NAMSAP Update

The Intersection of Policy and Public Health

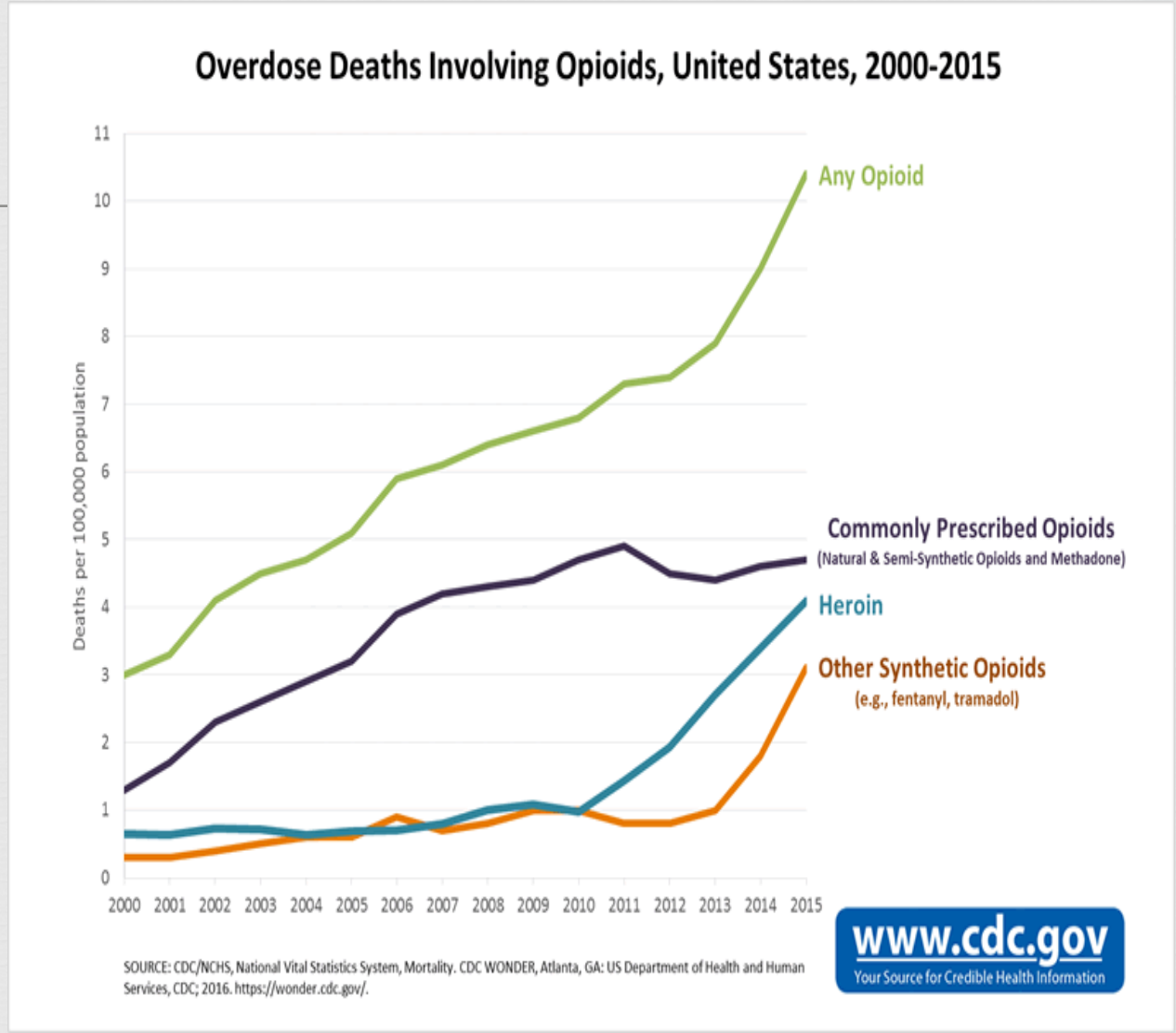
Opioids – How We Got Here

- Beginning January 1, 2006, Medicare began Part D prescription drug coverage
- Effective January 1, 2006: "*All WC settlements that occur on or after January 1, 2006, must consider and protect Medicare's interests when future treatment includes prescription drugs along with the future medical services that would otherwise be reimbursable by Medicare.*"
- Effective January 2, 2007: CMS review of future prescription drug treatment in WCMSAs begins

