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CLIENT ALERT

The New CMS Policies on Prescription Drug Set-Aside Guidelines

As everyone is now likely aware, CMS has set forth new policies effective June 1, 2009 for the methodology of pricing future prescription drug treatment costs and expenses contained within MSA proposals, submitted on and after that date.ⁱ

CMS will independently price future prescription drug treatment costs and expenses, on a going forward basis, by utilizing the RED BOOK Drug References in order to evaluate the sufficiency of the drug cost component.ⁱⁱ This means CMS will now use as its standard, the so called average wholesale price or “AWP.” [*Average whole price – is a list price used for invoices between drug wholesalers and pharmacies or other purchasers and is not in any sense real “wholesale”. In actuality, since it contains no adjustments for discounts, purchasing allowances or other considerations, it is nothing more than simply a retail price.*] In other words, CMS will be using the “sticker price” for its pricing basis. It has been long recognized that the AWP is the “going price” or the suggested retail price which does not reflect the actual price for which the drugs can be bought by wholesalers or distributors in the real market. In the real world, including workers’ compensation, a significant amount of the actual market is priced through PBM’s who manage pharmacy benefits on behalf of their clients. Through formulary management, negotiated price arrangements with drug manufacturers and the PBM’s own network of retail pharmacies, it is estimated that more than *one third* of all drug sales are managed through PBM’s.ⁱⁱⁱ

For purposes of reflecting the extent of medical treatment, CMS is also requesting that *the last two years of treatment and prescriptive drug records be furnished*. They go on to state that 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*

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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 MSA proposal as supported by the medical and other records provided.”

The policies in effect are:

- MSA submissions need to account for future prescription needs that are deemed **reasonably probable** even if recent medical records or payment histories do not otherwise support the use;
- The concept of “**tapering**” will be considered where the treating physician considers it possible and in the best interests of the applicant. They go on to state, “CMS will consider all evidence in making a WCMSA determination. Does this mean they will look beyond what the treating physician recommends?”
- CMS **permits the submission of UR reports** reflecting that the applicant should be taking none, fewer, different or less frequently taken drugs. However, more weight will be accorded to the treating physician’s opinion but at least the UR reports may be given consideration here.
- For both submitted brand name and generic drugs, CMS will reference the **RED BOOK**. If the submission is for a generic drug but there is none, they will use the pricing on the RED BOOK for a brand name. If the brand name is priced and submitted, they will also use the RED BOOK.^{iv} If there is no pricing on the drug, CMS will refer to the RED BOOK for the brand name pricing.
- Generic drugs are available from multiple manufacturers. Therefore, without supporting pricing documentation for prices from generic drug manufacturers within the submission, CMS will compare the generic drugs in the proposal and use the **lowest priced** generic drug listed in the RED BOOK. (but still at retail)
- **Other evidence and supporting arguments are allowable.** This means CMS will consider “all documents submitted with a WCMSA proposal.” Therefore, the supporting medical record should not only be referenced but when necessary, it should be **appended to the submission.**
- “**Off label Use**” The term “off label use” refers to the practice of having a physician prescribing medication for a purpose other than the formal one for which it was approved for use by the FDA. Thus, off label use is permitted and even seemingly encouraged. This means that a physician can prescribe a medication, once approved by the FDA, for “any other purpose that in their professional judgment is both safe and effective.”

- Beneficiaries are permitted to insist upon brand name drugs, even where generic drugs are available. [Here, CMS ignores Lab C 4600.1 which mandates the usage of the generic drug equivalents *unless under (b) it is otherwise unavailable or when the prescribing physician specifically provides in writing that a nongeneric drugs must be dispensed.*”]
- This retail based pricing policy is also applicable to closed WCMSA cases that are reopened on or after June 1, 2009.

WHAT THIS MEANS

By its new policies, CMS is effectively pricing future drug costs on retail or “sticker basis,” without factoring in any level of discount or giving any consideration to the actual price paid for the drugs in the world of the real marketplace. Therefore, CMS will not use or otherwise even recognize *any other pricing, discounting, or calculation methods when determining the adequacy of the prescription drug amounts in WCMSA proposals.*” In many cases, the use of the RED BOOK will result in a pricing structure which is well beyond the actual price actually paid through a PBM and its use of formularies, negotiated pricing from drug manufacturers and its own retail pharmacy networks. Unfortunately, the use of the RED BOOK will likely increase the estimated future costs of drug pricing for purposes of giving consideration to an MSA submission.

WHAT YOU CAN DO

Since future drug costs in an MSA submission will now be priced at the retail or “sticker” level,” careful review of the medical record is required, in order to determine what actual drugs are necessary as part of the future medical care aspect and if so, *to what specific nature and extent.* In other words, we may not be able to change the price of the drug but we can make sure that every MSA submission contains a reasonable reflection of what medications and drugs are needed, based upon the medical record; the actual nature and extent of that need, including off label prescriptions from treating physicians.

