

PRESCRIPTION DRUGS & THE MSA

Understanding CMS' New Prescription Drug Policies – Practical Approaches for Claims Handling & Settlement

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Perhaps the most significant development on the Medicare Set Aside (MSA) front in the past few years has been the Centers for Medicare and Medicaid Services' (CMS') recent enactment of new policies for calculating future Medicare Part D prescription drug costs for MSA proposals in workers' compensation cases. Effective June 1, 2009, CMS began independently pricing future Part D drugs related to a claimant's workers' compensation injury/illness for MSA purposes.

CMS released its new policies through its *April 3, 2009 policy memorandum* (hereinafter "April Memorandum") and a subsequently released document entitled *CMS Prescription Drug Set-Aside Guidance for Submitters Effective: June 1, 2009* (hereinafter "RX Guidance" document).

CMS' *April Memorandum* can be obtained at http://www.nuquestbridgepointe.com/docs/uploads/cms_memo_4-6-2009.pdf.

CMS' *RX Guidance* document can be obtained at <http://www.nuquestbridgepointe.com/news/uploads/msarxguidance.pdf>.

At the present time, CMS' new policies are resulting in alarming and unprecedented increases in required MSA amounts in many instances. In turn, this is causing considerable problems on the claims handling and settlement fronts on a number of levels – case values are increasing significantly, settling claims is becoming more difficult, and CMS' inconsistent application of its new policies is creating confusion and uncertainty.

CMS' new policies have fundamentally changed the landscape and introduced an added layer of complexity to claims handling and settlement. CMS' new policies require analysis on three levels: (a) **Policy** – Understanding CMS' new policies as specifically stated in the *April Memorandum* and *RX Guidance* document; (b) **Practical**: Understanding how CMS' practical implementation of its new policies are impacting claims and settlements; and (c) **Perspective**: Recognizing that current claims and settlement practices may need to be modified.

Through this article, the author aims to place the issue into proper focus. This analysis is presented as follows:

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PART I

CMS' Prior Approach to RX Drugs (1/1/06 to 6/1/09)

Understanding the Prior Landscape – Where We Have Been

Medicare Part D – Brief Background

By way of background, through the Medicare Modernization Act of 2003 (MMA) the Medicare program began to provide limited outpatient prescription drug coverage as “Part D” of the Medicare program as of January 1, 2006. While Medicare has covered certain in-patient drugs under Part B for a number of years, enactment of Part D was significant in that outpatient drug coverage began to be provided on a scale not before seen in the program’s history.¹

Part D is provided through “traditional” Medicare (Parts A and B), or via Medicare advantage (Part C) depending on the program in which the beneficiary is enrolled. Part D is a voluntary program for most beneficiaries.² The program is provided through private plans approved by the federal government.

Part D is not a monolithic program; rather it is comprised of a variety of different plans. For example, in 2010 it is estimated that there will be roughly 1,576 prescription drug plans offered nationwide.³ In terms of structure, Part D does not provide coverage for all classes of drugs. Furthermore, the program does not pay all of the beneficiary’s costs. Rather, there is a yearly premium for Part D followed by a tiered cost sharing model consisting of a co-pay and deductible schedule.⁴

A detailed examination of Part D’s specific program components is beyond the scope of this article. If the reader is interested in learning more about Part D in terms of program mechanics, components, etc., he/she may wish to consult the resources listed in the endnote following this sentence.⁵

Part D & The MSA – CMS’ Initial Approach

With the commencement of the Part D program, CMS released a policy memorandum dated December 30, 2005 through which it announced that MSA arrangements needed to include coverage for Part D prescription drugs for all settlements that occurred on or after January 1, 2006.⁶

In order to clarify certain technical points, CMS released a second memorandum dated July 24, 2006 “superceding” the December memorandum. Notwithstanding the technical clarifications in the July memorandum, the primary basis of CMS’ policy remained the same as follows:

All WC settlements that occur on or after January 1, 2006 must consider and protect Medicare’s interests when future treatment includes prescription drugs along with the future medical services that would otherwise be reimbursable by Medicare. The recommended method to protect Medicare’s interests is to include a WCMSA as part of the WC settlement. However, if the WC claim settled prior to January 1, 2006, the WCMSA proposal does not need to include an amount for future prescription drug treatment.

The inclusion of Part D prescription drugs as part of a MSA is required *regardless* of whether or not the claimant is currently enrolled in Part D. CMS’ policy on this point, which remains in force at the present time, is set forth in the July 24, 2006 Memorandum as follows:

Question 7: Should submitters include an amount for future prescription drug expenses if the claimant has not enrolled in a Part D plan?

Answer 7: Yes. Claimants who have not enrolled in a Part D plan need to include future prescription drug expenses in their WCMSA proposals if the current treatment records indicate that the claimant has been prescribed drugs and/or may need future prescription drug treatment related to the WC injury.

While CMS required inclusion of Part D prescription drugs as part of MSA calculations, the agency did *not* publish any guidelines regarding the *pricing methodology* for calculating future Part D expenses.⁷ Initially, CMS was scheduled to commence independently pricing future Part D drug costs as of January 1, 2007; however, the agency subsequently abandoned those plans.⁸

In addition to not establishing a pricing methodology for future Part D expenses, CMS did not necessarily establish a formal review process to assess a submitter’s drug calculation, indicating rather that the submitted amount would be “noted.” CMS’ “approach” before enactment of its new policies is perhaps best encapsulated by the following statement contained in the July 24, 2006 memorandum:

For a WCMSA proposal received by COBC on or after January 1, 2006, CMS will provide in its written opinion the total WCMSA amount that adequately protects Medicare's interests with regard to the claimant's future medical treatment. However, CMS' written opinion will also note the submitted prescription drug amount.

