Building Off of a Pharmacy Program to Promote a Strong Settlement

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Our Presenters

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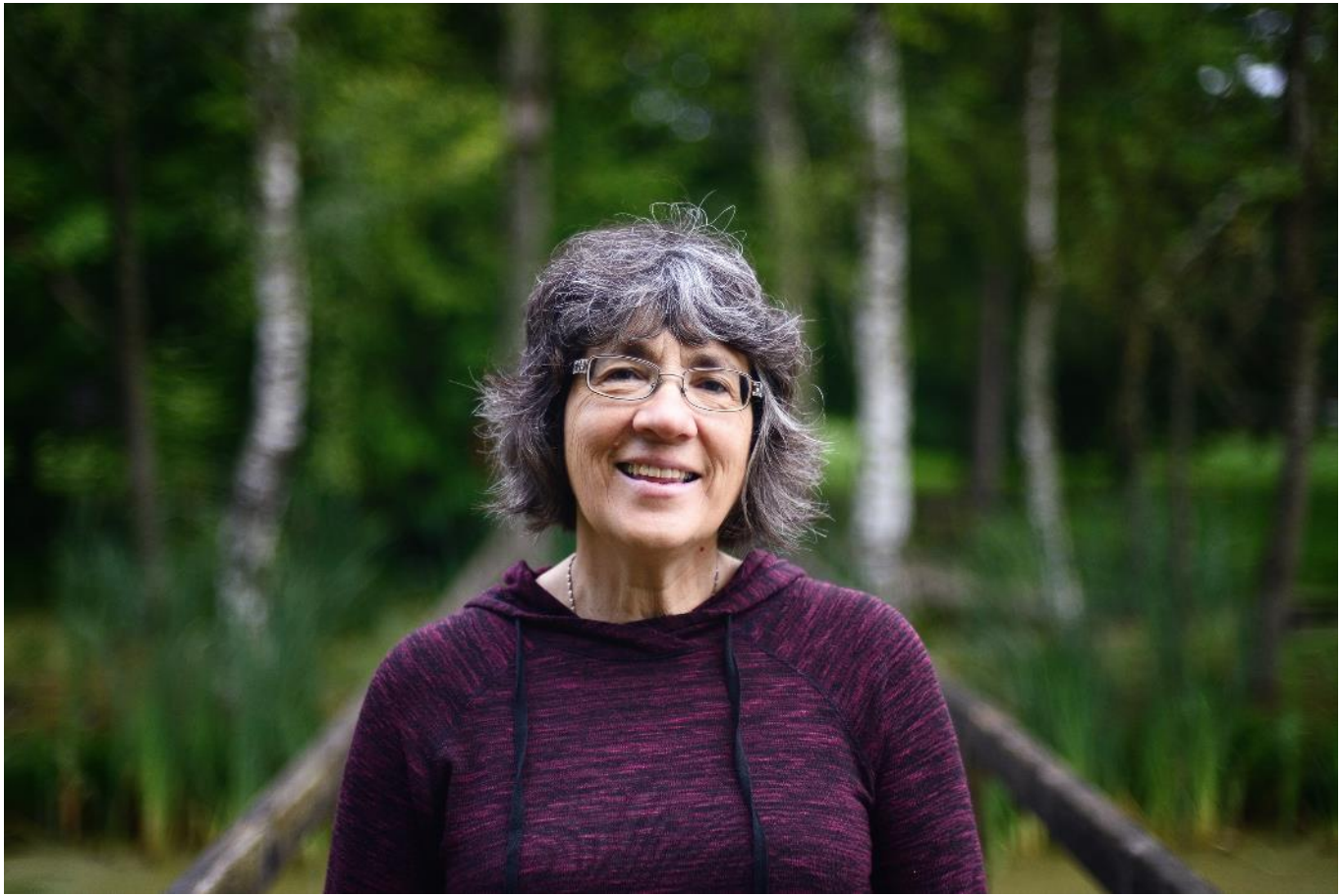
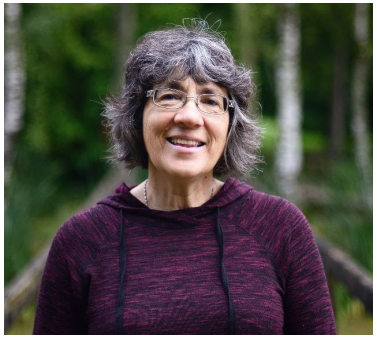
Agenda

