Order Amending Schedule VI to the Controlled Drugs and Substances Act (Additional Fentanyl Precursors): SOR/2026-38

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CONTROLLED DRUGS AND SUBSTANCES ACT

P.C. 2026-163 February 26, 2026

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, considering that it is necessary in the public interest, makes the annexed *Order Amending Schedule VI to the Controlled Drugs and Substances Act (Additional Fentanyl Precursors)* under section 60 [a] of the *Controlled Drugs and Substances Act* [b].

Order Amending Schedule VI to the Controlled Drugs and Substances Act (Additional Fentanyl Precursors)

Amendments

1 Part 1 of Schedule VI to the *Controlled Drugs and Substances Act* [b] is amended by adding the following after item 32:

33 Phenethyl bromide ((2-bromoethyl)benzene)

34 Propionic anhydride (propanoic anhydride)

35 Phenethyl iodide ((2-iodoethyl)benzene)

36 Phenethyl chloride ((2-chloroethyl)benzene)

2 Part 2 of Schedule VI to the Act is amended by adding the following after item 6:

7 Benzyl chloride ((chloromethyl)benzene)

Coming into Force

3 This Order comes into force on April 12, 2026.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Order or the Regulations*.)

Issues

There is widespread recognition of the damage to people and communities in Canada that has been caused by illegal fentanyl. On February 28, 2025, the then-Minister of Mental Health and Addictions issued a Ministerial Order under the *Controlled Drugs and Substances Act* (CDSA) to temporarily control three chemicals that can be used to illegally produce fentanyl (phenethyl bromide, propionic anhydride and benzyl chloride). This action was taken to prevent these precursor chemicals from being imported and used in the illegal drug market.

After the Ministerial Order was issued, Health Canada finalized a scientific assessment, which found that two additional precursors, phenethyl chloride and phenethyl iodide, can be used as alternatives to phenethyl bromide to illegally produce fentanyl. These two chemicals are not currently controlled under the CDSA.

The temporary controls set out in the Ministerial Order are set to expire on April 13, 2026, for phenethyl bromide, and May 28, 2026, for propionic anhydride and benzyl chloride. Canada must take steps to schedule these substances under Schedule VI of the CDSA for controls to continue. Additionally, phenethyl chloride and phenethyl iodide also need to be controlled under Schedule VI of the CDSA to prevent them from being imported and used by illegal fentanyl producers. Without these controls in place, these chemicals pose a significant risk to public health and public safety.

Background

As part of Canada's Border Plan, the Government of Canada is taking concrete action to further strengthen border security, including by increasing support for law enforcement agencies to detect, intercept and

curb the illegal trade of fentanyl and its precursors. The Government of Canada is also committed to combatting the threat posed by illegal synthetic drugs, including the associated risk of overdose deaths and harms.

Canada has seen substantially elevated numbers of drug poisonings since national surveillance by the Public Health Agency of Canada began in 2016. The most recent available data on opioid- and stimulant-related poisonings in Canada can be found at the following link: Opioid- and Stimulant-related Harms in Canada. In addition to the devastating public health and social harms associated with the consumption of illegal synthetic opioids, such as fentanyl, Canada is also extremely concerned about their impact on public safety, including security challenges associated with their illegal production, diversion, trafficking and related crimes.

Legal framework regulating precursors

Fentanyl and fentanyl analogues are highly potent synthetic opioids that are controlled in Canada under Schedule I of the CDSA. Precursors are chemicals that are used in the production of a controlled substance. While some precursors have legitimate uses, they can also be used in the illegal production of controlled substances, like fentanyl and its analogues. In Canada, precursors are controlled under Schedule VI of the CDSA and subject to the *Precursor Control Regulations* (PCR). Under the PCR, precursors are classified based on their risk profile: Class A precursors are essential ingredients or building blocks used in the production of controlled substances, while Class B precursors are common reagents, such as solvents, acids and bases.

To legally conduct regulated activities with Class A and Class B precursors, authorization under the PCR is required. This includes the following:

- For Class A precursors, a Class A precursor site-specific licence is required to produce, package, sell/provide, export, or possess for those purposes, or to import Class A precursors. Permits are also required for their importation and exportation.
- For Class B precursors, a Class B precursor registration is required to produce a Class B precursor for sale or provision, and for its importation and exportation. Export permits are only needed when exporting to specific destinations that have requested a pre-export notification through the International Narcotics Control Board.
- Preparations and mixtures that contain no more than 30% by weight/volume of a Class B precursor, either alone or with any other precursor of the same class, are exempted from certain provisions of the PCR.