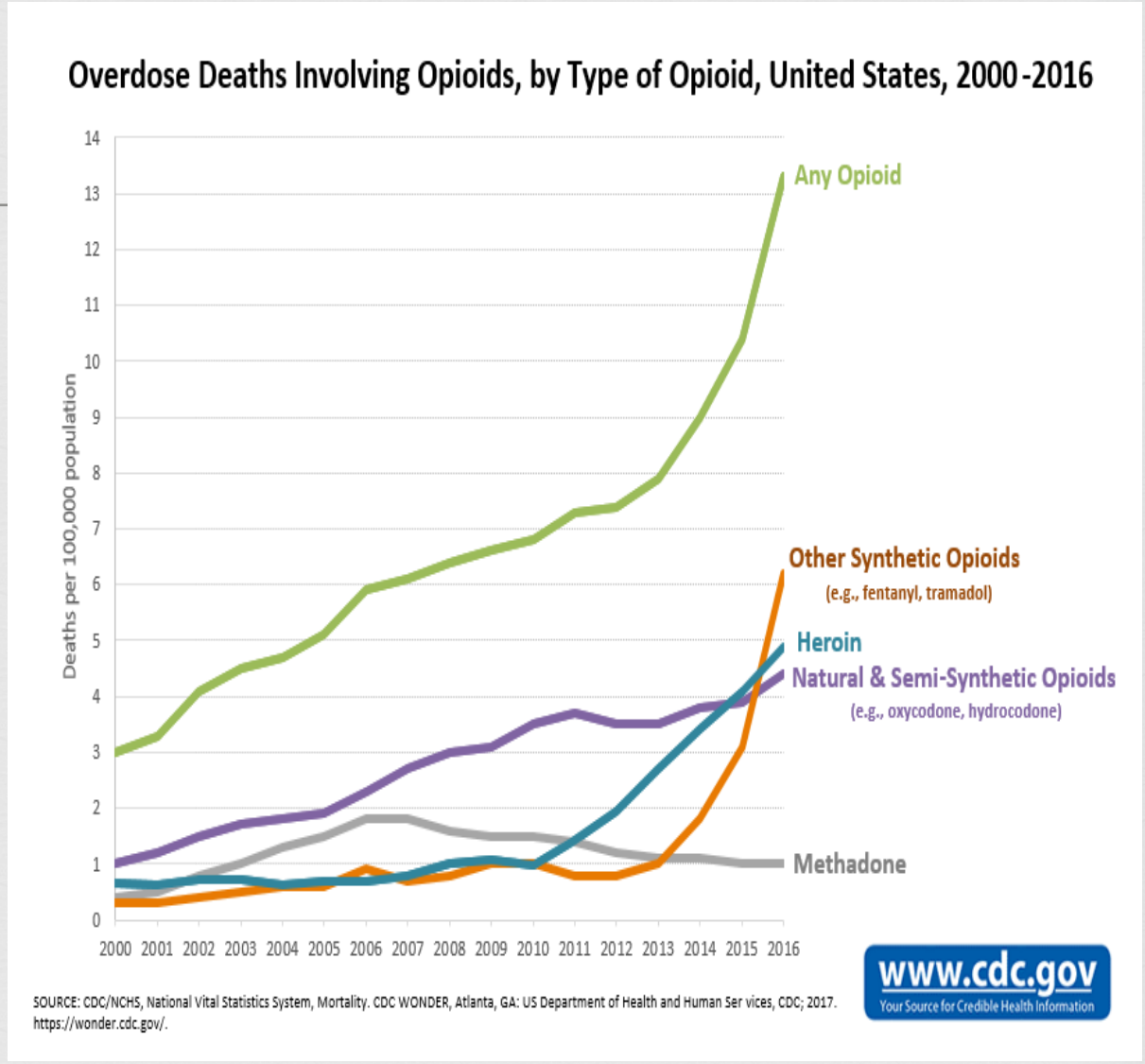
Opioids – How We Got Here

- Late 1990's: Pharmaceutical companies get FDA approval for long-acting opioids, campaign begins to reassure the medical community that opioids are safe
- Widespread diversion and misuse of these medications starts occurring, before it became clear that these medications could indeed be highly addictive [1]
- Copy of a confidential Justice Department report shows that federal prosecutors investigating the company found that Purdue Pharma knew about "significant" abuse of OxyContin in the first years after the drug's introduction in 1996 and concealed that information [2]

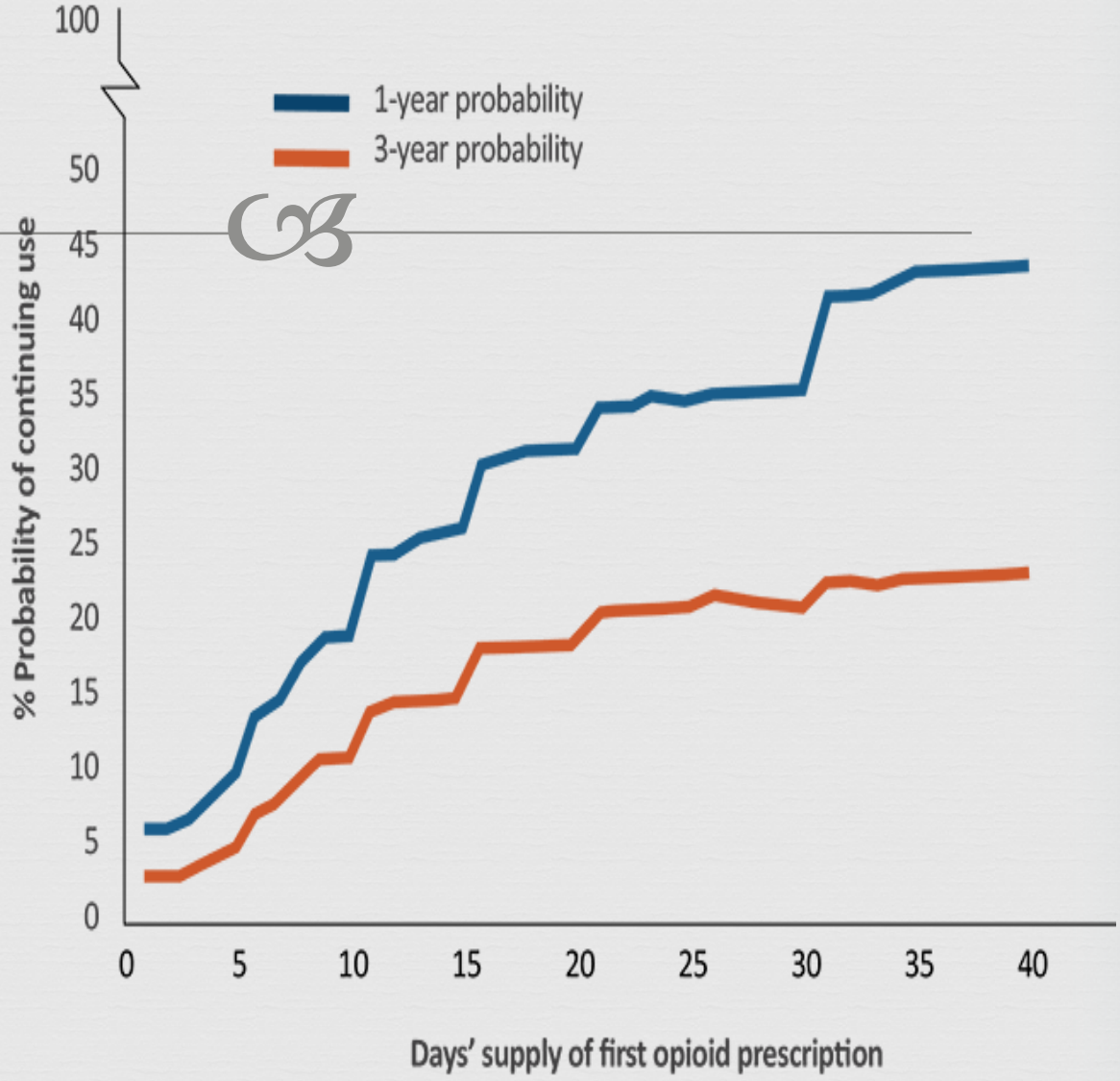
Opioid Involved Overdose Deaths, United States, 2000-2015



Opioid Involved Overdose Deaths by Opioid Type, United States, 2000-2016



Impact of Length of Initial Opioid Rx on Probability of Long Term Use



Source: Centers for Disease Control and Prevention, 2

Opioids – How We Got Here

- Over the past two decades, more than 200,000 people have died in the United States from overdoses involving prescription opioids. [3]

- Medicare Set-Asides are not immune to similar issues
  - Approximately 20,000 MSAs submitted to CMS per year
  - Approximately 50% of current cases include one prescription drug (=10,000 per year)
  - Of those, approximately 70% contain opioids (=7,000 per year)
  - Of those, approximately 71% include drugs dangerous when taken with opioids (=4,970 per year)
  - How many since 2006?