- How pharmacy and settlement programs work together by reviewing a case study
- Pharmacy program clinical tools that help to address high-risk claims
- Evaluating a claim to review red flags and clinical concerns
- Medicare Set-Aside what is it and why is it important?
- Clinical mitigation efforts to help prepare for an MSA
- Clinical tools to reduce pharmacy costs
- What is needed to submit and MSA

CASE STUDY

Meet Cheryl



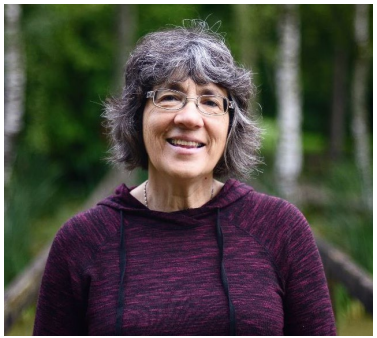


MEET CHERYL

On January 19, 1992, Cheryl, now a 65-year-old female, sustained injuries to her cervical and lumbar spine following an accident at work.

Diagnoses:

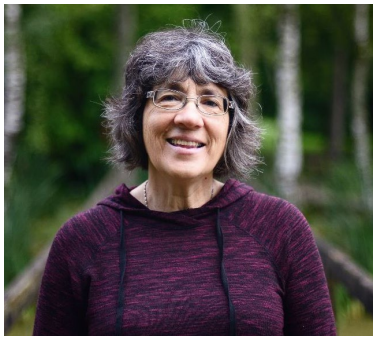
- Bulging discs
- Low back pain
- Neck pain
- Spinal stenosis
- Degenerative disc disease
- Radiculopathy
- Migraines
- Cervical spondylosis
- Complex regional pain syndrome (CRPS)



Surgeries and Procedures:

- Lumbar fusion
- Cervical fusion
- Right medial branch block

MEET CHERYL



MEET CHERYL

Medications:

Name	Strength	Use
Buprenorphine Patch (Butrans)	20 MCG/HR	Topical long-acting opioid analgesic for pain
Hydrocodone-Acetaminophen Tab	7.5-325 MG	Short-acting opioid analgesic for pain
Diclofenac Sodium Gel	1%	Topical non-steroidal anti-inflammatory (NSAID) used to treat pain and inflammation
Lidocaine Patch	5%	Topical anesthetic for pain
Gabapentin Cap	300 MG	Anticonvulsant for treatment of neuropathy/radiculopathy
Ondansetron Orally Disintegrating Tab (ODT)	8 MG	Antiemetic for nausea
Venlafaxine HCl Cap ER 24HR	75 MG	Antidepressant for neuropathic pain
Alprazolam Tab	1 MG	Benzodiazepine for anxiety
Cyclobenzaprine HCl Tab	10 MG	Muscle relaxant for spasm
Methocarbamol Tab	750 MG	Muscle relaxant for spasm
Tizanidine HCl Tab	4 MG	Muscle relaxant for spasm

PHARMACY PROGRAM CLINICAL TOOLS

to address
high-risk claims

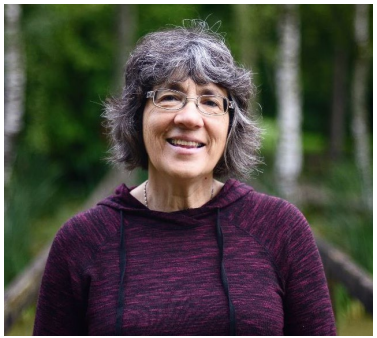
Primary Purpose of Pharmacy Benefit Management Programs

Optimize medication utilization at the population and individual claimant level

- Manage a network of pharmacies
- Adjudicate prescription transactions within client parameters
- Develop formulary controls
- Building clinical programs around quality, utilization, client goals/objectives
- Mitigate sub-optimal therapeutic treatments
- Streamline medication therapy for claimants
- Provide medication-related data to adjustors and payers

Pharmacy Benefit Management Clinical Tools

- Medication plans and formularies
- Point-of-sale edits
- Drug information delivery
- Predictive modeling and information analytics
- Clinical review and risk identification
- Claim monitoring; opioids and other medications
- Provider outreach



MEET CHERYL

Clinical Concerns:

- Compliance
- Relatedness to the industrial injury
- Dose appropriateness
- Duration and duplication of therapy
- Drug-drug and drug-disease interactions
- Prescribed medications were costly and had safe, cost-effective alternatives available