A person may also apply to Health Canada for a precursor authorization certificate to facilitate the importation or exportation of preparations and mixtures containing Class A precursors or Class B precursors (where those Class B precursors are not already exempt from the application of the PCR) if specified conditions are met.

Neither the PCR nor the CDSA prohibits possession of a precursor, although possession for the purposes of exportation is prohibited. Additionally, under section 7.1 of the CDSA, the possession, production, sale, importation and transport of anything, including a precursor, with the intent of using it to produce or traffic in a controlled substance is prohibited. Under the PCR, a person who procures a Class A precursor as an “end user” (i.e. a person who purchases a Class A precursor from a license holder and signs an “end-use declaration”) can possess, transport, send and deliver a Class A precursor without additional authorization. For example, research activities with Class A precursors typically fall within the

scope of permitted end-user activities (e.g. possession); as a result, researchers rarely need to seek additional authorization from Health Canada for research activities.

Temporary Ministerial Order to control three precursors

On February 28, 2025, the then-Minister of Mental Health and Addictions and Associate Minister of Health issued a Ministerial Order under paragraph 60.1(1)(a) of the CDSA to temporarily control three precursors — phenethyl bromide, propionic anhydride and benzyl chloride — under Schedule V of the CDSA for a period of one year to protect public health and safety, as these chemicals have significant potential to be used in the production of illegal drugs. The Ministerial Order also included carisoprodol, a sedative-like drug, which also poses a risk to public health and safety. Longer-term controls for carisoprodol came into effect on December 19, 2025; this drug is now listed in Schedule IV to the CDSA and regulated as a targeted substance.

Controls for phenethyl bromide came into force on April 14, 2025, while controls for propionic anhydride and benzyl chloride came into force on May 29, 2025. While it is in effect, the Ministerial Order prohibits the importation, exportation, production, trafficking and possession for the purposes of trafficking of these three precursors.

Because these precursors have legitimate pharmaceutical, industrial and research uses, simultaneous with the Ministerial Order, Health Canada issued a class exemption for persons conducting otherwise prohibited activities with preparations or mixtures that contain no more than 30% by weight/volume of phenethyl bromide, propionic anhydride and benzyl chloride, to permit certain limited uses of these substances. While the

Ministerial Order is in effect, anyone not subject to the class exemption must apply to Health Canada for a subsection 56(1) exemption to conduct activities with these substances.

Bill C-12, *the* Strengthening Canada's Immigration System and Borders Act

As part of its Border Plan, the Government of Canada introduced Bill C-12, also known as the *Strengthening Canada's Immigration System and Borders Act* (the Bill), on October 8, 2025. Part 2 of the Bill would amend the temporary accelerated scheduling pathway that allows the Minister of Health to add precursor chemicals to Schedule V of the CDSA. It would also make related amendments to the PCR. If Bill C-12 receives royal assent before the *Order Amending Schedule VI to the Controlled Drugs and Substances Act (Additional Fentanyl Precursors)* and the *Regulations Amending the Precursor Control Regulations (Additional Fentanyl Precursors)* [Governor in Council (GIC) regulatory amendments] come into force, the requirements of the PCR will apply immediately to any precursors controlled under Schedule V of the CDSA. As a result, anyone wanting to conduct activities with these substances would have to apply to Health Canada for authorization under the PCR, while the temporary controls are in effect. Under the Bill, propionic anhydride and phenethyl bromide would be regulated as Class A precursors, and benzyl chloride would be regulated as a Class B precursor.

Public health and public safety risks

Most of the essential building blocks that can be used to produce fentanyl are already controlled in Canada. While it is not possible to produce fentanyl without using one of these already controlled building blocks, the five precursors below can also be used to illegally produce fentanyl. As a

result, Health Canada has concluded that long-term control of these precursors is needed to address the significant risk they pose to public health and safety.

