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ONE SOURCE FOR MEDICARE SECONDARY PAYER COMPLIANCE

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The "private cause of action" provision of the Medicare Secondary Payer Act (MSPA), 42 U.S.C. ss 1395 y(b)(3)(A) has been the subject of several recent Court decisions. This provision establishes "a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A)" 41 U.S.C. ss 1395y(b)(3)(A). The following is a summary of the *Bio-Medical Applications of Tennessee, Inc. vs Central States Southeast and Southwest Areas Health and Welfare Fund*, 656 F. 3d 277 (6thCir.2011), *Raymand Nawas vs State Farm Mutual Automobile Insurance Company No.13-11158*, and *Humana Insurance Company vs Farmers Texas County Mutual Insurance Company and Mid-Century Insurance Company of Texas* (Cause No. 13-CV-611-LY) decisions.

Bio-Medical Applications of Tennessee, Inc. vs Central States Southeast and Southwest Areas Health and Welfare Fund, 656 F. 3d 277 (6thCir.2011),

The Bio-Medical case addressed the concept of "primary" and "secondary" payers in the context of coverage for kidney dialysis treatment. The facts of the case involved a patient with end-stage renal disease (ESRD) who had a health insurance policy through Central States. Central States insurance plan provided for the termination of coverage on the date the insured becomes entitled to Medicare benefits. In this claim, the patient was diagnosed with ESRD in August of 2005 and became eligible for Medicare benefits three months later. Her initial dialysis treatment at one of Bio-Medical's centers was paid by Central States. Central States terminated her insurance coverage as of November 1, 2005. Bio-Medical sued Central States for its non payment of the dialysis treatment under two theories. It asserted an ERISA claim for unpaid benefits under the patient's insurance policy as the patient's assignee and a private cause of action for double damages under the MSPA for Central States violation of the statute.

The Court, after a lengthy discussion of the MSPA, found that a group health plan is prohibited from denying coverage to one of its insureds because the individual became eligible for Medicare. The plain language of the MSP, 42 U.S.C. ss 1395y(b)(1)(C)(i) provides that " A group health plan …..may not take into account that an individual is entitled to or eligible for (Medicare benefits due to end stage renal disease) during the (30)-month period which begins with the first month in which the individual becomes entitled to benefits.". It also noted that 42 C.F.R. section 411.108(a)(3) gave coverage termination as a specific example of "take into account". The Court noted that "the shifting of costs from private plans to public was exactly the evil that the Act sought to correct". (page 7).

The remedy for the injured healthcare provider and the proper amount of damages was also addressed by the Court. The Court interpreted the private cause of action language, when read as a whole, to allow a lawsuit against the primary plan noting that the "primary plan" may be a tortfeasor whose responsibility to pay has been demonstrated by judgment or settlement or "other means". 42 U.S.C.ss1395y(b)(2)(B)(ii). The demonstrated responsibility requirement however was limited to tortfeasors. The Court pointed to the "other means" language in the provision that had been defined by 42 C.F.R ss 411.22(b)(3) to include a "contractual obligation". In light of this, an insurance contract demonstrated a traditional private insurance plan's responsibility to pay. The Court also found that "double damages" under the private cause of action provision should be sufficient to motivate these lawsuits against private insurers. The specific amount of the double damages however wasn't determined by this Court since this issue was remanded to the district court for a determination.

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Raymand Nawas vs State Farm Mutual Automobile Insurance Company

Raymond Nawas v. State Farm Mutual Automobile Insurance Co., decided by the US. District Court for the Eastern District of Michigan on September 15, 2014, primarily involved a claim for no fault insurance benefits. When the plaintiff's insurance company refused to pay medical bills he had incurred following a motor vehicle accident, Medicare conditionally paid them. The plaintiff then filed a multi-count complaint which was premised, in part, upon the Medicare Secondary Payer (MSP) Act which the defendant insurance company then sought to have dismissed. The defendant argued the plaintiff's claim was premature because a claim under the MSP Act cannot be pursued until the defendant's obligation to the plaintiff's underlying no-fault insurance claim has been established by a judicial determination or settlement. This argument was rejected and the plaintiff's claim under the MSP Act was allowed to proceed.