Goal of Clinical Mitigation

- Identify high-risk claims that will benefit from clinical review and intervention
- Allow for settlement with the lowest defensible Medicare Set-Aside allocation

MULTIDISCIPLINARY APPROACH

Analytics

Identify economic and therapeutic utilization drivers

Pharmacists

Pharmacy experts create action plans

Physicians

Clinicians discuss treatment plans with treating physicians

Nurses

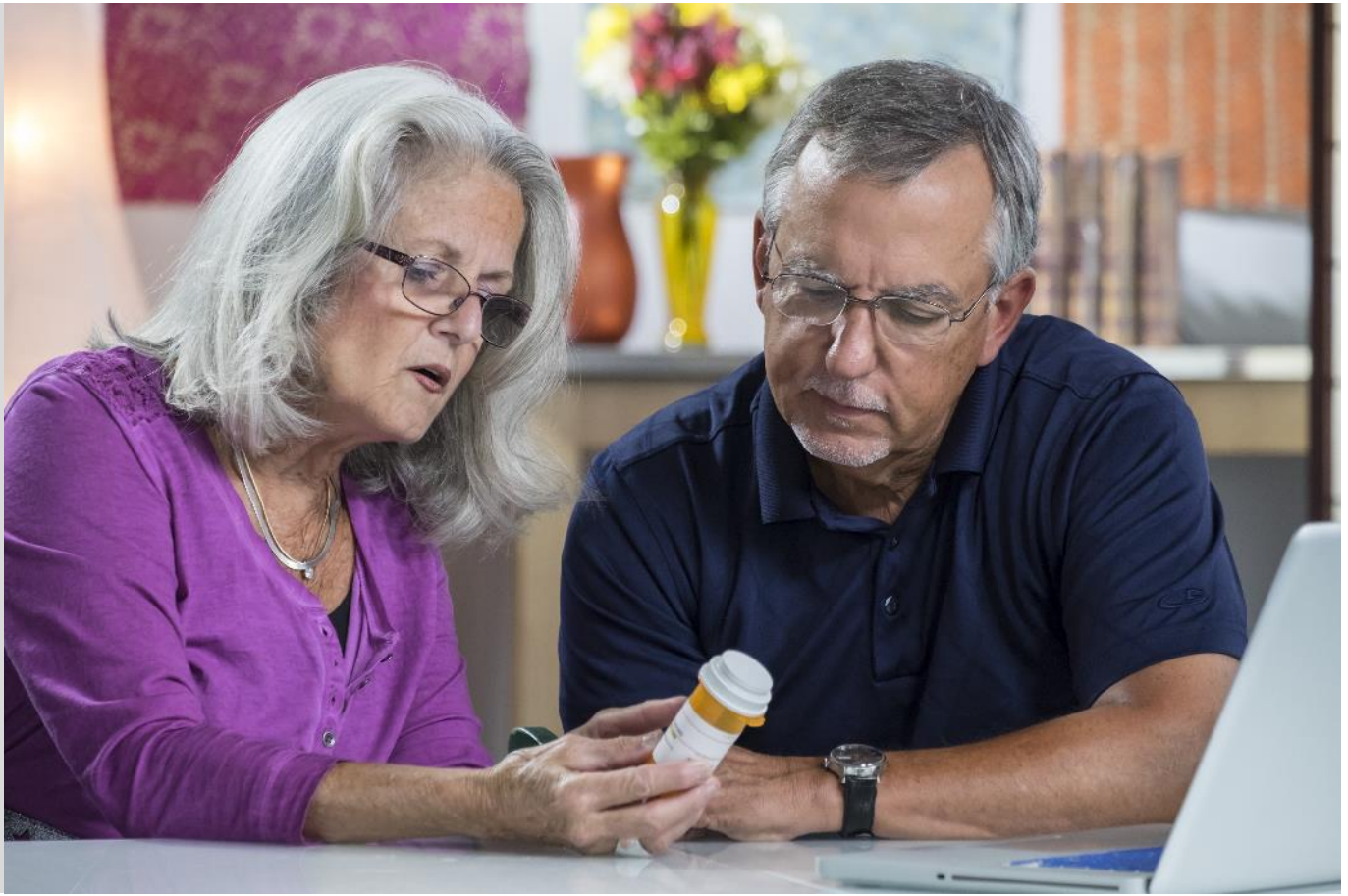
Clinical expert for medical/DME items and follow up after peer outreach

