IDFPR

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Objectives

- Understand why IDFPR (and the MDB) adopted the FSMB Guidelines
- Identify the key features of the FSMB Guidelines
- Develop a plan for integrating these guidelines into your clinical practice

Opioids: The History

Opioids and narcotic analgesics have been used for millennia as effective drugs used for the treatment of pain.

The Sumerians in Mesopotamia first cultivated the poppy plant about 3400 BCE. Its cultivation and use eventually spread throughout Europe and Asia.
(Rosenblum, A. et al., 2008)

Opioids: The History (Continue)

Several developments occurred beginning over 200 years ago transforming the clinical perceptions and use of opioids, and ushering in the modern era of the clinical use of opioids.

Morphine was extracted from opium in 1803 in Germany by the German pharmacist, Friedrich Serturner.

He isolated its most valuable component, the alkaloid, the active ingredient in the plant that causes pain relief.
He called it morphine, after the Greek god of dreams Morpheus.

Opioids: The History (Continue)

Other analgesics were developed over the next century, including:

1916-Oxycodone (Approved by the FDA in 1950)

1920-hydrocodone

1959-fentanyl

Opioids: Pharmacology

There are at least three classical opioid receptors:

- Mu (μ) (agonist morphine): Mu receptors are found in the brainstem and medial thalamus.

-Kappa (κ) (agonist ketocyclazocine): Kappa receptors are found in the limbic areas, brain stem, and spinal cord.

-Delta (δ) (agonist delta-alanine-delta-leucine-enkephalin): Delta receptors are located in the brain; their effects are not well studied.
(Inturriai, C. 2002), (Trescot, A. et al., 2008)

Opioids: Pharmacology (Continue)

Opioids can act at these receptors as agonists, antagonists or partial agonists, which will be reviewed below.

Opioids may also be classified according to their mode of synthesis into alkaloids, semi-synthetic and synthetic compounds.

Endogenous opioids or endorphins in the CNS opioid receptors were discovered in early 1970s. (Pergolizzi, J. et al., 2017)

Opioids: Pharmacology (Continue)

Classification of opioids

Agonists	**Antagonists**	**Agonist/antagonists**	**Partial agonists**
Morphine	Diprenorphine	Dezocine	Buprenorphine
Codeine	Naloxone	Nalorphine	Meptazinol
Oxycodone	Naltrexone	Pentazocine	
Tramadol	Nalmefene	Nalbuphine	
Diamorphine		Butorphanol	
Hydromorphone			

(Vallejo, R. et al, 2011)

Drug Scheduling (Continue)

A Listing of drugs and chemicals and their schedule are located at Controlled Substance Act (CSA) Scheduling or CSA Scheduling by Alphabetical Order. A substance need not be listed as a controlled substance to be treated as a Schedule I substance for criminal prosecution (DEA, 2019)

Drug Scheduling (Continue)

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse: heroin, lysergic acid diethylamide (LSD) and marijuana.

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous: Combination products with less than 15 mgs of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamines, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone, fentanyl and Dexedrine.

Drug Scheduling (Continue)

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence: Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids and testosterone.

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Tramadol and Ambien.

Drug Scheduling (Continue)

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin codeine or per 100 milliliters (Robitussin AC), Lomotil and Lyrica.

Opioids: A Brief History of the Opioid Crisis

There are many commentaries that
attempt to explain how this crisis unfolded.
None perfectly.

Opioids: A Brief History of the Opioid Crisis (Continue)

The three phases of an intertwined epidemic narrative
(Dasgupta, N. et al., 2018)

The root causes of the current opioid crisis is deeper that the popular narrative suggests.

There could be considered three phases that slowly evolved over 30 years.

Opioids: A Brief History of the Opioid Crisis (Continue)

First, in the 1980s and 1990s, it there was a “ revelation” that pain was undertreated. Beginning in the 1990’s, there was the efforts of the American Pain Society to recognize pain as the fifth vital sign, echoed later by the VA and Joint Commission.

Opioids: A Brief History of the Opioid Crisis (Continue)

Previously, chronic pain was managed with cognitive behavioral therapy.
An Institute of Medicine report attributed the rise in chronic pain prevalence during the 1990s to the following:

-greater patient expectations for pain relief
-musculoskeletal disorders of an aging population
-obesity
-increased survivorship after injury and cancer
-increasing frequency and complexity of surgery
(IOM, 2011)

Opioids: A Brief History of the Opioid Crisis (Continue)

Insurers limited coverage of behavioral pain therapy.