Phenethyl bromide, phenethyl chloride and phenethyl iodide

- Research shows that phenethyl bromide (Chemical Abstracts Service Registry Number 103-63-9) and two chemically related substances — phenethyl chloride (Chemical Abstracts Service Registry Number 622-24-2) and phenethyl iodide (Chemical Abstracts Service Registry Number 17376-04-4) — can be used to illegally produce fentanyl.
- There is evidence that phenethyl bromide is being used in clandestine laboratories in Canada, and, since the temporary controls were put in place, significant amounts of phenethyl bromide have been found in domestic clandestine laboratories. Data from the Precursor Incident Communication System of the International Narcotics Control Board indicates that, between 2020 and 2023, approximately 4 300 kg of phenethyl bromide were intercepted (originating in Asia, with North America being the destination), often with other known fentanyl precursors.
- To date, phenethyl chloride and phenethyl iodide have not yet been intercepted at the border or found in clandestine laboratories.

Propionic anhydride

- Research shows that propionic anhydride (Chemical Abstracts Service Registry Number 123-62-6) can be used to illegally produce fentanyl. This chemical is classified as a List I chemical under the United States' *Controlled Substances Act*.

- Since the temporary Ministerial Order was issued, an illegal shipment of propionic anhydride was intercepted at the Canadian border.

Benzyl chloride

- Research shows that benzyl chloride (Chemical Abstracts Service Registry Number 100-44-7) can be used to illegally produce fentanyl. This chemical is classified as a List II chemical under the United States' *Controlled Substances Act*.
- At present, there is no evidence that this precursor chemical is being imported and used in illegal drug production in Canada, but it has been seized in large quantities in other countries.

Objective

The objective of the GIC regulatory amendments is to enact strict long-term controls on activities with the following five fentanyl precursors: phenethyl bromide, phenethyl chloride, phenethyl iodide, propionic anhydride and benzyl chloride. These controls aim to prevent the importation of these precursors to Canada to be used in illegal drug production, thereby addressing the significant risk they pose to public health and safety.

Description

The GIC regulatory amendments add phenethyl bromide, phenethyl chloride, phenethyl iodide and propionic anhydride to Part 1 of Schedule VI to the CDSA as Class A precursors; they are also being added to the Schedule to the PCR with a corresponding maximum quantity of "0" in Column 2 of the Schedule. This threshold determines the application of certain provisions in the PCR for Class A precursors regarding (1) exempted sale or provision by a specific person (i.e. whether an end-use declaration is required for sale); and (2) certain record-keeping and transportation

documentation requirements. The GIC regulatory amendments also add benzyl chloride to Part 2 of Schedule VI to the CDSA as a Class B precursor. Class B precursors are not listed in the Schedule to the PCR.

The GIC regulatory amendments will come into force on April 12, 2026, before the temporary controls in the Ministerial Order expire. This prevents a lapse in the control of phenethyl bromide, propionic anhydride and benzyl chloride and provides stakeholders with time to comply.

Regulatory development

Consultation

Prior to the Ministerial Order being issued, stakeholders were consulted on the proposal to temporarily schedule phenethyl bromide, propionic anhydride and benzyl chloride through a Notice of Intent (NOI) that was published in the *Canada Gazette*, Part I, on February 14, 2025. Health Canada also held a technical briefing for potentially impacted sectors, which included participants from industries representing oil and gas, chemistry, paint and coatings, mining, and food and beverages.

Stakeholders cited the use of benzyl chloride in pharmaceutical, chemical and research industries, and in the manufacturing of products, such as lubricants and other chemicals used in the oil, gas and mining industries. They also indicated that benzyl chloride is sometimes found in trace amounts (as impurities) in certain products, including as disinfectants, cleaners, food packaging and personal care products. Two pharmaceutical companies also indicated that they use propionic anhydride in drug manufacturing.

Once the Ministerial Order was in effect, Health Canada sent a survey to potentially impacted stakeholders to determine the impact of a proposal to schedule phenethyl bromide, propionic anhydride and benzyl chloride as

well as phenethyl chloride and phenethyl iodide on a long-term basis under Schedule VI to the CDSA and the Schedule to the PCR. The survey was sent to controlled substances licence holders, precursor licence and registration holders, precursor authorization certificate holders and drug establishment licence holders.

The survey was open for 30 days, and Health Canada received 27 responses from the following:

- 1 industry association;
- 2 government organizations;
- 24 industry members.

Of the 27 respondents, 10 stakeholders indicated that they use one or more of the precursors.

Two of the respondents to the survey were government organizations, which stated that they use the precursors as reference standards but rarely need to purchase or import the precursors. They indicated that the proposal would impact them minimally because they would need to amend their existing PCR licences.

