited in the July audit report update for deficiencies in accurately and correctly submitting bids for the 2010 plan year. CMS requested that Arcadian submit a detailed description of the policies and procedures in place to ensure that bids are complete, accurate and consistent with CMS instructions at the time of submission and policies, procedures and steps Arcadian has in place to ensure it will accurately and fully review and verify its 2011 bids before submitting the final actuarial certification and bid attestation.

According to Arcadian's vice president of marketing, Monica Lewis, Arcadian submitted a corrective action plan (CAP) in May 2010 to remedy the errors related to the June 2009 Part D bid. The CAP "was accepted by CMS without comment," she tells *PDN*.

Moreover, Lewis says that Arcadian successfully submitted its 2011 bid in June and has not "been notified of any errors with the submission."

Health Net, Inc. also received a request for a CAP because of issues CMS identified relating to miscalculation of beneficiary copayment amounts. CMS indicated that the CAP should provide:

- ◆ *Identification and analysis of the root causes* of copayment inaccuracies;
- ◆ *A discussion of how Health Net's pre-2010 planning* did not identify the copayment issues;
- ◆ *A discussion of the steps Health Net has taken to correct* the copayment calculation problem;
- ◆ *A discussion of the process Health Net has developed and adopted* to ensure that copayment-related system errors will not reoccur, with specific attention to how preparation for contract year 2011 will include implementing safeguards against the generation of inaccurate copayments; and
- ◆ *A monthly report that demonstrates that Health Net monitors* the accuracy of the copayments charged to its members at the point of sale.

While not addressing the specific copayment issues it experienced, Health Net spokesperson Amy Sheyer tells *PDN* that the plan sponsors submitted a CAP to CMS

addressing the above issues, and the agency accepted it. Health Net is also "monitoring the results," she says.

Contact Lewis at molewis@arcadianhealth.com and Sheyer at amy.l.sheyer@healthnet.com. View the updated audit report at www.cms.gov/MCRAAdvPartDENrolData/CAP/list.asp#TopOfPage. ✧

Fox Begins to Pay Claims After Pressure from Congress, Industry

Fox Insurance Co. agreed on July 19 to send \$13.6 million in outstanding Medicare Part D payments to its plan administrator, ProCare Pharmacy Benefit Management. This comes after being ordered by CMS and the Senate Finance Committee to satisfy its fiduciary obligation and pay its outstanding claims.

Fox was terminated from participation in the Part D program on March 9, becoming the first stand-alone Prescription Drug Plan (PDP) to be kicked out of the program (*PDN 4/10, p. 1*). CMS terminated the plan for "significant deficiencies," including failure to provide access to prescription drug benefits by imposing unauthorized prior-authorization and step-therapy criteria.

On May 17, CMS sent a letter to Fox reminding it of its obligation to pay outstanding claims (*PDN 6/10, p. 12*). This letter was in response to numerous complaints from pharmacies about delinquent payments submitted to the agency by the National Community Pharmacists Association (NCPA).

According to CMS, between beneficiary premiums and monthly capitated payments Fox received from the agency, it was paid more than \$30 million for February and \$33 million for March to provide coverage.

Sens. Chuck Grassley (R-Iowa) and Max Baucus (D-Mont.), ranking member and chairman of the Senate Finance Committee, also asked Fox to pay its outstanding claims. The senators sent a letter to the insurer June 30, asking for information on the more than \$60 million CMS paid to the sponsor in February and March. The letter requested that by July 9 Fox provide information on how much of the \$63.5 million in outstanding claims was being held as of July 1, how many claims for service provided before March 9 have been received but remained unpaid and whether Fox intends to pay any and all filed outstanding claims.

Now, ProCare is closing Fox claims and is beginning to process payments for claims submitted between Feb. 16 and March 1, 2010. Fox still owes several million dollars in unpaid claims for March, but it will pay them as soon as it clarifies a few lingering claims issues with ProCare, said attorney Thomas Barker,

with Foley Hoag LLP in Washington, D.C., which is representing Fox in its dealings with CMS.

