

MEDICAL BOARD ISSUES NEW RULES FOR ADMINISTERING, DISPENSING AND PRESCRIBING DRUGS

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A new regulation, effective November 3, 1997, will affect every physician who writes prescriptions or administers or dispenses drugs. Physicians' obligations, when writing a prescription, or dispensing drugs in the office, are now codified to include an affirmative obligation to conduct an examination or evaluation of the patient's condition before writing a prescription or dispensing a drug, and assurance that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient. Even greater regulatory standards and requirements are created for the prescription or dispensing of drugs scheduled as controlled dangerous substances. Failure to strictly adhere to these complex and highly specific requirements can lead to disciplinary action, including loss of license. It will also create a new benchmark for plaintiffs' lawyers in malpractice actions.

INFORMATION REQUIRED ON WRITTEN PRESCRIPTIONS:

The new regulation also carries forward an obligation, rarely followed, but always at issue in disciplinary actions, that a practitioner include certain specific information on each written prescription. The information includes:

1. The prescribing practitioner's full name, address, telephone number and proper academic degree or identification of professional practice for which licensed;
2. The full name, age and address of the patient;
3. The date of issuance;
4. The name, strength and quantity of the drug prescribed;
5. Words, in addition to numbers, to indicate the drug quantity authorized if the prescription is for a Schedule II controlled substance, for example: ten (10) Percodan; or five (5) Ritalin 5 mg.;
6. The number of refills permitted or time limit for refills, or both;
7. The handwritten original signature of the prescribing practitioner;
8. An explicit indication, by initials placed next to "do not substitute," if it is the prescribing practitioner's intention that a specified brand name drug be dispensed;
9. The prescribing practitioner's D.E.A. number, if the drug is a controlled substance; and
10. Adequate instruction for the patient as to frequency; a direction of "p.r.n." or "if needed" alone may be used if appropriate.

ADDITIONAL ADVICE TO PATIENTS WHEN PRESCRIBING:

Other requirements placed on physicians when writing a prescription include an obligation of a prescribing practitioner to advise each patient by adequate notice, for example, by a sign or pamphlet in the waiting room of the office, that the patient may request the practitioner to substitute a generic drug for any brand name drug prescribed. Further, each practitioner shall use only written prescription blanks which shall be imprinted with the words "substitution permissible" and "do not substitute," with a space for the prescribing practitioner's initials next to the chosen option, and which shall not include preprinted information designed to discourage or prohibit substitution.

DISPENSING MEDICATION FROM OFFICE SUBJECT TO SEVERE REGULATION AND RESTRICTION:

Physicians who dispense medication from their offices (including those who provide free samples) are now subject to stringent new requirements, clearly intended to deter them from dispensing, rather than writing a prescription. Keep in mind that the Board has broadly defined a drug as meaning any article recognized in the official U.S. Pharmacopoeia, official Homeopathic Pharmacopoeia of the U. S. or official National Formulary, or any supplement to those sources, including, but not limited to, a controlled substance, a prescription legend drug, an over-the-counter preparation, a vitamin

or food supplement, or any compounded combination of any of the above or transdermal patch or strip, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or medical condition in humans or intended to affect the structure or function of the human body. For purposes of the new regulation, dispensing is defined as the distribution of drugs for the personal use of a patient and does not include the in-office administration of drugs by way of injection, vaccine, allergenic extract or nebulized preparation, or the provision of multiple dose vials of injectable medications.

Physicians who dispense drugs in the office are now officially obligated:

To maintain those drugs in an area kept in an orderly and sanitary manner, and in accordance with standard pharmaceutical practice and manufacturer recommendations concerning storage conditions, including refrigeration, where necessary. A practitioner shall not maintain in inventory any drugs which are outdated, misbranded, deteriorated, adulterated, recalled, unlabeled, damaged, discontinued or which were previously dispensed to a patient. @

Not only must physicians who dispense medication adhere to these strict standards, as if they were a pharmacy, but they face serious additional obstacles, as well. These include a requirement that the disposal of any drugs must comply with all local, State and Federal requirements and not pose a health hazard. In addition, all drugs dispensed must be recorded in the applicable patient record and must also be recorded in a permanent, contemporaneous dispensing log. Drug samples which are not controlled substances and which are packaged and labeled by the manufacturer, however, need be recorded only in the patient record, not the dispensing log. With this one exception, the dispensing log must include, at a minimum, the full name of the patient, the complete name of each drug dispensed, the strength and quantity of the drug dispensed, instructions as to the frequency of use, the date of dispensing, and the identity of the dispensing practitioner, if more than one practitioner dispenses in the office.

