

Ministry of Health and Long-Term Care

Proposed new regulation made under the
Health Sector Payment Transparency Act, 2017

The [Health Sector Payment Transparency Act, 2017](#) (HSPTA) is new legislation intended to strengthen transparency about financial relationships that exist within Ontario's health care system and increase public trust and confidence.

The HSPTA received Royal Assent on December 12, 2017 as part of the [Strengthening Quality and Accountability for Patients Act, 2017](#). Once proclaimed into force, HSPTA will require the medical industry, including pharmaceutical manufacturers and medical device companies, to report annually to the Minister of Health and Long-Term Care all transfers of value (TOV) provided to certain categories of individuals and organizations involved in the health care sector.

Requiring pharmaceutical manufacturers, and medical device companies, and their affiliates, and other prescribed payors to disclose information about their financial relationships with health care providers will better enable patients to make more informed decisions about their health care.

The Ministry of Health and Long-Term Care is proposing a new regulation necessary to support the implementation of the reporting scheme established under the Act. The proposed regulation would do the following:

- Specify the categories of individuals and organizations that will be "recipients" when they receive a transfer of value (TOV) either directly or indirectly from one of the payors listed in the Act;
- Further specify what constitutes a "transfer of value" and "intermediary";
- Add community pharmacies and laboratories to the list of payors;
- Establish exemptions to the reporting requirements;
- Set the value threshold for reporting;
- Establish the information, manner and frequency of reporting;
- Outline the process for requesting corrections of posted information.

The ministry is seeking feedback on this regulatory proposal. A draft regulation is included as part of this public consultation.

SUMMARY OF PROPOSED REGULATION

The ministry is proposing a new regulation under the [Health Sector Payment Transparency Act, 2017](#). The draft regulation is included as part of this consultation, and is summarized as follows:

"Recipients"

The HSPTA requires the reporting of information about financial relationships that exist within Ontario's health care system between the medical industry ("payors", such as

drug and medical device companies) and health care providers (referred to under the Act as “recipients”).

The ministry is proposing that the following individuals and organizations be prescribed as “recipients” under the Act:

- member of a health regulatory college
- hospital or a psychiatric facility
- licensed long-term care home
- home care provider contracted by a LHIN
- non-profit community health centre, Aboriginal health access centre, family health team, nurse-practitioner-led clinic
- primary care nursing, interprofessional, or maternal care service provider
- non-profit community mental health and addiction service provider
- non-profit palliative care provider, including hospice
- physiotherapy clinic
- independent health facility
- pharmacy
- laboratory or specimen collection centre
- health regulatory college
- association that advocates for the interest of health care professionals or organizations.
- advocacy organization
- a foundation or other health charity
- group purchasing or shared services organization
- university, college or post-secondary institution
- a person fulfilling the requirements to become a member of a regulated health profession
- researcher or non-profit health research institute/organization
- anyone who is a board member, director, trustee, officer, appointee, employee, or agent of the above
- subsidiary, as defined in the Business Corporations Act, of the above
- an immediate family member of any individual outlined above.

“Transfer of Value”

The HSPTA defines “transfer of value” as “a transfer of value of any kind and includes a payment, benefit, gift, advantage, perquisite or any other prescribed benefit.”

The ministry is proposing to clarify that a “transfer of value” under the Act would not include the fair market value of goods that are sold under a bill of sale or purchase agreement.

The ministry is also proposing that “transfer of value” under the Act would include the following benefits:

- cash or cash equivalents;
- in-kind items or services;
- security, security option, or any other ownership or investment interest;
- compensation for services, including consulting fees or speakers fees;
- honoraria;
- grants and donations;
- event sponsorships;
- membership fees
- rental or facility fees;
- rebates and discounts;
- items that are provided on a value-added basis in connection with a procurement;
- supplies and equipment, including information technology;
- licences and copyright fees, including software licences and article re-prints;
- renovations or leasehold improvements;
- entertainment, social and sporting events;
- food and beverages;
- travel and accommodation;
- personal gifts;
- royalties;
- referral fees;
- payments to cover marketing and advertising costs;
- inventory listing or stocking fees; and
- charitable contributions made in the name of a recipient within the meaning of the Act.

See also the following section “Exemptions” for transfers of value that would be exempt from reporting.

Exemptions

The HSPTA provides for exemptions to the reporting requirements set out in the Act, including a dollar value reporting threshold.

The ministry is proposing to prescribe the following exemptions under which payors would not be required to report a transaction:

- Transactions that have a dollar value of less than \$10
- Salary and benefits provided as part of employment
- Medical products intended to be provided to patients free of charge
- Educational materials and items intended for use within a clinical setting
- Compensation for expert testimony or other services with respect to a legal proceeding
- Benefits provided by a drug manufacturer in accordance with ordinary commercial terms as set out in the regulations under the *Ontario Drug Benefit Act*.

Additional “payors”

The definition of “payor” in the HSPTA includes a manufacturer that sells a medical product, anyone who produces and assembles a medical product for a manufacturer, a wholesaler or distributor that facilitates the sale of a medical product, a marketing firm that promotes a medical product, or any organizer of continuing education events on behalf of a manufacturer.