While these new policies pose a real challenge to MSA submissions, they also open an opportunity to re-visit the way in which we set forth and calculate the drug piece of the equation, within a proposed MSA submission.

Here are some points to consider for future MSA submissions:

- 1) IS EACH DRUG LISTED IN THE MSA ACTUALLY NEEDED? CHECK EACH DRUG AND ITS USAGE:** When you review a potential MSA analysis, be sure to examine each drug *which is listed.* Do not simply assume that each drug listed is actually required or that it has been specifically recommended by a treating physician within the medical record. For example, if a particular drug is given a cost projection, based upon a lifetime of usage, review the actual medical reports describing the particular drug and if that drug was

recommended, whether there were conditions or limits imposed upon its use. Don't accept a drug without some support for its future use, contained in the medical record; (Med Line has a decent web site which at least gives you the intended use of each drug <http://www.nlm.nih.gov/medlineplus/druginformation.html>)

- 2) **SUPPORT YOUR DEFENSE TO ANY DISPUTED BODY PART SO THAT THE MSA REFLECTS WHAT BODY PARTS ARE IN ISSUE:** Even though CMS claims they accord more weight to a treating physician's opinion, don't forget that if there is a disputed body part, this contention should be clearly set forth in the MSA submission and the legal or evidentiary basis for the dispute, demonstrated by the record. There may be other legal arguments to support an opposition to the opinion of a treating physician, so don't be timid about pointing that out to CMS within the submission. This can be done in a supporting narrative, a letter from your counsel in which they point out various aspects of the record and of course the record itself. You can submit evidence which indicates that a specific body part should not be part of the industrial injury, based upon evidence. That evidence should be copied and furnished to support your position. The stronger the argument, the greater detail provided, the better chance that the reviewer will not simply follow the treating physician's opinion, especially where there is detailed documentation supported by a clear explanation as to why the MSA does not include a certain body part and therefore future drugs and medications, at least not at full price.
- 3) **CLARIFY UNRESOLVED OR INCOMPLETE MEDICAL OPINIONS FROM THE TREATING PHYSICIAN OR QME, WHEN ALLOWABLE:** Remember, if the treating physician's opinion is unchallenged, then CMS will default to those findings. Therefore, you may want to consider obtaining specific clarification from the treating physician and/or a QME as to what specific future drugs are recommended, their duration and intended future use and whether tapering is indicated. (Some pain physicians may ignore the tapering issue and this is important)
- 4) **DON'T FORGET TO REFER TO AND INCLUDE WITHIN THE SUBMISSION, THE UTILIZATION REVIEW REPORTS:** While these may not be persuasive on their own, they are certainly allowed and in conjunction with a strong and logical argument, they could be important in order to support your position, especially if they are in accord with the opinions of a DQME or PQME.
- 5) **BE AWARE:** A physician may prescribe medications on an "off use" basis for symptoms which may be out of that physician's actual scope of practice or for conditions which might not be industrial or even related to the industrial injury. That is why you need to review and check every listed medication within the MSA analysis, prior to submission.
- 6) **PRICE ALL DRUGS WITHIN THE MSA SUBMISSION:** Remember, if the submitter has not priced a drug, CMS will look at the MSA and then reference the RED BOOK for the associated **brand name price**. Therefore, all drugs need to be priced in the submission.

- 7) DID THE TREATING PHYSIICAN FOLLOW LABOR CODE SEC. 4600.1 OR DID THE APPLICANT RECEIVE BRAND NAME DRUGS WHEN HE/SHE SHOULD HAVE HAD THE GENERIC EQUIVALENT?** If the treating physician has not followed the Code or if the generic equivalent was available at the time of prescription, then be sure to **PRICE THE DRUGS FOR THE GENERIC AND NOT THE BRAND NAME IN THE MSA SUBMISSION. FAILING TO CHECK THIS POINT IN THE MEDICAL RECORD CAN LEAD TO AN UNNECESSASRILY EXPENSIVE CONCLUSION.**

ⁱ As is the case, CMS issues rules through its memoranda, reflecting policies and procedures. Fortunately, these are usually brief and to the point.

ⁱⁱ The Redbook is published by Thomson PDR. The 2009 Red Book 113th Ed, set for release 5/30/09.

ⁱⁱⁱ "Prescription Drug Pricing in the Private Sector" by Congressional Budget Office (1/2007) –a CBO Paper at Pp. 10.

^{iv} The Redbook is priced at the "average wholesale price" but this is often very much higher than the actual price that can be obtained or that is priced within a PBM.

^v CMS Memorandum of 4/3/09.