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WCMSA Reference Guide; Challenges, Pitfalls and the Industries Response

The guide was created to provide a resource to submitters on what documentation is to be provided with the submission and how the current Workers' Compensation Review Center (WCRC) completes its review process. This article will try to make sense of the CMS reference guide released on May 29, 2014, and why the submission process isn't working as it was intended.

Medicare remains the secondary payer and is prohibited under the MSP to make payment where payment has already been made. The WCMSA submission process deals with the future medical services related to a WC settlement and allows, on a voluntary basis, to obtain certainty that the amounts set aside for future Medicare allowable expenses are appropriate. Any claimant who receives a settlement with an amount allocated for future medicals must take Medicare's interest into account. If Medicare's interests are not taken into consideration, Medicare may refuse to pay for future medical until the entire settlement funds have been exhausted.

The Medicare Secondary Payer (MSP) is the term used to describe the statute of the Social Security Act that Medicare may not pay for medical expenses if, when payment "has been made or can reasonably be expected to be made under a workers' compensation plan, an automobile or liability insurance policy or plan (including a self-insured plan), or under no-fault insurance". (See 42 U.S.. § 1395y(b)(2) and § 862(b)(2)(A)(ii) of the Social Security Act for the full definition).

The primary reason to submit a proposed MSA to CMS for review is to obtain approval of the amount that must be appropriately exhausted; it is important to note that the process is not required.

According to the May 29, 2014 reference guide, "There are no statutory or regulatory provisions requiring that you submit a WCMSA amount proposal to CMS for review. If you choose to use CMS' WCMSA review process, the Agency requires that you comply with CMS' established policies and procedures in order to obtain approval." If the parties choose to utilize the CMS submission process, they must comply with the CMS guidelines set forth in the guide and CMS memos.

CMS submission process and required documents:

tThe proposed MSA amount with supporting documents can be submitted via the WCMSA Portal or via CD to the COB&R. Once the WCRC receives the proposed MSA, it will determine if all necessary information is correct, such as: claimant contact information, date of injury, life expectancy, settlement meets threshold, administration method is provided, funding method is provided, state of jurisdiction was provided, treatment records are valid and up to date, and current pharmacy records. The WCRC will then complete an independent review of the documentation provided and submit their recommendations to the appropriate Regional Office. The review process appears to be simple enough – let's take a closer look.

According to the WCMSA reference guide, the most frequent reasons for development requests or requests for additional information released are the following:

1. Insufficient or out of date medical records
2. Insufficient payment histories
3. Failure to provide settlement details or court rulings
4. Referenced documents are not provided
5. State statutes referenced in submission cover letter are not provided

For the purpose of this article, we will be reviewing the first development requests – insufficient or out of date medical records, which include part D drug utilization information. The CMS submission sample and guide note that two years of current

treatment records are to be provided with the submission. Both the sample and guide clearly identify "current treatment records" as the last treatment records provided for the industrial injury – regardless of how old they are. The two years are treatment years, not calendar years. The WCRC often confuses the "treatment" years with "calendar" years. The development requests will ask for the last two years of current treatment records as the treatment records provided are not within six months of submission date and if treatment did not occur in the last two years, consider providing non-industrial records for review. Non industrial treatment records are not essential for the review process. One concern with providing non-industrial treatment records is the WCRC's independent review of the records to determine if the treatment is related to the WC injury. The WCRC reviewers are not the primary treating physicians for the claimant and should not be making determinations as to what is related and what is not. These types of requests place undue burden on all parties involved in the CMS submission process. Often, records are not obtainable as treatment has not occurred or the claimant refuses to provide non-industrial treatment records. If the non-industrial records are provided to push the review through, the submitter runs the risk of CMS including treatment or part D drugs that are unrelated.

The industry's response to the exorbitant amount of development letters was to push back. The CMS Central Office agreed to make changes to the submission guide and clarify the two years of current treatment records language. The results are mixed and not consistent as the WCRC continues to release development letters for records that are non-existing and therefore, non-treatment records need to be provided.

What does the WCRC do with the current treatment records and how do they come up with their recommendations?

The WCRC takes previous injuries that affect the resolution of the accepted injury and any underlying medical conditions that may affect the type of future care or length of care

into consideration. Per the WCMSA Reference Guide, the reviewers use evidence-based rationale for the determinations. Furthermore, the guide notes that the evidence-based rationale are guidelines only and the review must take the past history use and future recommendations provided in the records and peer-reviewed literature into consideration.

While evidence-based medicine takes into consideration best practices and individual factors, the WCRC tends to allocate based on general guidelines that they have established. Some examples are: the frequency of diagnostic studies, joint replacements, durable medical equipment (DME) replacements, spinal cord stimulator (SCS) and intrathecal pump (ITP) replacements, and equipment/supply items. WCRC allocates certain medical services at a set frequency regardless of the specific circumstances of the particular case. WCRC allocates x-rays every 3 to 5 years; MRI studies every 5 to 7 years; joint replacements every 15 years; canes, braces, and other DME items every 3 years; and SCS/ITP every 7 years. This does not take into consideration the individual circumstances of the particular case.

