Opioids and the BME

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NJCARES

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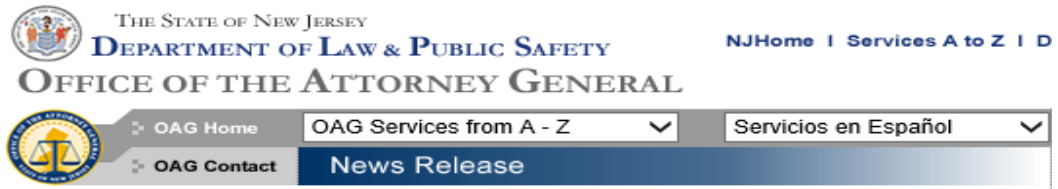

THE STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
OFFICE OF THE ATTORNEY GENERAL

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New Jersey Attorney General Announces Creation of New Office to Fight Opioid Addiction Crisis

Unveils Office's Key Initiatives at Multi-State Symposium on Opioid Crisis

TRENTON – Attorney General Gurbir S. Grewal today announced the creation of a new office within the Office of the Attorney General dedicated to fighting the opioid epidemic.

The Office of the New Jersey Coordinator of Addiction Response and Enforcement Strategies ("NJ CARES") will be responsible for overseeing addiction-fighting efforts across the Department of Law and Public Safety and creating partnerships with other agencies and groups similarly committed to identifying and implementing solutions to the opioid crisis and drug addiction.

Sharon M. Joyce, Acting Director of the Division of Consumer Affairs and a Deputy Director in the Division of Law, has been named Director of NJ CARES. Under Joyce's leadership, the office will roll out a series of new addiction-fighting programs, including the creation of around-the-clock "Opioid Response Teams" in municipalities throughout New Jersey, an electronic data-sharing network to exchange opioid-related data among state agencies, and an online portal providing the public with real-time updates on overdose deaths and other addiction-related information.

Agency Partners

Division of Law

Suing opioid manufacturers engaged in deceptive sales and marketing campaigns:

- Insys Therapeutics, Inc. (Subsys)
- Purdue Pharma, L.P. (Oxycontin)
- Janssen Pharmaceuticals, Inc., a subsidiary of Johnson and Johnson (Nucynta and Nucynta ER)
- Sackler Family

Division of Law (cont.)

Licensing Enforcement Actions against Indiscriminate Prescribers:

- Ignoring explicit prescribing restrictions; off-label use of TIRF drugs
- Prescribing in excessive amounts and dosages
- Prescribing without a legitimate medical purpose; failure to diagnose underlying conditions
- Serious recordkeeping violations (mischaracterizing etiology of pain, failure to sign/adhere to pain management agreements)

Division of Consumer Affairs

- Issues orders revoking, suspending or restricting professional licenses and CDS prescribing registrations
- Reviews PMP data to identify red flags for diversion and notifies appropriate law enforcement agency or professional licensing board
- PMP Integration

Division of Criminal Justice

Investigating and prosecuting drug-related offenses:

- Targeting heroin and fentanyl sources of supply
- Violations of New Jersey's strict liability law for drug-induced death

Operation 4K Boyz Paterson

Overdoses Linked to Paterson Heroin Stamp Logos

January 1 – August 1, 2019

- 10 Defendants Arrested
- 27,000 Wax Folds of Heroin and Fentanyl
- 1 Kilogram of Bulk Heroin
- 400 Grams of Fentanyl
- $60,000 in U.S. Currency

New Jersey Office of the Attorney General - New Jersey Division of Criminal Justice - Paterson Police Department

New Jersey State Police

- Identify and mitigate suppliers and distribution networks of lethal drug batches
- Analysis of drug seizures, overdoses and criminal behavior
- Combines heroin stamp data from forensic labs with suspected overdose data to deploy resources and predict future drug-related incidents

NJ CARES

- Increased access to treatment and recovery services
  - Operation Helping Hand
  - Opioid Response Teams
- Increased access to naloxone
- Prescriber education
- Online portal: updated information on opioid-related deaths, naloxone administrations, and opioid prescriptions dispensed

