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Health care professionals payment transparency in Ontario

Prepare for province's version of Sunshine Act

The dawn of payment disclosure requirements

The relationship between Health Care Professionals (HCPs) and pharmaceutical companies has always been under the microscope. In Canada, public scrutiny has risen regarding potential conflicts of interest and adverse impacts. This has resulted in increased public pressure to pass legislation requiring payments made to HCPs to be reported to government bodies and ultimately make them available to the public.

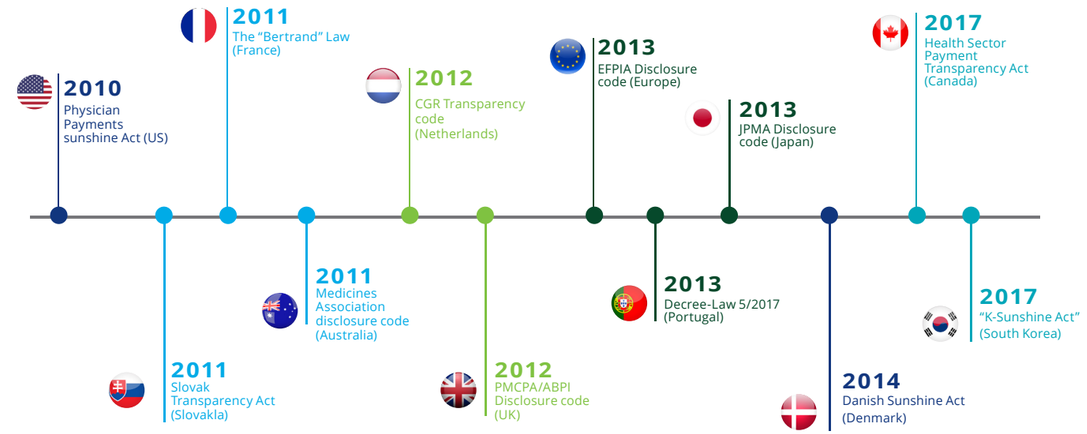
Transparency is not a new issue in other jurisdictions. The Physician Payments Sunshine Act was passed in the US in 2010, a lead soon followed by other nations. The timeline below shows countries that have been enacting transparency laws and codes over the course of the last seven years.

In June 2017, 10 members of Innovative Medicines Canada (IMC) voluntarily published aggregated sums of their payments to Canadian HCPs and health care organizations (HCOs). Although this pro-active move by the IMC members was the first of its kind in Canada, some industry stakeholders have commented the disclosure didn't go far enough in quashing the scrutiny around transparency.

However, with Ontario passing its Health Sector Payment Transparency Act in 2017, it becomes the first province in Canada to formally address transparency of such payments made by pharmaceutical and medical device companies. It includes creating a central online database that will be publicly available for anyone to scrutinize financial relationships between pharmaceutical companies and HCPs or HCOs.

A key driver for this legislation is to empower patients to make better, more informed choices for their own health care. However, with this information in the public domain, patients won't be the only interested parties: in addition to regulator and enforcement authorities, the media, competitors, and watchdog groups will all be sure to delve deeply into the data.

Global transparency timeline



What challenges might you face?

The regulation is due to come into force on January 1, 2019 but it is not too early to begin preparing for it. New compliance requirements can create challenges for businesses. Through our extensive experience helping clients manage reporting requirements in other markets, we understand the challenges you might face:

- **Data consistency and quality** – data is not always in the same structure and format, which can make linking, analyzing, and even interpreting it difficult. It can also suffer from integrity issues, requiring the expert managing of HCP/HCO master data of variable quality.
- **Process development/ enhancement** – existing processes may need to be enhanced as they may not be structured to facilitate compliance. New processes may need to be developed for HCP/HCO definition, inventory, identification, data collection, analysis, and reporting to enable accurate and timely internal and external reporting.
- **Change management** – the new requirements will affect many individuals within companies and it will be imperative that all affected parties understand resulting changes to their roles, responsibilities, and accountabilities.
- **Stakeholder engagement** – employees might see compliance projects as not their responsibility, resulting in poor adoption of new processes. External stakeholders such as HCPs and HCOs will also need to be informed of their roles in the reporting process.
- **Publicly available information** – data will be available for scrutiny by multiple stakeholders.

Questions to consider

- What is your level of readiness and where does the governance of your transparency reporting currently reside?
- Do you have a clear understanding of the risks and impacts of transparency reporting to the public?
- How is transparency disclosure currently perceived within your organization (e.g., just another compliance requirement)?
- Are there potential or perceived conflicts of interest, or areas that you see most at risk as a result of transparency requirements?
- Do you have a centralized repository for contracts and for payments to HCPs and HCOs (by specialty, type of benefit)?
- Do you use data, analytics, and/or a third-party or custom solutions for transparency reporting?
- Does your company currently have an automated end-to-end HCP engagement process (e.g., fair market value check, payment, engagement approval, contract)?

Accelerate your success
Deloitte has global experience in transparency reporting requirements, with our member firms having helped clients prepare to comply with regulations such as the Physician Payments Sunshine Act in the US and the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code.

We also conducted a study on HCP transparency activity in numerous countries, which has provided us with insights into current and anticipated regulatory requirements for tracking payments and transfers of value that pharmaceutical and medical device companies make to HCPs and HCOs. The key findings of that study tell us that:

Governance and Centres of Excellence (COEs)

- The governance of transparency programs continues to shift within organizations.
- Companies are establishing centres of excellence to better gain visibility into transparency related risk, to improve efficiency, and to create consistent processes.

Automation of Reporting

- Automating the end-to-end HCP engagement process is not a common practice.
- This is expected to change as companies seek to develop a more proactive and standardized approach to monitoring compliance risk.

Transparency Solutions

- Outsourcing transparency reporting operations is becoming more common.
- There's a trend toward using third-party systems and solutions to gain advantages provided by vendors and to lower the cost of ownership.

Drawing from the findings of this study and from Deloitte's experiences around the world, we're well positioned here in Canada to help your organization prepare for the implementation of the Ontario legislation. We've also developed accelerators to help clients with the design, implementation, and monitoring of their transparency programs. For details, see the table on the opposite side.

Transparency in Ontario

Design, implementation, and monitoring of transparency programs

Areas affected by transparency reporting	We have helped clients with the following:
Program governance and Centres of Excellence (COEs)	• Transparency requirements interpretation • Overall transparency program (data collection and reporting) • Detailed work-stream plans for processes and requirements, technical build, and change management • Program management deliverables (issue and risk logs, actions log, etc.)
Process and requirements validation	• Data collection processes (including templates to capture direct and indirect spend on HCPs and HCOs) • Data reporting processes (including pre-disclosure, inquiry resolution, and transparency reporting)
Consent management	• Consent management process • Examples of consent for disclosure language in contracts • Examples of consent records to capture HCP/HCO consent • Roles and responsibilities for consent collectors, consent viewers, and consent administrator roles
Change management	• Stakeholder engagement plan for transparency • Change impact assessment for local and global functions • External communications to HCPs/HCOs and third-party providers • High-level training strategy and approach
Data repository	• Deloitte's HCP/HCO transparency repository aggregates transfer-of-value data • Portal to capture and correct data • Consent management solutions

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