The CMS' written opinion will provide the total WCMSA amount, which is a combination of the future medical treatment reviewed by CMS and the future prescription drug costs noted in the submitter's cover letter. The parties to the WC settlement must note the total WCMSA amount in the final settlement agreement. Once the final settlement agreement is submitted to CMS' COBC, the claimant and all other parties to the WC settlement can rely on CMS' written opinion regarding whether the WC settlement adequately protects Medicare's interests.⁹

The lack of specific pricing and other guidelines from CMS created an interesting and difficult challenge for the industry as it struggled to find the balance between using the most effective pricing and calculation method to contain future Part D prescription costs, while at the same time still reasonably protecting Medicare's interests.

As a result, a variety of different methods and approaches emerged to address the issue. Examination of these prior methods is beyond the scope of this article. For a detailed review of the various approaches that were commonly used during the period of January 1, 2006 to June 1, 2009, the reader may wish to review an excellent article authored by Patty Meifert entitled *Mechanisms for Containing Medicare Part D Prescription Drug Costs in MSA Allocations*, Settlement News (June, 2007). This article can be obtained at http://www.nuquestbridgepointe.com/services/med-res/mechanisms_for_containing_medicare_part_d_drug_costs_in_msa_allocations.pdf.

In general, prior to the enactment of CMS' new policies, common methods used to calculate future Part D costs included (a) average wholesale price (AWP), (b) workers' compensation reimbursement rate, (c) actual billed amount, and (d) lowest attainable cost. Other approaches included generic substitution, reduction via rated age, and in certain circumstances, use of pharmacy utilization reviews.¹⁰

In addition, calculation using Part D's tiered co-pay and deductible formula was a popular (but controversial) method in some quarters. Under this approach, parties were able to significantly reduce future Part D costs by

taking advantage of what is referred to as the Part D "donut hole" which is that part of the Part D cost sharing structure where the beneficiary is responsible for 100% of his/her drug costs.¹¹ For the reasons outlined in Part II of this article, use of the Part D formula, as well as other "discounting methods," would now appear to be prohibited under CMS' new policies.

With a general understanding of the state of affairs that existed prior to June 1, 2009 under our belts, the focus now shifts to how CMS' new policies have significantly changed the picture.

PART II

CMS' NEW Prescription Drug Policies (6/1/09 to Present) *Navigating the New Terrain – Where We Are Now*

Though the *April Memorandum* and *RX Drug Guidance Document*, CMS began independently pricing future Medicare Part D costs regarding workers' compensation MSAs effective June 1, 2009.

To understand the practical impact of CMS' new policies, it is helpful to approach the issue from two levels: First, it is important to analyze the new directives as *stated* in the *April Memorandum* and *RX Guidance* document. This aspect is discussed in this section. Second, it is necessary to assess how CMS is implementing its new guidelines in terms of the actual calculation of the prescription drug allocation amount. This component is examined in Section III.

CMS' April 3, 2009 Memorandum

The starting point in understanding these new changes is CMS' *April Memorandum*.

The *April Memorandum* sets forth the main components of CMS' new policies in reference to: (a) intent and scope; (b) the pricing methodology to be used for calculating future Part D drug costs, and (c) how the new policies will be applied to what CMS considers "closed cases" as follows:

Intent & Scope

The basic intent and objective behind CMS' new policies is stated as follows:

The purpose of this memorandum is to set forth the Centers for Medicare & Medicaid Services' (CMS') procedures regarding the methodology of pricing future prescription drug treatment costs/expenses in Workers' Compensation Medicare Set-Aside Arrangement (WCMSA) proposals.

References to "prescription drugs" in this document are limited to those prescription drugs covered by Medicare for the treatment of the Workers' Compensation (WC) related injury(ies) and/or illness(es)/disease(s) (hereinafter referred to as "WC injury") at issue.¹²

Pricing Methodology & Related Matters

Under CMS' new policies, Average Wholesale Price (AWP) is the pricing methodology to be utilized to calculate future Part D covered costs for those drugs related to a claimant's workers' compensation injury/illness. On this point, CMS states:

Effective with complete WCMSA submissions received by CMS' Coordination of Benefits (COB) Contractor on or after June 1, 2009, where the WC related injury warrant(s) the need of prescription drugs for the ongoing treatment of the WC related injury, **CMS' independent pricing of the prescription drug amount will be calculated and priced using average wholesale price (AWP). The CMS will not use or recognize any other pricing, discounting, or calculation methods when determining the adequacy of the prescription drug amounts in WCMSA proposals.** The CMS will apply the following procedures to all WCMSA proposals received on or after June 1, 2009. This procedure will also apply to all closed WCMSA cases that reopen on or after June 1, 2009, as noted below.¹³ (Emphasis Added).

In regard to situations where a submitted proposal after June 1, 2009 (a) fails to include an amount for future prescription costs or (b) uses generic pricing where generics are not available, CMS states:

If an entity submits a WCMSA proposal to CMS' COB contractor that does not contain an amount for prescription drugs for the treatment of a WC related injury and if, upon further review, CMS deems that the WCMSA warranted the need for prescription drugs for the treatment of the WC related injury, CMS will default to pricing using a pricing strategy of AWP for brand name drugs in determining the adequacy of the prescription drug amount.

If an entity submits a WCMSA proposal to CMS' COB Contractor and the submitter priced the future prescrip-

tion drug treatment costs/expenses as being "Generic" and there is no "Generic" available, CMS will default to the AWP pricing for brand name drugs in determining the adequacy of the prescription drug amount.¹⁴

MSAs Submitted Prior to 6/1/09 Where CMS Requested Additional Information Which Was Not Received Until After 6/1/09

As stated above, the new policies apply to MSA submissions received by the COBC on or after June 1, 2009.

In this regard, a question arises as to how CMS will handle MSA proposals received prior to June 1, 2009 but for which CMS requested additional information that was not received until after said date. CMS refers to these cases as "closed cases."