Opioid Crisis in New Jersey

Overdose Deaths*	Naloxone Administrations	Opioid Prescriptions
1,387	5,577	1,874,269
January 1 through June 30, 2019	January 1 through May 31, 2019	January 1 through June 15, 2019
*2019 Monthly Reports Suspected	2019 Data	2019 Data
*2018 Monthly Reports Suspected (3,118 deaths)	2018 Data	2018 Data
2017 Confirmed	2017 Data	2017 Data
2016 Confirmed	2016 Data	2016 Data
2015 Confirmed	2015 Data	2015 Data
2014 Confirmed	2014 Data	2014 Data
2013 Confirmed		2013 Data
2012 Confirmed		

County Specific Data

Click on any county to jump to specific data available below

BRACH | EICHLER LLC
Counsellors at Law

NJHMR
HEALTHCARE MARKET REVIEW

Statewide Historic Data

Historic Data (2013-2018)

Statewide	2013	2014	2015	2016	2017	2018
Suspected Overdose Deaths	1,336	1,304	1,587	2,221	2,737	3,118
Naloxone Administrations	N/A	N/A	7,227	10,308	14,356	16,082
Opioid Prescriptions Dispensed	5,256,462	5,346,517	5,640,864	5,252,333	4,867,130	4,266,645

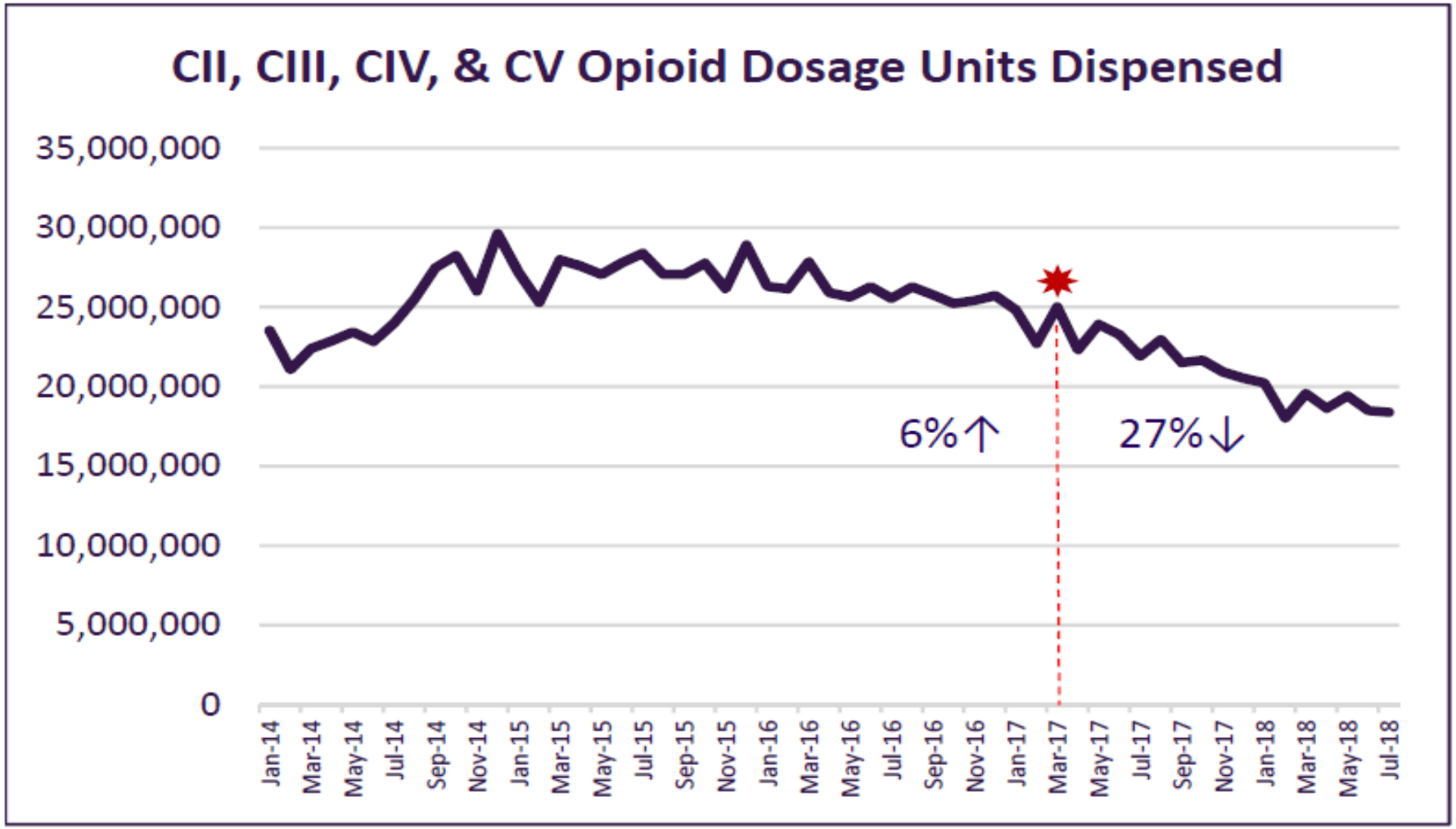
Historic Population Based Data (2013-2018)

