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STANDING COMMITTEE ON PUBLIC ACCOUNTS

PERFORMANCE AUDIT: IMPLEMENTATION AND OVERSIGHT OF ONTARIO'S OPIOID STRATEGY

(2024 ANNUAL REPORT OF THE OFFICE OF THE AUDITOR GENERAL OF
ONTARIO)

1st Session, 44th Parliament
4 Charles III

ISBN 978-1-4868-9870-1 (Print)
ISBN 978-1-4868-9867-1 [English] (PDF)
ISBN 978-1-4868-9869-5 [French] (PDF)
ISBN 978-1-4868-9866-4 [English] (HTML)
ISBN 978-1-4868-9868-8 [French] (HTML)

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The Honourable Donna Skelly, MPP
Speaker of the Legislative Assembly

Madam,

Your Standing Committee on Public Accounts has the honour to present its Report and commends it to the House.

A handwritten signature in black ink that reads "Tom Rakocevic".

Tom Rakocevic, MPP
Chair of the Committee

Queen's Park
May 2026

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1st Session, 44th Parliament

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INTRODUCTION

On October 27, 2025, the Standing Committee on Public Accounts held public hearings on the Implementation and Oversight of Ontario's Opioid Strategy (Auditor General's 2024 Annual Report), overseen by the Ministry of Health.

The Committee welcomes the Auditor's 2024 findings and recommendations and now presents its own findings, views, and recommendations in this report. The Committee requests that the Ministry provide the Clerk of the Committee with written responses to the recommendations within 120 calendar days of the tabling of this report with the Speaker of the Legislative Assembly, unless otherwise specified.

ACKNOWLEDGEMENTS

The Committee extends its appreciation to officials from the Ministry of Health. The Committee also acknowledges the assistance provided by the Office of the Auditor General, the Clerk of the Committee, and Legislative Research.

BACKGROUND

The audit was conducted between January and October 2024, and released in December 2024 as part of the Auditor's 2024 Annual Report.¹ The Auditor explains that in this performance audit,

we examined the Province's strategy for responding to this worsening health crisis. We asked whether the Opioid Strategy was responsive to the needs of Ontarians. We looked at whether opioid-related health care services and other necessary services are available, accessible and well co-ordinated. We also evaluated the oversight and monitoring of health care provider billing, prescribing and dispensing practices.²

The Ministry of Health accepted all seven of the recommendations made in the audit report.

Opioid Crisis

There are more than 100 types of opioids, a class of drugs used as pain relievers.³ Opioids are frequently prescribed by health care practitioners but the Auditor notes that they can also be obtained "through the illegal drug market, where they are often stronger and/or contaminated with other substances that can put people's health at even greater risk and can be fatal."⁴

¹ Office of the Auditor General of Ontario (AG), "Performance Audit: Implementation and Oversight of Ontario's Opioid Strategy," *Annual Report, 2024*, p. 65.

² AG, "Implementation and Oversight of Ontario's Opioid Strategy," news release, December 2024.

³ AG, report, p. 10.

⁴ Ibid.

As the Auditor explains, “when prescribed and used as directed, opioids can be effective pain killers.... With prolonged use, misuse or abuse, opioids can lead to tolerance, dependence, addiction ..., overdose and even death.” The Auditor notes that the opioid crisis has escalated with “an increase in the illegal supply of more potent opioids such as fentanyl.”⁵

Opioid use disorders (previously called opioid addiction), and deaths from opioid overdoses, have skyrocketed across Canada and internationally, leading to a public health crisis.⁶ The Auditor notes that in Ontario, the opioid crisis “continues to escalate ... with both opioid-related deaths and emergency department visits increasing significantly over the last decade (2014–2023), by almost 300%. In 2023, an average of seven Ontarians per day died from opioid-related causes.”⁷

Opioid Strategy

In 2016, the Ministry of Health released its Strategy to Prevent Opioid Addiction and Overuse (Opioid Strategy or Strategy). In 2017, the Ministry announced \$222 million funding over three years to implement the Strategy, and in 2018/19, funding for the Strategy was raised to over \$260 million.⁸

The Auditor notes that the Opioid Strategy “was weighted more toward harm reduction, which included expanding proven harm-reduction services such as naloxone-distribution and Consumption and Treatment Services (CTS) sites.”⁹ (The Auditor explains that harm reduction is an “evidence-based, client-centred approach to reducing the health and social harms associated with addiction and substance use, without necessarily requiring people who use substances to abstain or stop using.”¹⁰)

Roadmap to Wellness

In March 2020, the Ministry released “Roadmap to Wellness: A Plan to Build Ontario’s Mental Health and Addictions System” (Roadmap to Wellness) with a \$3.8 billion investment over 10 years. The Roadmap to Wellness is the Province’s broader strategy to transform the mental health and addictions system. The Ministry established the Mental Health and Addictions Centre of Excellence (MHA CoE) within Ontario Health, with a legislated mandate to implement the Roadmap to Wellness strategy.