Recent CMS approvals noted additional medical services were included by WCRC as it was "reasonable and predictable" that these services would be required based on the diagnosis and progression of this condition. These services were not recommended in the last two year of treatment.

Although CMS does routinely allocate PRN medications for life expectancy, their duration of use is typically not chronic. Acute medications are those that are used for the short-term or for those conditions that one will recover from. Examples of conditions and associated medications which are considered for acute use include:

- Anti-Nausea (Ondansetron/Prochlorperazine)
- Skeletal Muscle Relaxants (Cyclobenzaprine/Tizanidine/Carisoprodol)
- Ulcer Medications (Omeprazole/Esomeprazole/Lansoprazole)
- Analgesics (Ibuprofen)

- Opioids (Hydrocodone/Oxycodone/Tramadol)
- Sleep Aids (Zolpidem/Temazepam)
- Anti-Anxiety (Alprazolam)

While not an all-inclusive list, this illustrates that certain conditions will not require life-long use with medications. Certain medication classes, such as ulcer medications, have durations stated on the label for use up to 8 weeks only. After such time, medical consultation is recommended, as an underlying condition may be present.

In comparison, chronic (aka maintenance) medications are those which treat a chronic disease state, such as:

- Cardiovascular (Amlodipine/Diltiazem)
- Diabetes (Metformin)
- Lipid Lowering (Simvastatin/Pravastatin)
- Epilepsy (Topamax/Carbamazepine)

Again, while not an all-inclusive list, medications used to treat these types of conditions are indicated to be taken long-term, and not on an intermittent schedule.
A majority of conditions seen in workers compensation are for acute conditions involving pain or a condition in which a curative outcome is expected. Due to CMS guidelines, these acute conditions are grouped into the chronic, life-long category, but it is inconceivable that, for example, either muscle relaxants or sleep aids would be taken every day for the rest of someone's life.

CMS will always allocate the prescription version of Prilosec (omeprazole) unless there is documentation to prove the over-the-counter (OTC) version is being provided. In many cases, the records note the utilization of Prilosec 20mg and the pharmacy ledger does not document that this medication is being dispensed. With the presence of a current and complete ledger, if Prilosec is not documented, it should be assumed the OTC formulation is being provided to the claimant.

- Opioids (Hydrocodone/Oxycodone/Tramadol)
- Sleep Aids (Zolpidem/Temazepam)
- Anti-Anxiety (Alprazolam)

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As an example:

Drug	*Cost for Prescription Strength (AWP*)*	*Cost for Over the Counter (AWP*)*
Prilosec 20 mg (brand)	$8.1767	$0.6664
Omeprazole 20 mg (generic)	$06931	$0.2014
Prevacid 15 mg (brand)	$11.0503	$0.6895
Lansoprazole 30 mg (generic)	$5.6682	$0.3426

**AWP per date of newsletter*

Another common scenario is CMS allocating some Part D drugs because they feel it is "reasonably probable and predictable that this/these medications will be utilized during life expectancy". These drugs are not documented on the pharmacy ledger as being currently dispensed yet CMS will include them routinely for life expectancy.

Part D medications are allocated routinely for life expectancy regardless of the FDA indications for use. Many Part D medications are indicated for short-term use only. However, CMS routinely allocates the monthly quantity presently being dispensed for life expectancy.

What Are The Alternatives?

It is not the intent of this article to imply that Medicare's interest should not be considered in WC settlements, but instead to point out where the process is not working and to provide alternatives. Time delay due to repeated requests for additional records strap the WCRC resources which cause cases to close and go to the back of the line. As a result, the carriers are faced with additional cost; paying benefits while waiting to obtain CMS approval. The CMS review process is inconsistent and the results are unpredictable.

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Many questions have been asked by insurance leaders: What is the true cost of submitting a case? What is the chance that the claimant will use the total amount allocated by CMS due to their "trends" that inflate the amount? What are the alternatives?

Should I consider submitting a WCMSA proposal?

As referenced in the WCMSA Reference Guide, "an individual or beneficiary may consider seeking CMS approval of a proposed WCMSA amount for a variety of reasons. The primary benefit is the certainty associated with CMS reviewing and approving the proposed amount with respect to the amount that must be appropriately exhausted. It is important to note, however, that CMS approval of a proposed WCMSA amount is not required." The Guide outlines the consequences of failing to protect Medicare's interests and concludes by stating "once the CMS-approved set-aside amount is exhausted and accurately accounted for to CMS, Medicare will pay for future Medicare-covered expenses related to the WC injury that exceeded the approved set-aside amount."

What about those set-aside proposals that don't meet CMS Review Thresholds or those simply not submitted to CMS based on an organization's "internal" CMS Review Thresholds? While CMS has never addressed these cases publicly (to our knowledge), as a Professional Administrator of WCMSAs, NQBP has never had an issue with Medicare becoming a primary payer on those WCMSAs which haven't been approved by CMS and have been temporarily exhausted. Are they reviewing these cases? Or does having the non-approved WCMSA Professionally Administered meet the definition of "protecting their interests"?