Statewide	2013	2014	2015	2016	2017	2018
Population for Every One Overdose Death	6,631	6,800	5,590	3,996	3,248	2,857
Population for Every One Naloxone Administration	N/A	N/A	1,227	861	619	554
Opioid Prescriptions Dispensed in 2018	1.69	1.66	1.57	1.69	1.83	2.09

OFFICE OF THE CHIEF STATE MEDICAL EXAMINER (OCSME)

Drug Related Deaths - 2017

COUNTY	TOTAL	HEROIN	FENTANYL	ANALOG	MORPHINE	COCAINE	OXYCODONE	METHADONE
Atlantic	169	95	86	31	4	42	13	10
Bergen	129	68	59	40	2	35	19	4
Burlington	149	87	85	30	2	49	21	11
Camden	307	205	170	58	3	129	40	13
Cape May	59	34	34	0	1	14	5	2
Cumberland	75	46	50	5	0	23	4	1
Essex	370	237	161	83	0	157	33	20
Gloucester	123	73	77	27	4	44	11	4
Hudson	141	89	45	28	3	43	15	5
Hunterdon	22	12	16	8	0	5	2	0
Mercer	106	57	59	30	0	37	10	5
Middlesex	235	114	137	86	3	53	28	5
Monmouth	172	98	94	39	2	42	18	8
Morris	89	53	42	30	1	26	10	2
Ocean	189	100	93	43	7	41	24	11
Passaic	131	86	68	8	0	54	11	7
Salem	19	12	9	4	0	6	5	0
Somerset	49	30	21	13	0	18	3	2
Sussex	36	22	19	11	1	7	3	5
Union	131	76	83	16	3	55	19	4
Warren	36	19	21	12	0	10	5	1
TOTAL	2737	1613	1429	602	36	890	299	120



*Mandatory 5-day emergency rule for initial opioid Rx: March 1, 2017

Development of BME Prescribing Limitations

- Passage of P.L. 2017, c.28---Five Day Rule
  Effective May 16, 2017

- Adoption of BME emergency rules
  Effective March 1, 2017

- Passage of P.L. 2017, c. 341---PMP lookups/new delegates
  Effective January 16, 2018

Drug Scheduling

I	Illicit: Heroin, LSD, Marijuana
II	Opioids: fentanyl, hydrocodone, hydromorphone, meperidine, morphine, oxycodone, oxymorphone, methadone
III	codeine, buprenorphine
IV	Benzodiazepines: alprazolam, lorazepam, diazepam, clonazepam • Sedatives and muscle relaxants • Tramadol
V	Cough medicines with codeine

Prescribing for Acute Pain
Initial Prescriptions

The Five-Day Rule: Initial Opioid Prescriptions for Acute Pain

- Five-day supply limitation (opioids—any schedule)
- Lowest effective dose of immediate release opioid drug
- NO initial prescriptions for ER or long-acting opioids
- Indicate on the prescription that it is the initial prescription

Exceptions to Opioid Prescribing Limitations

- Patients currently in active treatment for cancer
- Patients receiving hospice care from a licensed hospice
- Patients receiving palliative care
- Resident of a long-term care facility
- Medications prescribed for treatment of substance use or opioid dependence

