15 December 2025

Via email

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Marie Doyle, Assistant Commissioner, Health Services, CSC

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Dr. Asim Masood, Chief Medical Office of Health, CSC
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Re: Urgent Concerns Regarding CSC's Recent Opioid Agonist Treatment (OAT) Policy Changes

Dear Commissioner Kelly and Assistant Commissioner Marie Doyle,

We write as clinicians, addiction-medicine specialists, and health researchers working in substance use care and correctional health across Canada. We are deeply alarmed by Correctional Service Canada's (CSC) recent policy change designating extended-release buprenorphine (XR-BUP or Sublocade) as the first-line opioid agonist treatment (OAT) option available in federal institutions ("new OAT policy"), while removing buprenorphine/naloxone (BUP/NAL or Suboxone) from the open-formulary.

Under the new OAT policy, Sublocade is positioned as the "preferred" treatment option for opioid use disorder (OUD). BUP/NAL is no longer an open-formulary medication and must now be accessed through a restrictive and non-formulary request – an opaque process to patients. For those who cannot secure approval through this process, BUP/NAL would have to be paid for out of pocket, which is not feasible for most people in custody. Methadone remains on the formulary, but early reports from clinicians and patients suggest that methadone is now available only under very limited circumstances, effectively inaccessible for most people who are not already on it.

While Sublocade is an effective and preferred option for some patients, no national or international guideline recommends it as the sole or preferred first-line treatment. Limiting access to BUP/NAL and methadone, by adding procedural hurdles, contradicts well-established standards of care, undermines patient autonomy, and creates foreseeable clinical risks. Reports from incarcerated people, since October 2025, indicate that the new OAT policy is already resulting in forced transitions, inadequate informed consent, and avoidable harms. We also have concerns around the evidence relied upon in developing the police and the nature of any industry influence.

We strongly urge CSC to pause implementation, reinstate access to the full range of OAT options based on the standard of care in the community — in keeping with section 86 of the *Corrections and Conditional Release Act*, which requires CSC to provide essential health care in conformity with "professionally

accepted standards" and the *Mandela Rules*,[1] which require equivalence of care for people deprived of liberty — and establish an independent review of the OAT policy.

1. Patient Autonomy, Coercion, and Safety

The new OAT policy formalizes the erosion of patient autonomy and encourages coercive treatment practices.

As described in CSC materials, BUP/NAL is no longer an open-formulary medication and can be accessed only through a non-formulary request requiring a prescriber to attest that it is the *"only medication"* that would work for the patient. It remains unclear what prescribers consider a valid clinical justification, on what basis this assessment should be made, and whether people in custody are being informed regarding how to initiate the process at all. This process also creates delays in timely treatment initiation or continuation for anyone seeking access to a medication that is no longer on the formulary. Since at least October 2025, we have heard multiple reports of people being forced or pressured to switch from BUP/NAL to Sublocade despite clear preferences to remain on their existing therapy, with some experiencing increased cravings or destabilization after being switched involuntarily. At the same time, recent reports from clinicians and people in prison indicate that methadone initiation appears to be permitted only in very limited circumstances. As a result, most people are unable to access either first-line OAT option unless they are pregnant or allergic to Sublocade.

CSC documentation also suggests that people who decline switching to Sublocade (absent pregnancy or allergy) may be "supported" to stop OAT altogether. This amounts to coerced detoxification. National OUD guidelines explicitly warn against detox-only approaches due to sharply elevated risks of relapse, overdose, and death.[2] Conditioning access to standard-of-care treatment on accepting an injectable formulation is coercive, clinically inappropriate, and dangerous.

We have also heard reports of individuals being told they must accept Sublocade "or get nothing at all," of questions or concerns being dismissed, and of people receiving little or no information about the risks, side effects, or alternatives. These practices violate the right of people in custody to a standard of care equivalent to that available in the community, where both methadone and BUP/NAL remain first-line, guideline-recommended options.

2. Clinical and Scientific Concerns

CSC's policy is inconsistent with every major OUD treatment clinical guideline. Canadian, U.S., and European guidelines all identify methadone and BUP/NAL as co-equal first-line therapies.[3] None recommend Sublocade as the sole first-line option. The College of Family Physicians of Canada's position

[1] United Nations General Assemblv. *United Nations Standard Minimum Rules for the Treatment of Prisoners (the Nelson Mandela Rules) : resolution / adopted by the General Assembly*, A/RES/70/175, 8 January 2016, available at www.refworld.org/legal/resolution/unga/2016/en/119111.

[2] I. Yakovenko et al., "Management of opioid use disorder: 2024 update to the national clinical practice guideline," *CMAJ* (2024) 196:E1280-90.

