IQVIA COMPLIANCE & TRANSPARENCY SOLUTIONS FOR CANADA

Transparency Readiness Roadmap Webinar Q&A

This document addresses the questions submitted during the March 21, 2018 webinar. Responses are based on information known as of April 18, 2018 and the relevant dates of the legislation (the *Ontario Health Sector Payments Transparency Act 2017)* used for reference.

Questions Regarding the Transparency Act and Timing

1. **A question was posed as to whether or not the legislation only related to recipients located in Ontario.**

   The legislation that was referred to during the webinar is directed to recipients located in Ontario.

2. **A question was posed as to whether or not all provinces will implement transparency in the same way, as there would be added complexity if each province were to be implemented differently.**

   The transparency reporting effort is not only about back-end reporting. Many organizations do not have adequate processes or controls pertaining to all transfers of value. Normalizing management processes to govern these activities and capturing valuation and event data, including from third-party sources, have consistently been the most troubling aspects of the transparency programs around the world.

   Once clients are able to control and manage their interactions, then you can focus on the actual configuration of the report to payment types, thresholds, applicable recipients, etc. However, without consistent practices and data, companies spend an inordinate amount of time filling in gaps and searching for missing transactions.

   As we support clients in building out their spend-capture systems we are more focused on process and control, recognizing that with it comes easier reporting, including reporting to evolving or changing requirements.

3. **In the presentation, we talk about the Ontario Ministry of Health consulting with associations. A question was posed to determine the names of the associations which were consulted.**

   The Ontario Ministry of Health consulted with a number of Pharmaceutical/Medical Device Associations, medical colleges, patient groups and individuals. To our knowledge, a consultation list has not been made public.

4. **In the presentation, we covered timelines to start data collection and reporting for Ontario. Since data collection is supposed to commence for Jan 2019 transfers of value (TOVs), a question was posed regarding multi-year grants which have started prior to Jan 2019 and whether or not retroactive reporting will be required.**

   It is our understanding that retroactive reporting will not be required, however, it has been confirmed in a discussion with the Ontario Ministry of Health that a multi-year grant that has a scheduled payment in 2019 would require the capture of that portion of the grant.

5. **A question was posed as to the inevitability of transparency laws in Canada and whether or not that would change depending upon the governing party.**

   Transparency is part of Compliance and, although we are seeing some delays as the Ontario Ministry of Health takes time to review stakeholder feedback, global trends all point to Canada following suit.

6. **Our presentation highlighted the importance for organizations to start preparing in 2018 so that they can start capturing data Jan 2019. A question was posed as to how to start building a system to track information when the specific fields of information have not yet been published.**

   The draft Act does indicate a preliminary list of data fields that will be required for reporting. The key is to adopt systems and processes that will ensure spend data is accurately captured, at the level of detail required for current and future requirements.

Questions Regarding Transfers of Value

7. **In our presentation, the abbreviation 'TOV' was used. A question was posed as to what this abbreviation means and if patient support programs may or may not be included.**

   TOV stands for Transfer of Value. A transfer of value is defined by the Act as "a transfer of value of any kind and includes a payment, benefit, gift, advantage, perquisite or any other prescribed benefit."

   If there is any form of transfer of value directly or indirectly made to an HCP (or any other defined recipient as per the Act) in the context of a Patient Support Program (PSP) (e.g. payment to infuse, payment for a nurse navigator, etc.) then this would be reportable.

8. **The Act includes reporting of 'in kind services'. A question was posed regarding how to track in kind services as this can be much more difficult to capture than payments.**

   There has been -- and continues to be -- debate on the proper treatment of in-kind services. Of particular interest has been material support in securing reimbursement. In the US there has been an unwritten acceptance that some limited support, such as obtaining prior authorizations, represent a necessary support activity with no independent value.

   However, once manufacturers provide further or more substantial activities (e.g., Health Canada reimbursement documentation, appeal letters, etc.), they are forced to answer the question of which activities are "support" functions and which may be "services", whereby services have an independent value. We advise clients to establish clear definitions and criteria to keep activities in the "support" category to not invoke concerns of transparency which may also then invoke bribery and corruption concerns.

9. **In the presentation, we noted that 'rebate & discount' was also considered a TOV. A question was posed as to whether this included the 'rebates & discount' paid as the result of annual negotiated commercial contracts the companies have with various supplies, partners, vendors, etc. or to discounts for drugs sold to a group of doctors (e.g., a clinic).**

   According to the draft regulations Section 2 (2) TOVs do not include the fair market value of goods that are sold by a payor to a recipient for consideration under a bill of sale or purchase agreement. Section 8 (12) of the draft Regulations however, indicate a transfer of value includes rebates, discounts and items that are provided on a value-added basis in connection with a procurement, with the following subcategories (i) rebates, (ii) discounts, and (iii) other value adds.