With respect to "closed cases," CMS states as follows:

The CMS will apply the following procedures to all WCMSA proposals received on or after June 1, 2009. This procedure will also apply to all closed WCMSA cases that reopen on or after June 1, 2009, as noted below.

NOTE: With regard to closed cases, when the CMS' COB contractor receives the previously requested necessary documentation, the case is considered a new WCMSA submission and the requirements included in all of CMS' current published policy memorandums related to: (1) future medical treatment; and (2) future prescription drug treatment will be applied to the new WCMSA submission.¹⁵

CMS' RX Guidance Document

The next step in understanding CMS' new policies requires examination of the *RX Guidance* document.

By way of background, following the release of the *April Memorandum* many questions remained regarding various aspects of CMS' new policies, including the extent to which CMS would consider or accept certain approaches for calculating future Part D costs.

In response, CMS released its *RX Guidance* document. The objective of the *RX Guidance* document is stated as follows:

Since the publication of the April 3, 2009 CMS policy memorandum announcing prescription drug reviews, which becomes effective June 1, 2009, submitters of

Workers' Compensation Medicare Set-aside Arrangements ("WCMSAs") have raised several questions concerning how certain situations will be treated by CMS and the Workers' Compensation Review Contractor ("WCRC").

The issues raised have concerned the following themes, which CMS addresses directly below from a policy and procedural perspective: the source used for evaluating the sufficiency of the prescription drug component of WCMSAs; required documentation; tapering of drug use; expiration of patents; off-label use; drug utilization review findings; brand name or generic drugs; and multiple manufacturers of a particular drug.¹⁶

CMS references eight (8) specific approaches in the *RX Guidance* document outlined in their entirety as follows:

1. Source for Evaluation of Sufficiency of WCMSA Prescription Drug Component:

The WCRC is using **RED BOOK® Drug References** to evaluate the sufficiency of the prescription drug component of WCMSAs.

2. Documentation:

It is imperative that submitters furnish accurate, complete, legible, and current medical and prescription drug records for the last two years that the claimant has been receiving treatment in connection with a workers' compensation illness, injury, or disease.

It is CMS' preference that WCMSA proposals are not submitted until the beneficiary or claimant has reached maximum medical improvement or "MMI," as discussed in CMS' July 23, 2001 memorandum, which reads in part "...These set-aside arrangements are typically not created until the individual's condition has stabilized so that it can be determined, based on past experience, what the future medical expenses may be...."

In addition to the qualification of having realized a state of MMI, it is always CMS intention that the beneficiary or claimant receives the appropriate medical treatment as determined by his or her treating physician.

If WCMSA proposals are submitted once the beneficiary or claimant has reached a state of "MMI," the prescription drugs used by the beneficiary or claimant should be known. **However, if the prescription drugs are not obvious from the medical records, it is incumbent upon submitters to ascertain that information to the best of their ability,**

either through close coordination with the beneficiary or claimant, or his or her representative, treating physician(s), and/or pharmacy(ies) where he or she regularly has prescriptions filled. The CMS will determine the sufficiency of the WCMSA proposal as supported by the medical and other records provided.

Note: Submitters need to account for future prescription drug needs that are reasonably probable and predictable even if recent medical records or claims payment histories do not demonstrate their current use.

For example, short courses of antibiotics are usually required for recurrent urinary tract infections, commonly seen with neurogenic bladders. Also, a course of narcotic pain medication is usually necessary for probable future surgery. If not, a conservative pricing method for these and other future probable prescription drug needs will be considered in evaluating the sufficiency of the prescription drug component of WCMSAs, in addition to reviewing current and past treatment patterns specific to the beneficiary or claimant and/or the injury after-effects while being treated.

3. Tapering of Use:

Where the treating physician believes tapering is possible and is in the best interests of the beneficiary or claimant, CMS will consider all evidence in making a WCMSA determination, including medical evidence of current actual tapering.

4. Expiration of patent:

Patents for brand name medications do expire and less expensive generic equivalents do usually become available thereafter. On the other hand, new more expensive brand name drugs often replace drugs whose patents are expiring. Finally, beneficiaries and claimants may insist on brand-name drugs even where generics are available. All of these concepts, along with the evidence submitted in a particular case, will be considered by CMS and the WCRC in determining the sufficiency of a proposed WCMSA amount.

5. Off-label Use:

Off-label use of medications in the United States is both legal and common. Once a drug has been approved for sale by the Food and Drug Administration ("FDA") for one purpose, physicians are free to prescribe it for any other purpose that in their professional judgment is both safe and

effective. Physicians are not limited to prescribing a drug only for official, FDA-approved indications.

6. **Utilization Review:**

Where submitters furnish utilization review reports indicating that a beneficiary or claimant should be taking none, fewer, different, or less frequent drugs, this evidence will be considered. **Reports of actual drug use from treating physicians will be given more weight than utilization review reports.**

7. **Brand or Generic:**

As stated in the April 3, 2009 CMS memorandum, where drugs are indicated and the submitter has not priced drugs, or where a submitter prices for a generic drug where there is none, CMS will compare the WCMSA proposal to average wholesale price for brand name drugs.

If drugs are indicated, but the medical and other records are silent or unclear about whether a beneficiary or claimant is taking a brand or generic drug and both versions exist, then CMS will compare the WCMSA proposal to the *generic drug* where the submitter has proposed a generic drug, and CMS will compare the WCMSA proposal to the *brand name drug* where the submitter has proposed a brand name drug or has not proposed a drug at all.

8. **Multiple Manufacturers:**

Brand-name drugs are only available from one manufacturer, whereas generic drugs are available from multiple manufacturers.