Pharmaceutical innovation propagated extended-release formulations, transdermal patches, and nasal sprays.

Medical device manufacturers drove a proliferation of novel implants.

Some pharmaceutical marketing improperly minimized the addictive potential of the newer opioid preparations.

Opioids: A Brief History of the Opioid Crisis (Continue)

Second, in around 2010, concerns increase over intertwining opioid analgesic and heroin use. After remaining stable for years, heroin overdose deaths tripled between 2010 and 2014. (CDC, 2014)

Some patients who used prescription opioids transitioned to a more potent and cheaper alternative. Clinicians and policymakers began to reassessed the effectiveness and safety of opioid analgesics. (Mars, S. et al., 2014)

Opioids: A Brief History of the Opioid Crisis (Continue)

Third, beginning in 2013, there was the emergence of potent and less bulky products, for example, illicitly manufactured fentanyl and its analogs.

Between 2013 and 2016, deaths attributed to fentanyl analogs spiked by a s 540%.
(Katz, 2017)

Individuals entering drug treatment are more likely to report having started opioid use with heroin, not a specific prescription analgesic.
(Cicero T. et al., 2017)

Opioids: A Brief History of the Opioid Crisis (Continue)

Another has been a social construct to explain the crisis,
i.e. the Social Determinants of Health.

A structural analysis focuses on “diseases of despair,”
referring to the interconnected trends in fatal drug overdose,
alcohol-related disease, and suicide.
(Meldrum M., 2016)

An analysis focused on the Midwest, Appalachia, and New England
combined mortality rates for diseases of despair increased as county
economic distress worsened.
(Monnat S., 2016)

Opioids: A Brief History of the Opioid Crisis (Continue)

Poverty and substance-use problems operate synergistically, reinforced by psychiatric disorders and unstable housing.

In much of the country, the counties with the lowest levels of social capital have the highest overdose rates.
(Zoorob M. & Salemi J., 2017)

The Role of Government Organizations and Non-Government Organizations

There are several government organizations (GO) and non-government organizations (NGO) that influence the development and regulation of licensed controlled substances, including federal and state level governmental organizations, and academic, medical specialty society and other non-government organizations.

Although not formally synchronizing their agendas and activities, many times a synergic process occurs to advance and improve the science and practice of treating patients with opioids and other controlled substances by GO and NGO.

The Role of Government Organizations and Non-Government Organizations (Continue)

The FDA

The DEA

The FSMB

The NIH

SAMHSA

The CDC

The APS

The Opioid Guidelines

These have been developed due to several historical processes leading up to their development:

-The American Pain Society set forth pain treatment guidelines in 1995
-Pain as a 5th vital sign started to be advocated in 1999, which was later rescinded by the AMA (Scher, 2018)
-The Joint Commission added credence to this in 2001

The Opioid Guidelines (Continue)

Some of the central issues then still exist now:

-Pain is entirely subjective
-Physicians and other HCPs still consider pain as a 5th vital sign
-There are significant variance with prescribing patterns across specialties, geographic areas, health systems and insurance coverage
-Physicians may prescribe opioids out of habit incorrectly and may be concerned about negative web reviews

The Opioid Guidelines (Continue)

Some of the central issues then still exist now:

-Poor communications about chronic pain and opioids between clinicians and patients may lead to poor patient experiences and physician reported visit difficulty (Henry, 2018)

- There is no maximum daily dose as with other therapeutics

-Hyperalgesia, the effect of ongoing or worsening pain

These Guidelines have been to address some of these variables and confounding effects on the safe and consistent use of chronic opioids

FSMB vs CDC Guidelines

FSMB

- Chronic, non-cancer pain
- Committee
  - Board members, clinicians, representatives of specialty societies, etc.
- Adopted by many state boards
- Guidance (“consider”)
- 22 pages

CDC

- Chronic, non-cancer pain
- Steering Committee, expert group, stakeholder group, peer review, etc.
- New
- Proscriptive (“should”)
- 51 pages

The Opioid Guidelines (Continue)

The 2016 CDC Recommendations for Prescribing Opioids for Chronic Pain Outside of Active Cancer, Palliative, and End-of-Life Care

The goals of the guidelines was similar to the APS guidelines 7 years earlier; to improve opioid prescribing through guidelines to ensure patient safety.

Long-term opioid therapy is defined as use of opioids on most days for >3 month.