RECENT DEVELOPMENTS

Consumption and Treatment Services (CTS) sites

Also known as “supervised consumption services sites,” CTS sites are a type of “evidence-based harm-reduction.”¹¹ These sites are “spaces for people to

⁵ AG, report, p. 1, 10.

⁶ See Health Canada, “Federal actions on the overdose crisis,” June 2025.

⁷ AG, report, p. 1.

⁸ AG, report, p. 14.

⁹ AG, report, p. 15.

¹⁰ AG, report, p. 14.

¹¹ AG, report, p. 24.

consume their own substances, including opioids, in a supervised setting.”¹² The Auditor reports that CTS sites have been shown to prevent overdose deaths; prevent disease transmission by providing clean, sterilized tools; and connect clients to addiction treatment options and other health and support services.¹³

In August 2024, while the audit was underway, the Province announced that it was “protecting the safety of children and communities by banning supervised drug consumption [CTS] sites within 200 metres of schools and child care centres.”¹⁴ The government announced it was “also mandating new protections to better protect community safety near remaining sites.”¹⁵

The Ministry explained that this would result in “the closure of nine provincially-funded sites and one self-funded site, located in Ottawa, Guelph, Hamilton, Thunder Bay, Kitchener and Toronto, no later than March 31, 2025.”¹⁶

Homelessness and Addiction Recovery Treatment (HART) Hubs

The Ministry explained that the provincially-funded CTS sites that closed down would “be encouraged to submit proposals to transition to Homelessness and Addiction Recovery Treatment (HART) Hubs.”¹⁷ (The Ministry noted that HART Hubs “will not offer ‘safer’ supply, supervised drug consumption or needle exchange programs.”¹⁸)

The Ministry added that the HART Hubs model connects “people with complex needs to comprehensive treatment and preventative services that could include: primary care; mental health services; addiction care and support; social services and employment support; shelter and transition beds; supportive housing; and other supplies and services, including naloxone, onsite showers and food.”¹⁹

2024 AUDIT OBJECTIVE AND SCOPE

According to the Auditor:

The audit objective was to assess whether the Ministry of Health (Ministry) has effective processes and procedures in place to:

- implement Ontario’s Opioid Strategy and initiatives that are responsive to the needs of Ontarians;
- oversee and coordinate the delivery of evidence-based services for people who require opioid-related services in an equitable, integrated and timely manner, and in accordance with applicable legislation, policies and agreements;

¹² Ibid.

¹³ Ibid.

¹⁴ Ministry of Health, “Ontario Protecting Communities and Supporting Addiction Recovery with New Treatment Hubs,” news release, August 20, 2024.

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ Ibid.

- monitor and enable appropriate opioid-prescribing and dispensing practices in accordance with applicable legislation, policies and standards; and
- measure and publicly report on the performance of publicly funded services for people who require opioid-related services.²⁰

The Auditor further notes that:

Our audit scope focused on the provincial health sector's response to the opioid crisis, not on policing efforts to investigate and enforce laws related to illegal opioid-related activities. Specifically, our audit focused on the following two areas:

- the availability, accessibility and coordination of opioid-related services and other necessary services that are funded and overseen directly by the Ministry and delivered in the community; and
- the Ministry's oversight and monitoring of opioid-related services and physician billings, as well as opioid-prescribing and dispensing practices.²¹

MAIN POINTS OF 2024 AUDIT

The Auditor's overall conclusions were that:

The Ministry does not have effective processes in place to meet the challenging and changing nature of the opioid crisis in Ontario.