In the absence of supporting documentation concerning prices from generic drug manufacturers within the WCMSA submission, CMS will compare generic drugs in the WCMSA proposal and use the lowest priced generic drug as listed in the RED BOOK® Drug References in accordance with the April 3, 2009 procedure memorandum.

The RX Guidance document concludes with the following statement:

The CMS wishes to emphasize that CMS and the WCRC will review and consider all documents submitted with a WCMSA proposal. Submitters are encouraged to present any evi-

dence they believe is helpful towards a set-aside determination. Nothing said in this guidance should be considered a discouragement of that principle.

Also, CMS wishes to stress that while there may be some general guidelines that can be stated, most determinations rest on the individual facts and evidence pertinent to the particular claimant whose WCMSA proposal is being considered. Moreover, CMS may revisit this guidance periodically and is always seeking and researching new information on these and other subjects that affect the WCMSA review process.¹⁷ (Emphasis Added).

CMS' Application of the New RX Policies – "Crunching the Numbers"

The focus now shifts to analyzing just how CMS is implementing its new procedures in practice.

That is: *How is CMS allocating future prescription drug costs? What is the agency requiring? What approaches is the agency taking? How receptive is CMS to accepting the approaches outlined in the RX Guidance document?* Early reports back from the trench on these fronts have been less than encouraging.

While CMS advised that AWP based on Red Book was the pricing methodology to be used to calculate prescription drug costs, it is crucial to understand that the agency did *not* provide any information or sampling regarding how it would actually allocate future Part D costs in terms of frequency and duration. Here is where the problems begin.

It was not until several months after June 1, 2009 when the industry began receiving its post-June 1, 2009 submission responses back from CMS did it start to realize the exact approaches CMS was employing to actually calculate future Part D allocation amounts. When this piece of the puzzle began to surface, it quickly became apparent that CMS was utilizing approaches that were yielding unimaginable, unprecedented, and many cases, unreasonable increases in required prescription allocation amounts.

This has caused problems in the following respects:

- First, the industry has now learned that CMS is utilizing approaches that can result in much larger allocations for future Part D drug costs than were ever anticipated. This is having an effect on case valuation, MSA projections and settlements.
- Second, there is a “zone” of cases that present particular problems. These are cases where MSAs were submitted *after* June 1, 2009 but *before* the industry became aware of how CMS would actually allocate future prescription costs.

The main problem with these cases is that the parties in many instances reached or finalized their settlements *before* actually realizing the impact that CMS’ actual application of its policies would have. At the time the parties settled these cases, the industry had no idea that CMS would actually utilize calculation approaches that would result in the type of increased amounts for future drug costs that started to be returned. This is causing problems as additional amounts (in some instances, quite sizeable sums) are now needed to fund the prescription allocation in the amount required by CMS.

As parties with cases in this “zone” are realizing, CMS’ actual practical application of its new policies is causing significant problems as they are either receiving responses back from CMS requiring much larger amounts for future costs than was anticipated, or now having to amend the MSA projection prepared during this time period. On a more global level, these problems raise the larger issue of the need to possibly modify settlement approaches (this issue is discussed in Part III of this article).

Currently, sounds of stunned “sticker shock” can be heard across the industry as it begins to realize the significant impact of CMS’ actual application of its new policies. To a large extent, it must be remembered that CMS’ practical application of its new policies is literally unfolding before the industry’s eyes, on a case by case basis. As this “learning” process continues, it is rapidly becoming apparent that CMS’ approach is far from an exact science in terms of consistency, clarity, or reasonableness.

At the present time it is difficult to outline and analyze every specific approach CMS has been discov-

ered to be taking that has, or could, result in increased prescription allocations. New examples and evidence are literally being unearthed every day with each submission response received.

Nonetheless, certain “broader brush” observations and issues are emerging that warrant consideration, including:

CMS Allocating Drug Costs Over Claimant’s Life Expectancy In Certain Cases*

One recurring (and troubling) observation involves CMS’ approach in situations where the medical records and payout history do *not* document the frequency for a particular drug. *In these situations, CMS has been observed to allocate future Part D costs over the claimant’s total life expectancy.*

This practice is resulting in significantly higher prescription drug amounts and raises legitimate questions as to the “reasonableness” of this approach, medically and practically. In addition, this approach speaks to the larger issue of the need to consider procuring information from the claimant’s treating providers(s) as part of the underlying claim. This is discussed in more detail in Part III below.

Drug Tapering*

A popular approach to potentially reduce future drug costs is “drug tapering.” In the *RX Guidance* document, CMS states the following regarding drug tapering:

Where the treating physician believes tapering is possible and is in the best interests of the beneficiary or claimant, CMS will consider all evidence in making a WCMSA determination, including medical evidence of current actual tapering. (Source: Item #3 in CMS’ RX Guidance Document).

As noted, CMS indicates that evidence of drug tapering will be “considered” in certain circumstances. NuQuest contacted CMS in an effort to obtain a better understanding as to the type of information CMS would entertain to support a reduction of future drug costs via drug tapering. CMS’ response to this inquiry indicated that more weight would be placed on the treating physician’s opinion. In addition, the agency’s response suggested that evidence of future anticipated tapering from the treating provider may be considered on a patient specific basis.

Utilization Reviews*

Another popular approach to help reduce future prescription drug costs are “utilization reviews.” In the *RX Guidance* document, CMS states as follows:

Where submitters furnish utilization review reports indicating that a beneficiary or claimant should be taking none, fewer, different, or less frequent drugs, this evidence will be considered. **Reports of actual drug use from treating physicians will be given more weight than utilization review reports.** (Source: Item #6 in CMS’ *RX Guidance* Document; Emphasis added).

On this issue, NuQuest contacted the WCRC in an effort to learn when and to what extent utilization reviews may be accepted. The information received in response from CMS suggests that that agency is taking a conservative approach in terms of accepting utilization reviews, with more weight being afforded to the opinion of the treating provider(s).