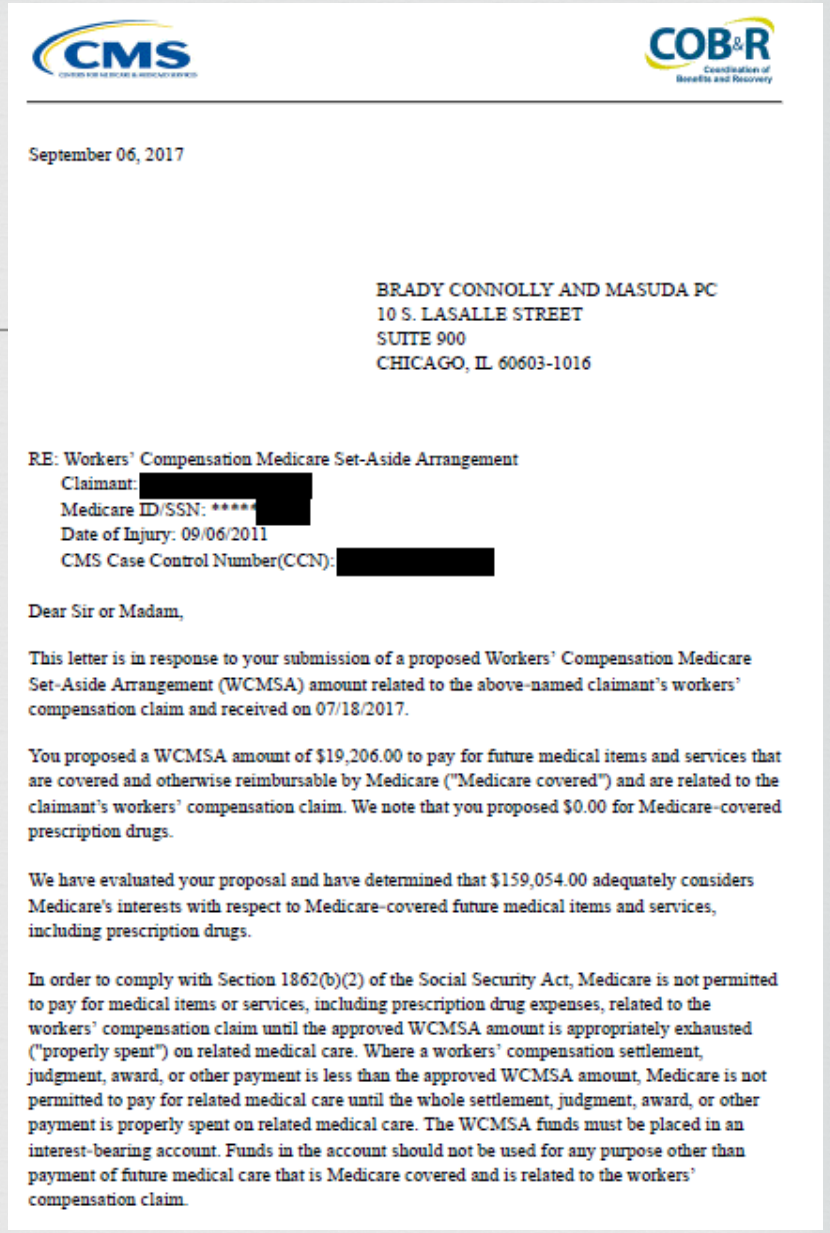
Opioids

- Current CMS Policy – WCMSA Reference Guide V2.7, March 19, 2018
  - "The WCRC compiles a drug list from medical records and pharmacy records. This list is then used to project future drug costs for the duration of a claimant's life expectancy. The reviewers must see prescription drug and medical treatment payment records/histories dated within 6 months of the date of submission or reopening."

Opioids

- Current CMS Policy – WCMSA Reference Guide V2.7, March 19, 2018
  - DEFAULT POSITION: "Usually, the latest weaned dosage is extrapolated for the life expectancy"
    - (How many don't live to this life expectancy because of the opioids and/or drug interactions?)
  - The WCRC takes all evidence of drug weaning into account, although in most circumstances the WCRC cannot assume that the weaning process will be successful.
  - Where a treating physician believes tapering is possible and in the best interests of the claimant, CMS will consider all evidence in making a WCMSA determination, including medical evidence of current actual tapering.

Opioids in the MSA



CMS

COB&R Coordination of Benefits and Recovery

September 06, 2017

BRADY CONNOLLY AND MASUDA PC
10 S. LASALLE STREET
SUITE 900
CHICAGO, IL 60603-1016

RE: Workers' Compensation Medicare Set-Aside Arrangement
Claimant: [redacted]
Medicare ID/SSN: *****[redacted]
Date of Injury: 09/06/2011
CMS Case Control Number(CCN): [redacted]

Dear Sir or Madam,

This letter is in response to your submission of a proposed Workers' Compensation Medicare Set-Aside Arrangement (WCMSA) amount related to the above-named claimant's workers' compensation claim and received on 07/18/2017.

You proposed a WCMSA amount of $19,206.00 to pay for future medical items and services that are covered and otherwise reimbursable by Medicare ("Medicare covered") and are related to the claimant's workers' compensation claim. We note that you proposed $0.00 for Medicare-covered prescription drugs.

We have evaluated your proposal and have determined that $159,054.00 adequately considers Medicare's interests with respect to Medicare-covered future medical items and services, including prescription drugs.

In order to comply with Section 1862(b)(2) of the Social Security Act, Medicare is not permitted to pay for medical items or services, including prescription drug expenses, related to the workers' compensation claim until the approved WCMSA amount is appropriately exhausted ("properly spent") on related medical care. Where a workers' compensation settlement, judgment, award, or other payment is less than the approved WCMSA amount, Medicare is not permitted to pay for related medical care until the whole settlement, judgment, award, or other payment is properly spent on related medical care. The WCMSA funds must be placed in an interest-bearing account. Funds in the account should not be used for any purpose other than payment of future medical care that is Medicare covered and is related to the workers' compensation claim.