The ministry is proposing to prescribe the following additional categories of “payors”:

- pharmacy
- laboratory or specimen collection centre

“Intermediaries”

An intermediary is defined as a person or entity who provides or facilitates a transfer of value to a recipient on behalf of a payor. An intermediary is required to provide to the payor any information relating to a transaction that the payor needs to comply with the payor’s reporting obligations under the Act. The Minister may also request that an intermediary report this information to the Minister directly.

The ministry is proposing to include within the regulations provisions that would clarify the role of intermediaries as:

- Any person who assists in providing a TOV from a payor to a recipient is considered an intermediary for the purposes of the Act, irrespective of

whether the payor directs how the TOV is to be used, or is aware of the identities of the recipients when the TOV is provided.

The proposed regulation sets out the circumstance under which a recipient will *not* be considered an intermediary. Both of the following criteria must be met:

- the payor is not directing how the TOV should be used; and
- a published and commonly accepted ethical guideline or accreditation standard would be breached if the names of the final recipients were disclosed to the payor.

The proposed regulation sets out the circumstances under which a market research firm will *not* be considered an intermediary and will *not* be required to report the names of the final recipients. The following criteria must be met:

- the payor does not know the identify of the recipients; and
- knowing the identity of the recipients would place the manufacturer in breach of an obligation set out within a published and commonly accepted ethical guideline.

In this circumstance, a market research firm would be treated as a recipient.

Information to be reported

The HSPTA outlines that the payor is required to include, as part of its reporting obligations, the name of the parties to the transaction including any legal and operating names, individual's name, profession or title, business addresses, date of the transfer of value, exact or approximate dollar value, and description of the transfer of value including the reasons for it.

The ministry is proposing to further prescribe the following information that must be reported:

For businesses:

- Business name and business identification number, legal name of business and Ontario or Canadian corporate number
- An individual who is the administrative contact for the business and their full legal name, job title, e-mail address, and phone number

For individuals:

- Full legal name
- Designation as a health care professional
- Name of the regulated health College(s), licence number, and title
- Designation as any other professional and name of licensing body
- Name of employer
- Job title

Transfers of Value

- Dollar value of transfers of value including any taxes paid
- Any intermediary that was a party to the transaction
- Nature of transfer of value as one of the following:
 - Cash or cash equivalent;
 - In-kind items or services;
 - Security, security option, or any other ownership or investment interest.
- Category of transfer of value under the following:
 1. Charitable donations.
 2. Grants.
 3. Food and beverage.
 4. Fees for service as speaker.
 5. Fees for professional services and consulting.
 6. Gift and entertainment.
 7. Travel and accommodation.
 8. Education
 9. Royalties, memberships and subscriptions.
 10. Current or Prospective Ownership or Investment Interest.
 11. Research.
 12. Rebates, Discounts, and Items that are provided on a value added basis in connection with a procurement.
 13. Operational Support.
 14. Marketing and Advertising.
 15. Partnering agreements with organisations.
- Optional contextual statement of no more than 250 characters to further describe the reason for the transfer of value

Manner and frequency of reporting, Commencement

The HSPTA provides for the manner and frequency of reporting to be prescribed by regulation.

The ministry is proposing the following reporting requirements:

- Payors will report transfers of value to the Minister of Health and Long-Term Care no later than June 30th of the following calendar year.
- Payors will report transfers of value through an electronic data collection platform created and maintained by the Minister

The ministry is proposing that the Act and regulation would come into force on January 1, 2019, with the first annual reporting to the ministry from payors required by June 30, 2020.

Corrections

The HSPTA provides that requests to correct reported information may be made to the Minister. The process for requesting and dealing with requests is to be set out in the regulations.

The ministry is proposing adding the following as part of the correction process:

- A payor is required to notify recipients in writing of the information it intends to report to the Minister about each transfer of value it provided to the recipient in the previous calendar year.
- The payor must provide the information to the recipients no later than March 31st, and provide a minimum of 45 days for the recipient to review the information before it is submitted to the ministry.
- If the recipient wishes to have the information corrected, the recipient must ask the payor to correct the information and provide substantiating materials to support the request.
- Once the payor receives a request to correct information, the payor must respond to the recipient with its decision within 30 days.
- If the payor *agrees* with the recipient's request to correct information, the payor must provide the corrected information to the ministry within 15 days.
- If the payor *denies* the recipient's request to correct information the payor must, within 15 days, submit to the Minister a request to mark the information as "disputed".
- The recipient or the payor can submit a request to the Minister to correct information up to 12 months after the information has been published.

Other

The HSPTA provides for regulations to prescribe or define certain sections of the Act.

The ministry is proposing the following additional provisions:

- Definition of “drugs” excludes non-medical cannabis
- Payors, intermediaries, or recipients must retain records with respect to any transactions for at least seven years from the date of the transaction.
- Method of serving compliance orders include:
 - Personal service
 - Registered mail to the last known address (considered received the fifth business day after the day it was mailed)
 - Fax to the last known fax number (considered received the first business day after it was sent)
 - Commercial courier to the last known address (considered received the second business day after the commercial courier received the document).