Phenethyl bromide, phenethyl chloride and phenethyl iodide

One company confirmed that they import phenethyl chloride and phenethyl iodide to sell to other entities for research and development purposes; however, they indicated that there is very little demand for these chemicals and anticipate future demand will be sporadic.

The company also commented that they find Health Canada’s import-permitting process to be burdensome and asked Health Canada to consider issuing blanket import permits for individual companies. This comment falls outside the scope of the proposal.

One company that provides chemicals for sale indicated that phenethyl chloride and phenethyl iodide may be used to manufacture non-controlled active pharmaceutical ingredients as well as controlled substances, such as fentanyl and morphine analogues. The stakeholder did not provide information pertaining to quantities used, imported, or sold. They stated that the GIC regulatory amendments for phenethyl bromide, propionic anhydride and benzyl chloride would have minimal impacts on their operations, as they already hold a licence under the PCR. They indicated that some of their customers could also face an increased administrative burden.

Health Canada did not hear from any domestic pharmaceutical manufacturers to indicate that these substances are used in pharmaceutical manufacturing in Canada.

No comments were received on phenethyl bromide.

Propionic anhydride

Two pharmaceutical industry stakeholders stated that they use propionic anhydride in their operations. However, they also stated that the proposal would impact them minimally because they purchase propionic anhydride as “end users” and would not need to amend their existing PCR licences.

Another chemical industry stakeholder stated that they import propionic anhydride. They stated the proposal would impact them minimally because they would need to amend their existing PCR licence.

Benzyl chloride

One stakeholder explained that benzyl chloride appears as an impurity in some of their products, at less than 1% by weight or volume. They indicated that adoption of the proposed changes would minimally impact them, as they would only need to update their internal policies and procedures. This

is because preparations and mixtures containing a Class B precursor, either alone or with any other precursor of the same class that does not constitute more than 30% of the preparation or mixture by weight or volume, are exempted from the application of the PCR.

Another stakeholder from the pharmaceutical industry stated that they use benzyl chloride as a raw material in their manufacturing processes with yearly use of the precursor dependent on customer demand. They indicated that they would need to take steps to comply with the PCR, including applying for Class B registration, if the precursor was controlled on a long-term basis.

Indigenous engagement, consultation and modern treaty obligations

Health Canada examined the geographical scope and subject matter of the initiative in relation to modern treaties in effect and did not identify any potential modern treaty implications nor any adverse impacts on potential or established Indigenous or treaty rights.

Instrument choice

Controlling phenethyl bromide, propionic anhydride and benzyl chloride under the CDSA provides border and law enforcement agencies with the authority to continue to take action in relation to activities with the precursors that contravene the CDSA. Without the GIC regulatory amendments, the Ministerial Order would expire and there would be a lapse in control of the three precursors, and law and border enforcement agencies would have fewer tools to take action to halt the illegal importation, distribution and use of chemicals. Additionally, controlling phenethyl chloride and phenethyl iodide under the CDSA provides new tools to law and border enforcement to use to prevent their illegal distribution and use.

As a result, controlling the five precursors by adding them to Schedule VI of the CDSA is the recommended option.

Regulatory analysis

Benefits and costs

Baseline scenario

Precursors temporarily controlled under the Ministerial Order — phenethyl bromide, propionic anhydride and benzyl chloride

Phenethyl bromide, propionic anhydride and benzyl chloride are temporarily controlled under a Ministerial Order, which is set to expire on April 13, 2026, for phenethyl bromide, and on May 28, 2026, for propionic anhydride and benzyl chloride.

While the Ministerial Order is in effect, entities must obtain a subsection 56(1) exemption under the CDSA to conduct activities with these three chemicals.

Once the Ministerial Order expires, the prohibitions under the CDSA will no longer apply to these three precursors. Activities (e.g. production, sales/provision, packaging and possession for the purposes of these activities) involving the precursor chemicals could be carried out without the need for authorization, and no reporting or record-keeping obligations would apply.

Precursors not temporarily controlled under the Ministerial Order — phenethyl chloride and phenethyl iodide

Phenethyl chloride and phenethyl iodide are not currently controlled under the CDSA. Therefore, activities involving these chemicals may be conducted without the need for authorization under the CDSA.

Regulatory scenario

Under this scenario (i.e. the GIC regulatory amendments), all five precursors (phenethyl bromide, phenethyl chloride, phenethyl iodide, propionic anhydride and benzyl chloride) will be subject to long-term control under the CDSA and regulated under the PCR. Entities engaging in activities with these precursors will be required to comply with licensing and/or registration requirements, as well as operational obligations outlined in the PCR.