The District Court noted Medicare was at one time the primary payer of health costs for eligible individuals. However, rising health care costs led Congress to enact the MSP Act which designated "certain private entities – such as a group health plan, a worker's compensation plan or an automobile or liability insurance plan – as 'primary payers' that have the responsibility to pay for a person's medical treatment." Under the Act, if the primary payer has not paid for the rendered medical treatment or fails to make payment in a timely manner, then Medicare has the option of "conditionally" paying for covered medical services which have been or is reasonably expected to be paid by a primary payer. Medicare may then seek reimbursement of any conditional medical payments from the primary payer.

The District Court also noted the MSP Act created a private right of action, with double recovery, to encourage private parties who are aware of non-payment by primary plans to bring actions to enforce Medicare's rights. This provision of the MSP Act was relied

upon by the plaintiff in this case. He alleged since the defendant insurance company refused to pay his no-fault insurance claim, Medicare stepped in and made conditional payments to his medical providers and therefore he sought to recover from the defendant double the amount of the conditional payments.

The defendant's argument the claim was premature was based upon the interpretation of the MSP Act's "demonstrated responsibility" provision which states in pertinent part:

> "A primary plan…shall reimburse (Medicare) for any payment made by (Medicare)…with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver or release of payment for items or services included in a claim against the primary plan or the primary plan's insured…"

In support of its argument, the defendant relied upon Geer v. Amex Assurance Co. (09-11917, 2010 WL 2681160, E.D. Mich. July 6, 2010). The Geer court had accepted this argument and dismissed the MSP Act claim in the insurance context as the plaintiff had not yet "established" a claim against the defendant insurance company through a judgment, settlement or the like. In so doing, the Geer Court adopted the reasoning of Glover v. Liggett Group (459 F.3d 1304, 11th Cir. 2006), a case which arose in the context of a tort claim brought by a plaintiff against a cigarette manufacturer.

In Nawas, the Court went on to state, "Having considered the reasoning of these cases, the Court concludes that defendant's argument is not well-taken. First, the Sixth Circuit disavowed the position taken by the Eleventh Circuit in Glover and limited this argument to tortfeasor liability only. The Sixth Circuit had also previously conducted an extensive analysis of the MSP Act's "demonstrated responsibility" provision in the Bio-Medical

Applications v. Central States case, 656 F.3d 277 (6th Cir. 2011) and held that the "demonstrated responsibility" language does not prohibit or delay direct actions against insurance companies by policy holders seeking to enforce Medicare's Secondary Payer Act rights."

The Court further explained that it believed Congress had added the "demonstrated responsibility" provision as a condition precedent to and limiting principle only for tortfeasor liability under the Act, noting the Medicare Modernization Act made no other major changes to the MSP Act. Therefore, there was no reason to believe that Congress intended to affect the liability of primary plans other than tortfeasors, that is, traditional primary plans like private insurers. It went on, "Moreover, the concept of demonstrated responsibility makes sense only in the context of tort (where no evidence of responsibility exists until it is adjudicated), rather than in the context of an insurance contract (where insurers assume the responsibility of payment for enumerated contingencies). The Court concluded the "demonstrated responsibility" provision limits only lawsuits brought against tortfeasors, not lawsuits brought against private insurers.

Accordingly, the defendant's motion to dismiss the plaintiff's claim was denied, thereby allowing the matter to proceed toward a determination on the merits of the underlying case as well as leaving intact State Farm's exposure for double damages should it ultimately not prevail in the case.

Humana Insurance Company vs Farmers Texas County Mutual Insurance Company and Mid-Century Insurance Company of Texas

Medicare Advantage Organizations (MAOs) have become increasingly aggressive in their quest for conditional payment reimbursements for medical treatment provided related to workers' compensation and personal injury liability claims.

The question presented in Humana Insurance Company v. Farmers Texas County Mutual Insurance Company and Mid-Century Insurance Company of Texas included, among other things, whether MAOs, such as Humana, may pursue a private cause of action under 42 U.S.C. § 1395y(b).

