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Ms. Becky Sutton
Administrator
Hartley Hall Nursing Home
1006 Market Street
Pocomoke City, Maryland 21851

Dear Becky:

You asked me whether, or under what circumstances, a physician may prescribe methadone as an analgesic. The question has arisen in the wake of a presentation in which the presenter apparently indicated some uncertainty about the legal situation. In my view, both federal and State law are clear: A registered physician who considers methadone to be a clinically appropriate response to a patient's pain may issue a prescription for that drug.

Federal law: The general requirement for the prescribing of controlled substances is that the prescription be "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a).[1] Prescribing a controlled substance for pain management is, of course, a "legitimate medical purpose."

Methadone, a Schedule II controlled substance manufactured in liquid and tablet form, has been approved by the Food and Drug Administration as an analgesic. Consequently, a physician who prescribes methadone for pain management, after an appropriate clinical assessment of the patient and consideration of alternatives, does so "for a legitimate medical purpose ... in the usual course of ... professional practice." To be sure, additional

[1] A practitioner usually may not prescribe controlled substances unless he or she has first registered with the Drug Enforcement Administration and obtained a registration number. 21 C.F.R. § 1306.03(a)(2)).

requirements – in particular, separate registration with the Drug Enforcement Administration (DEA) – apply to the administering and dispensing of methadone for treatment of narcotic addiction. DEA, *Practitioner's Manual* 22 (2006). These additional requirements, however, do not apply to prescribing methadone as an analgesic. As the DEA recently confirmed, "While a physician must have a separate DEA registration to dispense methadone for maintenance or detoxification, no separate registration is required to prescribe methadone for pain." DEA, Policy Statement on Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52716, 52723 (September 6, 2006).

State law: The applicable State law parallels federal law. The general rule is that a prescription for what Maryland law calls a "controlled dangerous substance" must be "for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice." COMAR 10.19.03.07C(1). The regulations then impose the following restriction: "A prescription may not be issued for the dispensing of [scheduled] narcotic drugs ... for detoxification treatment or maintenance treatment." COMAR 10.19.03.07C(3). By its plain language, this regulation has no effect on the prescribing of methadone for pain, rather than for detoxification or maintenance.

Another regulation, COMAR 10.19.03.07F, embeds in Maryland law the federal requirements when methadone is used for maintenance or detoxification. This regulation, however, concludes by again recognizing that a substance like methadone, although widely used in addiction treatment and specially regulated in that context, can be used for pain management as well: "A physician or authorized hospital staff may administer or dispense narcotic drugs ... to an individual with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts." COMAR 10.19.03.07F(3)(b).[2]

In summary, my view is that, if a physician adheres to appropriate clinical practice, there is no legal barrier to the physician's prescribing of methadone for pain management. I hope that this letter of advice, although not to be cited as an Opinion of the Attorney General, is fully responsive to your inquiry. Please let me know if I may be of further assistance.

Very truly yours,

Jack Schwartz
Assistant Attorney General
Director, Health Policy Development

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[2] The last phrase is evidently intended to embrace the concept of an "analgesic ladder," in which Schedule II controlled substances are used only after the clinician has evidence that other approaches to managing the patient's pain are unlikely to succeed.