Specifically, the Ministry did not:

- effectively implement Ontario's 2016 Opioid Strategy and initiatives that are responsive to the needs of Ontarians;
- effectively oversee and coordinate the delivery of evidence-based services for people who require opioid-related services in an equitable, integrated and timely manner, and in accordance with applicable legislation, policies and agreements;
- adequately and proactively monitor and enable appropriate opioid-prescribing and dispensing practices in accordance with applicable legislation, policies and standards;
- adequately measure and publicly report on the performance of publicly funded services for people who require opioid-related services; and

²⁰ AG, report, p. 16.

²¹ Ibid.

- provide a thorough, evidence-based business case analysis for the 2024 new model, Homelessness and Addiction Recovery Treatment (HART) Hubs, to ensure that they are responsive to the needs of Ontarians.²²

ISSUES RAISED IN THE REPORT AND BEFORE THE COMMITTEE

The Ministry of Health (Ministry) explained that it “has accepted the findings of the Auditor General’s report and acknowledges the need for a comprehensive continuum of care for mental health and substance abuse disorders that includes opioid addictions.”²³ The Committee heard that the Ministry also agrees with the Auditor recommendation that the Ministry “should focus on comprehensive care that includes both pharmacotherapy for opioid use disorder but also wraparound services and supports.” The Ministry’s strategy “includes improving oversight and coordination with its partners at Ontario Health, local public health units and right across the health care system.”²⁴

Opioid use has changed in recent years, the Ministry explained. When the Strategy was launched in 2016, “addiction and fatalities were driven in large part by prescription opioid misuse” but less than a decade later, “synthetic opioids are now the predominant form of opioids used by people today for non-medical purposes.”²⁵ The Committee heard that this has been exacerbated by what is termed “polydrug use,” with users consuming more than one psychoactive substance at a time. This contributes to the complexity of providing care and treatment for people with mental health and substance use disorders.

The Committee heard that the Province has created and is continuing to open hundreds of new addictions treatment beds through the Addictions Recovery Fund, with over half allocated to northern Ontario, to reflect regional priorities, as well as Indigenous-led bed-based programs. Investments in developmentally appropriate substance use treatment for children and youth include Youth Wellness Hubs.²⁶ The Committee heard that the range of substance use services available through Youth Wellness Hubs varies across sites.

Ontario’s Opioid Strategy

The Committee notes the Auditor General’s finding that the Roadmap to Wellness does not include a distinct opioid strategy. The Committee notes the Ministry’s explanation that opioid-related initiatives are being addressed within the broader continuum of mental-health and addictions services established through the Roadmap to Wellness.

The Committee asked how the Ministry has adapted its approach to reflect changes in the opioid and substance use landscape. The Ministry explained that

²² AG, report, p. 2.

²³ Standing Committee on Public Accounts, Committee *Hansard*, October 27, 2025, p. 28.

²⁴ *Ibid.*

²⁵ Committee *Hansard*, p. 34.

²⁶ Committee *Hansard*, p. 29.

through the Roadmap to Wellness, the Ministry is “building a comprehensive and connected mental health and addictions treatment system that offers high quality, evidence-based services and supports where and when people need them.”²⁷ This includes a commitment to building a data and digital infrastructure for the community mental health and addictions service sector, although the Ministry did not describe any specific funding. The resulting data and performance metrics will “provide evidence to drive strategic decisions at all levels of care from informing individual client treatments to shaping provincial health policy and improving system performance.”²⁸

The Committee also asked about the role of the Mental Health and Addictions Centre of Excellence in improving care for Ontarians living with an opioid use disorder. The Ministry explained that the Centre of Excellence within Ontario Health is foundational to the Roadmap to Wellness: it is “responsible for system management, coordination of services and driving meaningful quality improvements to ensure more consistent patient experiences across the province.”²⁹

The Committee noted the Auditor’s recommendation that the Ministry “should develop a new holistic strategy including all best practices targeted at addressing the current drivers of the opioid crisis, reducing opioid-related harms and preventing opioid addictions and overdose.”³⁰ The Ministry explained that the opioid strategy is integrated within the components of the Roadmap to Wellness.³¹

Committee Recommendations

The Standing Committee on Public Accounts recommends that:

1. The Ministry of Health, within the existing Roadmap to Wellness, establish a clear opioid-related performance framework—including measurable objectives, indicators, and annual public reporting—to ensure that Ontario’s response to opioid use remains evidence-based, transparent, and aligned with the province’s broader mental-health and addictions goals.
2. The Ministry of Health, in collaboration with Ontario Health and the Mental Health and Addictions Centre of Excellence, develop and publish an annual public dashboard of standardized indicators—covering prevention, treatment, recovery, and harm-reduction outcomes, disaggregated by region and demographic—to support transparent, evidence-informed decision-making.
3. The Ministry, in collaboration with Ontario Health and other involved ministries, ensure that service providers are supported in accessing and implementing the data and digital infrastructure plan and requirements including through appropriate planning and resource allocation.