Humana made conditional payments for medical treatment its MAO enrollees received due to injuries sustained in separate motor vehicle accidents. The six enrollees were, at the time of their accidents, insured by Farmers. Humana sought reimbursement from Farmers and filed suit when Farmers refused to reimburse Humana, contending it had a right of recovery under the Medicare Secondary Payer Act (MSP).

On February 26, 2014, the United States Magistrate Judge issued a Report and Recommendation recommending that the court grant the motion to dismiss Humana's federal claims asserting it has a private cause of action under the MSP. Humana's objections and Farmer's response were filed. The United States District Court for the Western District of Texas reviewed the entire case de novo and on September 24, 2014 published its opinion.

In its opinion, the court noted the plain language of the MSP establishes two separate causes of action against noncompliant primary plans: (1) a federal cause of action and (2) a private cause of action with no particular plaintiff specified.

As the Fifth Circuit had not addressed the issue presented here, the court relied on In re Avandia Mktg., 685 F.3d 353 (3d Cir. 2012), which held that the text of § 1395y(b)(3)(A) "unambiguously provides Humana with a private cause of action." Id. at 365. The Third Circuit found that any private plaintiff may bring an action for damages where a primary plan fails to appropriately reimburse a secondary payer for conditional payments made as this provision's broad scope placed no limitations on which entity may file suit for reimbursement and double damages. The court found this analysis persuasive enough to reject the magistrate judge's recommendation to grant Farmers' motion to dismiss Humana's cause of action for double damages under § 1395y(b)(3)(A).

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Stay Ahead of the Game!

It has been eight years since the start of the Prescription Drug Component to Medicare, otherwise known as "Part-D." When this program began on January 1, 2006 as a result of the Medicare Modernization Act of 2003, signed into law by then President George W. Bush, no one knew for sure what this all meant. For seniors, it meant a prescription drug component to their existing Medicare benefits, thereby providing some relief to already skyrocketing prescription costs.

For payers in the workers' compensation industry, this meant something entirely different. Medicare-Set Aside Arrangements, commonly known as MSAs and a part of the lexicon since 1980, would now need to include medications as part of the allocations. Prior to 2006, only expenses related to Medicare Part A and B were included. Now, a separate section needed to be created for prescription medications that claimants were either currently taking or were expected to take over the course of their lifetime that were related to the injury.

No big deal, it seemed. Pricing could be calculated using fee schedules or another pricing methodology. At the time, the Part-D money allocated for did not seem that bad. However, things changed in 2009, when CMS mandated that AWP (Average Wholesale Price) be used as the sole pricing method for MSAs using REDBOOK as the only source. This change in pricing methodology and sourcing can be equated to buying a car at "sticker" price, something no one does, as it represents the highest possible price. Pharmacies typically use WAC (Wholesale Acquisition Price) or even MAC (Maximum Allowable Cost) as their pricing to the consumer. AWP pricing has some inherent flaws built into it; for example, it does not take into consideration manufacturer discounts, and very little pricing is based on AWP without some sort of built-in reduction in price.

By using AWP as the sole pricing source, the entire outlook for workers' compensation cases, especially those with an MSA pending settlement, was changed. Back in 2006,

Part-D may have only contributed to 20-30% of the entire cost contained within an MSA. From 2009 to the present day, Part-D, as part of the total expense in an MSA, continues to increase, and may now be closer to 70% of the entire cost in an MSA. This one change made the challenge of settling a case that much harder.

However, there are measures that you can take to ensure settlement and possibly lower costs in the MSA as it relates to Part-D. By staying ahead of your claim and focusing on generic medications, you can realize significant savings for your claim.

The Proactive Approach

All too often, any intervention made in a claim is done at the last minute. When a claimant begins a drug regimen, it is expected, on average, that at least ten medications will be used simultaneously at any one point in time. As the months and years go by, claimants get used to their drug regimen, and physicians are reluctant to change them, as they see no reason to.