Subsection 56(1) exemptions issued during the temporary control period for phenethyl bromide, propionic anhydride and benzyl chloride will no longer be applicable. Instead, authorization through licensing (for Class A precursors) or registration (for Class B precursors) will be required to conduct regulated activities with the precursors.

The Bill C-12 scenario

The timing of Bill C-12's passage cannot be predicted. If Bill C-12 comes into force before the GIC regulatory amendments come into force, the requirements of the PCR will apply with respect to activities involving phenethyl bromide, propionic anhydride and benzyl chloride for the period of temporary control. The baseline scenario described above will be adjusted to reflect the following:

- entities conducting certain activities with phenethyl bromide and propionic anhydride will be required to obtain or amend a licence for Class A precursors, and for certain activities with benzyl chloride, obtaining or amending a registration for Class B precursors will be required; and
- entities conducting activities with these substances pursuant to a subsection 56(1) exemption will also need to apply for the appropriate authorizations under the PCR.

Because some licence and registration applications or amendments would have already been submitted in compliance with Bill C-12 under the baseline scenario, the number of entities expected to be impacted under the regulatory scenario would be reduced. The incremental impact of the GIC regulatory amendments would therefore be reduced.

If Bill C-12 comes into force after the GIC regulatory amendments come into force, this will not have any implications for the cost-benefit analysis, as both the baseline and regulatory scenarios will remain as described above.

Regardless of the timing of Bill C-12's passage, this will not have any impact on the analysis for phenethyl chloride and phenethyl iodide, as these two precursors are not subject to temporary controls.

Benefits

The GIC regulatory amendments will ensure strict federal oversight of legitimate activities with these precursors. They will also help prevent these chemicals from being illegally imported into Canada and from being used in the illicit production of fentanyl, thereby protecting public health and public safety. Scheduling the precursors on a long-term basis allows the Canada Border Services Agency (CBSA) and law enforcement agencies to continue to take action, following the expiry of the temporary Ministerial Order, against the illegal importation, distribution and use of phenethyl bromide, propionic anhydride and benzyl chloride. The GIC regulatory amendments also provide these agencies with new tools to prevent the illegal distribution and use of phenethyl chloride and phenethyl iodide.

Costs

The GIC regulatory amendments are not expected to impose significant costs on regulated parties (applicants and licence and registration holders under the PCR), end users or the Government. For instance, the costs for stakeholders to submit licence or registration applications, obtain criminal record checks and to review the PCR are not expected to exceed $50,000 (undiscounted) over 10 years. The costs associated with the GIC regulatory amendments are discussed in detail below.

Licence and registration holders

Costs associated with applying for a licence or registration — new licence and registration holders

Following the coming into force of the GIC regulatory amendments, entities that do not currently hold a Class A precursor licence will need to apply for a licence to conduct activities involving phenethyl bromide, phenethyl chloride, phenethyl iodide and propionic anhydride. Entities that do not already hold a Class B precursor registration will need to apply for registration to conduct activities with benzyl chloride, unless the activities are covered by applicable exemptions specified in the PCR.

To estimate the number of new licence or registration applications, Health Canada relied on data about the number of subsection 56(1) exemptions issued since the Ministerial Order came into effect and industry survey results. When the Ministerial Order came into force, a small number of entities that did not already hold a licence or a registration applied for and were issued subsection 56(1) exemptions. [1] Responses to Health Canada's survey indicate that additional entities that do not hold a licence or registration under the PCR intend to apply for authorization (either through a licence or a registration) under the PCR to conduct activities with the precursors following their long-term control. It is also assumed that a few entities currently operating under the class exemption may need to apply

for a Class A precursor licence once that class exemption is revoked. Given the above, Health Canada anticipates that over the next 10 years a limited number of businesses may apply for new authorizations.

Considering the above, Health Canada estimates that approximately 10 new licence applications and 10 new registration applications, all from industry, will be submitted over the next 10 years. Of these 20 applications, 10 (5 licences and 5 registrations) are expected in the first year after the amendments come into force, with the remaining 10 distributed over the subsequent 9 years.