10. **The Act includes indirect payments as well as direct payments. A definition and example of indirect payment (i.e. through third-party vendors) was requested.**

    An indirect payment would be a payment made to an intermediary (a person or entity deemed to be providing or facilitating a transfer of value on behalf of a payor). This may include honoraria paid for market research, even blinded research, whereby the market research firm may independently recruit and compensate participants. They must then provide the payment details to the manufacturer for transparency reporting. This concern is also frequently raised in the context of independent medical education, where the medical education provider may be paying the honoraria for an independently recruiting instructor. Yet, if those funds were secured via a grant from the manufacturer, then the manufacturer must report those payments.

Questions Regarding Impacts of Transparency

11. **Our opinion was requested as to whether we feel that these transparency regulations will negatively impact the provision of "unrestricted" grants.**

    Unrestricted grants, we believe, will be impacted in that the payor will now require full visibility and accountability from the recipient on how the transfer of value was used. The onus remains on the payor to disclose all transfers of value (direct or indirect). Recipients will have to be prepared to account for all transfers in a detailed manner back to the payor.

12. **A question was posed as to the transparency impacts around the world and if these laws negatively impacted interactions between pharma and HCPs?**

    The learnings from our interactions is that at the beginning there is some hesitation from stakeholders, but once a clear understanding of the parameters of the legislation or self-regulation is set out, stakeholders continue to interact with industry.

    We have had the unique benefit of having partnered with global, regional and local manufacturers throughout the world, with customers in over 100 countries, helping to manage compliance with transparency laws. While we would not attribute specific changes in HCP behavior to transparency, transparency has contributed to other key engagement trends.

    First and most notably, many manufacturers continue to rationalize and reduce the overall number of KOLs they engage in fee-for-service types of activities. Secondly, and perhaps in response to this, many healthcare organizations, trade organizations and governments are enacting caps on total benefits their HCP constituents may receive from manufacturers.

13. **A question was posed as to the Act's impact on compassionate care, i.e. pharma donations of certain medications for patients who lack insurance and otherwise could not afford it?**

    According to the Ontario Ministry of Health's Summary of Proposed Regulation, the Ministry is proposing to prescribe an exemption under which payors would not be required to report a transaction which are classified as "medical products intended to be provided to patients free of charge".

Questions Regarding Roles and Responsibilities

14. **A question was posed as to who in an organization should own these processes, i.e. manage the implementation project, reporting process, etc.**

    This begs the question of accountability and responsibility for compliance. In more mature companies the obligation to ensure appropriate engagements with reportable recipients falls squarely on the commercial, medical or R&D engagement sponsor. This responsibility includes ensuring effective data capture of the engagement. However, achieving this objective often necessitates a change in culture which takes time, and is an initiative that requires compliance and executive support.

    For those reasons, early on in the formation of the transparency program the compliance department often stays in command and over time the improved processes and controls of the engagement sponsors is leveraged to ensure compliant reporting. When that state is achieved, then the compliance role is to ensure that reporting capabilities are in place to report on the data received from engagement sponsors.

15. **In the presentation, we covered the proposed penalties for violations of the Act which included a category for individuals as well as corporations. A question was posed as to who is defined as an individual, in other words, can an employee of a company who prepared the report be held responsible and be fined.**

    The term individual is referenced in section 17(1) a, of the Act. This section of the Act refers to the monetary fines and makes the distinction between corporate and individual fines but does not define the individual. An assumption can be drawn that individual employees may be liable for inaccurate reporting. Preliminary discussions with Ministry employees suggests that it would not only be a corporation that would be responsible but that an individual could also be held responsible.

16. **In the Act, it mentions a validation period (45-day window) that allows HCPs to validate the transfer of value amounts that a payer will be reporting. A question was posed as to whether or not the manufacturer has to reach out to the HCP if the HCP did not respond to the original validation notice within the validation period.**

    As far as we know, payors would report to the Ontario Ministry of Health as per the reporting schedule. Should a recipient not agree to the disclosed amount, then the recipient can request a correction from the Minister.

17. **In the presentation, we talked about reporting recipient information to the Ontario Ministry of Health. A question was posed regarding privacy and whether or not companies will need to consider privacy notifications to recipients when building implementation plans. In addition, the expected level of HCP awareness was also brought into question.**

    Consent from the recipient to disclose information to the Minister will not be required. However, best practice would dictate that all recipients are informed that any transfer of value can/or may be made public to the Ontario Ministry of Health. In terms of level of awareness, since the legislation is public, the onus would be on the HCP and their respective organizations to prepare for upcoming requirements.

General Questions about the Presentation

18. **A question was posed regarding the currency that was used in the webinar presentation.**

    All dollar figures mentioned in the presentation are in Canadian dollars. The Ontario legislation also references Canadian dollars and not USD.

For additional information, please contact:
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