



MEDICARE SECONDARY PAYER  
SOLUTIONS  
A DIVISION OF RITSEMA & LYON, P.C.

## NEWSLETTER APRIL 2009

On April 3, 2009, the Centers for Medicare and Medicaid Services (CMS) issued a formal Memorandum announcing that it will begin independently pricing future prescription drug treatment costs as part of the MSA review process. CMS indicated it will only allow calculations of future prescription medication costs using the Average Wholesale Price (AWP). CMS also stated it will not use or recognize any other pricing, discounting, or calculation methods in determining the adequacy of prescription drug amounts and that it will accept a generic version of prescription medication only when that generic is currently available on the market.

The memo also stated that if an MSA Proposal is submitted to CMS that does not contain an amount for prescription drugs, and the review contractor deems the MSA warranted the need for prescription drugs to be included, CMS will calculate a prescription medication amount using the AWP of brand name drugs for that claimant.

The April 3, 2009 Memorandum raises many issues and leaves many questions unanswered by CMS.

### **Issue 1- Required Use of Wholesale Price**

The phrase "Average Wholesale Price" leads most to believe that it is the average price paid by a pharmacist or physician for a particular drug. However, the AWP is actually provided by each drug manufacturer and is not verifiable. There are no laws or regulation(s) defining the calculation of the AWP and the AWP is not required to be updated regularly.

On the retail market, customers typically pay the AWP minus a percentage ranging from 5 to 15 percent. There is sometimes an even deeper discount for insurance companies. Over the last decade, the AWP has been the subject of several law suits questioning whether the AWP was arbitrarily inflated by drug manufacturers and retailers of prescription medications. In fact, much of the litigation centered on drug manufacturers inflating the AWP to increase the reimbursement rate paid by Medicare and Medicaid. Most of these lawsuits settled resulting in the defendants paying back funds to insurance companies, Medicare and Medicaid, and consumers who paid co-pays or other out of pocket expenses for prescription drugs.

## **Issue 2 – CMS' Failure to Recognize Patent Expiration and Generic Alternatives**

By requiring parties to submit an MSA that calculates prescription drug costs using only the AWP, CMS is passively forbidding the use of patent expiration data when calculating prescription medications because the AWP does not provide predicted costs when a medication's patent expires. Consideration of patent data is a valid method for the calculation of prescription drug costs. Research and experience have demonstrated an overall 45% decrease in drug costs following patent expiration. CMS' refusal to allow patent reductions is contrary to proven pricing patterns in the prescription medication industry and will result in a significant increase in costs to parties settling claims involving prescription medication.

## **Issue 3 – Submission of MSA Proposals Where Claimant's Need for Future Prescription Medication is Unclear**

Medicare's Memorandum 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 work-comp 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."

While not specifically stated in any prior Memorandum since the implementation of the prescription medication portion of the MSA in January 2006, Medicare has taken the position that if a claimant used prescription medication at any time during the course of his treatment, an allocation for future prescription medication will be required as part of the MSA.

Historically, CMS has allowed parties to a settlement to include any amount for future prescription medication when the type and frequency of a claimant's needs are unknown and the amount is speculative. Depending upon how much prescription medications the claimant took in the past, this amount typically ranges from \$200.00 to \$1,000.00.

When a claimant is not currently taking prescription medication and no medical record indicates the need for medication in the future, it is difficult to specify with certainty whether or not prescription medication will be required.

CMS' memo leaves unclear how it will deem an amount appropriate and how it will choose brand name drugs when no drugs are currently being used. Of serious concern is the possibility that CMS will arbitrarily add prescription drug costs to a Medicare set-aside that are not warranted.

## **Issue 4 – Will CMS Require Current Prescription Drug Use for Claimant's Lifetime?**

If CMS chooses to analyze the medication portion of the Medicare set-aside the same way that it analyzes the medical treatment portion of the set-aside, it is likely that CMS will take claimant's current prescription drugs, price them at the AWP and extrapolate the amount

over the claimant's life expectancy. CMS will probably disregard the fact that claimants are not always using their current drugs for their lifetime or that certain drugs do not indicate lifetime use. Very rarely is a snapshot of claimant's drug use indicative of the claimant's lifetime need for prescription medication resulting from a work-related injury.