[3] See I. Yakovenko et al., ibid; American Society of Addiction Medicine, *National Practice Guideline for the Treatment of Opioid Use Disorder,* 2020, available at www.asam.org/quality-care/clinical-guidelines/national-practice-guideline; M. Dematteis et al., "Recommendations for buprenorphine and methadone therapy in opioid use disorder: a European consensus" *Expert Opin Pharmacother* (2017) 18(18).

statement on OAT in prison likewise emphasizes that people in custody must have access to all evidence-based OAT medications.[4]
As noted above, CSC's policy also raises concerns under its statutory duties to provide health care that meets professionally accepted standards and to support independent, patient-centered clinical judgment.[5] A model that restricts access to guideline-recommended first-line treatments is difficult to reconcile with these obligations.

The available clinical evidence does not support elevating Sublocade into a single first-line treatment. Multiple studies demonstrate worse treatment retention with Sublocade than with BUP/NAL, and buprenorphine of any form has retention outcomes equal to or lower than methadone.[6] Treatment retention is among the strongest predictors of improved health outcomes[7] restricting access to medications with stronger retention profiles risks destabilizing individuals whose current therapy is effective.

The scientific foundation CSC has cited is also limited.[8] A central systematic review included only ten studies: many small, heterogeneous, non-randomized, and short in duration, including XR-BUP formulations not currently available in Canada.[9] The lead author (and signature to this document) has clarified that the review findings support Sublocade as an additional option — not a replacement for existing first-line therapies. Another cited U.S. study involved a predominantly heroin-using population, making the findings difficult to extrapolate to Canada's fentanyl-dominated context.[10] Moreover, the study provided markedly different levels of post-release support across treatment groups: individuals receiving Sublocade were offered free, ongoing injections and follow-up, whereas those receiving sublingual buprenorphine were given only a seven-day supply. These structural differences confound any differences observed in treatment outcomes.

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[4] College of Family Physicians of Canada, *Position Statement on Access to Opioid Agonist Treatment in Detention*, November 2019, available at www.cfpc.ca/CFPC/media/Images/PDF/201912-Position-Statement-Prison-Health-Opioid-Therapy.pdf.
[5] *Corrections and Conditional Release Act*, SC 1992, c 20, ss. 86-86.1.
[6] See, e.g., R. Ivasiy et al., "Retention and dropout from sublingual and extended-release buprenorphine treatment: A comparative analysis of data from nationally representative sample of commercially-insured people with opioid use disorder in the United States," *Int J Drug Policy* (2025) 138:104748; A. Iacono et al., "Characteristics, treatment patterns and retention with extended-release subcutaneous buprenorphine for opioid use disorder: A population-based cohort study in Ontario, Canada," *Drug Alcohol Depend* (2024) 254:111032; B. Nosyk et al, "Buprenorphine/Naloxone vs Methadone for the Treatment of Opioid Use Disorder," *JAMA* (2024) 332:21; L. Degenhardt et al., "Buprenorphine versus methadone for the treatment of opioid dependence: a systematic review and meta-analysis of randomised and observational studies," *The Lancet* (2023) 10(5):386-402.
[7] See, e.g., C. Timko et al., "Retention in Medication-Assisted Treatment for Opiate Dependence: A Systematic Review," *J Addict Dis* (2109) 35(1).
[8] C. Russell et al., "Feasibility and effectiveness of extended-release buprenorphine (XR-BUP) among correctional populations: a systematic review," *Am J Drug Alcohol Abuse* (2024) 50(5):567-587; K. Lee et al., "Real-world Evidence for Impact of Opioid Agonist Therapy on Nonfatal Overdose in Patients with Opioid Use Disorder during the COVID-19 Pandemic," *Journal of Addiction Medicine* (2023) 17(6):374-381; A. O'Connor et al, "Community buprenorphine continuation post-release following extended release vs. sublingual buprenorphine during incarceration: a pilot project in Maine," *Health & Justice* (2024) 12:28; J. Lee et al., "Comparison of Treatment Retention of Adults With Opioid Addiction Managed With Extended-Release Buprenorphine vs Daily Sublingual Buprenorphine-Naloxone at Time of Release from Jail," *JAMA* (2021) 4(9).
[9] C. Russell et al., ibid.
[10] J. Lee et al., supra.

Even when clinically appropriate, many people receiving Sublocade require supplemental BUP/NAL to manage cravings or withdrawal.[11] CSC's guidance acknowledges this need only narrowly, allowing prescribers to provide supplemental buprenorphine/naloxone during induction. However, the policy offers no mechanism for supplementation beyond that stage, despite real-world evidence that ongoing supplemental dosing is often necessary. As a result, clinically necessary adjustments may be impossible to meet under the current framework.

Since at least October 2025, people inside federal institutions have also reported painful injections, inadequate preparation or monitoring, large injection-site masses, severe allergic reactions, and trauma or fear related to injection. Some described the immediate return of cravings after involuntary transition. These experiences underscore that Sublocade is not appropriate as a universal first-line treatment and should never be imposed without proper assessment, consent, or alternatives.