²⁷ Committee *Hansard*, p. 34.

²⁸ Committee *Hansard*, p. 39.

²⁹ Committee *Hansard*, p. 45.

³⁰ Committee *Hansard*, p. 42.

³¹ *Ibid.*

Consumption and Treatment Services (CTS) Sites and Homeless and Addiction Recovery Treatment (HART) Hubs

CTS sites provide a space for people to consume their own substances, including opioids, in a supervised setting that provides clean, sterilized tools and overdose-prevention support if needed.

The Committee notes the Auditor's finding that it was a "positive development" to invest "\$378 million in treatment, recovery and housing through the Hubs model," but also the Auditor General's finding that "the proposed changes to harm-reduction services were decided upon without proper planning, comprehensive impact or risk analysis, or public consultations."³² The Committee asked about the evidence-based business case for the government's decision to close the supervised Consumption and Treatment Services (CTS) sites across Ontario. The Committee also asked about whether this decision has the potential to increase opioid-related harms such as overdoses and public drug use.

The Ministry explained that the government "remains committed to supporting individuals experiencing addiction and homelessness through a comprehensive and integrated system of care" through such initiatives as the Homeless and Addiction Recovery Treatment (HART) Hubs.³³ The Committee heard that the Ministry worked with partners to support continuity of care for clients during the transition from CTS sites to HART Hubs. At the time of the hearings, 15 of 29 Hart Hubs were functioning across the province, but none were yet operating at full-service.³⁴

The Committee heard that the Ministry is establishing an evaluation framework for the HART Hubs, with reporting on outcome focused indicators. Once there is a stabilized dataset it will make it possible to establish targets for net new service provision and net new clients.³⁵

Committee Recommendations

The Standing Committee on Public Accounts recommends that:

4. The Ministry of Health evaluate the implementation of the Homeless and Addiction Recovery Treatment (HART) Hubs model through measurable indicators, such as service utilization, services offered, client health indicators (including but not limited to treatment initiation rates, treatment initiation by treatment type, retention in treatment rates, hospitalizations and emergency department visits, opioid-related mortality, and all-cause mortality), and housing outcomes, with interim evaluation milestones during the first year of operation, and publicly release the aggregated results annually at a provincial and regional level.

³²AG, p. 25.

³³ Committee *Hansard*, p. 31.

³⁴ Committee *Hansard*, p. 40.

³⁵ Committee *Hansard*, p. 39.

5. The Ministry of Health continue to
 - a) expand integrated treatment pathways, including RAAM clinics, HART Hubs, and hospital-based OAT programs; and
 - b) report annually on access, wait times, treatment retention, service utilization, and acute health care utilization (opioid-related hospitalization and emergency-department visits and first responder calls, and opioid-related mortality rates) to ensure resources reflect community needs.
6. The Ministry of Health report back to the Committee with information on outcomes (including but not limited to hospitalizations, emergency department visits, first responder calls, and opioid-related mortality trends), associated with changes in the delivery of addiction services, including transitions involving Consumption and Treatment Services (CTS) sites and other service models (disaggregated by region) to support ongoing monitoring and evaluation of service delivery across the system.

Rapid Access Addiction Medicine (RAAM) Clinics

Rapid access addiction medicine (RAAM) clinics are walk-in clinics designed to be a low-barrier option for people to obtain quick access to substance use disorder treatment services, without the need for a referral or appointment.

The Ministry explained that the RAAM clinics are “now a critical part of the community mental health and addictions care continuum with 89 RAAM clinics in operation across Ontario providing low barrier access to comprehensive assessment, peer support and care coordination.”³⁶

The Ministry explained that “a significant number of people have a co-occurring or concurrent mental health and substance abuse diagnosis” and this shows a need for services that treat both mental illness and substance use issues simultaneously.³⁷ The Committee heard that the Roadmap to Wellness strategy emphasizes concurrent disorder capable services.