Alternative Solution

The industry as a whole is growing more concerned with the delays that regularly occur with CMS while attempting to gain their approval. Couple these concerns with frustration over the additional requests CMS is issuing during the review process and their

calculation methodology, and one has created a perfect storm prohibiting employers, TPAs, and carriers from settling their claims in a timely manner, while continuing to incur costs in the attempt to resolve the claim.

NQBP has created a solution to address the concerns noted above while maximizing your MSA savings potential and eliminating the costs associated with protecting Medicare's interests.

This solution will allow for these same organizations to "certify" they have met all the requirements under the Medicare Secondary Payer (MSP) statute, while mitigating their risk. The program demonstrates Medicare's interests were taken into consideration, while controlling the cost of each claim.

How can NuQuest help?
NuQuest continues to develop logical, reasoned, and realistic approaches to assist the industry in meeting the ongoing and varied challenges posed by CMS' policies.

Call 1-866-858-7161 option 2 and find out how we can assist you today.

PART II
Celebrex Available Late 2014

Over the last year, two highly utilized branded medications in workers' compensation are now available generically. In 2013, Lidoderm® patches became available under the generic name Lidocaine and more recently, Cymbalta®, under the generic name Duloxetine, have brought some relief to the workers' compensation industry by way of lower costs and a lower Part-D allocated amount.

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Later this year, Celebrex® will join both Cymbalta® and Lidoderm® in being made available under its generic equivalent, Celecoxib. Although release of the generic was fought in the US courts for some time, the makers of Celebrex® (Pfizer) reached settlement agreements with both Teva and Actavis, allowing for the marketing and distribution of Celecoxib by December 2014.

Celebrex® is FDA indicated for the following conditions: Acute pain in adults, ankylosing spondylitis, osteoarthritis, rheumatoid arthritis, primary dysmenorrhea, and juvenile rheumatoid arthritis. The generic version Celecoxib will carry the same FDA indications as the brand name, along with the same Black Box Warning in regards to the cardiovascular risk with usage. Celebrex® is available in strengths of 50mg, 100mg, 200mg, and 400mg capsules. With current costs close to $350 per month, the generic version of Celebrex will be welcomed relief for all.

Typically, true cost savings with generic medications will not be realized until at least three to six months after initial release. This is due to recoupment of research costs and other expenses which were needed to bring the generic to market. Furthermore, although Celecoxib is scheduled for a December 2014 release, the brand Celebrex must still be allocated in an MSA until such time where Celecoxib is officially released. Please refer to the CMS Prescription Drug Set-Aside Guidance for Submitters June 1, 2009 tip sheet point #7, which states “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.”

Although generic Celebrex is on the horizon, there are other brand name drugs that may possibly take its place and find themselves on your claims payment history. Zorvolex® is a branded version of Diclofenac which has similar indications as that with Celebrex. This is something to keep a close eye on as we move through 2014 and toward the release of Celecoxib.

References:
1. E-Facts and Comparisons Online. Clinical Drug information, 2014.
2. FDA Approves First Generic Versions of Celecoxib. US FDA May 30, 2014 Press Release. www.fda.gov

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PART III

Tramadol to have Controlled Status beginning August 18, 2014

Tramadol (Ultram®) was released into the market in 1995 as a non-controlled substance. It is indicated for the treatment of moderate to moderately severe pain in adults. When initially released, there was hope that Tramadol® could effectively be used in those with non-cancer-related pain and have less abuse potential as commonly known opioids exhibit due to its pharmacologic properties.

However, this was not the case. Since 2008, Tramadol® usage has been steadily climbing with reports of close to 40 million prescriptions being filled annually in US pharmacies. In the state of Florida alone, overdoses caused by Tramadol have also increased at an alarming rate and thereby are filling Emergency Rooms statewide.

Beginning August 18, 2014, all Tramadol-containing products (Tramadol®, Tramadol ER®, Ultracet®) will now be classified as a Schedule IV controlled substance. Although ten states had already re-classified Tramadol® as a controlled substance, this final rule now officially classifies Tramadol® as a controlled substance in all states, for which special handling will commence. By being designated as a controlled substance, Tramadol® will now be subject to limited refills per prescription and potentially quantity limits as well.

The action that was taken is similar to what was seen with Carisoprodol back in 2011. It is the hope that by designating Tramadol® as a C IV controlled substance, its subsequent and possible misuse will decline. Ironically, some studies state that when Tramadol® is used in combination with Carisoprodol the overall abuse rates increase by 30%.

Only time will tell if this is a positive move, but this will be welcomed in the workers' compensation arena where all too often, misuse and abuse of opioid medications are a fact of life.
The final rule can be found in the following link:
http://www.gpo.gov/fdsys/pkg/FR-2014-07-02/pdf/2014-15548.pdf

1 Milwaukee Journal/Sentinel MedPage December 2013.
1-2 Reeves et al. Abuse of Combinations of Carisoprodol and Tramadol
2 Reeves et al. Abuse of Combinations of Carisoprodol and Tramadol