Douglas Hoey, acting executive vice president of NCPA, said the association appreciated Fox's "efforts to set things right." He called this a "first step." This is "only a step in solving the problem. We will be watching to make sure every penny owed is paid, and hope no Part D plan sponsors will require this amount of attention in the future. That's the only way for the Medicare Part D program to be truly successful."

Contact Barker at (202) 261-7310 and visit NCPA at www.ncpanet.org. ✦

Proposed Bill Would Allow Off-Label Coverage for All Part D Drugs

House lawmakers have taken steps to increase coverage of Part D drugs through introduction of a bill that would allow Medicare Part D to cover prescriptions used for off-label indications. This would put the Part D benefit in sync with Medicare Part B and give Part D plans the same flexibility as commercial plans have. The bill goes further than CMS's 2010 call letter and the Medicare Improvements for Patients and Providers Act (MIPPA), and it is likely to increase beneficiaries' use of the Part D appeals and exceptions process.

Reps Mary Jo Kilroy (D-Ohio) and Mac Thornberry (R-Texas) introduced on July 15 the Part D Off-Label Prescription Parity Act (H.R. 5732). The bill would allow Part D plans to cover prescriptions used for off-label indications if such uses are supported by peer-reviewed medical literature.

Today off-label indications supported by peer-review literature are covered under Medicare Part B. Under Medicare Part B, CMS allows carriers to consider "the major drug compendia, authoritative medical literature and/or accepted standards of medical practice" in determining whether an off-label use is medically accepted.

In 2008, through MIPPA, Congress required CMS to apply the Part B standard to Part D cancer drugs used off-label. Part D plans are not required to cover prescriptions for off-label indications used to treat conditions other than cancer if they are not listed in statutorily identified compendia. For non-cancer treatment drugs, plans may not cover off-label uses unless the use is listed in specific compendia (prescribing guides published by private companies) identified in the law.

The change included in MIPPA led to Maximus Federal Services, the Part D independent review entity (IRE), to reverse its original decision in *Layzer v. Leavitt*, that there was no evidence supporting the use of a particular drug for Layzer's medical condition. The IRE found that a search of relevant compendia was sufficient

to find that using a certain drug to treat ovarian cancer was a medically accepted indication. The decision was rendered based on Congress' decision to expand Part D coverage to off-label uses of anti-cancer drugs in MIPPA (*PDN* 6/09, p. 1).

CMS also has changed its position on off-label use since the inception of Part D. In the agency's 2010 call letter, it indicated that Part D sponsors may not require enrollees to try and fail a drug supported only by an off-label indication in statutory compendia unless supported by "widely used treatment guidelines or clinical literature" that CMS considers best practice, before covering a drug with an on-label indication. In the agency's previous "fail-first" policy, Part D sponsors required patients' treatments with off-label drugs to fail before they would reimburse for using drugs that were FDA-approved. This is a version of "step therapy" where a more cost efficient drug must be utilized first. If that drug is not effective, the plan will cover a more expensive medication.

The Medicare Rights Center has come out in support of the legislation and said it and the Multiple Sclerosis Society worked closely with Kilroy and Thornberry in developing the bill. Ilene Stein, policy counsel for the center, tells *PDN* that this a small, but important step forward. The legislation accounts for concerns on either side — safety and easy access to needed medication, she says.

Usually, the beneficiary or his or her provider submits a copy of peer-reviewed literature supporting off-label use of a medication during the exceptions and appeals process. Then the plan evaluates whether the off-label use is medically necessary. Stein says the language of the bill would allow for the use of peer-reviewed literature at the determination point also.

In addition to supporting the legislation, the center has also continued to pursue litigation to secure Part D coverage for off-label treatments. In addition to the *Layzer* case, the center brought a suit on behalf of Layzer and Ray Fischer, who suffers from muscular dystrophy. Fischer's medications do not fall under the off-label exception for cancer treatments. The suit is now pending, says Stein.

Contact Stein at (202) 637-0961, ext. 5. ✦

Data Validation Audits Are Imminent

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Richard Merino, a director at FTI Consulting, told listeners during a June 22 AIS-sponsored webinar, entitled "Medicare Data Validation Audits: Preparing Your Data for Upcoming CMS Audits," that while these audits are a "novel concept" to CMS, they are similar to other CMS audits as the agency "expects a certain amount of delegation and oversight from plan sponsors." DeAngelis also spoke at the Webinar.

