CMS Prescription Drug Set-Aside Guidance for Submitters
Effective: June 1, 2009

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.

1. Source for Evaluation of Sufficiency of WCMSA Prescription Drug Component: The WCRC is using RED BOOK® Drug References [1] 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

[1] RED BOOK® Drug References is updated continuously. The CMS WCRC thus makes it a standard practice to utilize the most current version of this resource when evaluating the sufficiency of the prescription drug component of a given WCSMA proposal.

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 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 evidence 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.