There are both a simple summary of the guidelines (CDC, n.d.) and the guideline documentation available, the later also having an extensive reference list.

The Opioid Guidelines (Continue)

The 2016 CDC Recommendations (Continue)

Determining When to Initiate or Continue Opioids for Chronic Pain

1) Nonpharmacologic therapy and nonopioid pharmacologic therapy preferred
   Opioids should be combined with nonpharmacologic or nonopioid therapies
2) Before starting opioids establish treatment goals with all patients
   Consider how therapy will be discontinued if benefits < risks
   Continue opioids only if there is clinically meaningful improvement
3) Before starting and periodically during opioid therapy, discuss known risks

The Opioid Guidelines (Continue)

The 2016 CDC Recommendations (Continue)

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4) When starting opioid therapy prescribe 1st use immediate-release opioids.
5) When opioids are started the lowest effective dosage are to be used
   Use caution when prescribing opioids at any dosage
   Reassess benefits and risks when increasing dosage to =50 MME/day
   Avoid increasing dosage to =90 MME/day or carefully justify the decision
6) Prescribe the lowest effective dose of immediate-release opioids
   Prescribe no greater quantity than needed for the expected duration of pain
   3 days or less will often be sufficient, > 7 days will rarely be needed

The Opioid Guidelines (Continue)

The 2016 CDC Recommendations (Continue)

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

7) Evaluate benefits/harms with patients within 1 to 4 weeks of starting opioids
Evaluate benefits/harms of continued therapy with patients every 3 months
If benefits < harms optimize other therapies and taper/discontinue opioids

The Opioid Guidelines (Continue)

The 2016 CDC Recommendations (Continue)

Assessing Risk and Addressing Harms of Opioid Use

8) At start of and then periodically, evaluate risks for opioid-related harms.
   The management plan to have strategies to mitigate risk, such as naloxone
9) Review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP)
   Review the PDMP data when starting opioid therapy for chronic pain and then every prescription to every 3 months

The Opioid Guidelines (Continue)

The 2016 CDC Recommendations (Continue)

Assessing Risk and Addressing Harms of Opioid Use

10) Utilize urine drug testing before starting opioid therapy and consider urine drug testing at least annually
11) Avoid prescribing opioid pain medication and benzodiazepines together when possible
12) Offer or arrange evidence-based treatment, i.e. MAT, with buprenorphine or methadone with behavioral therapies for patients with opioid use disorder

Federation of State Medical Boards (FSMB)

- 70 Member Boards
- Advocacy
- Education
  - Boards
  - Public
- Database
- Exams
  - USMLE
- Policy
  - *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* (2015)

The Opioid Guidelines (Continue)

The 2017 Federation of State Medical Boards (FSMB) Guidelines for the Chronic Use of Opioid Analgesics

-Sought the input from both clinicians and policy stakeholders
-Reflected both the CDC guidelines and FDA sources
-To be used as a guidance to state medical and osteopathic boards

The guidelines has several key elements like the CDC guidelines, and utilizes extended detail rich prose as oppose to a bullet point style. The key elements and their main points include the following:

The Opioid Guidelines (Continue)

The 2017 FSMB Guidelines (Continue)

Patient Evaluation and Risk Stratification

Reviews necessary documentation, re: History and physical, past treatments, the characteristics of the pain and indications for treatment

Development of a Treatment Plan and Goals

Reviews necessary written treatment plans, types of nonopioid therapeutics and need for further diagnostic testing and referrals

Informed Consent and Treatment Agreement

Reviews elements of a proper informed consent and a separate written treatment plan (FSMB, 2017)

The Opioid Guidelines (Continue)

The 2017 FSMB Guidelines (Continue)

Initiating an Opioid Trial

Reviews non-opioid and non pharmacological treatments to consider first and need for initial short-term opioid treatment trials

Ongoing Monitoring and Adapting the Treatment Plan

Explains reviewing and documenting a patient's clinical progress, the review of a state's PDMP and measurement tools to assess pain

Periodic and Unannounced Drug Testing

Reviews the role of urine drug screening (FSMB, 2017)

The Opioid Guidelines (Continue)

The 2017 FSMB Guidelines (Continue)

Adapting Treatment

Details how clinicians must adapt treatment plans regularly tailored to the patient's progress, or lack of, and need to note aberrant behavior

Consultation and Referral

Reviews the criteria to refer to pain specialists, psychiatrist and others depending on the patient's needs and utilizing opioid treatment programs