Entities seeking authorization will incur costs related to (1) completing an initial application form for a licence or a registration, (2) renewing their licences or registrations every three or five years, respectively, and (3) applying for criminal record checks for responsible personnel (senior person in charge, responsible person in charge and alternate responsible person in charge) during both the initial application and the renewal of the licence or registration. Entities applying for Class A precursor licences must also implement physical security measures. In addition, all applicants will incur costs associated with reviewing the PCR to understand applicable regulatory requirements and to fulfill record-keeping (including end-use declarations) and reporting obligations.

Administrative costs per activity (in 2024 dollars) are estimated using the following assumptions:

- reviewing the PCR: 5.2 hours per licence holder (all four responsible personnel) at a wage of $50.04/hour; [2] 0.8 hours per registration holder (one senior person in charge) at a wage of $75.60/hour;
- preparing and submitting applications: four hours for licence or three hours for registration at a wage of $41.52/hour;

- licence or registration renewal: one hour per application at a wage of $41.52/hour;
- criminal record check application:
    - licence holder — four employees will do a criminal record check (three at the staff level and one at the management level), spending two hours per employee filling out the application at a weighted wage rate of $50.04,
    - registration holder — one management-level employee will do a criminal record check, spending two hours filling out the application at a wage rate of $75.60;
- record-keeping/reporting: two hours per licence holder per year or half an hour per registration holder per year at a wage of $41.52/hour

In addition, applicants will incur a cost of $70.00 per application to conduct a criminal record check in support of their application.

Accordingly, the costs (undiscounted in 2024 dollars) for a single new licence or registration applicant are estimated below.

Incremental impacts to licence or registration holders — unit costs

	Preparing and submitting one initial application	Criminal record check applications and fees	Licence or registration renewal	Record keeping and reporting	Reviewing the PCR
New licence holders	$166.09	$680.33	$41.52	$83.04	$260.22
New registration holders	$124.57	$221.20	$41.52	$20.76	$58.59

Furthermore, new licence holders will incur costs to implement physical security measures. These costs will vary depending on the volume of the precursors stored at the site and the security measures installed. While Health Canada acknowledges the financial impact of these security requirements, it is not possible to monetize these costs due to a lack of information on the potential new licence holders and the extent of security measures they will need to implement.

Costs associated with amending licences or registrations — existing licence or registration holders

Once the GIC regulatory amendments come into force, entities that currently hold a precursor licence or registration will need to amend their existing authorizations to include the newly controlled precursors before conducting any regulated activities with them.

Using the same data sources and analytical methods as above, Health Canada estimates that approximately 30 licence or registration amendment applications will be submitted over the next 10 years, evenly divided between Class A precursor licences and Class B precursor registrations. Twenty amendment applications (10 licences and 10 registrations) are expected in the first year, [3] with the remaining 10 amendment applications (5 licences and 5 registrations) distributed over the subsequent 9 years.

Based on industry feedback, each amendment is expected to require approximately 30 minutes to complete. Using an hourly wage rate of $41.52, the estimated cost to complete one amendment is $20.76 (in 2024 dollars).

Costs associated with import/export permit applications — new and existing licence and registration holders

Once the GIC regulatory amendments come into force, licence holders intending to import or export Class A precursors will need to apply for a permit each time they conduct this activity. Since the issuance of the Ministerial Order, only one legal importation of one of the chemicals that are temporarily controlled has occurred, which indicates little legitimate import activity. Thus, Health Canada assumes one import/export permit application will be submitted annually for any of the chemicals proposed for control over the next 10 years. [4] Industry input indicates that preparing an import/export permit application requires approximately 30 minutes. Applying the wage rate of $41.52/hour, the estimated cost for each application is $20.76 (in 2024 dollars).

Costs associated with obtaining precursor authorization certificates — new and existing licence and registration holders

Under the regulatory scenario, some companies may choose to apply for a precursor authorization certificate to facilitate the importation, exportation and domestic sale of certain preparations and mixtures containing Class A and Class B precursors if certain conditions are met. Data from subsection 56(1) exemption applications submitted during the temporary control period, along with the industry's responses to the survey, indicate that the legitimate importation of these precursors is limited. Additionally, Health Canada has issued very few precursor authorization certificates to date for any precursors controlled under the PCR. As a result, Health Canada assumes that no more than one application will be submitted over the next 10 years. It is assumed that completing an application requires approximately four hours. Applying a wage rate of $41.52/hour, the estimated time for one certificate application will cost $166.09 (in 2024 dollars).