Pursuant to DVA requirements, plans must obtain any primary source documentation needed for the audit from all delegated and related entities. This will be especially challenging for Part D plans, which often rely heavily upon vendors or delegates to fulfill certain functions related to administering their plans. Functions commonly delegated include claims processing, pharmacy benefit administration, sales and marketing, bid preparation and customer service.

The “stakes are high” for obtaining information from delegated entities, Merino warned. It is very important to understand how the data coming from delegates align with data validation standards and measures, he explained, because the accuracy and completeness of these data are very important for the success of the DVAs.

Key questions sponsors need to address with respect to delegated entities are:

- ◆ *Who are the delegated entities?*
- ◆ *What are the delegated entities specifically contracted to do?*
- ◆ *Where do the data emanate from?*
- ◆ *What DVA standards are delegated entities upholding at the delegate level?*

Sponsors are responsible for meeting CMS requirements regardless of whether they perform a particular function or it is delegated to an outside entity, noted Merino. Thus, he said, “plans need a way to oversee and understand what the delegates are doing and where the data come from.”

Plug and Play

Sponsors have a “lot of work to do in a short amount of time,” said Tim Nugent, a managing director in FTI Consulting’s New York office, who also spoke at the webinar. Since the timing of the DVAs “does not allow for a wealth of ramp-up time,” for a DVA contractor to get educated on a sponsor’s core system or plan operations, sponsors need to find a “plug-and-play” contractor. The firm should have the appropriate technical, audit, compliance, operational and systems expertise, he explained.

To perform the project in this tight time frame, Nugent advised sponsors to have coordinated planning and delivery across all project teams; effective coordination of complex and concurrent project work streams; clear and consistent communication and reporting to key stakeholders; proactive and timely identification and resolution of issues throughout the project; and change management.

Work plans need to be “living, breathing documents” that are able to change if needed, he said.

Sponsors must develop sample audit templates as quickly as possible, recommended Nugent. To do this, he suggested looking at CMS’s revised Organizational Assessment Instrument (OAI). “Look at how the OIA forms work and how they may tie into sampling,” he said.

Sample audits could include a matrix identifying systems in place for each of the core measures, a key stakeholder matrix identifying contacts for each core measure, and a documentation log identifying all documents requested for each core measure.

Plans Should Use OAI as Roadmap

One area where sponsors need to use a detailed approach is assessing the DVA standards. The OAI is the key to planning, said Nugent. It lays out where everything is, how it works and how testing and sampling will be performed, he explained.

Nugent described the various sections of the OAI as detailing the contacts for each measure, what the data sources are for each measure, what documents are needed for each measure and what was actually looked at. Once the OAI is filled out, sponsors should know where they have to go, he contended. After this phase, the DVA contractor will perform source validation and sample testing.

Although sponsors could most likely face a range of consequences for failing to prepare complete and accurate data, there is much unanswered by CMS at this point, said DeAngelis. It is one of many things CMS can put on a radar screen to oversee plans as contractors, she noted, along with corrective action plans, risk-adjusted data validation audits, monitoring audits and risk-based audits. “Look at it as part and parcel,” she said, since CMS will take DVAs into account each year to determine whether a plan should remain a contractor or get a service area expansion.

Merino explained that CMS will use these audits to “profile plan sponsors” and compare them to one another. It is a “tool that CMS has laid out there,” and it is one aspect of the agency’s “paradigm shift” from risk-based to data-driven audits, he said. “CMS will use more data-based reviews to evaluate plan performance,” Merino maintained, and it is the “easiest way to do an apples-to-apples comparison” to see who is an outlier, he added.

Merino contended that enforcement could be as drastic as suspending marketing privileges or eliminating Medicare contracts.

Contact DeAngelis at (704) 460-2437, Merino at (704) 280-8594 and Nugent at (212) 499-3692. ✦

To purchase a recording and accompanying materials of the June 22 AIS webinar, please call (800) 521-4323 or visit the MarketPlace at www.AISHealth.com.