Opioids in the MSA

Recommended WCMSA: $159,054.00 **Pricing Method:** Fee **WC State:** ILLINOIS
Recommended WCMSA Lump Sum [] or
Recommended WCMSA Structured Payments: [X]
Recommended Initial Deposit: $14,459.00
Annual Amount: $6,885.00 x 21 yrs.
Anniversary Date: 11/15/2018
Type of Recommendation: Counter-Higher
If not eligible for WCMSA, reason:

Service	Freq	Every X Yrs	# of Years	Price Per Service	Total
ORTHOPEDIC VISITS	1.00	1.00	22.0	$104.52	$2,299.44
PHYSICIAN VISITS/PCP	3.00	1.00	22.0	$104.52	$6,898.32
LUMBAR MRI	4.00	22.00	22.0	$1,824.40	$7,297.60
LUMBAR X-RAY	7.00	22.00	22.0	$133.64	$935.48
METABOLIC PANEL	1.00	1.00	22.0	$48.67	$1,070.74
COMPLETE BLOOD COUNT	1.00	1.00	22.0	$30.50	$671.00
VENIPUNCTURE	1.00	1.00	22.0	$11.60	$255.20
PHYSICAL THERAPY	24.00	22.00	22.0	$122.85	$2,948.40
Total:					$22,376.18

Opioids in the MSA

Prescription Drugs (for Medicare-covered and reimbursable drugs for the WC injury only):

(HYDROCODONE, ALPRAZOLAM, ONDANESTRON, TRAZODONE, DULOXETINE, OMEPRAZOLE AND MELOXICAM)WAS INCLUDED INTO THE WCMSA AS IT MET THE DEFINITION OF A MEDICARE PART D DRUG, WAS USED FOR A MEDICALLY ACCEPTABLE INDICATION, AND WAS FOUND TO BE PRESCRIBED FORA DIAGNOSIS RELATED TO THE INJURY WITHIN THE MEDICAL/PHARMACY RECORDS.

According to available documentation, this claimant is currently receiving the following drugs: ONDANSETRON HYDROCHLOR..., ACETAMINOPHEN/HYDROCOD..., MELOXICAM, TRAZODONE HYDROCHLORIDE, DULOXETINE HYDROCHLORIDE, OMEPRAZOLE, ALPRAZOLAM,

Drug	National Drug Code	Amount Per Unit (Dosage)	Per Day	Per Week	Per Month	# of Years	Price Per Units	Total
ACETAMINOPH	53746-0110-10	325 MG-10 MG	0.00	0.00	30.00	22	$0.64	$5,068.80
ALPRAZOLAM	59762-3721-04	1 MG	0.00	0.00	60.00	22	$0.88	$13,939.20
ONDANSETRON	50268-0622-15	8 MG	0.00	0.00	28.00	22	$0.94	$6,948.48
TRAZODONE H	42291-0833-90	50 MG	0.00	0.00	120.00	22	$0.41	$12,988.80
DULOXETINE	47335-0382-83	30 MG	0.00	0.00	90.00	22	$1.92	$45,619.20
OMEPRAZOLE	51079-0007-19	20 MG	0.00	0.00	60.00	22	$0.51	$8,078.40
MELOXICAM	61442-0126-10	7.5 MG	0.00	0.00	60.00	22	$2.78	$44,035.20
							Total:	$136,678.08

Opioids in the MSA

CMS

COB&R
Coordination of Benefits and Recovery

July 13, 2017

BRADY CONNOLLY AND MASUDA PC
10 S. LASALLE STREET
SUITE 900
CHICAGO, IL 60603-1016

RE: Workers' Compensation Medicare Set-Aside Arrangement
Claimant: [redacted]
Medicare ID/SSN: ****[redacted]
Date of Injury: 08/07/2009
CMS Case Control Number(CCN): [redacted]

Dear Sir or Madam,

This letter is in response to your submission of a proposed Workers' Compensation Medicare Set-Aside Arrangement (WCMSA) amount related to the above-named claimant's workers' compensation claim and received on 03/16/2017.

You proposed a WCMSA amount of $11,444.00 to pay for future medical items and services that are covered and otherwise reimbursable by Medicare ("Medicare covered") and are related to the claimant's workers' compensation claim. We note that you proposed $412.00 for Medicare-covered prescription drugs.

We have evaluated your proposal and have determined that $209,890.00 adequately considers Medicare's interests with respect to Medicare-covered future medical items and services, including prescription drugs.

In order to comply with Section 1862(b)(2) of the Social Security Act, Medicare is not permitted to pay for medical items or services, including prescription drug expenses, related to the workers' compensation claim until the approved WCMSA amount is appropriately exhausted ("properly spent") on related medical care. Where a workers' compensation settlement, judgment, award, or other payment is less than the approved WCMSA amount, Medicare is not permitted to pay for related medical care until the whole settlement, judgment, award, or other payment is properly spent on related medical care. The WCMSA funds must be placed in an interest-bearing account. Funds in the account should not be used for any purpose other than payment of future medical care that is Medicare covered and is related to the workers'

Opioids in the MSA

Proposed Future Medical WCMSA Amount: $11,444.00
Proposed Future Rx WCMSA Amount: $412.00
Total Proposed WCMSA: $11,856.00
Proposed Initial Deposit: $1,129.00
Total Settlement Amount: $287,500.00

Recommended WCMSA: $209,890.00 **Pricing Method:** Fee **WC State:** ILLINOIS
Recommended WCMSA Lump Sum [] or
Recommended WCMSA Structured Payments: [X]
Recommended Initial Deposit: $19,990.00
Annual Amount: $9,495.00 x 20 yrs.
Anniversary Date: 07/14/2018
Type of Recommendation: Counter-Higher
If not eligible for WCMSA, reason:

