



OCS Section 56 Class Exemption for Practitioners Prescribing Methadone to Inpatients in a Hospital Setting

The Office of Controlled Substances (OCS) has issued the section 56 class exemption, which affects practitioners practising in a hospital setting. As of March 17, 2017, practitioners will no longer have to obtain a temporary methadone s.56 exemption to continue the treatment of a patient who was admitted to a hospital and has been prescribed methadone.

Please see the letter and exemption notice from Health Canada's OCS Acting Director for clarification and conditions starting on page two.

Verify a Practitioner

To verify if a practitioner is exempted to prescribe methadone or for other inquiries please contact the Methadone Program directly at: exemption@hc-sc.gc.ca, phone: (613) 946-5139, toll free: 1-866-358-0453

Application Forms

If you would like to request any application forms for a Methadone Exemption, send an email to exemption@hc-sc.gc.ca.

Guidelines for opiate dependence treatment

British Columbia, Saskatchewan, Ontario and Quebec have their own provincial guidelines that should be followed by practitioners prescribing methadone in those provinces. For all other provinces, the Health Canada guidelines: "[The use of opioids in the management of opioid dependence](#)"

Best practices document: [Methadone Maintenance Treatment](#)



Health
Canada

Santé
Canada

Healthy Environments
and Consumer Safety
Branch

Direction générale,
Santé environnementale et
sécurité des consommateurs

Address Locator 0300B
Ottawa ON K1A 0K9

Your file Votre référence

Our file Notre référence

2017-03-17

16-106434-496

To Whom it May Concern,

On February 24, 2017 the Office of Controlled Substances (OCS) sent a letter and a draft section 56 (s.56) class exemption for practitioners prescribing methadone to in-patients in a hospital setting in order to provide an opportunity for concerns regarding the proposed issuance of a s.56 class exemption. The OCS would like to thank everyone who took the time to consider the impact of the issuance of the draft s.56 class exemption.

Before March 6, 2017 stakeholders were encouraged to share their concerns regarding the issuance of a s. 56 class exemption which impacted the issuance of temporary exemptions for methadone. Comments were received from various stakeholders, but no major concerns regarding the issuance of the s.56 class exemption were expressed by stakeholders.

Therefore, please be advised that the OCS, has issued the section 56 class exemption which will affect practitioners practicing in a hospital. As of date of issuance of the exemption, practitioners will no longer have to obtain a temporary methadone s.56 exemption in order to continue the treatment of a patient who was admitted to a hospital and have been prescribed methadone.

In response to comments received and in order to provide clarity, the section 56 exemption does not apply to federal, provincial or municipal correctional facilities.

As previously mentioned, the s.56 class exemption will only apply when all its conditions are met. The conditions of the exemption are as follows:

- the patient must be taking methadone prior to their hospitalization;
- the practitioner must be licensed as a nurse practitioner or to practice medicine, dentistry or veterinary medicine;
- the patient must be under the practitioner's professional treatment at a hospital;
- the provision of the methadone must be necessary to ensure the continuation of the patient's methadone treatment;
- the practitioner must not be named in an active notice of restriction from Health Canada regarding narcotics;
- provincial/territorial guidelines or conditions must be followed; and,
- methadone must be dispensed or prepared by the hospital pharmacy or by the hospital affiliated pharmacy.

Thus, this exemption does not apply to practitioners, including those practicing in a hospital, prescribing to patients who are not already being prescribed methadone.

We would again like to highlight that general methadone s.56 exemptions (i.e. those issued to a practitioner who prescribes methadone in their practice) will not be impacted by the issuance of this class exemption.

A copy of the finalized s.56 class exemption is attached for your reference. It is our intention to post the exemption on the Health Canada website.

In regards to the College's continual collaboration, once more the OCS extends its thanks for your contribution. Please do not hesitate to contact our Office via email at exemption@hc-sc.gc.ca if you have any questions or concerns.

Yours Sincerely,



Carol Anne Chénard
Acting Director
Office of Controlled Substances
Healthy Environments and Consumer
Safety Branch
Health Canada

Attachment



SECTION 56 CLASS EXEMPTION FOR PRACTITIONERS PRESCRIBING METHADONE TO INPATIENTS IN A HOSPITAL SETTING

Pursuant to section 56 of the *Controlled Drugs and Substances Act* (CDSA), practitioners are hereby authorized to administer methadone to a person or animal, or prescribe, sell or provide methadone for a person or animal.

The terms used in this exemption have the same meaning as they do in the CDSA and the Narcotic Control Regulations (NCR) except as defined below:

Hospital means a facility, other than a federal, provincial or municipal correctional facility,

- (a) that is licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness, or
- (b) that is owned or operated by the Government of Canada or the government of a province and that provides healthcare.

Practitioner means a person who is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry, veterinary medicine and nurse practitioner who has not been named in a notice in s. 59 of the NCR, unless a notice of retraction has been issued under s. 60.

This exemption is only applicable if the following terms and conditions are met.

(A) Practitioners must:

- (1) Be working as practitioners in a hospital setting;
- (2) Only administer, sell, provide or prescribe methadone to a patient while that patient is under their professional treatment at a hospital;
- (3) Only administer, sell, provide or prescribe methadone to a patient when the methadone is required for a condition for which that patient is receiving treatment;
- (4) Only administer, sell, provide or prescribe methadone as an analgesic agent or for the management of opioid dependence;
- (5) Ensure that the regular treating practitioner is informed of the patient's hospitalization and coordinate the issuance of methadone prescriptions when the patient leaves the hospital; and,
- (6) Comply with any terms, conditions or guidelines related to the sale, provision, administration or prescription of methadone set by the practitioner's provincial or territorial licensing bodies in the province or territory where the practitioner is practising.

(B) The patient must already be receiving methadone treatment prior to their hospitalization.

- (C) Any methadone prescribed, sold or provided under the authority of this exemption must be prepared or dispensed by a hospital pharmacist who practices at a pharmacy that is affiliated with the hospital at which the patient who requires the methadone is located.
- (D) For greater certainty, the practitioner must also comply with applicable provisions of the CDSA and the NCR, including those related to record-keeping.

This exemption will remain in effect until revoked. **Failure to comply with the terms and conditions of this class exemption may result in a contravention of the CDSA and its regulations.**

Signed for and on behalf of the Minister of Health



Carol Anne Chénard
A/Director, Office of Controlled Substances
Controlled Substances Directorate
Healthy Environments and Consumer Safety Branch

Effective Date: March 17, 2017