2007-01 JOINT POLICY REGARDING ISSUANCE OF MULTIPLE PRESCRIPTIONS FOR SCHEDULE II CONTROLLED SUBSTANCES

BOARD GUIDELINE

Guidelines on Certain Prescribing Practices

Adopted by the Board of Registration in Medicine on October 22, 2008

On December 19, 2007, the Drug Enforcement Agency issued a revised regulation, 21 C.F.R. §1306, allowing practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same Schedule II controlled substance. The Massachusetts Drug Control Program and the Board of Pharmacy have determined that issuing multiple Schedule II prescriptions, in accordance with the requirements of the amended federal regulation, is permissible under M.G.L. c. 94C.

The Board of Registration in Medicine concurs with the opinion expressed by the Massachusetts Drug Control Program and the Board of Registration in Pharmacy in their "Joint Policy regarding the Issuance of Multiple Prescriptions for Schedule II Controlled Substances."

The "Date of Issuance" referred to in G.L. c.94C, § 23 shall be the "Do Not Fill Before" date indicated by the prescriber. The "date written" under 94C, § 23 shall be the date the prescription was written and signed by the prescriber. Accordingly, each written prescription will become invalid thirty (30) days after its date of issuance, as is required by G.L. c. 94C, § 23 and the Board of Medicine's regulation at 243 C.M.R. 2.07(5).

The federal regulation states that "Where a prescription that has been prepared in accordance with Section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date." The DEA interprets this to mean that no verbal modifications can be made to the earliest date on which the Schedule II prescription may be filled.

243 CMR 2.07(5) states that "a licensee who violates M.G.L. c. 94C also violates 243 C.M.R. 2.00." A Massachusetts physician who prescribes in accordance with the Joint Policy regarding the Issuance of Multiple Prescriptions for Schedule II Controlled Substances" does not thereby violate any Board of Registration in Medicine law, regulation or policy on prescribing. Any conflict between the "Joint Policy regarding the Issuance of Multiple Prescriptions for Schedule II Controlled Substances" and any existing Board policy or regulation on prescribing shall be interpreted in favor of the "Joint Policy."

At the same time, the Board would like to clarify that a Massachusetts physician who prescribes in accordance with the "Joint Policy on Prescribing and Dispensing of Dextro-and Levo-Amphetamines," issued by the Drug Control Program and the Board of Registration in Pharmacy, does not thereby violate any Board law, policy or regulation on prescribing. The Drug Control Program and the Board of Registration in have determined that methylphenidate and single entity drug products containing the Dextro and/or Levo isomers of amphetamine may be dispensed in a sixty day supply when prescribed for inattention and impulsivity-hyperactivity disorder or narcolepsy. Any conflict between the "Joint Policy on Prescribing and Dispensing of Dextro- and Levo- Amphetamines" and any existing Board policy or regulation on prescribing shall be interpreted in favor of the "Joint Policy."

Joint Policy on Prescribing and Dispensing of Dextro- and Levo- Amphetamines

MDPH, Drug Control Program and Board of Registration in Pharmacy

Prescribers and pharmacists have asked whether Adderall® , a Schedule II amphetamine product, may be dispensed in a sixty day supply. Adderall® has federal Food and Drug Administration (FDA) indications for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) and narcolepsy. The Drug Control Program and the Board of Registration in Pharmacy have determined that methylphenidate and single entity drug products containing the dextro and/or levo isomers of amphetamine may be dispensed in a sixty day supply when prescribed for an inattention and impulsivity-hyperactivity disorder or narcolepsy. Quantity limits for controlled substances in Schedules II and III are set forth in M.G.L. 94C § 23(d) which reads, in part, as follows:

> *In regard to a controlled substance in Schedule II or III, no prescription shall be filled for more than a thirty-day supply of such substance upon any single filling; provided, however, that with regard to dextro amphetamine sulfate and methyl phenidate hydrochloride, a prescription may be filled for up to a sixty-day supply of such substance upon any single filling if said substance is being used for the treatment of minimal brain dysfunction or narcolepsy.*

For the purposes of fulfilling the intent of the statute, the DCP and the Board find that:

1. the term "minimal brain dysfunction" means Attention Deficit/Hyperactivity Disorder (ADHD) or other accepted term for an inattention and impulsivity-hyperactivity disorder.
2. the term "dextro amphetamine sulfate" means a single entity drug product that contains the dextro and/or levo isomers of amphetamine and the salts thereof.

Therefore, a patient with narcolepsy, Attention Deficit/Hyperactivity Disorder (ADHD) or other inattention and impulsivity-hyperactivity disorder may now obtain a sixty day supply of Adderall® (there is no requirement that the diagnosis be written on the prescription).

This information is provided by the Drug Control Program within the Department of Public Health.