Legal

Provide support and ex-parte opinions

CLAIM EVALUATION

to review red flags and clinical concerns



Preparing for Eventual Settlement

- Has medical and prescription spending stabilized or is it still increasing?
- Are related medical and prescriptions anticipated for the long term?
- Will a Medicare Set-Aside be needed?
- Is the claimant working, disabled/unable to work, or applied for Social Security disability benefits?
- Are reserves posted adequate to cover future related medical expenses?
- Will clinical mitigation reduce medical/Rx use and costs?
- Will the anticipated settlement amount meet the CMS review threshold for MSAs?

CMS Review Thresholds

CMS does not have the resources to review every settlement to assure protection of Medicare's interests.

A WCMSA may be submitted to CMS for review as follows:

The claimant is currently a Medicare beneficiary and the total settlement amount is greater than $25,000.

- The claimant has a "reasonable expectation" of Medicare enrollment within 30 months of the settlement date and the anticipated total settlement amount is expected to be greater than $250,000.
- The above are CMS workload review thresholds and not a substantive dollar or "safe harbor" threshold. Even if a case does not meet current CMS guidelines for review of an MSA, Medicare's interest must still be adequately protected.

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CMS Thresholds

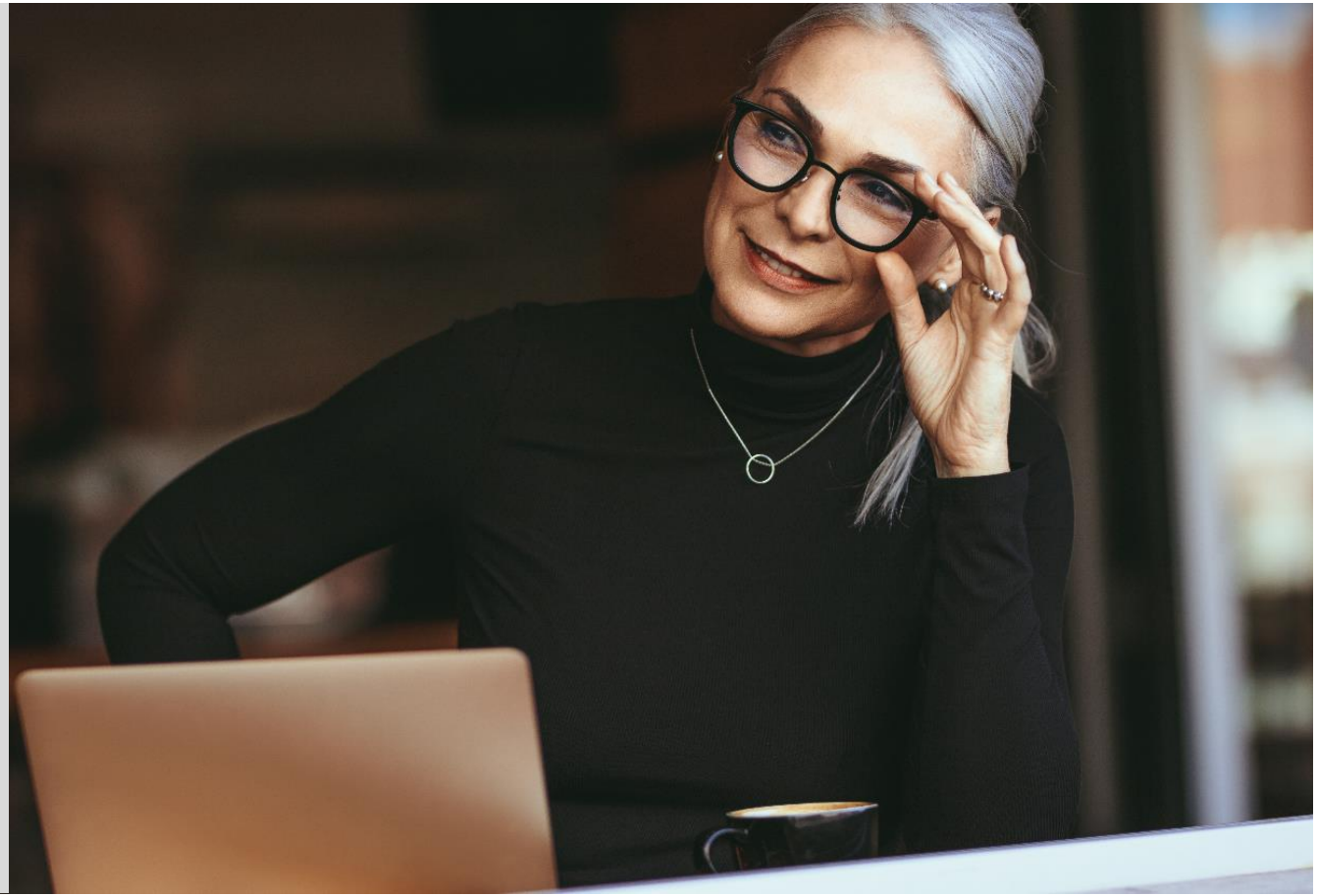
Medicare Status at Time of Settlement	Total Settlement Amount	MSA Recommended?	CMS Threshold Met?
Medicare Beneficiary	$25k or Less	Yes	No
Medicare Beneficiary	Greater than $25k	Yes	Yes
Not entitled to Medicare in next 30 months	$250k or Less	No	No
Not entitled to Medicare in next 30 months	Greater than $250k	No*	No
Will be entitled to Medicare in next 30 months	$250k or Less	Yes	No
Will be entitled to Medicare in next 30 months	Greater than $250k	Yes	Yes