Service	Freq	Every X Yrs	# of Years	Price Per Service	Total
PHYSICIAN VISITS/PCP	4.00	1.00	21.0	$70.87	$5,953.08
LUMBAR MRI	4.00	21.00	21.0	$1,361.38	$5,445.52
LUMBAR X-RAY	7.00	21.00	21.0	$153.49	$1,074.43
METABOLIC PANEL	1.00	1.00	21.0	$51.43	$1,080.03
COMPLETE BLOOD COUNT	1.00	1.00	21.0	$32.65	$685.65
VENIPUNCTURE	1.00	1.00	21.0	$12.31	$258.51
PHYSICAL THERAPY	24.00	21.00	21.0	$137.22	$3,293.28
Total:					$17,790.50

Opioids in the MSA

Drug	National Drug Code	Amount Per Unit (Dosage)	Per Day	Per Week	Per Month	# of Years	Price Per Units	Total
ACETAMINOPH	13107-0046-05	325 MG-10 MG	0.00	0.00	120.00	21	$3.37	$101,908.80
DULOXETINE	60505-2997-08	60 MG	0.00	0.00	60.00	21	$1.36	$20,563.20
GABAPENTIN	00093-4443-10	600 MG	0.00	0.00	120.00	21	$2.28	$68,947.20
CYCLOBENZAP	10135-0595-10	10 MG	0.00	0.00	90.00	21	$0.03	$680.40
							Total:	$192,099.60

SUBMITTER'S RE-REVIEW REQUESTS REMOVAL OF THE MEDICATIONS GABAPENTIN, CYCLOBENZAPRINE, DULOXETINE, REMOVAL OF LAB STUDIES AND A REDUCTION IN THE MEDICATIONS OXYCODONE ACETAMINOPHEN AND HYDROXYZINE TO A TOTAL OF 117 OXYCODONE ACETAMINOPHEN TABLETS OVER LIFE AND A TOTAL OF 28 HYDROXYZINE TABLETS OVER LIFE. NEW EVIDENCE IS THE FOLLOWING: 1) EXCERPTS FROM OFFICIAL DISABILITY GUIDELINES INFORMATION; 2) A SECTION OF THE ILLINOIS CODE; 3) ILLINOIS WORKERS COMPENSATION CASE LAW; 4) A 3/30/17 UTILIZATION REVIEW (UR) DECISION AND 4/2/17 UR APPEAL DECISION; AND 5) A SECTION FROM THE CMS WCMSA REFERENCE GUIDE. THE 3/30/17 UR DECISION AND UR APPEAL DECISIONS ARE DATED AFTER THE DATE OF THE ORIGINAL SUBMISSION AND THEREFORE ARE INELIGIBLE FOR REVIEW. ELIGIBLE NEW EVIDENCE AND RECORDS IN THE ORIGINAL FILE WERE REVIEWED. AS RECORDS DOCUMENT THAT THE MEDICATIONS GABAPENTIN, CYCLOBENZAPRINE, DULOXETINE, HYDROXYZINE AND OXYCODONE ACETAMINOPHEN ARE CURRENTLY PRESCRIBED FOR THE INDUSTRIAL INJURY BY A TREATING PHYSICIAN WHO HAS NOT RECOMMENDED WEANING OF ANY MEDICATIONS. NO CHANGES TO MEDICATIONS IN THE WCMSA WILL BE MADE. AS

NAMSAP Recommendations

Sent: Monday, December 18, 2017 5:40 PM
To: sherri.mcqueen@cms.hhs.gov; seema.verma@cms.hhs.gov
Cc: McNabb, Brian (Cassidy) (Brian_McNabb@cassidy.senate.gov); Lucas, Jeff (Cassidy) (Jeff_Lucas@cassidy.senate.gov); Jill Dulich (Jill.Dulich@NatCouncil.com); 'Gary Patureau'; amanda.burd@cms.hhs.gov
Subject: Follow-up: Opioids in the WCMSA

Dear Ms. McQueen,

Thank you for taking the time to speak with us last week concerning how CMS currently forecasts future prescription drug recommendations in the WCMSA for beneficiaries with long-term opioid usage in their claim history. We look forward to working with CMS to address the above concerns, to do our part to bring "all hands on deck" in minimizing (or even eliminating) the WCMSA's role in perpetuating the opioid epidemic in our country. The National Council of Self Insurers joins NAMSAP in our concerns about how opioids are currently handled by the WCRC in WCMSAs. CMS' current policy: does not follow evidence-based medicine or guidelines; effectively sanctions and endorses the harmful, long-term opioid use by the beneficiary; and needs to be changed.

We first mentioned concern that the recommendations section of the WCMSA approval letter includes an itemization of medications, including opioids, that are projected at the same dosage and frequency as has been filled in the six to twelve months before submission, over the full life expectancy of the beneficiary. While this may not ultimately be what the beneficiary uses the WCMSA funds for, the recommendations section sends the wrong message to the beneficiary about the efficacy and safe duration of opioid usage without acknowledging the high likelihood of misuse and abuse when taken chronically.

Second, we expressed concern that the WCMSA includes monies that overfund the anticipated future medical needs of the beneficiary. The opioids in particular are priced, as mentioned above, in doses never meant to be taken over life expectancy. In our experience, 80% of WCMSAs are overfunded, and many of those never touched, which lends support to this position.

Third, the WCMSA monies are given to the beneficiary directly, with no gatekeeper to oversee the post-settlement opioid usage. Beneficiaries taking long-term opioids, many in excess of a 40 milligram daily Morphine equivalent doses (MEDs), are given tens to hundreds of thousands of dollars without any of the safeguards which would occur if Medicare or Part D providers were coordinating the benefits, including drug utilization review and red flags for both high MED usage and obtaining prescriptions from multiple prescribers.

There are, of course, serious and grave public health considerations stemming from each of our concerns.

You requested a list of options from NAMSAP to address what we see as the institutionalizing of opioid misuse and abuse within the context of the WCMSA. Here are some of our thoughts:

Evidence Based-Medicine: CMS can begin with the already-existing Reference Guide as a basis to bring evidence-based guidelines to the recommended WMCSA allocations in cases involving opioids, specifically by using the CDC guidelines.

- NAMSAP proposes following the CDC guidelines for tapering every beneficiary from long-term opioids at a rate of 10% per week until fully weaned.
- An exception may be made for terminal patients and those with malignancy.
- Such a recommendation would also serve the benefit of reducing the chances of dangerous and possibly lethal polypharmacy combinations with other medications such as benzodiazepines, sedatives and muscle relaxants.

- We also recommend that WMCSAs involving beneficiaries who have demonstrated negative Urinary Drug Screens (UDS) within the last six months have a zero opioid MSA allocation recommendation to prevent the likelihood of diversion and the risks associated therewith.