The Committee asked about the Ministry’s progress in expanding access to evidence-based and Health Canada-approved treatments for opioid use disorder such as opioid agonist therapy (OAT), a medication-assisted treatment that prevents withdrawal symptoms and reduces drug cravings. The Ministry noted that, as recommended by the Auditor General, the Ministry is expanding services that provide OAT through RAAM clinics, and there are now 89 such clinics (up from 11 in 2016).³⁸

The Committee also heard that the Mental Health and Addictions Centre of Excellence has created a standard provincial dataset for data to be submitted by the more than 300 publicly funded mental health and addiction service providers,

³⁶ Committee *Hansard*, p. 29.

³⁷ *Ibid.*

³⁸ Committee *Hansard*, p. 36.

including RAAM clinics, by December 2026. This data will enable analytics and reporting to drive quality and performance improvements, among other things.

Committee Recommendations

The Standing Committee on Public Accounts recommends that:

7. The Ministry commit to accelerating access to evidence-based and Health Canada-approved treatments for opioid use disorder such as opioid agonist therapy (OAT) and injectable opioid agonist therapy (iOAT).
8. The Ministry of Health continue to
 - a) expand integrated treatment pathways, including RAAM clinics, HART Hubs, and hospital-based OAT programs; and potential pathways in outpatient and primary care settings for OAT; and
 - b) report annually on client health outcomes (including but not limited to treatment initiation rates, treatment initiation by treatment type, retention in treatment rates, hospitalizations and emergency department visits, opioid-related mortality, and all-cause mortality), access, wait times, treatment retention, and service utilization to ensure resources reflect community needs.

Naloxone Programs

Naloxone is a medication used to temporarily reverse an opioid overdose. The Committee asked about the concerns raised by the Auditor about the distribution of naloxone kits, reimbursements, and pharmacies' distribution practices. The Ministry explained that it "monitors naloxone claims under the Ontario Naloxone Program for pharmacies quarterly to identify unusual billing or distribution practices" and addresses inappropriate practices.³⁹

The Ministry explained that "when irregularities are detected, referrals are made to the regulatory bodies such as the Ontario College of Pharmacists or law enforcement."⁴⁰ The Ministry also noted that "collaboration between the Ontario Naloxone Program and the Ontario Naloxone Program for Pharmacies has been strengthened to maximize access and reduce duplication. These measures ensure naloxone remains widely available while maintaining program integrity."⁴¹

Committee Recommendations

The Standing Committee on Public Accounts recommends that:

9. The Ministry of Health continue to strengthen the monitoring of naloxone claims from pharmacies regularly to identify and address unreasonable or unusual naloxone claims and/or distribution practices.

³⁹ Committee *Hansard*, p. 47.

⁴⁰ *Ibid.*

⁴¹ *Ibid.*

10. The Ministry of Health consider taking steps itself to address unreasonable or unusual naloxone claims and/or distribution practices at the pharmacy level.

Monitoring of Prescriptions and Physician Billing

The Committee asked what resources are being used to try to reduce the prescribing of high-dose opioids by healthcare practitioners.⁴² The Ministry explained measures being taken to strengthen oversight of prescribing and dispensing through the Narcotics Monitoring System and MyPractice reports as well as its updated pharmacy guidance to improve naloxone program governance.

Committee Recommendations

The Standing Committee on Public Accounts recommends that:

11. The Ministry of Health, in collaboration with Ontario Health and the relevant regulatory colleges:
 - a) publish annual, aggregate and de-identified summaries of opioid-prescribing and naloxone-distribution trends;
 - b) support the expanded adoption and effective use of existing clinical viewers and digital-health tools — in full compliance with privacy and confidentiality requirements — to improve prescribing safety and coordination of care; and
 - c) define clear performance thresholds to guide ongoing monitoring and system response.

Emerging Practices

The Auditor reported that “emerging practices,” such as new forms of treatment “exist in isolation and require evaluation.”⁴³ For example, injectable opioid agonist therapy (iOAT) is an alternative for people who have not benefited from traditional OAT therapy. While iOAT is used in other jurisdictions in Canada and internationally, it is not currently funded by the Ministry of Health. The Committee asked about the delays in expanding access to iOAT and OAT.⁴⁴

⁴² Committee *Hansard*, p. 46.

⁴³ AG, report, p. 9.

⁴⁴ Committee *Hansard*, p. 33.