Based on CMS memos in effect as of today

***If the case is catastrophic, payers may want to still consider an MSA due to the increased likelihood that the claimant will apply for SSDI.**

MEDICARE SET-ASIDE

What is it and why is it important?



What is a Medicare Set-Aside Allocation (MSA)?

- Monies set aside in a settlement to satisfy the Medicare Secondary Payer (MSP) Act.
- Not enforced until 2001 when CMS issued the “Patel Memo” pertaining to workers’ compensation cases.
- The government concluded that taxpayers were essentially paying for future medical bills that should have been covered by primary payers and settlements.
- MSA is established from a portion of the settlement amount that is used to pay for future medical treatment and prescription drug expenses related to the injury/illness that would otherwise be payable by Medicare.

Consider an MSA Allocation when an injured person…

- Is a Medicare beneficiary
- Is 62.5 years of age or older (30 months will be a Medicare Beneficiary)
- Has been out of work for over two years—regardless of age (could be on Social Security Disability-SSD)*
- Has applied / has applied and been denied / is appealing or is planning to appeal the decision / is re-filing for SSD
- Has end stage renal disease or ALS

• *It is recommended that Social Security verification is performed on all cases where the claimant has been disabled for two years or more

CLAIM EVALUATION

for clinical mitigation efforts

Claim Strategies to Reduce MSA Exposure

MSA allocations that are too high make it impossible for a case to settle

- Review PBM reports that flag high risk claims
- Evaluate each to determine if clinical mitigation will reduce MSA costs

Claim Strategies to Reduce MSA Exposure

Do not pay for treatment of denied or unrelated injuries/illnesses

- Paying for treatment of a denied condition is almost impossible to undo
- Payment for a treatment or a condition is considered by the WCRC as an acceptance of responsibility by the employer, TPA, WC carrier
- Adhere to the payment without prejudice period, if applicable

Claim Strategies to Reduce MSA Exposure

Do not pay for treatment of denied or unrelated injuries/illnesses

- Requesting a refund for an inadvertent payment may be possible to back out of a provider payment
- A subsequent court order showing that a condition was not claimed or not causally connected to the claim may become necessary
- For claim transactions, especially for fully denied claims, be sure payment for IMEs are labeled as medico-legal costs rather that as medical treatment.

MSA Cost Drivers

Treatment Plans

- Often outdated, vague and duplicative
- Allocate for treatments no longer applicable, effective or recommended

Prescription medications

- Larger MSAs have a higher percentage of mediations costs
- Physicians may not follow clinical guidelines or use the most cost-effective treatment

Procedures mentioned but not recommended

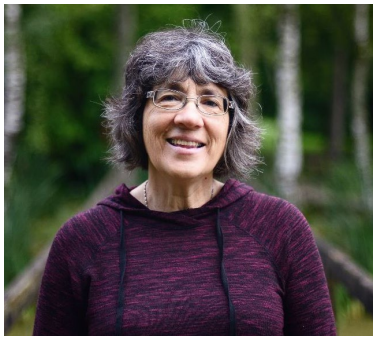
- E.g., Surgeries, spinal cord stimulator(SCS), intrathecal pain pump
- Recommendations do not meet clinical guidelines

