7/9/2008

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# MATERIAL RISK NOTICE FORM

In 1995 the Oregon Legislature created the Intractable Pain Law, Oregon Revised Statutes (ORS) 677.470-485, and in response the Oregon Medical Board created an Oregon Administrative Rule (OAR) 847-015-0030 that included the key points of the Material Risk Notice (MRN) required by the Law. The MRN is essentially a documentation of a detailed PARQ (Procedure, Alternatives, Risks and Questions ) conference. The 2003 Legislative Session amended the Law to require the Oregon Medical Board to provide an example of a MRN for the benefit of Oregon physicians treating chronic, intractable pain. Use of the Board' s example form was/is NOT mandatory, but some similar form is mandatory.

The 2007 Legislative Session made significant changes in the Intractable Pain Law, which essentially changed it from a law dealing with chronic, intractable pain treated by physicians licensed by the Oregon Medical Board to a law dealing with all types of pain treated by Health Care Professionals licensed by Health Professional Regulatory Boards. The Oregon Pain Commission (OPC) proposed these changes to the Legislature, and although they were reluctant to do so, they recommended elimination of ORS 677.485, the requirement for the MRN. If this had been left in the Law, the MRN would have been required for all types of prescribing for pain, including acute pain. At a meeting of the OPC in December 2006, there was concern about discontinuing the MRN, but it was assumed that the Health Care Regulatory Boards would address this issue with Administrative Rules. The Oregon Medical Board has left the Administrative Rule on Material Risk Notices in place with some changes (OAR 847-015-0030).

The MRN supplied here was created and approved by the Board. It is NOT intended to be a [1]Pain Contract! This MRN form has been kept on one page and covers the required components of the Administrative Rule (OAR 847-015-0030). The boxes are for diagnosis(es), drugs to be used, goals, alternative treatments and additional therapies. WARNING: Any attempt to modify the current document will most likely lead to frustration, compliments of your word processor. Either use it in the PDF form as displayed or create your own form.

The **diagnosis** box is for documenting the disease process(es) causing the pain. The **drugs** box is for listing the drug(s) that are to be used. If the opioids in the treatment plan are significantly changed, then the MRN should be reviewed with the patient and the document revised as needed. The **goals** include significant reduction of pain as already printed on the form. In addition the patient should choose in consultation with the provider achievable simple goals. Achieving these goals should be used as a measure of the success of the treatment plan. If the patient is not having improved

[1]The Board does look upon a Pain Contract as being part of the Standard of Care, when managing long-term opioid treatment of chronic pain.

function, the treatment is not working. Subsequent adding and subtracting goals may prove helpful in managing some patients.

A list of **additional therapies** gives the provider a chance to make the patient understand that the treatment for chronic intractable pain includes patient participation in his/her own care and serves as notification that their participation in such things as mental health evaluation, physical therapy, urine screens etc. may be needed. These items can also be addressed as part of a Pain Contract.

On the bottom of the form the patient is asked to acknowledge that the provider has reviewed with him/her the information on the form to the patient's satisfaction, and whether the patient has requested more information and received that information to his/her satisfaction. The provider signature testifies that the provider has reviewed the form with the patient.

Even though the original legal requirement for a consultation in all cases of chronic intractable pain has been eliminated, there will be many situations when the recognized standard of care in managing these patients will require such consultations. This is especially true for cases in which the diagnosis or the appropriate treatment is unclear, the treatment is not accomplishing the expected goals, or the patient's medical condition appears to be complex and very difficult to manage.

The Oregon Medical Board's website has links to the Oregon Revised Statutes (ORS) and Oregon Administrative Rules (OAR) for your convenience. Please refer to the left side of the Board's home page, http://www.oregon.gov/OMB/ .

# MATERIAL RISK NOTICE

This will confirm that you, _____, have been diagnosed with the following condition(s) causing you chronic intractable pain:

I have recommended treating your condition with the following controlled substances:

In addition to significant reduction in your pain, your personal goals from therapy are:

1. 2. 3.

Alternatives to this therapy are:

1. 2. 3.

Additional therapies that may be necessary to assist you in reaching your goals are:

1. 2. 3.

**Notice of Risk**: The use of controlled substances may be associated with certain **risks such as, but not limited to**:

1. **Central Nervous System**: Sleepiness, decreased mental ability, and confusion. Avoid alcohol while taking these medications and use care when driving and operating machinery. Your ability to make decisions may be impaired.
2. **Cardiovascular**: Irregular heart rhythm from mild to severe.
3. **Respiratory**: Depression (slowing) of respiration and the possibility of inducing bronchospasm (wheezing) causing difficulty in catching your breath or shortness of breath in susceptible individuals.
4. **Gastrointestinal**: Constipation is common and may be severe. Nausea and vomiting may occur as well.
5. **Dermatological**: Itching and rash.
6. **Endocrine**: Decreased testosterone (male) and other sex hormones (females); dysfunctional sexual activity.
7. **Urinary**: Urinary retention (difficulty urinating).
8. **Pregnancy**: Newborn may be dependent on opioids and suffer withdrawal symptoms after birth
9. **Drug Interactions** with or altering the effect of other medications cannot be reliably predicted.
10. **Tolerance**: Increasing doses of drug may be needed over time to achieve the same (pain relieving) effect.
11. **Physical dependence and withdrawal**: Physical dependence develops within 3-4 weeks in most patients receiving daily doses of these drugs. If your medications are abruptly stopped, symptoms of withdrawal may occur. These include nausea, vomiting, sweating, generalized malaise (flu-like symptoms), abdominal cramps, palpitations (abnormal heartbeats). All controlled substances (narcotics) need to be slowly weaned (tapered off) under the direction of your physician.
12. **Addiction (Abuse):** This refers to abnormal behavior directed towards acquiring or using drugs in a non-medically supervised manner. Patients with a history of alcohol and/or drug abuse are at increased risk for developing addiction.
13. **Allergic reactions**: Are possible with any medication. This usually occurs early after initiation of the medication. Most side effects are transient and can be controlled by continued therapy or the use of other medications

This confirms that we discussed and you understand the above. I asked you if you wanted a more detailed explanation of the proposed treatment, the alternatives and the material risks, and you (Initial one):

_____ was satisfied with that explanation and desired no further information

_____ requested and received, in substantial detail, further explanation of the treatment, alternatives and material risks

(Initials)

_____ DATE _____

PATIENT SIGNATURE

Explained by me and signed in my presence.

_____ DATE _____

PHYSICIAN SIGNATURE