Committee Recommendation

The Standing Committee on Public Accounts recommends that:

12. The Ministry of Health, through the Ministry's expert advisory structures, including the proposed clinical expert advisory group and existing advisory groups within Ontario Health and the Mental Health and Addictions Centre of Excellence, coordinate independent evaluation of emerging clinical approaches to the treatment of opioid use disorder to assess their effectiveness, outcomes, and potential risk on at least an annual basis.

CONSOLIDATED COMMITTEE RECOMMENDATIONS

The Standing Committee on Public Accounts recommends that:

1. The Ministry of Health, within the existing Roadmap to Wellness, establish a clear opioid-related performance framework—including measurable objectives, indicators, and annual public reporting—to ensure that Ontario’s response to opioid use remains evidence-based, transparent, and aligned with the province’s broader mental-health and addictions goals.
2. The Ministry of Health, in collaboration with Ontario Health and the Mental Health and Addictions Centre of Excellence, develop and publish an annual public dashboard of standardized indicators—covering prevention, treatment, recovery, and harm-reduction outcomes, disaggregated by region and demographic—to support transparent, evidence-informed decision-making.
3. The Ministry, in collaboration with Ontario Health and other involved ministries, ensure that service providers are supported in accessing and implementing the data and digital infrastructure plan and requirements including through appropriate planning and resource allocation.
4. The Ministry of Health evaluate the implementation of the Homeless and Addiction Recovery Treatment (HART) Hubs model through measurable indicators, such as service utilization, services offered, client health indicators (including but not limited to treatment initiation rates, treatment initiation by treatment type, retention in treatment rates, hospitalizations and emergency department visits, opioid-related mortality, and all-cause mortality), and housing outcomes, with interim evaluation milestones during the first year of operation, and publicly release the aggregated results annually at a provincial and regional level.
5. The Ministry of Health continue to
 - a) expand integrated treatment pathways, including RAAM clinics, HART Hubs, and hospital-based OAT programs; and
 - b) report annually on access, wait times, treatment retention, service utilization, and acute health care utilization (opioid-related hospitalization and emergency-department visits and first responder calls, and opioid-related mortality rates) to ensure resources reflect community needs.
6. The Ministry of Health report back to the Committee with information on outcomes (including but not limited to hospitalizations, emergency department visits, first responder calls, and opioid-related mortality trends), associated with changes in the delivery of addiction services, including transitions involving Consumption and Treatment Services (CTS) sites and other service models (disaggregated by region) to support ongoing monitoring and evaluation of service delivery across the system.

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7. The Ministry of Health commit to accelerating access to evidence-based and Health Canada-approved treatments for opioid use disorder such as opioid agonist therapy (OAT) and injectable opioid agonist therapy (iOAT).
 8. The Ministry of Health continue to
 - a) expand integrated treatment pathways, including RAAM clinics, HART Hubs, and hospital-based OAT programs; and potential pathways in outpatient and primary care settings for OAT; and
 - b) report annually on client health outcomes (including but not limited to treatment initiation rates, treatment initiation by treatment type, retention in treatment rates, hospitalizations and emergency department visits, opioid-related mortality, and all-cause mortality), access, wait times, treatment retention, and service utilization to ensure resources reflect community needs.
 9. The Ministry of Health continue to strengthen the monitoring of naloxone claims from pharmacies regularly to identify and address unreasonable or unusual naloxone claims and/or distribution practices.
 10. The Ministry of Health consider taking steps itself to address unreasonable or unusual naloxone claims and/or distribution practices at the pharmacy level.
 11. The Ministry of Health, in collaboration with Ontario Health and the relevant regulatory colleges:
 - a) publish annual, aggregate and de-identified summaries of opioid-prescribing and naloxone-distribution trends;
 - b) support the expanded adoption and effective use of existing clinical viewers and digital-health tools — in full compliance with privacy and confidentiality requirements — to improve prescribing safety and coordination of care; and
 - c) define clear performance thresholds to guide ongoing monitoring and system response.
 12. The Ministry of Health, through the Ministry's expert advisory structures, including the proposed clinical expert advisory group and existing advisory groups within Ontario Health and the Mental Health and Addictions Centre of Excellence, coordinate independent evaluation of emerging clinical approaches to the treatment of opioid use disorder to assess their effectiveness, outcomes, and potential risk on at least an annual basis.