Post-operative allocation recommendation: NAMSAP acknowledges that short-term opioids may be safely used post-operatively short-term.

- Post-operative allocations of opioids would be acceptable for 3-5 days.
- No more than five days of post-operative opioids should be considered in the allocation given the most recent findings from the CDC.

State law: With all this noted, allocation recommendations should acknowledge individual state law maximums that may limit opioids even further (e.g. 7-day maximum for opioid prescriptions in Louisiana, 5 day maximum in Ohio, etc.), and also limit the primary responsibility of the primary payer.

We also wanted to address your concerns about the Division's perceived lack of statutory and regulatory authority to prepare WCMSA allocations that do not directly extrapolate over life expectancy the same medication dosage and frequency as has been filled over the past 6-24 months. The Comprehensive Addiction and Recovery Act of 2016 ("CARA") gave Medicare programs the authority to limit the beneficiary's access to coverage for frequently abused drugs such as opioids simply upon: identification of high-risk behaviors; and with issuance of notice. In acting on CARA, CMS' own 2019 proposed rules for PDPs codify CMS' current drug utilization review (DUR) programs, which CMS pointed out led to a 61 percent decrease in very high risk opioid overutilizers from 2011 to 2016. Thus, there is clearly statutory and regulatory authority for taking the same types of actions NAMSAP proposes.

We hope the above possible solutions are helpful and provide food for thought. We truly hope we can work together to bring patient safety in balance with protecting the Medicare Trust Fund.

We look forward to CMS' written response, and the continued dialogue.

Gary Patureau and Amy E. Bilton
Co-chairs, Evidence-Based Medicine Committee
National Alliance of Medicare Set-Aside Professionals

NAMSAP Recommendations

- NAMSAP proposes following the CDC guidelines for tapering every beneficiary from long-term opioids at a rate of 10% per week until fully weaned.
  - An exception may be made for terminal patients and those with malignancy.
  - Such a recommendation would also serve the benefit of reducing the chances of dangerous and possibly lethal polypharmacy combinations with other medications such as benzodiazepines, sedatives and muscle relaxants.
  - We also recommend that WMCSAs involving beneficiaries who have demonstrated negative Urinary Drug Screens (UDS) within the last six months have a zero opioid MSA allocation recommendation to prevent the likelihood of diversion and the risks associated therewith.

NAMSAP Recommendations

- **Post-operative allocation recommendation:** NAMSAP acknowledges that short-term opioids may be safely used post-operatively short-term.
  - Post-operative allocations of opioids would be acceptable for 3-5 days.
  - No more than five days of post-operative opioids should be considered in the allocation given the most recent findings from the CDC.

- **State law:** With all this noted, allocation recommendations should acknowledge individual state law maximums that may limit opioids even further (e.g. 7-day maximum for opioid prescriptions in Louisiana, 5 day maximum in Ohio, etc.), and also limit the primary responsibility of the primary payer.

NAMSAP Response

NAMSAP
National Alliance of Medicare Set-Aside Professionals

Senator Richard J. Durbin
230 S. Dearborn Street, Suite 3892
Chicago, Illinois 60604

April 5, 2018

Dear Senator Durbin,

There is a Federal program buried deep within The Centers for Medicare and Medicaid Services ("CMS") which institutionalizes chronic opioid use and abuse. While the Administration, House, Senate and every state in the nation work mightily to try to solve the opioid crisis in the United States, this little known program encourages, intensifies and effectively orders long-term opioid use and abuse by Medicare beneficiaries. While CMS continues to address the opioid epidemic in other areas of the Medicare program, it has consistently discounted, disregarded and denied this persistent problem within its own Medicare Set-Aside ("MSA") policy. We write to bring your attention to this problem, and ask for your help in solving it.

Given Medicare's status as a secondary payer in every injury settlement, parties will often allocate monies in a settlement for future injury-related treatment. In 2001, CMS' Office of Financial Management, Division of MSP Program Operations formulated a program to review these allocations, called "Medicare Set-Asides" or "MSAs." The stated goal of CMS' MSA program is to estimate the total cost that will be incurred for all medical expenses otherwise reimbursable by Medicare for injury-related conditions during the course of the claimant's life, and to set aside sufficient funds from settlements, judgments, or awards to cover that cost. When the parties to a settlement participate in CMS' MSA review process, CMS requires the parties "*comply with CMS' established policies and procedures in order to obtain approval*"[ii] (emphasis added).

CMS publishes a Workers' Compensation Medicare Set Aside Arrangement Reference Guide to explain its methodology in reviewing and approving these MSAs. Relative to opioids, CMS allocates these dangerous and addictive drugs over the full life expectancy of the beneficiary at the same dosage and frequency as have been prescribed in the six to twelve months prior to MSA submission. This is true despite these medications having been proven deadly when taken over time. In fact, CMS' own Reference Guide states: "it is very rare that (CMS) would reduce a prescription set-aside allotment due to a drug warning and precaution as defined by the FDA."[i] CMS' projection methodology is contrary to CDC Guidelines and evidence-based studies on the efficacy and danger of these drugs. We estimate that 70% of all CMS-approved MSAs which include prescription medication include life-long allocations for opioids. The effect of CMS' current policy causes incalculable and unimpeded dependency, addiction and death.

As members of the National Alliance of Medicare Set-Aside Professionals (NAMSAP), we have been working for five years to appeal to CMS to change this policy. We provided two proposals to the Division of MSP Program Operations over the last two years. Most recently, we were joined by the National Council of Self-Insurers in this cause. Together, we recommended CMS change its policies in several ways, some of which were: to limit opioid allocations for acute pain to three days; to limit post-operative opioids in an MSA which includes a future

NAMSAP
National Alliance of Medicare Set-Aside Professionals

surgical projection to five days; and, in the case of chronic use, include a 10% per week mandatory tapering and weaning schedule, as recommended by the CDC, until fully weaned from opioids. Our efforts have led to no action from CMS. In light of this, we turn to you for assistance.

NAMSAP is reaching out to each member of Congress to educate you on the existence of this program and to ask for your help in bringing an end to CMS' dangerous policy before further damage is done to our aged and disabled citizenry. We enclose information on what an MSA is, along with actual examples of letters where CMS institutionalized long-term opioid use.