Thus, at this time, it is unclear to what extent CMS will actually *accept* utilization reviews. Accordingly, caution on this front is in order. Along these lines, the author believes due consideration should be given to CMS’ indication that it will afford more weight to the opinion of the *treating provider* as referenced in the above statement from the *RX Guidance* document. While the author is by no means trying to dissuade the reader from exploring this option, it would seem prudent not to overestimate the *potential* effectiveness of this approach at this juncture.

On a related front, NuQuest made inquiry to CMS as to whether or not evidence from “medical studies” would be considered. In response, it was indicated that medical studies may be considered to a limited extent in certain situations to address specific issues such as, overutilization, identifying possible drug interactions, and identifying drugs that may not be appropriate for long terms use (i.e. certain post surgical drugs) or should be discontinued for other reasons (i.e. age).

Brand vs. Generic Pricing*

Utilizing generic as opposed to brand name drugs is another popular approach to help reduce drug costs.

In the *RX Guidance* document, CMS states the following regarding generic and brand drugs:

As stated in the April 3, 2009 CMS memorandum, where drugs are indicated and the submitter has not

priced drugs, or where a submitter prices for a generic drug where there is none, CMS will compare the WCMSA proposal to average wholesale price for brand name drugs.

If drugs are indicated, but the medical and other records are silent or unclear about whether a beneficiary or claimant is taking a brand or generic drug and both versions exist, then CMS will compare the WCMSA proposal to the *generic drug* where the submitter has proposed a generic drug, and CMS will compare the WCMSA proposal to the *brand name* drug where the submitter has proposed a brand name drug or has not proposed a drug at all. (Source: Item #7 in the *RX Guidance* Document)

In addition to the information contained in the *RX Guidance* document, NuQuest obtained the following information from CMS regarding “brand vs. generic” pricing:

CMS Will Allocate “BRAND” When*:

1. The medical records and payout history documents that the claimant is taking both generic and brand.
2. The medical records and payout history do not indicate brand or generic.

CMS Will Allocate “GENERIC” When*:

1. The medical records indicate the claimant was prescribed brand and the payout history indicates generic.
2. The medical records and payout history do not document either brand or generic AND a statement from the prescribing provider indicates generic is acceptable, CMS will allocate generic.
3. The medical records and payout history do not document either brand or generic AND a statement from the claimant indicates they are using generic, CMS will allocate generic.

**Caveat: The author wishes to stress that the above discussed items are presented for informational purposes only based the information received by NuQuest from CMS and/or the WCRC as of the time this article was drafted. In this regard, the information is not provided, and should not be interpreted, as factual proclamations with regard to how CMS and/or the WCRC will in fact calculate future Part D costs and/or otherwise interpret or apply any of its stated directives or “guidance” statements. Furthermore, it must be noted that CMS could always change or modify its approach on these and other issues at any time.*

The observations and information presented in this section are provided as examples of some of the considerations that have emerged at this early juncture of CMS' new policies. The author recognizes that the reader may have had different experiences thus far, or received different information from CMS or the WCRC. This would not be surprising, and would only serve to underscore the larger point that CMS' new approach to prescription drugs is far from uniformed, consistent or clear at this time.

PART III

Claims Handling & Settlement *What Can I Do to Address the Issue?*

The significance of CMS' new policies must be recognized, not only in terms of their potential monetary impact, but in terms of what it means in the practical sense of day to day claims handling and settlement practices.

The question becomes: *What measures can or should be taken as part of claims handling to address the issue?* The author presents the following ideas for consideration:

1. Understand CMS' new prescription drug policies.

First, one must have an understanding of CMS' new policies. These are discussed at length in Part II of this article.

In summary, CMS' new prescription policies can be summarized as follows:

- CMS is now independently pricing future Medicare Part D prescription drug costs regarding MSAs. Average Wholesale Price (AWP) based on RED BOOK® Drug References is the pricing methodology CMS is using.
- CMS will *not* use or recognize any other "pricing, discounting, or calculation" methods.
- CMS' new policies apply to all workers' compensation MSA proposals received on or after June 1, 2009, as well as to all "closed" workers' compensation MSA cases (as that term is defined by CMS) that reopen on or after June 1, 2009.
- Through the *RX Guidance* document, CMS addresses the various approaches it may *consider* regarding

the calculation of future RX drug costs. It is unclear at this time to what extent CMS will actually *accept* the approaches outlined therein which could help reduce future RX drug costs.

- It must be recognized that CMS has stressed that "*while there may be some general guidelines that can be stated, most determinations rest on the individual facts and evidence pertinent to the particular claimant whose WCMSA proposal is being considered.*"¹⁸ Furthermore, CMS had indicated that it may "revisit" its guidelines periodically and is "*always seeking and researching new information on these and other subjects that affect the WCMSA process.*"¹⁹

2. Recognize the impact that CMS' new policies could have on case values and settlement.

CMS' new policies could significantly increase case values and MSA projections. This could occur for a number of reasons, including:

- If parties were using a lower, non-AWP pricing model prior to the new changes, they will likely experience an increase in future prescription drug projections based simply on the fact that the allocations must now be based on AWP.
- As noted, under CMS' new policies the agency "*will not use or recognize any other pricing, discounting, or calculation methods when determining the adequacy of the prescription drug amounts in WCMSA proposals.*"

Thus, if parties were using the Part D "donut hole" formula, or some other "discounting" approach to reduce the future prescription drug projection prior to the new changes, they will experience increased prescription drug costs (and potentially significant increases based on the specific situation) simply by the fact that they will no longer be able to reduce the costs by utilizing such approaches.