Required Documentation

Prior to issuance of initial Rx of CII CDS or any opioid:

- Take and document thorough medical history
- Conduct and document physical exam
- Develop treatment plan, focus on determining cause of patient's pain
- Access the PMP
- Medical record reflects findings on exam, treatment plan, PMP data

Opioid-Specific Discussion and Documentation

Prior to initial Rx of CII CDS or any opioid for treatment of acute pain:

Required discussion with patient if over 18 or emancipated minor, or patient's parent/guardian if under 18 and not emancipated

- Risks of addiction and overdose associated with opioids, danger of combining opioids with alcohol, benzodiazepines, and CNS depressants
- Reasons why Rx is necessary
- Alternatives available

Document the discussion in the medical record

Subsequent Prescriptions for Acute Pain

- No less than four (4) days after initial prescription issued
- Practitioner required to consult with patient
- Determines Rx necessary and appropriate to patient's needs
- Document rationale for subsequent Rx
- Determine no undue risk of abuse, addiction, diversion
- Document that determination

Prescribing for Chronic Pain and the Use of Pain Management Agreements

Prior to commencement of ongoing course of treatment with C II CDS or any opioid, requirement to enter pain management agreement:

- Documents understanding of practitioner and patient re. the pain management plan
- Establishes patient's obligations (responsible use, discontinuation, storage, disposal of opioids)
- Identifies meds and other modes of treatment included in the treatment plan
- Specifies monitoring and compliance measures
- Delineates process for terminating the agreement

Continuous Prescribing for Chronic Pain Practitioner Obligations

- Review course of treatment at least every three months
- Periodic efforts to stop or taper CDS, or utilize alternatives
- Assess patient for dependence prior to issuing each Rx and document
- Access the PMP **on a quarterly basis**
- Monitor compliance with PMA
- Random urine screens at least every twelve months
- Advise of patient/parent/guardian of naloxone availability
- Refer to pain management or addiction specialist for independent evaluation or treatment, if objectives not being met

Prescriber Obligations and the PMP

Mandatory Lookups

- First time prescribing a CII CDS **or any opioid** to a new patient (acute or chronic pain)
- **First time prescribing a CIII or CIV benzodiazepine**
- **First time prescribing a CDS other than an opioid or a benzodiazepine, if reasonable belief patient is seeking CDS for abuse, misuse, diversion**
- **Any time prescribing a CII CDS to a patient receiving care in ED of general hospital**
- **Quarterly basis for continuous Rx of CII CDS/opioid, or CIII or CIV benzodiazepines**

Expanded Class of Delegates

Delegates

- Licensed healthcare professionals (RN's, LPN's, dental hygienists)
- Medical/dental residents
- Certified medical assistants
- Registered dental assistants
- **Licensed athletic trainers** in clinical practice setting
- **Medical scribes** in hospital ED

Bi-annual audit to monitor for potential misuse of PMP

New Initiatives Affecting Opioids and the BME

- Move forward with proposed regulations to implement c. 341 and require co-prescribing naloxone
- PMP enhancements

PMP Enhancements

Unsolicited reporting based on thresholds

- Morphine milligram equivalents
- Multiple provider episodes
- Multiple pharmacy episodes
- Opioid and benzodiazepine combinations

Summary	
Total Prescriptions:	85
Total Prescribers:	46
Total Pharmacies	25

Opioids* (excluding buprenorphine)		Buprenorphine*	
Current Qty:	24.0	Current Qty:	0.0
Current MME/day:	20.0	Current mg/day:	0.0
30 Day Avg MME/day:	32.33	30 Day Avg mg/day:	0.0

