Informed Consent and Controlled Substance Agreements

Controlled substance agreements (CSA) and informed consent for opioid therapy are pillars of good, comprehensive opioid stewardship. CSAs and informed consent can be presented as separate documents or as part of the same document, but they are distinct processes with differing goals.

- **A Controlled Substance Agreement** is a planning document that clearly delineates patient expectations and sets the rules of the road for your practice. A CSA reinforces good opioid stewardship. It helps standardize clinician practice and educates patients on behaviors that are unsafe, illegal or are necessary to monitor for and mitigate risk of drug diversion, aberrancy or substance use disorder (ie urine drug screening & pill counts).
- **Informed consent** is a process which occurs between a physician and a competent patient regarding a specific medical intervention. Informed consent assures that patients are aware of their diagnosis, the purpose of the recommended medical intervention and the risks, benefits and alternatives to the medical intervention proposed. Informed consent for chronic opioid therapy is essential, considering the many risks and complications associated with opioids as a treatment modality.

It is best practice to review and update a patient's CSA and informed consent on a yearly basis. Below are examples of different controlled substance agreements, informed consent documents, patient education tools and risk mitigation tools with a brief descriptor.

Controlled Substance Agreements

Short, Controlled Substance Agreement

- Example 1 - adopted from the AAFP Chronic Pain Toolkit (CSA is on page 31)

Longer, Controlled Substance Agreements

- Example 2 - shared by Dr. Steven Wright
- Example 3 - CSAs by the Oregon Pain Guidance
- Example 4 - CSA developed by Greater Louisville Medical Society

Informed Consent Documents

- One Page Informed Consent with Patient Graphic
- Prescription Opioids for Patient Education

Combined Informed Consent / Controlled Substance Agreement Documents

- Example 5 - shared by Johns Hopkins is a combined informed consent & CSA
- Example 6 - Pennsylvania Sample Treatment Agreement
- Example 7 - Michigan OPEN Sample Treatment Agreement

Additional Documents

- High Risk Consent and Planning Form - is meant for patients identified at increased risk for adverse effects from COT, aids in safety planning and documentation of informed consent for increased risk.
- Chronic Opioid Therapy Shared Decision-Making Tool

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