We need your help to immediately address this dangerous, Federally-sponsored opioid policy. Please help us convince CMS that it is time to change its policy and put the health and welfare of its beneficiaries, of your constituents, first. NAMSAP stands ready to answer any questions you or your staff have regarding the MSA, how it works and how you can help. We thank you in advance for your assistance.

Sincerely,

Gary Patureau, CWCP, CMSP-F
Co-Chair, Evidence-Based Medicine Committee

Amy E. Bilton, JD, MSCC, CMSP-F
Co-Chair, Evidence-Based Medicine Committee

cc: Jessica McNiece /Jessica_mcniece@durbin.senate.gov
Max Kanner/ Max_kanner@durbin.senate.gov

Resources found at http://www.namsap.org/?page=CongressionalLetter

1. What is Medicare Secondary Payer and What is a Medicare Set-Aside?
2. CMS Reference Guide
3. CMS Submission Quality Improvement Data Analytics
4. CWCI Report: Opioids in Workers' Compensation Medicare Set-Asides
5. EBM Committee correspondence with CMS

About NAMSAP
The National Alliance of Medicare Set Aside Professionals (NAMSAP) is the only non-profit association exclusively addressing the issues and challenges of Medicare Secondary Payer (MSP) compliance and its impact on workers' compensation and liability settlements. Contact NAMSAP at 225.454.6164, info@namsap.org or via www.namsap.org.

[i] Workers' Compensation Medicare Set-Aside Arrangement (WCMSA) Reference Guide, CDBR-Q1-2018-v2.7, p. 1, March 19, 2018. https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Workers-Compensation-Medicare-Set-Aside-Arrangements/Downloads/WCMSA-Reference-Guide-Version-2_7.pdf

[ii] WCMSA Reference Guide at 30.

620 Florida Street, Suite 210, Baton Rouge, LA 70801 • (225) 454-6164 • www.NAMSAP.org

NAMSAP Recommendations

- Most recently, we were joined by the National Council of Self-Insurers in this cause. Together, we recommended CMS change its policies in several ways, some of which were:
  - To limit opioid allocations for acute pain to three days;
  - To limit post-operative opioids in an MSA which includes a future surgical projection to five days;
  - And, in the case of chronic use, include a 10% per week mandatory tapering and weaning schedule, as recommended by the CDC, until fully weaned from opioids

Clinically, how does CMS handle opioids?

- 2013 - Medicare Part D Overutilization Monitoring System (OMS)
  - Plan level controls for opioids, including safety edits and quantity limits
  - Improved DUR to identify 'high risk' beneficiaries
    - >120 MME / day
    - > 90 days
    - >3 prescribers
    - >3 pharmacies
  - Require case management with prescriber
  - Beneficiary specific POS edits to prevent ***Part D coverage of overutilization***
  - Data sharing between Part D plans
- OMS Results between 2011-2014
  - 26% decrease in beneficiaries identified as opioid over-utilizers
  - 39% decrease in opioid users identified as potential opioid over-utilizers.

Clinically, how does CMS handle opioids?

- 2018 Draft Call Letter – *Improving DUR Controls (Opioids)*
  - Identify high risk beneficiaries who use‘ potentiator’ drugs (i.e. Gabapentin) in combination with opioids
  - Implement a new PQA (Pharmacy Quality Alliance) measure to track ***Concurrent Use of Opioids and Benzodiazepines***
  - Expect all sponsors to implement ‘hard’ formulary-level cumulative safety edits at POS, overridden only by sponsor plan, to limit opioid Rx fills to 90 MME / day with 7 days supply
  - Implement a supply limit for initial opioid Rx fills for acute pain (e.g., 7 days) with or without a daily does maximum (e.g., 50 MME).
  - Expect all sponsors to implement ‘soft’ formulary edits, which can overridden by the pharmacist, based on duplicative therapy of multiple long acting opioids and concurrent use of opioids with benzodiazepines

Possible Changes?

- What does Medicare cover?
  - Current CMS call letters
  - What would Part D?
- What is the treating doctor doing?
- Medicare's interests vs. Beneficiary's interests
- Oversight?
  - Part D reimbursement from MSA?
  - Professional administration?
  - Urinary Drug Screen?
- State law changes & limitations

Case Study – Opioid Dependency

- 46 year old male with injury to back, neck, shoulder and arm. Diagnoses: lumbar radiculopathy, status post fusion X2, chronic pain, depression, erectile dysfunction, chronic constipation and sleep disturbance. Treatment included chronic pain management with the following prescription therapy:

Oxycontin 60 MG 4/Day	long acting opioid
Sertraline 150 MG 1/Day	anti-depressant
Gabapentin 500 MG 5/Day	neuropathic pain
Celebrex 200 MG 1/Day	NSAID
Oxymorphone HCL 10 MG 4/Day	short acting opioid
Amitriptryline 50 MG 1/Day	pain / sleep
Viagra 50 MG 10 / Month	erectile dysfunction

- Pre-MSA Triage identified MSA exposure of $1,234,551 due to long term use of long / short acting opioids combined with side-effect medications

Case Study – Opioid Dependency

- Concerns: Morphine Equivalent Dosage > 300 MG / Opioid dependence / Addiction
- Intervention: Peer-to-Peer recommendation to reduce long acting opioids and associated side effect drugs. Treating physician agreed to wean both long and short acting opioids. Patient refused compliance and was dismissed from practice. Identified new physician, presented PPR recommendations and obtained agreement to wean.
- Involvement / Oversight: Treating physician weaned / discontinued long acting opioid and replaced with Methadone. Patient did not tolerate Methadone. MS Contin ER 60 MG (Generic) was prescribed and well tolerated.
- MSA was prepared with written documentation to support discontinuation of long acting opioid medications and replacement with MS Contin ER. With removal of long acting opioids, side effect drugs were also removed. Changes to the medication therapy resulted in a projected savings of $1,224,000.
- MSA was submitted with total cost of $210,641 and approved by CMS.

Similar Concern: Polypharmacy

The overall prevalence of drug–drug interactions in patients on long-term opioids is 27%. [4]

- Anti-anxiety (incl. Cymbalta/Duloxetine)
- Benzodiazepines (incl. Xanax, Klonopin, Ativan)
- Muscle Relaxants (incl. Baclofen, Soma, Cyclobenzaprine)
- Antipsychotics (incl. Abilify)
- Anti-seizure medications (incl. Gabapentin, Tegretol)
- Sedatives & Sleep medications (incl. Ambien, Lunesta)

4 Pergolizzi, Joseph V. and Raffa, Robert B. "Common Opioid-Drug Interactions: What Clinicians Need to Know". Practical Pain Management. Web. 27 Sept. 2017.