Discontinuing Opioid Therapy

Reviews safely structured tapering programs and the need for an end strategy at the onset of treatment (FSMB, 2017)

The Opioid Guidelines (Continue)

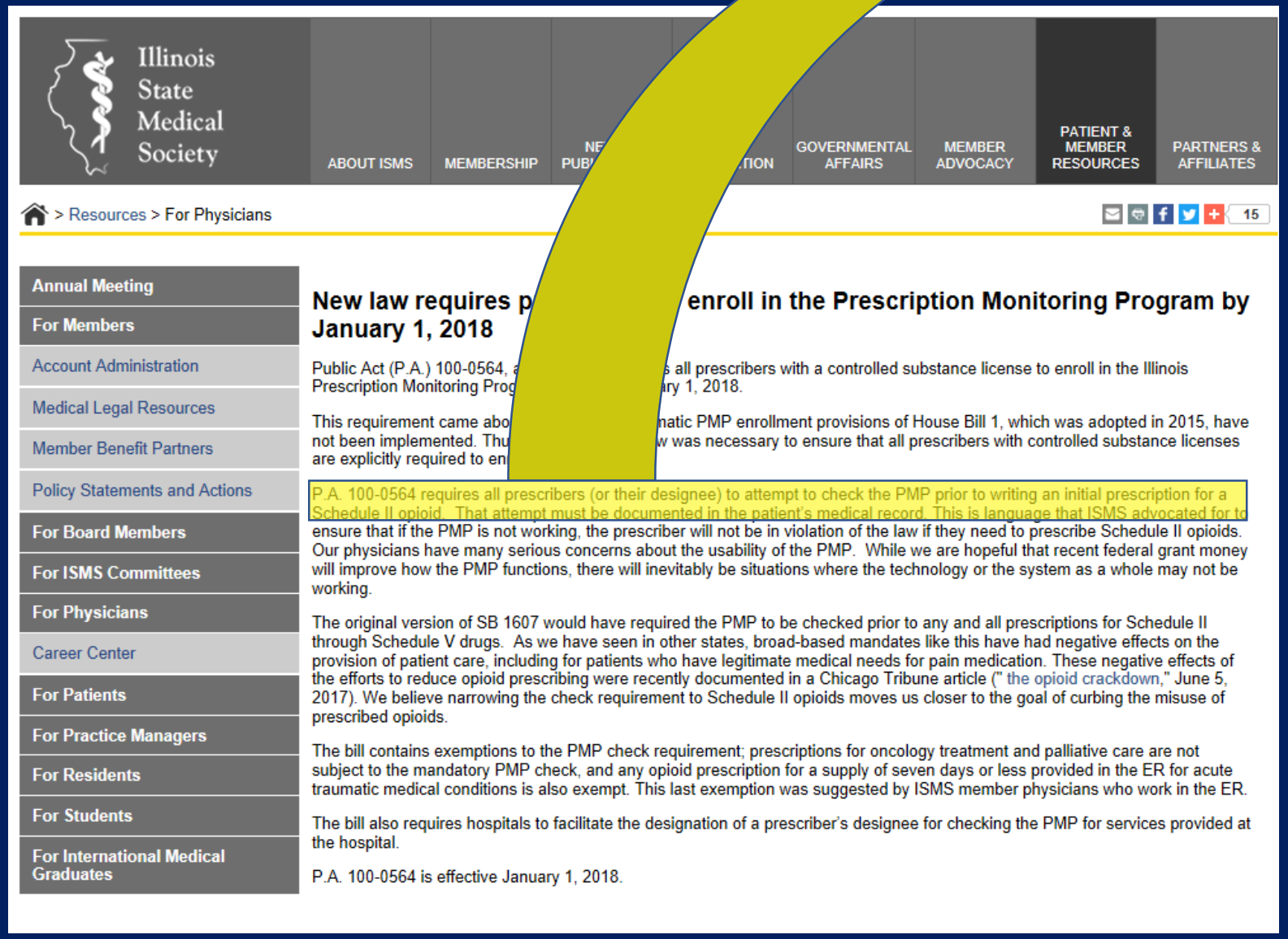
The 2017 FSMB Guidelines (Continue)

Medical Records

All the proper aspects of medical recording keeping centering around the use of opioids is reviewed with an emphasize on the informed consent, results of risk assessments and a proper history performed.