- **As noted in Part II above, there is a "zone" of cases that present particular concerns. This group of cases involves MSAs submitted *after* June 1, 2009 but *before* the industry became aware of how CMS was actually allocating future prescription costs.**

As explained, while the industry was aware of CMS' new *pricing methodology*, the agency did

not provide any information or sampling regarding how it would actually *allocate* future prescription drug costs in terms of frequency and duration. Once CMS' submission responses started to come back, the industry became aware that CMS was utilizing approaches to allocate future drug costs that were resulting in unprecedented and unanticipated increases for future Part D drug costs.

Complicating the matter further is the fact that many of these cases were finalized *prior* to obtaining CMS approval at a time when the industry had no idea of the practical consequence of CMS' new policies. This is currently creating obvious and significant problems for the party who assumed the responsibility for funding any amount required by CMS over the proposed MSA amount.

- **How CMS will actually allocate future Part D costs will also have a direct impact on many levels.** For example, as noted above, at the present time CMS has been observed allocating future Part D drug costs over the claimant's total life expectancy in some circumstances. This obviously could result in significantly higher prescription drug allocations. In addition, the degree to which CMS will accept certain approaches that could help lower the future prescription drug projection, such as drug tapering, utilization reviews, and/or any one of the other approaches referenced in the RX Guidance document remains unclear.

3. Determine whether new approaches to claims handling and settlement practices are in order.

A new day has dawn. CMS' new policies have totally changed the landscape. As a result, parties need to re-examine their settlement practices to ensure that the contingencies of CMS' new policies, and the real prospect that future prescription costs could be much higher than they have ever anticipated, are properly accounted for.

For example, over the past few years it has become common in some quarters for parties to finalize settlements before obtaining CMS approval of the MSA with one party typically

assuming the obligation to fund any amount over the proposed MSA figure in the event CMS required additional funding. This has become a common practice due largely to the fact that MSA allocators became quite proficient in understanding CMS' expectations, which, in turn, resulted in increased first time pass/acceptance rates. In those instances when CMS actually came back and required additional funding, the additional amount often times was relatively reasonable. Thus, the parties had the confidence to proceed with settling before obtaining CMS approval of the MSA.

However, given the current chaotic and uncertain state of CMS' new policies, finalizing settlement before obtaining actual CMS approval of the proposed MSA can cause considerable problems. In this regard, the practice of settling "contingent" upon CMS approval of the proposed MSA (which was commonly used at the beginning of phases of the MSA process years ago) may now need to be considered again. While the author realizes that this means the case will need to stay "open," the potential downside of potentially having to fund the type of additional sums CMS could require may outweigh the ideal goal of finalizing the settlement as quickly as possible.

On this latter point, from the author's observations and experience, the industry finds itself in a similar situation as it did back in 2001 and 2002 during the infancy of the MSA process. That is, the same uncertainty and inconsistency that the industry is currently experiencing regarding CMS' pricing of prescription drug costs is similar to the frustration it experienced during the early days of the MSA process related to the calculation of medical treatment. Accordingly, until some degree of clarity and consistency enters the process, the parties will need to seriously examine their settlement practices to determine if current practices adequately meet the new realities.

4. Examine options that could possibly help reduce the prescription drug allocation.

Take a proactive approach to address the issue head-on as part of claims handling.

There are several options to consider:

- **Obtain information regarding anticipated future Part D prescription drugs directly from the claimant's treating provider(s).** *(Assuming that contact with the claimant's providers in this manner is permitted under the law of the subject jurisdiction. Consult with your legal representative to determine whether such contact is in fact permitted in your jurisdiction).*

As noted, CMS has indicated that it affords greater weight to the opinions of the claimant's treating provider(s). Moreover, in situations where the medical records and payout history do *not* document the frequency for a particular drug CMS has allocated future drug costs over the claimant's total life expectancy.

Thus, obtaining evidence of the claimant's anticipated future Part D prescriptions from the claimant's treating provider(s) could play a pivotal role in keeping the future prescription allocation reasonable.

NuQuest's "**Medication Regimen Form**" is a tool specifically designed to help the claims adjuster obtain this information from the claimant's treating provider(s). NuQuest has experienced success using this approach. For more information regarding NuQuest's "**Medication Regimen Form**," see page 15 of this article.

- Determine if any of the approaches outlined in the *RX Guidance* document could be used to help reduce projected prescription costs. Remember, while CMS indicates that it will *consider* evidence from these approaches, it is unclear at this juncture to what extent it will actually *accept* the approaches outlined in the *RX Guidance* document.
- Obtain a rated age to reduce the claimant's life expectancy which can be helpful in reducing the number of years over which Part D drug costs will be projected. Remember, rated age usage is governed by CMS' specific directives and guidelines.

5. Increasing awareness at the claims level is imperative for proper claims handling.

Over the past few months, the author has noticed varying degrees of awareness, knowledge and understanding of CMS' new RX policies at the claims level which is causing considerable frustration and confusion. ***Communicating and educating about the new changes is absolutely essential for proper claims handling, and to optimize settlement prospects.***

Some ideas that may help to bridge the awareness and understanding gap are as follows:

Primary Payers:

- CMS' new prescription drug policies should be communicated to all levels of the claims handling process, along with any specific company protocols that should be followed.
- Case valuation and settlement practices may need to be modified.
- Communicating with defense counsel regarding how the issue will be addressed, including their expected role in this process (if any), is an important aspect that should not be overlooked. This is important in terms of ensuring that realistic and meaningful settlement and/or exposure analyses can be prepared.
- Communicate with your MSA vendor or allocator to ensure that you have the most up to date information in terms of approaches CMS is taking, emerging trends, areas of concern, etc.

Counsel:

- Address the new changes with your clients and discuss the potential complications and consequences.
- Counsel for the primary payers should determine if their client has any specific protocols or approaches to address the issue and what process (if any) you have in this process.
- Counsel for the injured worker should educate their clients about the significance of the new

changes and the potential complications same present in terms of reaching (and finalizing) settlements.