Polypharmacy

	Drug	National Drug Code	Amount Per Unit (Dosage)	Per Day	Per Week	Per Month	# of Years	Price Per Units	Total
*	ACETAMINOPH	13107-0046-05	325 MG-10 MG	0.00	0.00	120.00	21	$3.37	$101,908.80
*	DULOXETINE	60505-2997-08	60 MG	0.00	0.00	60.00	21	$1.36	$20,563.20
*	GABAPENTIN	00093-4443-10	600 MG	0.00	0.00	120.00	21	$2.28	$68,947.20
	CYCLOBENZAP	10135-0595-10	10 MG	0.00	0.00	90.00	21	$0.03	$680.40
								Total:	$192,099.60

	Drug	National Drug Code	Amount Per Unit (Dosage)	Per Day	Per Week	Per Month	# of Years	Price Per Units	Total
	ACETAMINOPH	53746-0110-10	325 MG-10 MG	0.00	0.00	30.00	22	$0.64	$5,068.80
*	ALPRAZOLAM	59762-3721-04	1 MG	0.00	0.00	60.00	22	$0.88	$13,939.20
**	ONDANSETRON	50268-0622-15	8 MG	0.00	0.00	28.00	22	$0.94	$6,948.48
*	TRAZODONE H	42291-0833-90	50 MG	0.00	0.00	120.00	22	$0.41	$12,988.80
*	DULOXETINE	47335-0382-83	30 MG	0.00	0.00	90.00	22	$1.92	$45,619.20
**	OMEPRAZOLE	51079-0007-19	20 MG	0.00	0.00	60.00	22	$0.51	$8,078.40
*	MELOXICAM	61442-0126-10	7.5 MG	0.00	0.00	60.00	22	$2.78	$44,035.20
								Total:	$136,678.08

* Contraindicated use with opioid

** Counteracts the side effects of the opioid

NAMSAP Recommendations

- NAMSAP proposes following the CDC guidelines for tapering every beneficiary from long-term opioids at a rate of 10% per week until fully weaned.
  - An exception may be made for terminal patients and those with malignancy.
  - Such a recommendation would also serve the benefit of reducing the chances of dangerous and possibly lethal polypharmacy combinations with other medications such as benzodiazepines, sedatives and muscle relaxants.
  - We also recommend that WMCSAs involving beneficiaries who have demonstrated negative Urinary Drug Screens (UDS) within the last six months have a zero opioid MSA allocation recommendation to prevent the likelihood of diversion and the risks associated therewith.

Case Study – Polypharmacy/Side Effects

- 49 year old male with a low back injury. Diagnoses: lumbar radiculopathy, status post fusion X2, chronic pain, depression, erectile dysfunction, chronic constipation, and sleep disturbance. Treatment included chronic pain management with the following prescription therapy:
  - Oxycodone HCl Tab 20 MG and Oxycodone HCl Tab SR 12HR 40 MG (opioid analgesics for pain)
  - Bupropion HCl Tab SR 12HR 150 MG (CNS - antidepressant for depression and off label for treatment of neuropathic pain)
  - Zolpidem Tartrate Tab 10 MG (CNS - sedative hypnotic for sleep)
  - Sildenafil Citrate Tab 50 MG (treatment for erectile dysfunction)
  - Lactulose Solution 10 MG/15ML and Lubiprostone Cap 24 MCG (treatment for constipation)

Case Study – Polypharmacy/Side Effects

- Concerns: compliance, duration of therapy, possible drug-drug interactions and medications exceeding recommended dosage guidelines. Additionally, the medications were being prescribed without documented efficacy, while more cost effective alternatives were available.

- Intervention: A comprehensive assessment was performed to indentify cost containment recommendations and address the therapy concerns. Through Peer-to-Peer Outreach, the treating physician indicated that the patient would be weaned to a lower dose of Oxycodone, Sildenafil Citrate would be switched to a lower-cost alternative, and Zolpidem Tartrate would be discontinued. The treating physician also noted that Lactulose and Lubiprostone had already been discontinued due to an improvement in the patients constipation diagnosis.

- Nurse Progress Monitoring was initiated and verified that these changes were made and remained for six months. The patient was prescribed Naproxen Tab 500 MG to assist with tapering him off of opioids. These changes to the medication therapy resulted in a projected savings of $413,213.88 over the life of the claim.

- MSA was later submitted that included the Rx changes made following Nurse Progress Monitoring. CMS approved the MSA.

Best Practices – Don't Wait for MSA

- Start with the right physician - Leverage data analytics to identify doctors who deliver the best outcomes - don't settle
- Identify early – Define RX triggers and escalate before claim moves in wrong direction
- Be proactive to address surgical, SCS, injection recommendations immediately - don't wait for MSA
- Leverage state jurisdictional options to enforce compliance
- Identify settlement / MSA obstacles through Pre-MSA assessment
- Leverage clinical expertise to affect treatment change
- Obtain written agreement to any change in treatment
- Remain involved through full treatment modification
- Provide CMS accepted language to document change

Resources

- Industry initiatives that support better outcomes
  - https://namsap.site-ym.com/page/EBMOpioidInitiative (NAMSAP)
  - https://turnthetiderx.org – US Surgeon General
  - www.supportprop.org - Physicians for Responsible Opioid Prescribing
  - www.acoem.org Guidelines for Chronic Opioid Use
  - www.iaiabc.org/opioids – Opioid use resources
  - https://namsap.site-ym.com/page/SubscriptionServices – ODG
  - http://www.medscape.com/resource/pain/opioid-policies#ME
  - http://www.cdc.gov/drugoverdose/ - CDC: Prescription Drug Overdose
  - http://www.pdmpassist.org/ - PDMP Training & Education
  - https://www.guideline.gov/summaries/summary/49933 - 2015 Beers Criteria
  - https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm - CDC opioid guide

Other NAMSAP Updates

Liability MSAs

(1) Submission?
- Review thresholds?
- Submission as an Option?
- Post-settlement submission?

(2) Compromise Formula?
(3) Use Medicare rates vs. U&C?
(4) Denial of payment?
(5) Professional vs. Self-Administration?
(6) Timeline?
(7) Impact on conditional payments?

Thank you!