Compliance with Controlled Substance Laws and Regulations

Explains the regulatory and federal references available and the need for the clinician to be in compliance with state and federal statutes related to controlled substance prescribing (FSMB, 2017)



Requires all prescribers to attempt to check the PMP prior to writing an initial prescription for a Schedule II opioid

The Chart Review

The CDC guidelines are complete and tend to offer bullet specific recommendations for safe chronic opioid prescribing practices.

The FSMB guidelines are also complete and tend to offer expanded, detail rich recommendations that amplify the CDC guidelines.

Both can be used when reviewing medical records.

The review of a provider's medical records should reflect best practices and evidence-based medicine that are encapsulated in these guidelines.

The Chart Review (Continue)

In reviewing medical records and practice patterns of physicians and other providers, bear in mind that there are differences between Chronic Opioid Treatment and Opioid Use Disorder.

Chronic Opioid Treatment
The treatment of chronic pain that has been properly evaluated, characterized and managed in such a manner that chronic opioid treatment would be considered a reasonable therapeutic regiment that meets the standard of care.

The Chart Review (Continue)

In reviewing medical records and practice patterns of physicians and other providers, be sure to review Morphine Milligram Equivalents (MME) where appropriate. Below is a brief list of the MME of common opioids; the toolkit has further references as well.

The Chart Review (Continue)

Morphine Milligram Equivalents

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone 1-20 mg/day	4
Morphine	1
Oxycodone	1.5
Oxymorphone	3

(CDC, n.d.)

The Chart Review (Continue)

The review should essentially focus on four key areas in the medical records and the care of the patient.
These key areas include:

-The five major supportive structures of Chronic Opioid Therapy
-The required Patient History component of the clinical encounter
-The required Patient Physical Exam/Medical Studies component of the clinical encounter
-The required Impression/Plan/Medical Decision-Making component of the clinical encounter

The Chart Review (Continue)

The Five Supporting Structures

-A complete informed consent at the initiation of Chronic Opioid Treatment
-A complete treatment contract at the initiation of Chronic Opioid Treatment
-A complete treatment plan at the initiation of Chronic Opioid Treatment
-Urine Drug Screening at the initiation of Chronic Opioid Treatment and periodically afterwards
-A review of the state Prescription Drug Monitoring Program at the initiation of Chronic Opioid Treatment and periodically afterwards

The Chart Review (Continue)

Various methodologies can be used to review medical records. One structured process would be to review records in two groups: a) the new patient or an established patient starting Chronic Opioid Treatment and b) the established patient on opioids having ongoing care and monitoring for Chronic Opioid Treatment.

Case One

Dr. Jones was the Chairman of the Department of Cardiology at a local hospital. His 30-year-old son had a history of painful peripheral neuropathy treated with long-term opioids by a pain physician, who recently retired. Dr. Jones, who was self-treating himself with long-term testosterone for hypogonadism, felt comfortable he could objectively and safely treat his son, just as his treats himself, until his son found another pain physician. He also decided not to maintain records as this was a short term agreement.

What concerns if any are present?

Case Two

Dr. Smith was a family physician and agreed to assume pain management for one of his patients. The patient was a 68 year old with diabetes, coronary artery disease and low back pain. The patient's previous physician was treating the later for several years with Fentanyl and morphine for breakthrough pain. Dr. Smith noted the patient never had an evaluation for the pain and elected not to initiate one as the patient was stable on narcotics, and also elected not to have any formal agreement or urine drug screening as he was otherwise a trustworthy and a long term compliant patient.

What concerns if any are present?

Case Three

Dr McCoy was an internist and was treating one of her patients with anxiety. The patient was started on Valium, did well, but the internist referred the patient to psychiatry as the patient also was chronically on Norco for ill-defined pain from an orthopedic surgeon. The patient refused. The internist felt pressured to continue benzodiazepines, did so and added Zoloft, an SSRI, in attempt to decrease the use of controlled substances. The patient refused this as well. The patient insisted she Felt fine with Norco and Valium and wanted no further interventions. Dr. McCoy compiled to avoid upsetting the patient.

What concerns if any are present?

Questions?

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Toolkits

The Guidelines

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Clinical Tools

2015 AGS Beers Criteria Pocket Guide. Accessed on 15 June, 2019 from: http://www.ospdocs.com/resources/uploads/files/Pocket%20Guide%20to%202015%20Beers%20Criteria.pdf

Toolkits (Continue)

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Morphine Milligram Equivalents
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Toolkits (Continue)

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Opioid Use Disorder

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Opioid Use and Opioid Use Disorder in Pregnancy

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