Define/Clarify:

I. PMC Registration

- A. Is there a way to provide a bright-line distinction between exempt and registered PMCs?
 - 1. Input suggested for the creation of a "safe harbor." What would this be and how would/could it be done? How can a "safe harbor" be designed to incentivize the treatment of chronic pain patients who fell off the grid by losing their original physician? The "safe harbor" could not be an exemption from all inspection because exemptions would need periodic confirmation, correct?
 - 2. Input indicated that we should consider multi-modal approaches to pain management for purposes of exemption. What is meant by this and how would it apply regarding area of specialty and personally performed interventions per the statute?
 - 3. Consider a presumption of exemption if the provider was sub-certified in pain management and ordered qualifying interventions for the majority of patients in addition to medication. What are "qualifying interventions" and at what interval, frequency, etc. are they ordered? How would this be verified?
 - 4. We discussed exemption for multi-disciplinary practices (spectrum of practice as well as comprehensive care vs prescription only clinics). Does this mean that all registered clinics provide only prescriptions to a majority of patients, or do they provide other treatment but just not to a majority of the pain patients?
 - 5. We discussed what treatments would help qualify a PMC as exempt. Should this include only personally performed interventions? (Possible presumption of exemption if sub-certified in pain management) Or should we include "and ordering qualifying interventions for majority of patients in addition to medication?"
 - 6. We discussed collaboration with other providers in providing comprehensive pain treatment. How would that be different than multi-modal or multi-disciplinary?
 - 7. Please consider statutory, rule, and policy requirements/changes for all of the above.

B. Incentive to register

1. Incentives—Are there ways to incentivize clinics to register? Advertising – Registered clinics would be able to advertise state board certification, so even if a clinic could claim exemption there would be incentive to register (ensure public confidence by allowing inspections?)

- 2. Administrative burdens What are they and is there anything that might lessen them?
- 3. Patients expressed concerns over the stigma of being a pain patient. What is the stigma? How would going to a registered clinic help ease any stigma?
- 4. Input seemed to indicate rule requirements for registered PMCs may discourage registration (see 195.4(c) through (f)). Are there certain requirements that discourage registration more than others? How do those requirements discourage registration?
- 5. Ensure you consider statutory, rule, and policy requirements/changes for all of the above.
- C. Who must register Tex. Occ. Code Section 168.002(7); Rule 195.4(b)(7)
 - 1. It was discussed that there are areas of specialty contemplated under the existing statute. Should ABMS/AOA with sub-certification in pain treatment be the only recognized "area of specialty" toward exemption? Therefore, if a provider does not have such sub-specialty, must register? Should every physician in the practice have such specialty in order for the practice to be exempt?
 - 2. Should only the medical director/ owner be liable for failure to register, or should all physicians associated with a pain clinic be liable?
 - 3. Please consider statutory, rule, and policy requirements/changes for all of the above.

D. Clarify audit vs. inspection vs. investigation process

- 1. Timeframe subject to review Should there be a different timeframe for an audit and inspection versus an investigation arising from a complaint? The consensus seemed to be that looking at a single month of patient encounters is insufficient to provide a good "snapshot" of operations at a practice. Would at least two months for an audit and/or inspection provide a better idea of how the clinic operates? Should there be a different time period for investigations i.e., 90 days? Depending on findings, a physician or clinic may be required to register or not be exempt as claimed.
- 2. Use of PMP and other tools to determine percentage of controlled substances being prescribed when doing audits and inspections Are there other records that need to be reviewed, such as records showing non-prescription treatment/interventions, non-CS prescriptions, or non-prescription CS like injections, steroids, Ketamine treatment done on-site?

- 3. Evidence of qualifying interventions How are or should procedure records be kept and maintained to allow review by TMB?
- 4. Scope of review When doing an audit should all prescribing done in the entire clinic be aggregated for review, or should each physician be subject to review individually? When doing an investigation, should it be focused only on the individually identified prescriber or the entire clinic if there are multiple physicians?
- 5. Should all clinics, exempt or otherwise, be inspected initially for verification of status? Or is there some method of documentation review/analysis that could be initially required? Should there be different requirements and frequency depending on number of inspections completed, issues found and corrected (onsite vs paper; more frequent inspections if serious issues identified; investigation opened if issues not corrected or indicate serious practice deficiencies/pill mill)
- 6. Please consider statutory, rule, and policy requirements/changes for all of the above.

II. General issues related to treatment of pain

- A. Continued work on definitions related to acute, chronic, post-surgical pain; Pre- and post-surgical Rx's vs pain treatment
- B. Stigma (patients and physicians)
- C. Administrative burden
- D. Continuity of care (termination of care, getting new physician)
- E. NarxCare score
- F. New patient should TMB allow continuation of previous script?
- G. Gold card Pre-authorization gold card from TDI could be a means of exempting pain management physicians from some TMB requirements. Are there pros and cons if TMB provided for such an exemption?
- H. Insurance maximum, out of pocket caps
- I. Please consider statutory, rule, and policy requirements/changes for all of the above.

III. PMC Applicability

Considering changes in required PMP checks and technological changes since PMC registration first appeared:

- A. Is PMC registration as useful as originally intended by the Legislature?
- B. Is PMC registration as necessary as originally intended by the Legislature?
- C. Are PMC registration exemption options swallowing up the point of registration?