- Counsel on both sides need to spread awareness of CMS' new policies via discussions with colleague and their participation in professional associations, educational blogs, listservs, etc.

6. Monitor CMS for any changes in policy.

As noted throughout this article, CMS' application of its new prescription drug policies in many respects remains in its infancy stages. This is a quickly evolving area and it is essential that the industry closely monitor CMS' future actions to assess practical impact and to make the necessary modifications to claims handling and settlement practices resulting there from.

Conclusion

CMS' new policies for the pricing of Part D costs in relation to MSAs is significant from a policy standpoint as it represents the agency's first attempt to implement specific guidelines in this area since it began to require the inclusion of future Part D covered expenses in 2006.

Perhaps more importantly, CMS' new policies are a "call to action" to the industry on a number of levels. The new

changes need to be understood and communicated to all levels of the claim process. In addition, current claims handling and settlement practices need to be assessed, and, if necessary, modified in order to properly meet the new challenges. On a more global scale, mobilization of various industry and practitioner organizations to address the problem at the agency level (or perhaps even the national level) may need to be considered.

As part of this process, it must be remembered that major aspects of CMS' new policies remain inconsistent and unclear. Furthermore, legitimate questions of reasonableness are being raised in certain areas. Thus, understanding that the industry is presently navigating in uncertain waters is crucial with respect to addressing the issue from a realistic perspective. In this regard, any proclamations of simple answers or "magic bullets" should be scrutinized, as they would seem to defy an informed, knowledgeable or reasoned assessment of the current situation.

NuQuest stands ready to assist the industry in meeting this latest challenge, as it has with all other challenges on the MSA front since 2001. NuQuest's *Medication Regimen Form* and *Medication Regimen Comparison* are specifically designed to assist parties address the issues and challenges of CMS' new policies.

For more information about these tools, see pages 15-16 of this article.

About the Author

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Prior to joining NuQuest, Mark practiced workers' compensation and liability legal defense for 10 years. During this time, he developed a national Medicare practice which included Medicare Set-Asides and Medicare Compliance. Mark is very active on the national MSA/Medicare educational and training circuit. He is a regularly featured speaker on MSA/Medicare issues before carriers/TPAs, state bar associations and industry specific organizations.

Mark has also published several articles on MSA/ Medicare issues. Mark can be reached at 786-457-4393 or via e-mail at mpopolizio@nqbp.com.

Endnotes

- ¹ The concept of including outpatient prescription drug coverage as part of the Medicare program has been an idea discussed and debated since the inception of the Medicare program. In 1988, limited outpatient prescription coverage was provided for certain catastrophic injuries via the Medicare Catastrophic Coverage Act. However, this coverage was short-lived and was repealed in 1989. See, *Prescription Drug Benefit Under Medicare*, The Henry J. Kaiser Family Foundation, October, 2008, at p. 1. (Obtained by the author via www.kaiseredu.org).
 - ² Part D is voluntary for most beneficiaries. However, individuals who are “dual eligibles” (individuals eligible for both Medicare and Medicaid) and other low income beneficiaries are automatically enrolled into Part D. See, *Medicare Prescription Drug Benefit – Fact Sheet*, November, 2009, The Henry J. Kaiser Family Foundation, at p. 1 (Obtained by the author via www.kaiseredu.org).
 - ³ The Henry J. Kaiser Family Foundation, *The Medicare Prescription Drug Benefit – Fact Sheet*, November 1, 2009 at p. 1. (Obtained by the author via www.kaiseredu.org).
 - ⁴ By way of illustration, in 2010 the “standard” Part D monthly premium is will average \$38.94. The Part D deductible is \$310, followed by a 25% coinsurance up to \$2,830 in total drug costs. This is followed by the “donut hole” where the beneficiary pays 100% of his/her drug costs until he/she has expended \$4,550 in drug costs (excluding the Part D premium). In the next tier, the beneficiary pays either 5% of total drug costs or \$2.50/\$6.30 for each prescription. See, The Henry J. Kaiser Family Foundation, *The Medicare Prescription Drug Benefit – Fact Sheet*, November 1, 2009 at p. 1. (Obtained by the author at www.kaiseredu.org).
- Note: For the reasons discussed in Part II of this article, use of the Part D co-pay and deductible formula, as well as other “discounting methods,” would now appear to be prohibited by CMS’ new policies.
- ⁵ For a more detailed overview of the Part D program, the reader may wish to commence his/her examination by reviewing the following resources: *Medicare & You 2010* accessible at www.medicare.gov; *Your Medicare Benefits* accessible at www.medicare.gov; and the many excellent resource materials published by the The Henry J. Kaiser Family Foundation (website: www.kff.org).
 - ⁶ Gerald Walters, CMS Memorandum to All Regional Administrators, “*Part D and Workers’ Compensation Medicare Set-Aside Arrangements (WCMSAs) Questions and Answers*,” December 30, 2005.
 - ⁷ Gerald Walters, CMS Memorandum to All Regional Administrators, “*Questions and Answers for Part D and Workers’ Compensation Medicare Set-aside Arrangements*,” July 24, 2006, FAQ No. 10.
 - ⁸ Gerald Walters, CMS Memorandum to All Regional Administrators, “*Questions and Answers for Part D and Workers’ Compensation Medicare Set-aside Arrangements*,” July 24, 2006, FAQ No. 13.
 - ⁹ Gerald Walters, CMS Memorandum to All Regional Administrators, “*Questions and Answers for Part D and Workers’ Compensation Medicare Set-aside Arrangements*,” July 24, 2006, FAQ No. 8.
 - ¹⁰ Patty Meifert, *Mechanisms for Containing Medicare Part D Prescription Drug Costs in MSA Allocations*, p. 1-2, NuQuest/Bridge Pointe “Settlement News,” June, 2007.
 - ¹¹ For an excellent overview of the Part D formula approach, including an actual example of how costs were significantly reduced by utilizing this formula, see pages 2 and 3 of author Meifert’s article. Again, for the reasons outlined in Part II use of the Part D formula, as well as other “discounting methods” would now appear to be prohibited under CMS’ new policies.
 - ¹² Gerald Walters, CMS Memorandum to Consortium for Financial Management and Fee for Service Operations, *Medicare Secondary Payer-Workers’ Compensation – INFORMATION*, April 3, 2009, p. 1.
 - ¹³ Gerald Walters, CMS Memorandum to Consortium for Financial Management and Fee for Service Operations, *Medicare Secondary Payer-Workers’ Compensation – INFORMATION*, April 3, 2009, p. 1.