NEWS BRIEFS

◆ **President Obama's decision July 7 to install CMS Administrator Donald Berwick, M.D., via a recess appointment has in general been met with applause by the health care industry.** Berwick previously served as president and chief executive officer at the Institute for Healthcare Improvement at Harvard Medical School and is a professor of health policy and management at the Harvard School of Public Health. Gorman Health Group, LLC CEO John Gorman tells sister publication *Medicare Advantage News* that Berwick is likely to be "very, very tough but fair" in his dealings with Part D and Medicare Advantage plans and will usher in a "new era of accountability for care." Berwick still needs to be confirmed by Congress in 2011. Under recess-appointment authority, he can serve until late 2011 without being confirmed. The CMS office has been without a permanent administrator since 2006.

◆ **CMS has created a new monthly report in its Health Plan Management System to advise Part D and Medicare Advantage plans on the timeliness with which they submit plan-generated enrollments to the agency.** According to CMS's July 15 memo, organizations must review the monthly report and take remedial actions if it indicates that they are not meeting a standard of 90% compliance. The agency established a threshold of 90% compliance for assessing enrollment processing timeliness instead of more typical standards of 95% or 99% because it acknowledged that some applications may be incomplete upon receipt by the organization or sponsor. Thus, CMS said "it may not be possible for an organization to achieve 100% compliance using the application date as a proxy for a completed enrollment request." CMS will begin issuing compliance letters in the next few months to sponsors that are not meeting the 90% threshold, the agency added. Go to www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoTimelyProcessing_07.15.10.pdf.

◆ **In a recently released interim final rule, CMS recognized the use of version 10.6 of the National Council for Prescription Drug Programs SCRIPT Standard for electronic prescribing under the Medicare Part D drug benefit.** According to the agency, "recognition" means the agency approves the use of the updated standard for e-prescribing, but it is not yet formally adopted as the new standard. New features in the version 10.6 standard will allow users to provide prescriber order numbers, drug NDC source data, pharmacy prescription fill numbers and the date of prescription sale. The rule is effective July 1, 2010, and comments

will be accepted through August 30. View edocket. access.gpo.gov/2010/pdf/2010-15505.pdf.

◆ **CMS released on Aug. 2 a final drug manufacturer agreement for the coverage gap discount program.** Under the agreement, manufacturers will provide beneficiaries who reach the Part D coverage gap in 2011 with a 50% discount on brand-name drugs and biologics. Based on industry comments, CMS revised the draft agreement to provide additional time for quarterly invoice payments by manufacturers within 38 days of receipt through the third-party administrator. The agency also is providing manufacturers with claims-level data necessary to validate invoices, without sharing private patient information. Manufacturers must sign agreements by Sept. 1 to continue to offer drugs under the Part D benefit. Go to www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage.

◆ **The state of Illinois advised certain Part D beneficiaries that if they receive a \$250 rebate from CMS in the same month they qualify for Medicaid, they must report the payment to the Department of Human Services.** The payment must be reported as a lump sum using Form HFS 1156, LTC Facility Notification. It will cause payment by the Healthcare and Family Services to be reduced by the amount received and should be collected by the facility as with regular patient credit amounts to prevent a payment shortage for the month the check is received. View the form at www.hfs.illinois.gov/assets/063010n.pdf.

◆ **Beginning in 2011, all Part D contracts with 600 or more enrollees as of July 2010 must contract with CMS-approved survey vendors to conduct Medicare Consumer Assessments of Healthcare Providers and Systems (CAHPS) survey data collection.** According to a recent CMS memo, the approved list of survey vendors will be available by the end of September. Vendors must successfully complete training in November to proceed with data collection in 2011, the agency said. The survey will be conducted annually between January and June. CMS also announced the launch of a new CAHPS survey website at MAPDPCAHP.org. The website provides contracted organizations with information on the 2011 survey, survey vendor requirements, information on survey vendor training and approval, data collection protocols and procedures and quality assurance guidelines. Go to www.cms.gov/PrescriptionDrugCovContra/Downloads/Memo2011CAHPS_06.25.10.pdf.

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