FRAMEWORK FOR THE IMPLEMENTATION OF THE NEW “DELEGATION” EXEMPTION: SAFETY, SECURITY AND TRANSFER OF METHADONE DOSES

THE NEW “DELEGATION” EXEMPTION

The new “delegation” exemption permits pharmacists to transfer custody of individually labelled and fully diluted daily methadone doses (“prepared doses”) to a physician or the physician’s delegate (a “properly qualified individual”) for custody and administration of those doses to patients. A “properly qualified individual” is defined by the College of Physicians and Surgeons of Ontario’s (CPSO) policy Methadone Administration in the Treatment of Opioid Dependence (the “Methadone Administration Policy”) as either:

1. A Registered Nurse, including a Registered Nurse in the Extended Class, or a Registered Practical Nurse who has successfully completed a medication course, either during his or her studies or after graduation; who has demonstrated to the satisfaction of the physician an understanding of methadone maintenance treatment, including the risks associated with methadone treatment; or

2. Another health professional regulated under Ontario’s Regulated Health Professions Act who has successfully participated in and completed the Methadone Treatment Workshop at the Centre for Addiction and Mental Health or equivalent training approved by the CPSO in how to safely and appropriately administer methadone, and has demonstrated to the satisfaction of the physician an understanding of methadone maintenance treatment, including the risks associated with methadone treatment.

In order to delegate custody or administration to a “properly qualified individual,” the physician must have applied for and been granted the new “delegation” exemption by Health Canada pursuant to section 56 of the Controlled Drugs and Substances Act.1

Drawing on existing CPSO and Ontario College of Pharmacists (OCP) policy and federal legislation, this memorandum explains the CPSO’s expectations of physicians regarding the security, handling, storage, and transportation of prepared methadone doses.

RESPONSIBILITY FOR DOSES

Under OCP policy, pharmacists are responsible for the safety and integrity of methadone until such time as they have dispensed directly to the patient or transferred custody of the methadone to an exempted physician or his/her delegate as defined by the Methadone Administration Policy.

TRANSPORTATION AND TRANSFER OF CUSTODY

The OCP requires pharmacists to transfer custody of the individually labelled doses of methadone dispensed pursuant to a prescription in a secure manner to a physician or his or her delegate, who signs that they have received the doses on a daily basis. Pharmacists

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1 S.C. 1996, c. 16.
must either directly hand the doses of methadone to the physician or his/her delegate, or use a method of transportation that ensures a means of tracking and safekeeping of the methadone while in transit (i.e., a chain-of-signatures). All methadone must be transported in an accountable and secure manner.

Only the physician or the physician’s delegate(s) may accept delivery of methadone doses. The physician or delegate who accepts the dose(s) of methadone must sign that they have received and accept custody of the methadone. A record of each transfer of methadone must be maintained.

Once the physician or delegate has accepted custody of the methadone, the physician assumes responsibility for the safety and security of those methadone doses. The physician maintains responsibility and is fully accountable for all doses until provided to the patient for observed consumption or as a carry; or, if unused, until the dose is returned to the pharmacy.

**Administration of Doses**

Only physicians holding the delegation exemption may delegate the acts of accepting, administering and transferring prepared methadone doses. Where a delegate is administering methadone, the administration must occur in accordance with the CPSO’s Methadone Administration Policy.

In all circumstances the following must be ensured:

1. The physician or delegate must witness doses provided for immediate consumption.

2. Prior to administering doses for observed consumption, or providing carries, the patient’s identity must be confirmed, in order to ensure that the methadone dose(s) are being given to the correct individual. The physician or delegate should also verbally confirm with the patient his or her expected dose.

Physicians or delegates who provide observed doses or carries to the patient must follow the requirements outlined in the current CPSO Methadone Maintenance Treatment Guidelines.

OCP policy states that new doses or changes to doses of methadone require a new prescription and must be dispensed by a pharmacist; and that there shall be no alteration of individually labelled doses of methadone once dispensed by the pharmacist.