Prescriptions

Filled	ID	Written	Drug	QTY	Days	Prescriber	Rx #	Pharmacy	Refills	Daily Dose	Pymt Type
02/01/2018	4	02/01/2018	TRAMADOL HCL 50 MG TABLET	30.0	4	A		1	0	37.5 MME	insurance
01/29/2018	11	01/29/2018	TRAMADOL HCL 50 MG TABLET	60.0	20	B		2	0	15.0 MME	paid
01/25/2018	8	01/25/2018	TRAMADOL HCL 50 MG TABLET	30.0	4	A		3	0	37.5 MME	paid
01/15/2018	8	01/15/2018	TRAMADOL HCL 50 MG TABLET	60.0	15	C		3	0	20.0 MME	paid
01/14/2018	3	01/14/2018	TRAMADOL HCL 50 MG TABLET	15.0	4	D		3	0	18.75 MME	insurance
01/11/2018	11	01/11/2018	TRAMADOL HCL 50 MG TABLET	60.0	20	B		2	0	15.0 MME	paid
01/03/2018	6	01/03/2018	TRAMADOL HCL 50 MG TABLET	120.0	30	E		4	0	20.0 MME	insurance
12/14/2017	6	12/12/2017	NUCYNTA ER 50 MG	180.0	30	F		5	0	120.0	insurance

Prescriber / Rx Information Removed For Privacy

Dispensers

Pharmacy	Address	City	State	Zip	Phone
1		DAYTON	NJ	08810	
2		SOMERSET	NJ	08873	
3		EDISON	NJ	08820	
4		PERTH AMBOY	NJ	08861	
5		SOUTH PLAINFIELD	NJ	07080	
6		RAHWAY	NJ	07065	
7		FRANKLIN PARK	NJ	08823	
8		WOODBRIDGE	NJ	07095	
9		EAST BRUNSWICK	NJ	08816	
10		NORTH BRUNSWICK	NJ	08902	
11		SOMERSET	NJ	08873	
12		PERTH AMBOY	NJ	08861	
13		ELIZABETH	NJ	07202	
14		PRINCETON	NJ	08540	
15		LINDEN	NJ	07036	
16		EDISON	NJ	08817	
17		SCOTCH PLAINS	NJ	07076	

Pharmacy Information Removed For Privacy

Therapeutic Class Summary

Therapeutic Class 4	Script Count	Dispensary Count	Prescriber Count	Total Quantity	Total Days Supply
OPIATE AGONISTS	81	25	43	4802.0	1116
BENZODIAZEPINES (ANXIOLYTIC,SEDATIV/HYP)	4	3	4	44.0	32

PMP Enhancements

Prescriber Report Cards

Comparisons with same role prescribers, and prescribers within your specialty

- Prescriptions by daily MME
- Opioid treatment duration
- Prescription volumes
- PDMP usage
- Patients exceeding multiple provider thresholds
- Dangerous combination therapy

DATE: 7/10/2018

DATE COVERED BY THIS REPORT: 1/1/2018 - 6/30/2018

NAME:

DEA #:

ROLE: Physician (MD, DO)

SPECIALTY: Family Medicine

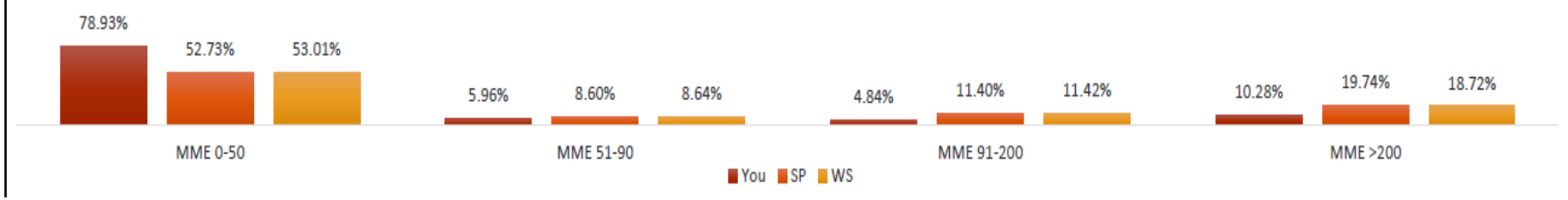
MEMBER NUMBERS IN YOUR PEER GROUPS: SIMILAR PRESCRIBER **(SP)**: 81 WITHIN YOUR SPECIALTY **(WS)**: 98