Taken together, the evidence does not support restricting access to BUP/NAL or methadone, two long-standing, evidence-based first-line OAT options. Doing so effectively creates a single-medication OAT system that is inconsistent with clinical standards and introduces predictable risks — including destabilization of people who are stable on their current therapy, reduced treatment retention, unmanaged withdrawal or cravings, and heightened vulnerability to relapse and overdose. CSC's approach overstates the strength of the existing evidence and disregards the well-documented harms that arise when people are denied access to the full range of evidence-based OAT options.

3. Pharmaceutical Influence and Cost Concerns

We have concerns around transparency in the development of this new OAT policy, particularly given reports of strong lobbying by Indivior, the manufacturer of Sublocade. Sublocade is the only OAT medication without a generic equivalent and is significantly more expensive than methadone or BUP/NAL.[12] These concerns are heightened by Indivior's history of regulatory settlements related to misleading marketing and anti-competitive behaviour.[13]

Ensuring that procurement processes, evidence assessments, and policy decisions are independent, evidence-based, and free from undue industry influence is critical, particularly given CSC's commitment to enhancing transparency and credibility in its interactions with Canadians, including through clear communication on issues of public concern.[14]

4. Systemic and Operational Concerns

The new OAT policy also raises significant operational concerns, particularly around implementation and continuity of care. Reports from institutions describe considerable confusion about how the policy is being

[11] A. Iacono et al., supra. See also The Ontario Drug Policy Research Network. [December 2025]. Evolving extended-release subcutaneous buprenorphine (BUP-ER; Sublocade®) treatment patterns in Ontario, 2021 to 2024. Available from: https://odprn.ca/research/publications/bup-er-treatment-patterns-in-ontario/

[12] See, e.g., A. Mendell et al., "Utilization *of Opioid Agonist Therapies in Canada*," *CADTH* (2023) 3(8).

[13] See, e.g., Federal Trade Commission, *Indivior, Inc. to Pay $10 Million to Consumers, Settling FTC Charges that the Company Illegally Maintained a Monopoly over the Opioid Addiction Treatment Suboxone,* 24 July 2020, available at www.ftc.gov/news-events/news/press-releases/2020/07/indivior-inc-pay-10-million-consumers-settling-ftc-charges-company-illegally-maintained-monopoly.

[14] See, e.g., Correctional Services Canada, *2024 to 2025 Departmental Plan*, 24 February 2025, available at www.canada.ca/en/correctional-service/corporate/transparency/reporting/departmental-plan/2024-2025.html.

applied, wide variability in how information is communicated to patients, and inconsistent adherence to injection protocols. These issues heighten the risk of adverse events and undermine the safe delivery of care.

Continuity of care during release planning is another major concern. Many individuals on parole remain tied to CSC-funded health services and therefore continue to have access only to Sublocade, even when their community lacks providers trained or authorized to administer it. This creates foreseeable gaps during the period of highest overdose risk and makes sustained stabilization far more difficult.[15] Sublocade's cost (approximately $700+ per injection) further creates barriers to continued treatment following release, particularly in provinces and territories where coverage is limited or requires prior authorization, raising additional concerns about long-term sustainability.

While some correctional staff have cited potential operational benefits, such as reducing diversion or alleviating pressures associated with daily observed dosing, these challenges call for strengthened health services and not the removal of widely accepted, evidence-based treatments.

Recommendations

We urge CSC to:

1. Reinstate full access to methadone and BUP/NAL as standard first-line OAT options.
2. Pause implementation of Sublocade as first-line OAT option pending an independent clinical and ethical review.
3. End coercive practices, including threats of detox or removal of OAT.
4. Ensure meaningful informed consent, including information on risks, alternatives, and injection procedures.
5. Strengthen clinical training, oversight, and monitoring for Sublocade administration.
6. Engage external addiction medicine experts, researchers, and people with lived experience to ensure OAT policy development is in line with standards of care in the community.
7. Take steps to support continuity of care for BUP/NAL, methadone, and Sublocade, so that people can maintain their existing OAT regimen on entry to custody and upon release, without treatment interruptions.
8. Commission an independent review of procurement processes, evidence sources, and clinical governance, and take steps to ensure transparency regarding the evidence relied on and any manufacturer engagement.

We remain ready to work collaboratively toward an evidence-based, patient-centred OAT model that respects autonomy, ensures equivalency of care, and aligns with national clinical standards. The current policy introduces significant medical, ethical, and human-rights risks that require urgent attention.

Sincerely,

[15] See, e.g., B. Fischer et al. "The burden of drug overdose deaths among correctional populations: implications for interventions," *CMAJ* (2024) 196(43).

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