It is the expectation of Health Canada and the OCP that pharmacists responsible for dispensing methadone will be responsive to prescribed changes in patients’ methadone treatment and be able to provide methadone in a timely manner. Physicians should work with pharmacists to ensure patients’ needs are met in a timely manner.

It is also the expectation of the CPSO that any new dose or change of dose requires a new prescription and must be dispensed by a pharmacist.
However, physicians are permitted to dispense methadone to patients in the rare circumstances where the following criteria are met:

1. Patient safety may be compromised due to a risk of withdrawal or overdose;

2. In the physician’s clinical judgment, a new dose or modified dose is necessary to avoid patient withdrawal or overdose; and

3. No pharmacist is available to provide the necessary dose within a reasonable period of time.

Examples of such rare circumstances include situations where a patient has missed three or more consecutive days of dosing and requires stabilization to prevent further withdrawal, and a pharmacist is not available to provide the necessary dose within a reasonable period of time; or where the patient has vomited a dose under direct observation, particularly in the case of pregnant patients where withdrawal could compromise the well-being of the fetus, and a pharmacist is not available to provide the necessary dose within a reasonable period of time.

Physicians who dispense methadone in these rare circumstances must do so in accordance with the requirements set out in the Drug and Pharmacy Regulation Act² (DPRA). DPRA requirements are set out in the OCP’s “Policy for Dispensing Methadone.”³

DESTRUCTION OF UNUSED DOSES

All unused doses must be returned to the dispensing pharmacy for destruction on a daily basis. These doses must be transferred in a secure manner in accordance with the guidelines for transportation and custody set out above. Once the pharmacist accepts custody of the unused/partially used doses, the pharmacist is responsible for the safety, security and destruction of those doses.

RECORD-KEEPING

All dosing information must be provided to the pharmacy to ensure accuracy and completeness of patient history. This should be done with the consent of the patient as part of the patient treatment agreement.

Under section 69 of the Narcotic Control Regulations,⁴ practitioners must keep and retain for a period of two years from the date of the making of the record, a record of:

- The kind, date and quantity of methadone received;

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³ This policy is available on the OCP website (www.ocpinfo.com), and may also be obtained from the CPSO Methadone Program.
⁴ C.R.C., c. 1041.
• The name and address of the person from whom the methadone was received and a record of the name and address of the dispensing pharmacy; and

• Particulars of the use to which the methadone was put, namely, whether it was for opioid dependence or analgesic.

Section 69 of the Narcotic Control Regulations also requires that the practitioner permit access to these records to the federal Minister of Health and provide any information respecting the methadone as the Minister may require.

In addition to the requirements under Section 69, the name of the patient who received each dose, the daily dose amount for that patient, and the date, time and place where the administration was observed should be recorded.

SAFE AND SECURE STORAGE

Under section 55(f) of the Narcotic Control Regulations, the practitioner must take “adequate steps” to protect any quantities of methadone on the premises or under his or her control against theft or loss.

The CPSO cannot provide legal advice on the meaning of “adequate” in the regulations, nor is the term “adequate” defined in the Narcotic Control Regulations. It is, however, the expectation of the CPSO that the following measures will be taken:

1. All methadone doses must be stored in a locked cabinet/refrigerator in a secure area within the physician’s office or clinic.

2. Only properly qualified individuals whom the physician has authorized to handle methadone may have access to the stored doses of methadone.

Practitioners are also required, under s. 55(d) of the Narcotic Control Regulations to permit an inspector to check all stocks of narcotics on the practitioner’s premises.

RECONCILING DOSES, LOST OR STOLEN DOSES

The physician and/or a delegate must conduct a daily reconciliation of doses received, administered and returned to the pharmacy. Preferably, this will occur both before the first dose and after the last dose for that day have been administered.

Any lost or stolen methadone must be reported to the Minister (Health Canada) within 10 days of discovering the loss or theft, as required by section 55(g) of the Narcotic Control Regulations. The form for reporting a loss or theft is available from the Office of Controlled Substances, or on-line at http://www.hc-sc.gc.ca/dhp-mps/substancontrol/substan/compli-conform/loss-perte/loss_rep-rap_perte-eng.php.

Approved by CPSO Council: April 2007