NUMBER OF PERSONS FOR WHICH YOU PRESCRIBED OPIOIDS *(MONTHLY AVERAGE)*			NUMBER OF PRESCRIPTIONS YOU WROTE FOR OPIOIDS *(MONTHLY AVERAGE)*		
88	7	7	638	13	14
You	Similar Prescriber (SP)	Within your Specialty (WS)	You	Similar Prescriber (SP)	Within your Specialty (WS)

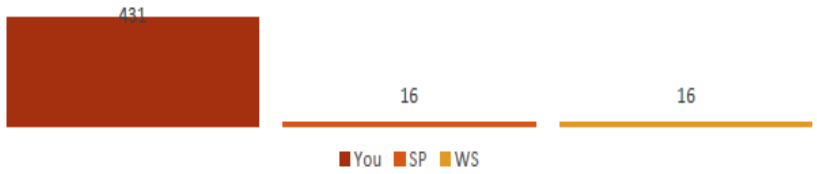
TOP MEDICATIONS PRESCRIBED *(FULL REPORT PERIOD)*

DEXTROAMPHETAMINE SULF-SACCHARATE/AMPHETAMINE SULF-ASPARTATE	HYDROCODONE BITARTRATE/ACETAMINOPHEN	ACETAMINOPHEN WITH CODEINE PHOSPHATE

PRESCRIPTIONS BY DAILY MME (MORPHINE MILLIGRAM EQUIVALENT) *(FULL REPORT PERIOD)*



ANXIOLYTIC / SEDATIVE / HYPNOTIC PRESCRIBING *(MONTHLY AVERAGE)*

PRESCRIPTIONS	DOSAGE UNITS
	

PDMP USAGE *(MONTHLY AVERAGE)*

PDMP REQUESTS BY YOU	PDMP REQUESTS BY YOUR DELEGATE(S)	SIMILAR PRESCRIBER AVERAGE	SPECIALTY FIELD AVERAGE
5	0	4	3

PATIENTS EXCEEDING MULTIPLE PROVIDER THRESHOLDS *(FULL REPORT PERIOD)*

PATIENTS EXCEEDING MULTIPLE PRESCRIBER THRESHOLD	PATIENTS EXCEEDING MULTIPLE PHARMACY THRESHOLD
25	15

DANGEROUS COMBINATION THERAPY

PRESCRIPTIONS FOR OPIOID + BENZO IN SAME MONTH		PRESCRIPTIONS FOR OPIOID + BENZO + CARISOPRODOL IN SAME MONTH	
25	35	15	20
BY YOU	BY YOU + OTHER PRESCRIBERS	BY YOU	BY YOU + OTHER PRESCRIBERS

PMP Enhancements

Auditing the bi-annual audit

- PMP ability run reports on who has performed audit
- Alert to audit
- Audit keeps your delegate active
- Failure to audit results in delegate lockout

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The Evolution Of Prescribing Standards

Joseph M. Gorrell, Esq., *Brach Eichler LLC*

Pain as the 5th Vital Sign

- 1990—Editorial by Mitchell B. Max, M.D. in the Annals of Internal Medicine
- "The current state of analgesic practice poses a paradox. Experts agree that most patients with acute pain and chronic cancer pain can be kept comfortable when treated with a simple regimen-an aspirin-like drug plus an attentively titrated dose of opiate. Yet surveys in the past 20 years suggest that, even in the world's leading hospitals, a large proportion of these patients are not given sufficient doses of these analgesics to maintain comfort."

Pain as the 5th Vital Sign

Dr. Max maintained that:

- The finding that therapeutic use of opiate analgesics rarely results in addiction has been widely published for a decade
- Many experts agree that many patients remain undermedicated
- Patients often fail to report or underreport pain, and physicians are "rarely held accountable"

Pain as the 5th Vital Sign

Dr. Max advocated:

- Making pain visible
- Educating physicians as to how to elicit their patients' pain
- Assure patients that their complaints will be addressed promptly
- Monitor physicians' response to complaints of pain

The Joint Commission's Pain Standards: Origins and Evolution (May 5, 2017)

- Noted Dr. Max's "clarion call " for improvement in pain assessment and treatment
- Noted quality assurance standards published by the American Pain Society in 1991
  - Chart and display pain and relief
  - Develop pain intensity measurement standard
  - Identify values for pain intensity rating and pain relief rating to elicit a review of current pain therapy

