SPRING 2020

Welcome to NBKL's "Medicare Secondary Payer Compliance Corner"

Medicare Secondary Payer compliance has not been slowed down by the COVID-19 pandemic. Our Spring 2020 edition of the NBKL MSP Compliance Corner highlights some recent CMS developments as well as solutions to some frequent MSP problems.

Get "Informed" About the New Consent to Release for Medicare Set-Asides / Julie Garrison

Approval of Workers' Compensation Medicare Set-Asides (WCMSA) by the Centers for Medicare and Medicaid Services (CMS) remains the "gold standard." WCMSA funds, first approved by CMS and then properly exhausted, guarantee Medicare will take over as primary payer for further treatment costs. And while submission of a WCMSA to CMS for approval is voluntary, CMS strongly encourages litigants to obtain approvals. However, in October 2019, CMS amended its WCMSA Reference Guide and Consent to Release document to require claimants understand the contents of a WCMSA submission, as well as the submission process and WCMSA administration, and agree to the proposed submission. This new WCMSA Consent to Release thus added an extra hurdle to submission of WCMSAs to CMS for approval.

Informed Consent

The new requirement compels informed consent for claimants. A complete understanding of WCMSA proposals, supporting submission materials, and the overall process will be challenging for those unfamiliar with the system. Initially, claimants, and sometimes their representatives, often do not understand the need or requirement for WCMSAs. A submission consists of at least seven separate parts: a submitter letter, the signed consent, a rated age evaluation, the WCMSA proposal, treating medical records from past two years or last two years of injury-related treatment (if no longer treating), current two-year history of prescription drug usage, and claim payment histories. The WCMSA proposal should delineate accepted and denied conditions and treatment and only project care based on past treatment and legitimate future recommendations. Sharing submission documents will be interesting at best.

Claimants may disagree with disputed and denied parts of claims – and the exclusion from WCMSAs of body parts, medical conditions, or specific treatment including prescription drugs. The impact of individual state workers' compensation laws or procedures on the MSA analysis is not common knowledge among laypeople. Claimants may not realize CMS conducts an independent review of submission materials and could approve a higher or lower WCMSA figure. Or that employers can decide to fund the CMS-approved amount or keep medical rights open. Claimants may not know an approved and funded WCMSA establishes a pool of money from which future related care should be paid, but that actual care will likely differ from medical services and procedures included in the submission and approval. These are but a few of the questions and concerns to be addressed by the informed consent process.

Informing claimants of the process and substance of WCMSA submissions will understandably impact claims handling and obtaining settlements. The timing of submissions is affected, too. The gathering, analysis and presentation of a WCMSA proposal and supporting documentation involves a snapshot in time based on current medical records including prescription medication histories and payment logs. Seeking claimants' consent may delay the submission process and even render submission documentation stale or incomplete. In such cases, the submission packet will change and the consent process stall.

Informing and Involving the Parties

Informing claimants means involving knowledgeable MSP professionals. A one-size-fits-all approach cannot address fact-specific explanations or claimants' questions and concerns. In requiring detailed communication and explanation about the preparation of a WCMSA proposal and the process of submitting proposal to CMS for approval, the new Consent requirement will facilitate informing and involving all parties. As attorneys well-versed in both MSP expertise and workers' compensation experience, we can inform the parties throughout the WCMSA analysis and submission process.

Where submission of a WCMSA is indicated, we recommend WCMSA proposals and supporting submission documentation be shared electronically by secured email with a claimant and his/her attorney. If desired, a follow-up phone conference with the claim handler, the claimant, claimant's attorney, and the MSP professional/WCMSA submitter, would allow full explanation of the WCMSA proposal and accompanying submission documents and an opportunity to address any questions and concerns. Where appropriate, claimants might allow their representatives to sign off on submissions. These measures will work during the current shelter-in-place orders, as well as when more normal business practices resume.

In our view, MSP professionals, and particularly attorneys specializing in MSP compliance, should participate in settlement discussions. When prepared by an experienced and knowledgeable attorney-specialist, a proposed WCMSA can reflect settlement value and address disputed and denied injuries and unrelated conditions. In such circumstances, the informed consent requirement might promote cooperation and a better meeting of the minds regarding resolution of claims.

As attorneys with MSP credentials and solid workers' compensation backgrounds, our MSP professionals can provide explanations, answer questions, defend our proposals and submissions, and help clients reach desired results. For starters, our MSP attorneys recently identified open WCMSA files where submission is likely and sent claimants and their counsel an outline of the new requirements and a sample of the new Consent form. We are ready to help you navigate the new Consent to Release submission process. Contact any attorneys on our MSP team to discuss your needs and questions.

Medicare Set-Aside Prescription Drug Changes – Some Pills Are a Little Less Bitter / Amy Bilton

For those of us who have been doing Medicare Set-Asides for over a decade, CMS' pricing of prescription drugs has been a difficult pill to swallow. Initially, we as an industry priced prescription drugs in a variety of ways: based on actual cost; using mail-order pharmacy prices; or sometimes even using prices from other countries to simulate the eventual generic pricing of a drug which was not yet available in the United States. In April of 2009, things changed. CMS published a policy memo advising submitters that CMS would start independently price prescription drug costs and expenses, calculating the prices using the average wholesale price (AWP) published in Red Book.