The type, frequency, and dosage of prescription medications change often with changes in the claimant's treatment and symptoms. Additionally, claimants are sometimes taken off of prescription drugs due to ineffectiveness, lack of need, or use of alternative pain therapies. Further, several drugs on the market that are used for acute injuries are harmful if taken over the long term and are not indicated for a lifetime use.

CMS' memo does not indicate how it will calculate adequate prescription drug funding and does not indicate whether the parties may limit prescription drugs based on their belief that lifelong treatment is not necessary or based upon a prescription medication utilization review.

#### **Issue 5 – Use of the Fee Schedule**

Medicare's memo does not take into account the fact that several states use Fee Schedule pricing for prescription drugs and very often the Fee Schedule price is based on the AWP minus a certain percentage. Pricing drugs based upon CMS' requirement of using the AWP could result in inaccurate cost projections for clients in states that use the Fee Schedule. If the state Fee Schedule is less than the AWP, a cost projection using the AWP will result in higher cost than that required under state law.

#### **Current Options for Settlement**

It is MSP Solutions' recommendation that if formal CMS approval of an MSA is recommended, the settlement should be contingent on CMS approval of the MSA as proposed until we know how CMS will implement the policies outlined in its April 3<sup>rd</sup> Memorandum. Unfortunately, it is unknown at this time whether CMS will require set-aside funds to be calculated with a brand name drug at the AWP for a claimant's lifetime. Because CMS refuses to provide guidance on this Memorandum, the industry will not know the limits and the methods of prescription medication funding until proposals are submitted after June 1<sup>st</sup> and approved by Medicare on their terms.

It is important to remember that the CMS memo is not law and it is not binding on the parties unless the parties choose to go through the formal MSA approval process and to be bound by CMS' determination of what is a reasonable MSA. Formal approval by CMS of an MSA is never required; it is optional. The MSP statute requires that the parties take into consideration Medicare's interests and not shift the burden for payment to Medicare. If a claim is settled and formal CMS approval is not obtained, and CMS decides to pursue action, the burden shifts to CMS to prove in a court of law that the MSA was unreasonable.

It is MSP Solutions' opinion that an MSA which funds prescription medications at retail costs for the claimant's lifetime is reasonable and that CMS would not be successful proving

otherwise. It is also MSP Solutions' opinion that limiting prescription medication costs based on facts unique to the case, such as a temporary need for narcotic medication or weaning based on treater recommendations, is not unreasonable and that CMS would be unsuccessful proving otherwise.

Therefore, if formal CMS approval of a settlement is not recommended, it is MSP Solutions' recommendation that prescription medication costs be calculated at retail prices, utilizing patent expiration data and limited based on the facts of the case and reasonableness of the limitation.

For questions or comments, please call Samantha Fite or Delores Dafoe at 303.675.4406 or toll free at 866.677.6717.

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MEMORANDUM

**DATE:** April 3, 2009

**FROM:** Director  
Financial Services Group  
Office of Financial Management

**SUBJECT:** Medicare Secondary Payer--Workers' Compensation--INFORMATION

**TO:** Consortium Administrator for Financial Management and Fee-for-Service Operations

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.

**NOTE:** 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.

The CMS will begin independently pricing future prescription drug treatment costs/expenses in WCMSA proposals beginning June 1, 2009. 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.

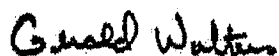
The CMS will apply the following procedures to all WCMSA proposals received on or after June 1, 2009. This procedure will also apply to all closed WCMSA cases that reopen on or after June 1, 2009, as noted below.

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 prescription 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.

**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.

Please direct questions or concerns to Frank Johnson of my staff at (410) 786-2892.



Gerald Walters

Attachment