The Joint Commission's Pain Standards: Origins and Evolution (May 5, 2017)

- Joint Commission's First Pain Standards—1997
  - Emphasis on the need to do systematic assessments and quantitative measures of pain (e.g., the 10 point scale)
  - Emphasis on the need to do systematic assessments of pain

Result: In hospitals a numeric pain scale became mandatory and an "acceptable" pain score became required for discharge

- Pain became the "fifth vital sign" and "the enemy that had to be eradicated"

The Joint Commission's Pain Standards: Origins and Evolution (May 5, 2017)

- No large national studies were conducted to assess the benefits (e.g. improved pain assessment) or risks
- By 2003, signs appeared that some practitioners had become overzealous in treating pain
- The Institute for Safe Medication Practices identified an "alarming increase" in oversedation and fatal respiratory depression
- A rapid increase in the prescription of opioids ensued
- At the same time, the FDA approved labeling for Oxycontin that said addiction was "very rare" and delayed absorption reduced the likelihood of abuse

The Joint Commission's Pain Standards: Origins and Evolution (May 5, 2017)

- In 2009, the Joint Commission eliminated the requirement that pain be assessed in all patients, recognizing that it was not appropriate for patients with certain diagnoses, and the fact that no similar standard existed requiring the universal assessment of other symptoms

Draft Standards-2017: Emphasis on Safe Opioid Use

- Identification of psychosocial risk factors for addiction
- Involving patients in their treatment plan
- Facilitate access to state drug monitoring data bases (e.g., the New Jersey PMP)
- Standards have yet to be adopted

CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016

- Response to the widespread and increasing use of Opioids and the epidemic of deaths and abuse
- The Guideline is specifically addressed to primary care physicians prescribing for pain, not specialists
- Estimates that 11.2% of the adult population experience substantial chronic pain
- Chronic pain is defined as pain conditions that last for three months or more

Twelve Recommendations for Treatment of Chronic Pain by the CDC

1. Nonpharmalogic therapy and nonopioid pharmalogic therapy are preferred and should be used, even if opioids are used
2. Treatment goals should be established before opioid therapy is commenced
3. Known risks should be discussed with the patient at the outset and during treatment
4. Immediate release opioids should be prescribed when opioid therapy is commenced, not extended release opioids

Twelve Recommendations for Treatment of Chronic Pain by the CDC (cont.)

5. At the outset of treatment, the lowest effective dose should be prescribed and care should be taken for any increase in dose, generally no more than 50 MME per day. For those already on 90 MME per day or more, they should be offered the opportunity to taper down
6. For the onset of acute pain, often three days of medication will suffice; 7 days will rarely be needed
7. Benefits and harms should be evaluated within 1 to 4 weeks of starting opioid therapy, and at least every 3 months

Twelve Recommendations for Treatment of Chronic Pain by the CDC (cont.)

8. Risk factors should be evaluated before beginning opioids and periodically during treatment
9. Physicians should review the PMP when starting therapy and every 3 months thereafter
10. Urine testing should be done prior to prescribing opioids for chronic pain and testing annually should be considered

Twelve Recommendations for Treatment of Chronic Pain by the CDC (cont.)

11. Physicians should avoid prescribing benzodiazepines with opioids "whenever possible"

12. Treatment for patients addicted to opioids, such as buprenorphine or methadone, plus behavioral therapy should be offered

April 10, 2019 CDC Letter to Daniel P. Alford, M.D., MPH, Professor of Medicine, Boston University

- Letter addressed concern with potential unintentional harms from misinterpretation of the Guidelines
- “CDC is committed to addressing the needs of patients living with chronic pain while reducing the risk of opioid-related misuse, overdose and death.”

April 10, 2019 CDC Letter to Daniel P. Alford, M.D., MPH, Professor of Medicine, Boston University (cont.)

- "The Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm."
- Tapering or reducing dosage should occur only when patient harm outweighs patient benefit of opioid therapy
- If done, tapering should be slow, e.g., 10% per week or 10% per month, to minimize opioid withdrawal