MSA review process

- Inclusion of any treatment mentioned in the last two years that was not specifically ruled out
- No formal appeals process when CMS counters with a higher MSA

CLINICAL MITIGATION TOOLS

to assist in reducing the MSA prescription costs



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Clinical Mitigation Program Tools

IDENTIFY CLAIMS

Based on pharmacy data, determine utilization opportunities

MEDICATION REVIEW

A pharmacist comprehensive review of medications and/or medical treatments

PEER OUTREACH

A specialty matched physician engages with the prescriber to discuss clinical issues

NURSE MONITORING / CASE MANAGEMENT

Ongoing communication and follow up between a nurse, the prescriber and the injured person.

MEDICARE SET ASIDE CLINICAL OUTREACH

Nurse reaches out to the treating physician for clarification of items

Prescription Medication Issues

Opioid Utilization

- Insomnia or Sedation
- Respiratory depression
- Constipation
- Depression
- Gastroesophageal Reflux
- Dependency concerns

Co-administration of a Benzodiazepine

- There is a five-fold increase in risk of opioid related overdose
- CDC recommends against concurrent use
- Increased sedation
- Elevated fall risk

Extended Skeletal Muscle Relaxant Use

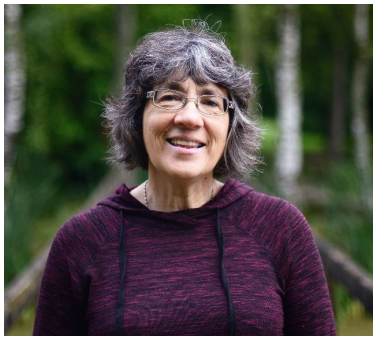
- Potential additive sedation effects
- Complications with discontinuation
- Only recommended for acute use
- Rarely indicated for long-term use

Medication Recommendations

BRAND TO EQUIVALENT GENERIC FORMULATION	
Cymbalta 60 mg $10.27/capsule	Duloxetine 60 mg $1.16/capsule
MS Contin 30 mg $9.59/tablet	Morphine sulfate ER 30 mg $0.73/tablet
Lyrica (all strengths) $9.82/capsule	Pregabalin $0.02 to $0.09/capsule
THERAPEUTIC ALTERNATIVES	
Omeprazole 40 mg $6.68/capsule	Pantoprazole 40 mg $0.23/tablet
Metaxalone 400 mg $6.40/tablet	Tizanidine 4 mg $1.46/tablet
Horizant (gabapentin ER) 600 mg $17.05/tablet	Gabapentin 600 mg $0.07/tablet
Zipsor (diclofenac potassium) 25 mg $9.36/capsule	Meloxicam 15 mg $0.05/tablet

Potential Cost-Effective Changes

ALTERNATIVE DOSAGE FORM	
Aripiprazole 10 mg $10.04/tablet	Aripiprazole 5 mg $0.45/tablet
Zolpidem ER 6.25 mg $1.60/tablet	Zolpidem 5 mg $0.10/tablet
Cyclobenzaprine 7.5 mg $3.97/tablet	Cyclobenzaprine 5 mg $0.06/tablet
PRESCRIPTION TO OTC FORMULATION	
Lidocaine 5% patch $3.76/patch	Lidocaine 4% patch (Aspercreme) OTC $1.58/patch
Naproxen EC 500 mg $1.21/tablet	Naproxen sodium 220 mg OTC $0.05/tablet
Ibuprofen 600 mg $0.22/tablet	Ibuprofen 200mg OTC $0.02/tablet



MEET CHERYL

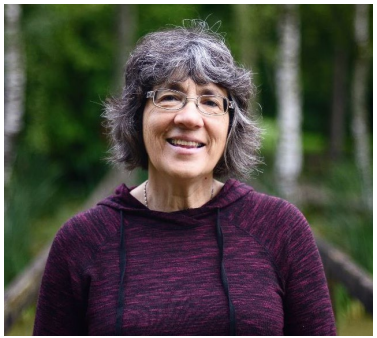
Pharmacy program tools

- A review of medications to identify cost containment recommendations, and address clinical concerns
- A specialty matched physician spoke with two treating physicians to discuss the case. Both physicians agreed to implement changes to the Cheryl's medication therapy.
- A nurse was initiated to follow up on the claim and work with the treating physician to confirm that the agreed-upon changes were implemented and that the claimant was successful with the new treatment plan.