The initiation of an early intervention program is essential to lowering costs. Understanding early on which medications are used, which treatments are considered, and the expected outcomes are a part of today's claim management process. Early intervention programs help to assess which medications are used at onset and can be used as a predictive model for the future. The acute phase of treatment is where the biggest impact can be made. Medications that are considered unrelated can be identified and excluded, and alternative treatments can be considered by the provider. Generic medications can be used early on and established as a part of care versus trying to change a claimant from a branded one after he or she has taken one for many years.

Studies have shown when opioids are introduced into the claim early on, outcomes are poor long-term. With the introduction of opioids early on, the chances for surgery and

medical intervention increase. Programs, which focus on identifying claims having the potential for opioid use or abuse, are necessary in controlling costs. Initiating a multi-disciplinary approach with all members of the claimant's healthcare team can also help to establish a plan for treatment and decide if opioids will be part of that treatment plan.

Once a claim moves from an acute to a chronic phase, other issues are seen. Acute pain now becomes chronic which usually brings an onset of both a psychiatric and psychological component. This translates into the introduction of antipsychotics and antidepressants into the claim. Known in the industry as "prescription creep", this is the basis of the increased use of medications on average by a typical workers' compensation claimant. Chronic conditions also see a chance for those unrelated medications or conditions to find their way into the claim. For example, cardiovascular or diabetic conditions have been exacerbated and medications used to treat these conditions are now related to the injury. This is why the early intervention strategies, such as claims and medication review, are essential at the onset.

A proactive review of claim files early on may assist in identifying the claims that will need an intervention and to what degree the intervention should occur. Some cases will need a simple adjustment and others will need a more intensive review and intervention. Your risk management consultant, nurse case manager, or even your MSA vendor may be able to assist you in identifying cases in question and assist in implementing strategies to counteract the increase of unnecessary drug therapies or other medical interventions.

Generic Medications

Recently, many brand name medications that commonly show up on claims payment histories became available as a lower cost generic. Medications such as Cymbalta® (Duloxetine) and Lidoderm® Patches (Lidocaine) are now available as a generic and

have lower costs associated with them. Over the next year, Nexium®, Abilify®, and Celebrex® are just some of the medications that will be available as generic, which will lessen the drug spend associated with their brand name counterparts.

Although branded medications are a part of any claims history, generic medications are used where available. 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.

Keep in mind that although Celecoxib is scheduled for a December 2014 release, brand Celebrex® and all brand name medications must still be allocated in an MSA until such time where the generic equivalent 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."

The table below shows the estimated release date of brand name medications that are commonly seen in workers compensation claims.

Upcoming Generic Releases*

Brand Name	*Generic Name*	*Month*	*Year*
Abilify®	Aripiprazole	April	2015
AndroGel®	Testosterone Gel	August	2015
Celebrex®	Celecoxib	December	2014
Lunesta®	Eszopiclone	December	2014
Nexium®	Esomeprazole	December	2014

*As of 9/2014. Ref: Community Catalyst

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It is also recommended that claims payment histories be reviewed to determine which DAW codes are inputted at the pharmacy point of sale. DAW (Dispense as Written) codes identify the reason why a specific brand or generic is dispensed based on the prescriber's instructions. Pharmacists are expected to utilize the correct codes based on the prescription provided to them. Some of the most common DAW codes are explained below.

DAW 0

Indicates no product selection indicated. This is the most common DAW code utilized when product selection is not at issue or a generic medication is dispensed. Medications that would be submitted with a DAW 0 include single source brand products (no generic) and generics

DAW 1

Indicates substitution not allowed by prescriber. This code is utilized when a prescriber indicates that a generic substitute is not allowed. When DAW 1 is submitted, it signifies that a generic equivalent to the prescribed medication is available, but the physician does not want his or her patient to utilize it. In workers' compensation, a DAW 1 should be audited to ensure that this was the correct direction of the physician.

DAW 2

Indicates substitution was allowed, but refused by the patient. This DAW code is used when the prescriber indicates that a generic equivalent is acceptable, but the patient prefers the branded medication instead. In workers' compensation, a DAW 2 should also be audited to ensure that this was the correct direction of the patient.

