



Government Affairs Alert

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CMS Issues Prescription Drug Set-Aside Guidance for Submitters

On June 2, 2009, the Centers for Medicare and Medicaid Services (CMS) issued a document entitled “CMS Prescription Drug Set-Aside Guidance for Submitters,” which provides further insight into methodology utilized by CMS for pricing of future prescriptions drug allocations. This document enhances the initial procedure memorandum dated April 3, 2009 in which CMS confirmed intent to review prescriptions drug allocations in Workers’ Compensation Medicare Set-Aside Arrangements (WCMSA) proposals effective June 1, 2009. To view the document, click [here](#).

CMS noted the June 2nd document was in response to questions and concerns raised by WCMSA submitters after publication of the April 3, 2009 memorandum. As a leader in the Medicare Set-Aside (MSA) industry, PMSI Settlement Solutions immediately reached out to CMS regarding the published prescription drug pricing methodologies in order to persuade CMS to revise these policies to be more fair and equitable. PMSI Settlement Solutions will continue efforts to further educate CMS on these issues and help shape future CMS policy decisions on claims settlement facilitation.

Summary of the “CMS Prescription Drug Set-Aside Guidance for Submitters”

CMS explains that although the current guidelines were published, they are not mandated policies and procedures and most determinations rest on the individual facts and evidence pertinent to the particular claimant. According to the document, the guidelines will remain fluid and may be revised on a periodic basis to incorporate new developments, information and issues which impact the WCMSA review process.

CMS confirmed the following points regarding/relating to or applying to future prescription drug allocations:

- Workers’ Compensation Review Contractor(s) (WCRC) will utilize the most current version of RED BOOK® Drug References to evaluate prescription drug component of WCMSAs.
- Submitters must furnish accurate, complete, legible, and current medical and prescription drug records for the last two years of the claimant’s medical treatment in connection with a workers’ compensation (WC) claim.



- CMS prefers WCMSA proposals be submitted after the claimant has reached maximum medical improvement (MMI) as defined in a memo dated July 23, 2001. This preference is based on the expectation that prescription drug use patterns will be established when a claimant reaches MMI. However, it is incumbent on the submitter to ascertain prescription drug information from the claimant, their representative, treating physician or pharmacy if prescriptions and drug utilization are not clearly noted in medical records.
- Claimants should receive appropriate medical treatment as determined by his or her treating physician, as the treating physician's opinion will be weighted above other opinions and utilization review reports. However, other documentation, including utilization review reports, will be considered when prescription drug determinations are made.
- Submitters should account for reasonable and probable future prescription drug needs even if recent medical records or claims payment histories do not demonstrate current use. For example, short courses of antibiotics are typically required for recurrent urinary tract infections commonly seen with neurogenic bladders even if records indicate no current short course antibiotic utilization.
- When the treating physician indicates tapering of prescription medications is possible and in best interests of claimant, CMS will consider this evidence.
- CMS recognizes expiration of brand drug patents and the eventual availability of less expensive generic equivalents as replacement therapy. However, new and more expensive brand name drugs often replace drugs with patent expirations and in some instances claimants insist on brand(s) even where generics are available. All of these concepts, along with the evidence submitted in a particular case, will be considered by CMS in determining the prescription drug allocation amount.
- CMS recognizes that off-label use of medications in the United States is both legal and common. CMS also recognizes that physicians, in their professional judgment, often prescribe a drug for purposes other than that approved by the Food and Drug Administration (FDA). As a result, physicians are not limited to prescribing a drug only for official, FDA-approved indications and this may impact future drug costs.
- If the submitter includes pricing for a generic drug when there is none available, CMS will utilize average wholesale price (AWP) for the brand name drug. If a brand drug is indicated, but records do not confirm utilization of a brand or generic drug CMS will utilize generic drugs where the submitter has proposed a generic drug. However, if the submitter has proposed a brand name drug or has not proposed a drug, CMS will use brand name drug pricing.



- In the absence of supporting documentation concerning prices from generic drug manufacturers within the WCMSA submission, CMS will use the lowest priced generic drug as listed in the RED BOOK Drug References.
- CMS will review and consider all documents submitted with a MSA proposal and submitters are encouraged to present any evidence they believe is helpful towards a set-aside determination. No statements in this new document should be considered a discouragement of that principle.

PMSI Settlement Solutions Client Support

PMSI Settlement Solutions has always been an advocate for our clients on CMS policies. PMSI Settlement Solutions' strategy in regard to prescription drug allocations focuses on **fair and accurate estimation of future drug treatment costs, while adequately considering Medicare's interests.** Through PMSI Settlement Solutions' staff of legal experts, nurses, physicians and pharmacists, we will continue to provide our clients with the lowest defensible allocations for compliance with the Medicare Secondary Payer laws and requirements.

As further information becomes available, PMSI's Government Affairs team will provide you with insight, analysis and opinion. For additional information, please contact your PMSI Representative, call us at 888.MSA.PMSI or visit us online at www.pmsisettlement.com.

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