AWP has been referred to as the "sticker price" of a drug and is generally determined based on the manufacturer's self-report, though there are other methods used to calculate AWP. Given this, AWP has been criticized as being inflated by around 20%. On the other hand, some of the prices listed in AWP are far less than the cost on the open market.

AWP can also change from month-to-month for a variety of reasons, including competition for market share and medications going generic. Lyrica's generic option, for example, meant a significant price drop and led to an increase in WCMSA cases being submitted once the generic pricing became available through the portal. In one of my cases, this change saved approximately one hundred thousand dollars. Lyrica's generic, pregabalin, also saw another

large reduction in AWP in March. The price per tablet now spans between 28 and 99 cents, depending on its strength.

In March, we also saw a substantial reduction in the AWP for Meloxicam, a popular non-steroidal anti-inflammatory (NSAID). On February 27, 2020, Exelan Pharmaceuticals reduced its price for Meloxicam 7.5 mg and 15 mg strengths down to five cents per tablet. This is a big jump compared to the $4.25 per pill we were used to seeing. Obviously, the impact of this reduction adds up over a beneficiary's 15- or 20-year life expectancy.

Similarly, but maybe not as impactful in dollars, through its "RX-to-OTC" program, the FDA just approved Voltaren (diclofenac sodium 1%) gel to be purchased over-the-counter in lieu of needing a prescription. When it becomes available, it will be sold under the name Voltaren Arthritis Pain. Its over-the-counter availability also means it should not be included in MSA proposals where it is being filled over-the-counter. Note CMS will likely want to see proof that the gel is being obtained over-the-counter for a few months before removing the drug from the MSA allocation. The cost of Voltaren was relatively low, proximally $.50 per dose, and will probably make a difference of between $1,000.00 and $5,000.00 in most MSAs.

Ultimately, these types of changes call for an audit of any Medicare Set-Aside proposal that has not yet been submitted to CMS, to see if these changes make your case any easier to settle. Because AWP changes daily, but CMS only uploads the AWP changes once per month (usually being reflected in the portal around the third or fourth of each month), the time is right to assess whether you may want to submit cases involving Meloxicam to CMS before AWP increases in price. We generally recommend waiting to submit Voltaren as OTC until it actually becomes available in stores.

It should be noted that a change in AWP pricing is not immediately seen in CMS' WCMSA portal. CMS downloads the pricing once per month, and the change is generally seen in the portal by the second of the following month. It is imperative for allocators to price all prescriptions in Red Book at the time of submission and not just rely on the price found on the CMS portal. When CMS has not yet reduced the AWP price on the portal, we allocate for the current Red Book price and provide a copy of the Red Book price information sheet in our submission.

Your partners at Nyhan, Bambrick, Kinzie & Lowry P.C. are always on the lookout for big price changes like this because we know they impact your settlements. If you ever have a prescription drug allocation that makes case cost prohibitive to settle, or where you have any questions about how claim handling procedures could be used to mitigate a prescription drug

component of an MSA, we stand ready to assist. Feel free to reach out to our MSA professionals at any time.

Going Abroad with a Future Medical Allocation/Medicare Set-Aside / Rasa Fumagalli

Attorney William Lowry recently wrote about workers' compensation insurance considerations when Illinois employees are working abroad. The blog post may be found here. This blog will look at situations involving tangential issues, i.e. workers' compensation settlements with future medical allocations or Medicare Set-Asides (MSAs) that will be spent overseas.

Although most workers' compensation settlement funds are spent in the US, there is a certain subset of settlement involving claimants who intend to use their settlement funds overseas where medical care will be established. These arrangements may be temporary or permanent in nature. When faced with a claimant who falls into this category, the issue of whether to fund a future medical allocation or MSA in connection with the settlement may become muddled. The different factors that may impact your decision are examined below.

Any workers' compensation settlement that closes out future medical benefits should avoid a cost shift of future injury related expenses to Medicare. This is due to Medicare's status as a secondary payer when a primary payer with a demonstrated responsibility for payment is available (42 U.S.C. Section 1395y(b)(2)). In deciding whether to fund a future medical allocation or MSA in connection with a settlement where the claimant has indicated he will be leaving the country, the following factors should be considered:

1. The nature of the injury and likelihood of future treatment. A soft tissue injury with two physician visits and two weeks of lost time is different than a low back injury that resulted in a failed back syndrome with ongoing medication management.

2. The number of credits or quarters the claimant has earned by paying Social Security and Medicare taxes. Would the claimant be eligible for Medicare on a spouse's record if he returned to the US?

3. The claimant's Medicare status at time of settlement.

By considering the above factors, the decision to include or exclude a sum for future medical, regardless of where the medical treatment is to be provided, will have a sound basis for it. For example, an employer who is engaged in settlement discussions with a Medicare beneficiary that intends to permanently relocate overseas for medication management, may not wish to pursue CMS' voluntary review of an MSA. A future medical allocation formulated on an evidence-based medicine model for drugs rather than CMS' projection methodology may be a better option in the case since the benefit of CMS' review may be of little value given claimant's plan to move. It is prudent, however, for the claimant to apportion some of his settlement for future injury related medical expenses should he decide to ever seek treatment in the United States.