End users

Once the GIC regulatory amendments come into force, end users (typically researchers or other individuals) will need to prepare and provide signed and dated end-use declarations to the licence holders from whom they acquire the scheduled precursors. It is assumed that they will spend 10 minutes to fill in one end-use declaration. Although Health Canada does not have information to be able to estimate how frequently this will occur, impacts on end users are expected to be minimal.

Government

Health Canada will incur costs for undertaking compliance promotion and enforcement activities to ensure that only authorized activities are conducted with these precursors. These costs can primarily be attributed to responding to inquiries.

Health Canada will also incur costs to process new licence and registration applications or amendments, import and export permit applications and applications for precursor authorization certificates.

A small number of federal government organizations, including Health Canada, that already possess a precursor licence and registration may incur costs associated with amending their authorizations, or applying for a permit to import or export Class A precursors. The overall costs related to these activities are expected to be low.

Small business lens

Analysis under the small business lens concluded that the GIC regulatory amendments will impact small businesses. Of the potentially affected companies, most are small businesses. [5] Small businesses will incur costs when applying for, renewing or amending a licence or registration,

applying for import/export permits or for precursor authorization certificates. Small businesses will also incur costs to meet record-keeping and reporting obligations.

Undertaking these actions is necessary to obtain authorizations and meet existing regulatory requirements. As a result, providing flexibility to small businesses is not feasible.

One-for-one rule

Order Amending Schedule VI to the Controlled Drugs and Substances Act (Additional Fentanyl Precursors) and *Regulations Amending the Precursor Control Regulations (Additional Fentanyl Precursors)*

The one-for-one rule applies, since there will be an incremental increase in administrative burden on businesses. The GIC regulatory amendments will be considered an IN under the rule.

All affected businesses are expected to incur administrative costs as outlined in the "Benefits and costs" section. As per the *Red Tape Reduction Regulations*, the assessment of administrative impacts was conducted for a period of 10 years commencing from registration (2026 to 2035). All values listed in this section are presented in 2012 dollars, discounted to 2012 at a rate of 7%.

The time spent by responsible persons in charge or alternate responsible persons in charge was monetized using an hourly wage of $31.41. This includes time spent reviewing the administrative provisions of the PCR, applying for, renewing or amending a licence or a registration, applying for criminal record checks (not including payment of fees), applying for import/export permits and precursor authorization certificates, and meeting record-keeping or reporting requirements. For senior persons in charge, the time spent reviewing the GIC regulatory amendments was monetized using an hourly wage of $57.18. Based on these estimates, the

total incremental administrative burden to all affected businesses is estimated to be $6,139 in present value (PV) over 10 years or $874 in annualized value (in 2012 dollars).

Order Amending Schedule V to the Controlled Drugs and Substances Act (Fentanyl Precursors and Carisoprodol)

In the Regulatory Impact Analysis Statement that accompanied the Ministerial Order that temporarily controls phenethyl bromide, propionic anhydride and benzyl chloride under the CDSA, Health Canada indicated that the Order would impose administrative burden on affected stakeholders should they need to apply for a subsection 56(1) exemption or import/export permits during the time the Order is in effect. Health Canada acknowledged that the Ministerial Order was an IN under the one-for-one rule. However, an estimate of administrative burden was not conducted at that time. Since the publication of the Ministerial Order, 12 applications for subsection 56(1) exemptions, each estimated to have taken two hours to complete, and one application for an import permit, estimated to have taken 30 minutes, were submitted to Health Canada. Using the same assumptions outlined in the section above, the total administrative costs to implicated licensed dealers and registration holders related to these activities are estimated at $298 (PV) or $42 in annualized value (in 2012 dollars).

Regulatory cooperation and alignment

Propionic anhydride and benzyl chloride are controlled under the United States' *Controlled Substances Act* as List I and List II chemicals, respectively. The United States has also proposed controls for phenethyl bromide and has asked stakeholders for more information on legitimate uses of related chemicals, including phenethyl chloride and phenethyl iodide.

Controlling these fentanyl precursors is in line with Canada's plan to detect and disrupt the illegal fentanyl trade as one element of Canada's Border Plan. It also aligns with Canada's commitment to strengthen the coordinated global response to the international public health and public safety challenges posed by synthetic drugs, as outlined in the Ministerial Declaration on Accelerating and Strengthening the Global Response to Synthetic Drugs.