Claim Strategies to Reduce MSA Exposure

Clean up medical records

- Remove inactive or discontinued surgeries, medications, and other irrelevant treatment modalities
- Obtain written clarification from the authorized treatment physician(s) and have treatment plans with suggested or pending treatment options that are no longer viable or recommended removed or clarified



MEET CHERYL

Pharmacy program outcomes

Medications	Current status	Estimated yearly savings based on CMS Pricing
Venlafaxine HCl Cap ER 24HR 75 MG #60	Venlafaxine HCl Cap ER 24HR 150 MG #30	$194.40
Cyclobenzaprine HCl Tab 10 MG #90	Discontinued	$32.40
Buprenorphine Patch 20 MCG/HR (Butrans) #4	Buprenorphine Patch 20 MCG/HR #4 (generic)	$3,590
Hydrocodone-Acetaminophen Tab 7/325 MG #60	Hydrocodone-Acetaminophen Tab 5/325 MG #60	$14.40
Ondansetron Orally Disintegrating Tab 8 MG #90	Promethazine 12.5 MG #30	$39,416
Methocarbamol Tab 750 MG #90	Methocarbamol Tab 750 MG #60	$39.60
Tizanidine HCl Tab 4 MG #60	Tizanidine HCl Tab 4 MG #30	$32.40

PROJECTED TOTAL LIFETIME SAVINGS FOR THIS CASE WAS **$823,080**

Claim Strategies to Reduce MSA Exposure

Opportunities will be missed if there is no plan for MSA success from the beginning

Know what injuries/illnesses are:

- Accepted/compensable and are being treated
- Pre-existing, comorbid conditions unrelated and have not been claimed
- Pre-existing, comorbid conditions unrelated and have been claimed to have been exacerbated/aggravated by the mechanism of injury
- Being treated by an authorized treating physician
- Being treated by an unauthorized, primary physician
- Have been claimed and denied
- Have been reported as compensable via Section 111 mandatory insurer reporting (MIR)

MSA SUBMISSION

What is Needed for MSA Submission?

Completed Assignment Sheet	Provides case party information
Social Security Release	For verifying Social Security and Medicare status
CMS Release	For CMS submission; *not required for MSA
Medical Reports	Last two years of treatment (not calendar years)
Payment History	Medical and indemnity two-year history; If denied treatment - all pay history since DOI
List of Accepted and Denied Body Parts	If any
Prescription Invoices	Showing quantity and frequency
Rated Age	Not required but will reduce the MSA

If the claim meets CMS thresholds, you may submit the recommended MSA to CMS for

- CMS' workers' compensation review contractor (WCRC) is the entity that reviews the submitted MSA and either agrees with the recommended amount or provides a counter low or counter high MSA amount if they disagree.
- In order to review the recommended MSA CMS/WCRC requires:
  - Proposed settlement amount
  - Funding and administration
  - Two years of medical records showing related care, treatment, and prescriptions
  - Payout showing medical care and prescriptions authorized and paid for during life of claim
  - Denial letter listing denied conditions/body parts

MSA Pharmacy Trends

- Individualized (Precision) Drugs with specific targeted indications
- Over-the-Counter (OTC) medications
- Pricing adjustments due to evidence of generic use
- Off- label use of medications
- Medication drug screens
- Metabolic panels measuring blood levels

CMS Submission of the MSA

- Consideration of professional administration with opioids
- Executed court approved final settlement documents must be submitted to effectuate the MSA approved
- Advantages of CMS review and approval
- Consequences of insufficient MSA amount or ignoring the MSA requirement
- Importance of a PBM, clinical mitigation, and MSA partners.

SUMMARY

Pharmacy Program Tools to Identify Clinical Concerns

- Identified claim as high risk
- Long-term utilization patterns
- Chronic opioid use
- Multiple prescribers
- Prescription costs

Red Flags

- Were identified by the PBM reports
- Claim handler addressed red flags using clinical mitigation services
- MSA cost drivers were reduced prior to CMS submission
- CMS approved the MSA for much less than originally anticipated

Impact of Pharmacy Program Outcomes on Settlement

- A settlement that is reasonable
- A settlement that does not shift the burden to pay related medical expenses to Medicare
- A settlement that funds an MSA that will be used to pay related medical expenses
- A settlement that complies with MSP regulations

Thank you

Questions?