

Opioid Regulations Section 9.0 (effective April 1, 2017)

New Opioid Prescription

- 7 day supply max
- Minors - discussion with parent/guardian of risks and why opioid are necessary

New Opioid Prescription for acute medical condition that requires > 7 day supply

- Document condition in medical record
- Document that non-opiate alternative was not appropriate
- PMP query
- Informed Consent
- Schedule & undertake follow-up visit

ALL Refills/Subsequent Prescriptions

(by same provider/practice for same episode)

- PMP query (if not done already) - required at either at 1st or 2nd prescription & provider's discretion thereafter
- Fluid drug screen – at provider's discretion
- Physical exam - required as part of EVERY follow-up and/or refill (refill without office visit ONLY if above >7day protocol done at initial script; otherwise office exam for any refill)
- Documentation of discussion (if not done already) about relevant history, risks/benefits of opioids and their alternatives, other available treatments and whether opioids are contra-indicated.
- Informed consent (if not done already)
- Schedule & undertake follow-up visits with evaluations (to determine changes/modifications in the treatment plan).
- Exemption: if >7 day protocol was initially followed as above, the prescriber CAN provide a subsequent 7 day refill without fulfilling the refill/subsequent requirements above (i.e. phone or eRx refill). This 7 day refill is to be used until pt returns to office for followup visit and physical exam.

Chronic Pain
(defined as any pain > 90 days)

- PMP query at prescriber's discretion OR at least every 6 months (at least) OR whenever -
 - concurrent benzodiazepines prescribed
 - 'at risk' assessment made (i.e. ORT/SOAP)
 - aberrant prescription behavior (i.e. requests for early/lost refills)
- Fluid drug screen every 6 months, at least
- Treatment Agreement
- Risk Assessment (must document)
- Document which alternative treatments have been tried (inc. non-pharmacologic treatments) and their adequacy/effectiveness for sufficient management of pain.
- Make efforts to address psychiatric and medial comorbidities
- Seek consult with addiction specialist, if adulterated drug tests, diversion or obtained controlled substances outside the Treatment Agreement (at provider's discretion and if such an addiction specialists is available based on community availability and patient's coverage).

Exemptions

Exemptions written into the regulation:

- Terminally ill/palliative care (inc. hospice care)
- Active cancer treatment and any subsequent cancer-related pain
- Hospital pts during hospital stay (or similar administration of supervised opioids during registered stay at other ambulatory facilities such as emergency departments, 23 hours observations, surgery centers and wound centers)
- Discharge prescriptions from inpt/outpt procedures are NOT exempt and are fully subject to above regulations. However, if >7 day protocol was initially followed as above, the prescriber CAN provide a subsequent 7 day refill without fulfilling the refill/subsequent requirements above.

Exemptions based on clinical guidelines:

- Emergency Department care – when following the DE ACEP Guidelines (inc max 72 hr. prescription); however, ED visits are considered separate episodes & are subject to the initial prescription requirements when not under DE ACEP Guidelines.

Background Info

- **PMP Query** – inquiry to the state PMP by prescriber or their delegate. Data from other sources, including PBM’s and Surescripts do not satisfy this requirement. The state archives the audit trail so there is no requirement to keep a copy of the query; however, if a prescriber chooses to archive their own copy, the copy can be via either print, scan, or import PDF into the EHR.
 - **Delegates** -need official & prescribers authorization. They are then attached to a single prescriber but can be separately assigned in the PMP system under multiple different prescribers. Delegates can cross cover within a practice when working with different prescribers (without changing their delegation).
- **Treatment Agreement** must include:
 - Patient’s agreement to take medications as prescribed, with a specific protocol for lost prescriptions and early refills.
 - Reasons that medication therapy may be re-evaluated tapered or discontinued, including but not limited to: violation of the Treatment Agreement or lack of effectiveness.
 - The requirement that all chronic management prescriptions are provided by a single prescriber or a limited agreed upon group of practitioners.
 - The patient’s agreement not to abuse alcohol or use other medically unauthorized substances or medications.
 - Acknowledgement that violation of the agreement may result in action as deemed appropriate by the prescribing practitioner, such as a change in the treatment plan, a referral to a pain specialist, or referral to an addiction treatment program.
 - Requirements that fluid drug screens be performed at random intervals at the practitioner’s discretion, but no less than six months.
- **Informed Consent** much include at least:
 - The drugs potential for addiction, abuse and misuse.
 - Risks of life-threatening respiratory depression associated with the drug.
 - Potential for fatal overdose
 - as a result of accidental exposure, especially children
 - when interacting with alcohol
 - Neonatal opioid withdrawal symptoms.
 - Other potentially fatal drug interactions, such as with benzodiazepines.