International obligations

The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (the Convention) to which Canada is a party, does not control phenethyl bromide, phenethyl chloride, phenethyl iodide, propionic anhydride or benzyl chloride. While the GIC regulatory amendments do not affect Canada's compliance with the Convention, the control of these chemicals used in the illegal production of fentanyl helps address international drug trafficking concerns. These controls are part of Canada's continued efforts to demonstrate leadership in the strict control of illegal drugs and precursor chemicals that can be used to produce them.

Effects on the environment

In accordance with the Cabinet *Directive on Strategic Environmental and Economic Assessment*, a preliminary scan concluded that a strategic environmental and economic assessment is not required.

Gender-based analysis plus

The GIC regulatory amendments would help prevent these five precursors from being illegally imported into Canada and used in the illegal production of fentanyl, thereby protecting public health and public safety. Although it is expected that Canadians affected by the drug crisis would benefit from the amendments, there is no evidence to indicate that the GIC regulatory

amendments will result in any disproportionate impacts to any affected groups or subgroups based on sex or gender, socioeconomic status, or other characteristics. Actions to disrupt the illegal importation of fentanyl precursors into Canada are expected to be experienced by all potentially impacted groups and subgroups affected by Canada's drug crisis.

Implementation, compliance and enforcement, and service standards

Implementation

The GIC regulatory amendments will come into force on April 12, 2026. The delayed coming into force will give anyone wanting to conduct legitimate activities with the five fentanyl precursors time to apply to Health Canada for authorization, such as a licence or registration.

Under the PCR, a licence is required for any person to produce, package, sell, provide, import, export and possess Class A precursors for these purposes, and a registration is required for any person to produce for the purpose of sale, for importation, and exportation of a Class B Precursor. Licence holders are required to apply to Health Canada for an additional permit to import and to export Class A precursors, while registered dealers require a permit to export Class B precursors to specific destinations. Any person who is not authorized to conduct regulated activities will be subject to the offences and penalties set out in sections 6 and 7.1 of the CDSA.

Health Canada has already encouraged potentially impacted stakeholders to apply for the necessary authorizations under the PCR. Health Canada will also send notification emails to potentially impacted stakeholders on the date the GIC regulatory amendments are published to ensure they are aware of the amendments and their implications.

Compliance and enforcement

Health Canada is responsible for authorizing (through licences, permits and exemptions) legitimate activities with substances scheduled under the CDSA and its regulations and for monitoring compliance with regulatory requirements.

The CBSA supports compliance monitoring for controlled substances and precursors at the border by confirming that imports are for legitimate purposes. Federal, provincial and local law enforcement are responsible for taking enforcement action in response to contraventions of the CDSA and its regulations. Under the CDSA, a range of penalties apply to the offences associated with the precursors included in the GIC regulatory amendments. The maximum penalty for indictable offences with respect to precursors listed in Schedule VI to the CDSA is imprisonment for a term not exceeding 10 years.

Service standards

No new service standards are being created. Service standards already exist for issuing licences and permits under the CDSA. Recognizing that the period between the publication of the GIC regulatory amendments and their coming into force is shorter than Health Canada's published service standards for authorization issuance, Health Canada has already encouraged potentially impacted stakeholders to apply for the necessary authorizations under the PCR. Health Canada will also prioritize requests for authorization related to these precursors so that impacted stakeholders can be in a position of compliance when the GIC regulatory amendments come into force.

Contact

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Footnotes

a S.C. 2018, c. 16, s. 206(6)

b S.C. 1996, c. 19

1 Of the 12 entities that submitted an individual subsection 56(1) exemption, 4 hold both a licence and a registration, 3 hold neither and the remaining 5 hold either a licence or a registration.

2 To review Class A precursor regulatory requirements, it is assumed that four employees — one responsible person in charge, two alternative responsible persons in charge and one senior person in charge — from a licence holder will be involved. Each individual is expected to spend approximately 1.3 hours on the review. The overhead adjusted wage rate is $41.52/hour for responsible and alternate responsible person in charge, and $75.60/hour for senior person in charge. The weighted average for the four responsible personnel is $50.04. All wage figures are derived from Statistics Canada Table 14-10-0417-01, Employee wages by occupation, annual.

3 Of the 20 anticipated applications, 16 are expected to originate from industry stakeholders.

4 Of the 10 anticipated applications, 8 are expected to originate from industry stakeholders.

5 For the purpose of the small business lens, a small business is any business, including its affiliates, that has fewer than 100 employees or less than $5 million in annual gross revenues.