A secondary issue also arises regarding the use of MSA funds for treatment overseas. If a claimant has moved overseas and has access to his MSA funds, there should not be any prohibition against their use for injury related medical treatment that is like that covered by Medicare in the US. This position is supported by Medicare's acknowledgement that MSA funds may be properly spent before a claimant becomes a Medicare beneficiary. In both above scenarios, the claimant does not have access to Medicare covered treatment. The expenditures from the MSA funds should be properly accounted for in case the claimant returns to the US in the future.

It is important to note that the parties' obligations to address Medicare's conditional payments prior to settlement and to comply with mandatory Section 111 reporting are not impacted by a claimant's relocation abroad. The failure to address these obligations may have ramifications against both the claimant and the primary payer. Although a claimant's plan to move overseas after settlement may muddy the issues when it comes to setting aside funds for future medical treatment, our team of Medicare Secondary Payer compliance attorneys is available to assist you with your analysis.

Answers by Amy / Amy Bilton

While development letters (CMS letters asking for additional information for a submitted MSA) have slowed over the last several months, we are still seeing them, nonetheless. We also are hearing from clients that they have old cases which seem "stuck" because CMS is asking for additional medical records that do not exist, or which they are unable to obtain. The question posed to me was: *What do you do when CMS will not approve a WCMSA proposal, and instead demands records that do not exist or are impossible to obtain?*

We often see this situation where a Petitioner remains on medication after being released from their surgeon. While there is no one sure-fire way to move such a case through, there are many things that can be tried. Obviously, options will vary based on jurisdiction and the status of the underlying case (whether it be closed or open for subpoena in your jurisdiction), but here are some possible options that have worked for us:

- Issue a subpoena to, or request records with the proper authorization from, the medical provider currently prescribing any medication to the claimant.

- Issue a subpoena for the records from the last known treating medical provider which includes a certification page that asks the provider to input the last date of treatment.

- Issue a subpoena to, or request records with the proper authorization from, medical records from the beneficiary's primary care physician and submit those in response.

- Verify you have all the medical records associated with the medical payment ledgers as CMS cross references these. Also, make sure that the final medical record has a release "as needed," "PRN" or "maximum medical improvement."

- If you do not know where the individual has been seeking treatment but do know where the individual currently lives, consider a medical sweep to identify treating medical providers.

- Request records from the individual state's prescription drug monitoring program, if available.

- Obtain a signed affidavit from the claimant attesting to the last date of injury-related care, which includes an attestation that the document was prepared under the penalty of perjury.

- Try to get a certification from the treating physician of the last day of injury-related care. You may even need to enlist the assistance of a nurse case manager, or even approve one additional visit to the doctor and follow-up where the lack of any interim treatment needs to be clarified.

Ultimately, the CMS submission process is a voluntary one, and parties cannot "make" CMS review and approve their MSAs. However, a development letter that asks parties to effectively "prove a negative" cannot be replied to because documents are either unavailable or nonexistent also creates a problem for CMS; it reduces the number of cases they use in their data in support of their claim that the MSP program saves money for the Medicare system as a whole. It is ultimately in CMS' interest to reply to as many WCMSA proposals as possible. I recently spoke with CMS about this issue, and we are working to find a solution that satisfies both CMS and the parties in workers' compensation claims. In the meantime, these are some of the things that worked for our office in our submissions.

There is obviously no "cookie cutter" answer to get your case out of development in these situations. These situations call for creativity and proactivity. If you have had trouble getting CMS' response after development letters like this, we are always available for consultation, and we ensure the NBKL team will take every step we can to bring a conclusion to your WCMSA submissions.

Our MSP Compliance Services

Our dedicated team diligently and efficiently streamlines and navigates the Medicare Secondary Payer (MSP) landscape for our clients. The attorneys, nurses, and paraprofessionals at NBKL guide you through the entire process from initial investigation through post-settlement. Our team's vast experience in workers' compensation defense, personal injury claims and MSP compliance makes us industry leaders in partnering with clients to achieve optimal claim resolutions while meeting all MSP requirements.

Services We Provide:

- Medicare Set-Asides ("MSA") (traditional and non-submit) including:
  - Legal Zero MSAs
  - Evidence Based Medicine MSAs
  - Future Medical Allocations/Life Care Plans
  - Advice and Recommendations to Mitigate MSA exposure
  - Analysis and Mitigation of competitor's MSA proposals
- Medicare Parts A & B Conditional Payment Analysis, Negotiation and Resolution
- Medicare Advantage Plan (Part C) and Prescription Drug Plan (Part D) Lien Investigation, Negotiation and Resolution

- Medicaid Lien Negotiation and Resolution
- Settlement Contract drafting to protect against past and future Medicare exposure
- Settlement Consulting on all aspects of MSP Compliance in Workers' Compensation and Liability cases
- Design and Implementation of MSP Compliance Programs

Contact us for information regarding the above services. Additional services may also be available upon request.