Each different drug dispensed, in whatever dosage form, except manufacturer packaged and labeled samples, must also be placed in a separate container with a safety closure cap (unless the patient requests otherwise), and include the full name of the patient, a list of the ingredients if the drug was compounded, not manufactured, the date of dispensing, and the identity of the dispensing practitioner. Whether prepackaged or not, a legible label must also be provided which includes the complete name of the drug dispensed, the strength and quantity of the drug dispensed, instructions as to the frequency of use, special precautions, as appropriate, and the expiration date of the drug.

The regulation (implementing state statutory requirements) prohibits a practitioner from charging any patient a fee for a drug packaged and labeled by a manufacturer as a sample, and for drugs, other than samples, the physician can charge a fee only sufficient to allow for a recoupment of a portion of overhead and administrative costs, @ which fee shall not exceed the actual acquisition cost plus ten percent. A Actual acquisition cost @ means the cost actually incurred by the physician in acquiring a drug from a supplier and does not include any amounts charged by any entity in which the practitioner has a direct or indirect financial or other beneficial interest.

Moreover, as required by statute, if any fee, at all, is charged for the medication, either directly or indirectly, no more than a seven day supply of the drug may be dispensed, the patient must be advised as to the alternative availability of the drug outside of the practitioner's office, and the actual acquisition cost of the drug to the practitioner must be disclosed to the patient, both in advance of purchase and again on the bill. The Board has reserved on the proposed provision that would have also prohibited the dispensing of a drug at a frequency greater than once every sixty (60) days (intended to prevent sequential distributions for seven-day periods). The requirements set out in this paragraph do not apply if the office at which the dispensing occurs is ten or more miles from the nearest pharmacy, if the drug is dispensed pursuant to an oncological or AIDS protocol, if the drug is a salve, ointment or drops, or if the drug is dispensed in, and directly related to, the services rendered to the patient at a hospital emergency room, a student health center or a publicly subsidized community health center, family planning clinic or prenatal clinic.

LIMITS ON PRESCRIBING, DISPENSING OR ADMINISTERING CONTROLLED SUBSTANCES:

Further, and of great significance is the requirement that when prescribing, dispensing or administering any controlled substance, a physician must ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. In addition, the medical record must reflect:

1. A recognized medical indication for the use of the controlled substance;
2. The complete name of the controlled substance;
3. The dosage, strength and quantity of the controlled substance; and
4. Instructions as to frequency of use.

A physician is prohibited from prescribing or otherwise authorizing Schedule II controlled substances in a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less. (The Board provides no reason why it permits a physician to write 120 10mg dosages of a Schedule II controlled substance, BID, but prohibits issuance of 240 dosages of 5mgs of the same substance QID).

PAIN MANAGEMENT EXCEPTION:

A physician may exceed the 120 dose, 30 day supply restriction if he is following a treatment plan designed to achieve effective pain management which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. In such cases, the treatment plan must state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The physician is also obligated to discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative.

More regulations apply when controlled substances are continuously prescribed for management of pain for three months or more. These restrictions do not seem to be limited to Schedule II substances. They include requirements that the physician:

1. Shall review, at a minimum of every three months the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;
2. Shall remain alert to problems associated with physical and psychological dependence; and
3. Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

Where treatment objectives are not being met the physician is obligated to assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities. In addition, an affirmative obligation exists to consider referring the patient for independent evaluation or treatment. The physician is also officially advised to remain alert to the possibility that the controlled substances may be misused or diverted by continuing the stigma currently attached to all chronic pain patients.

When controlled substances are prescribed for management of pain, records must also include copies of evaluations and consultations, a record of treatment plan objectives, evidence of informed consent, any agreements with the patient, and periodic reviews conducted.

PROHIBITIONS ON DRUGS FOR DETOXIFICATION AND USE OF AMPHETAMINES, SYMPATHOMIMETIC

AMINES, AND ANABOLIC STEROIDS:

Additional stringent rules apply to the use of narcotic drugs intended for purposes of detoxification or maintenance treatment, the use of amphetamines and sympathomametic amines, and the use of anabolic steroids in the treatment of patients. Physicians engaged in use of these drugs should consult N.J.A.C. 13:35-7.7 and 7.8 for specific requirements. It should be noted, however, that the Board broadly and, incorrectly, defines amphetamines and sympathomametic amines as Aa[ny] drug which, chemically and pharmacologically, acts as a central nervous system stimulant.