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DAW 4

Indicates that substitution was allowed, but the generic medication was not in stock. This DAW code is appearing more frequently due to recent drug shortages and back orders which have been prevalent in the industry over the last few years.

DAW 5

Indicates that substitution was allowed but the brand name was dispensed as the generic. This DAW code is used when the physician permits substitution, but the brand dispensed is utilized as the generic entity. Common medications seen with this DAW include antibiotics, such as Amoxicillin.

It is important to understand DAW codes and how they affect your bottom line. DAW is an often overlooked part of claims history, in part because many do not understand them or understand their impact on payment. A simple review can save hundreds if not thousands of dollars on your claims.

The NuQuest Approach

The comprehensive Pre-MSA Drug Regimen Review (PMDR) provides carriers with a detailed analysis of the medical aspects of a claim that are relevant to the Medicare Set-Aside (MSA) allocation.

Recommendations for potential cost savings are identified so that an accurate, reasonable proposal can be developed and submitted to CMS for approval. The PMDR provides case-specific recommendations to lower the proposed MSA amount and, ultimately, to expedite case closure.

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The three-fold goal of the PMDR is to:

- Identify a claimant's long-term medical cost exposure based upon available records and current MSA trends
- Recommend ways to reduce long-term medical costs
- Provide tools for obtaining documentation from treating physicians that support the alternate medical treatment plan

How to identify an appropriate file for intervention:

A PMDR may be an effective cost-management tool in many cases, but particularly in those involving:

- Claims with high medical and/or prescription drug costs
- Catastrophic injuries
- Complex injuries involving claimants who are relatively young and will require life-long treatment
- Multiple interventions are currently being implemented by treating physicians (e.g. repeat nerve blocks, facet blocks, trigger point injections, spinal cord stimulator or intrathecal pump utilization)
- Recommendations from treating physicians for multiple invasive procedures (e.g., spinal cord stimulator or intrathecal pump placement) and/or surgeries
- Brand name drugs prescribed routinely
- Multiple narcotics prescribed
- High quantities of drugs prescribed
- Drugs prescribed by multiple physicians

Example:

Case Overview

The claimant is a 56-year-old female who sustained a work-related injury while working as a seamstress when she reportedly slipped and fell. She underwent right shoulder

surgery, followed by right knee surgery. Diagnosis related to the claimant:

723.1	Cervicalgia
719.41	Right shoulder pain
724.2	Lumbago
719.46	Right knee pain
535.5	Gastritis
780.52	Sleep disorder

The Analysis

Medical Treatment

In considering potential reduction in Medicare–covered treatment costs, NuQuest/Bridge Pointe found that Medicare would include the following items in the future Medicare-covered treatment portion of the MSA:

Physical therapy	Physical therapy post-operative
Physician visits	Right knee Scynvisc injections
Diagnostic testing	Right knee cortisone injections
Equipment	Right knee reconstruction
Trigger point injections	

However, based on NuQuest/Bridge Pointe's experience with CMS' methodology for completing the MSA allocation, if the treating physician is able to provide medical documentation indicating that any of the right knee surgery should not be a future consideration, the surgery and associated costs would not be included in the MSA allocation. In this case, the right knee reconstruction surgery would not be included in the MSA, thus saving $11,369.

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PMDR Medical Treatment Recommendations

The greatest savings in any MSA is in reviewing the efficacy and efficiency of the prescription drug regimen. In this case, Tizandine 4 mg (Zanaflex) was recommended for treatment of the claimant's injury totaling $68,883 in lifetime costs.

Our recommendations per the drug regimen review were to consider tapering and eventual discontinuation of the Tizanidine, resulting in savings of $39,081. Efficacy of this class of medications appears to decrease overtime with continued use.

Result

The future Medicare-covered treatment costs were originally estimated at $117,833. Using the PMDR, we identified savings of $50,451 reducing the lifetime costs to $67,382.

Conclusion

The PMDR is an effective tool for identifying potential cost savings prior to preparation of the WCMSA. When recommended modifications to the current treatment plan are implemented, carriers can significantly reduce costs without jeopardizing the long-term health of claimants, or disrupting the physician-patient relationship.