Average Wholesale Price (AWP) is a calculation method intended to represent the average price at which wholesalers sell drugs to physicians, pharmacies, and other customers “based on data obtained from manufacturers, distributors, and other suppliers.” See, Patty Meifert, *Mechanisms for Containing Medicare Part D Prescription Drug Costs in MSA Allocations*, Settlement News (June, 2007), at p. 1, citing Medical Economics Staff, 2002 as referenced in *Red Book*.

- ¹⁴ Gerald Walters, CMS Memorandum to Consortium for Financial Management and Fee for Service Operations, *Medicare Secondary Payer-Workers' Compensation – INFORMATION*, April 3, 2009, at p. 2.
- ¹⁵ Gerald Walters, CMS Memorandum to Consortium for Financial Management and Fee for Service Operations, *Medicare Secondary Payer-Workers' Compensation – INFORMATION*, April 3, 2009, at p. 2.
- ¹⁶ *CMS Prescription Drug Set-Aside Guidance for Submitters Effective: June 1, 2009*, at p.1.
- ¹⁷ *CMS Prescription Drug Set-Aside Guidance for Submitters Effective: June 1, 2009*, at p.3.
- ¹⁸ *CMS Prescription Drug Set-Aside Guidance for Submitters Effective: June 1, 2009*, at p.3.
- ¹⁹ *CMS Prescription Drug Set-Aside Guidance for Submitters Effective: June 1, 2009*, at p.3.

NuQuest/Bridge Pointe Can Assist in Addressing the Challenges Created by CMS' New Rx Drug Policies

Medication Regimen Form

NuQuest's *Medication Regimen Form (MRF)* allows adjusters to easily request projected Part D prescription drug regimen information from the claimant's prescribing medical provider(s)* in an attempt to contain or reduce the prescription drug allocation amount.

The form requests the medical provider(s) opinion regarding the claimant's projected future Part D prescription drug regimen. The form presents the inquiries in an easy to follow format that the provider(s) are able to complete in minimal time.

How it Works:

The form can be obtained and used in any of the following three ways:

1. Receive a completed Medication Regimen Form as part of a completed MSA allocation.

NuQuest will prepare a *Medication Regimen Form* (one per each prescribing medical provider) listing all medications prescribed by the applicable provider. Simply forward the form(s) to each provider* and, upon obtaining a response, send the form back to NuQuest. NuQuest will update the MSA accordingly, per the completed form.

2. Obtain the form at any time from NuQuest/Bridge Pointe.

A blank *Medication Regimen Form* is provided via email attachment at the time a new referral is received by our Service Coordination team. The form can be completed, submitted to the prescribing medical provider(s)* and forwarded to NuQuest at any time thereafter.

- OR -

A copy of the *Medication Regimen Form* can be obtained by contacting a NuQuest representative at 1-866-858-7161, select option 2.

The form can be requested, prepared and submitted to the claimant's prescribing medical provider(s)* by the claims handler or other authorized party PRIOR to requesting an MSA and then sent to NuQuest as part of the MSA referral.

3. Utilize the form as part of a "Reconsideration Request" to CMS.

In cases where parties are filing a "reconsideration request" with CMS, the *Medication Regimen Form* may be helpful in presenting CMS with evidence of the claimant's projected future drug costs directly from his/her prescribing medical provider(s)* as part of the parties' overall efforts to obtain approval of a reduced future drug allocation.

* Assuming that contact with the claimant's providers in this manner is permitted under the law of the subject jurisdiction. Consult with your legal representative to determine whether such contact is in fact permitted in your jurisdiction.

Medication Regimen Comparison

NuQuest's *Medication Regimen Comparison (MRC)* provides a side by side cost comparison of the claimant's current medication regimen calculated over the claimant's life expectancy versus a pharmacist recommended projection.

This service provides the framework to analyze costs from the perspective of appropriateness vs. over-utilization; red flagging possible drug interactions; identifying drugs that may not be appropriate for long term use or which should be discontinued at some point (i.e. certain post surgery drugs); or which should be discontinued based on the claimant's age.

How it Works:

The *Medication Regimen Comparison* provides a comparative analysis as follows:

Table 1:

Provides a calculation of the claimant's current Medicare and non-Medicare allowable prescription drugs based on AWP/Red Book. This is calculated over the claimant's life expectancy which is the methodology CMS has been observed to be requiring on a more frequent and regular basis.

Table 2:

Provides a *pharmacist recommended projection* of the claimant's future anticipated Medicare and non-Medicare allowable prescription drug costs over the claimant's life expectancy based on AWP/Red Book.

A *Medication Regimen Comparison* can be completed prior to an MSA allocation. Information obtained from this service may provide supporting documentation to justify changes in the future prescription drug regimen. This information could then be submitted to the claimant's prescribing medical provider(s)* via the *Medication Regimen Form* and later utilized by NuQuest in completion of an MSA allocation, if applicable.

* Assuming that contact with the claimant's providers in this manner is permitted under the law of the subject jurisdiction. Consult with your legal representative to determine whether such contact is in fact permitted in your jurisdiction.

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