RNAO submission on proposed new regulation made under the *Health Sector Payment Transparency Act, 2017*

Draft regulation posted to Ontario's Regulatory Registry on Feb. 21, 2018

April 6, 2018

Summary of RNAO recommendations

Recommendation 1. Proceed with prescribing recipients under the Act, including the list of individuals and organizations appearing in Section 1 (Recipients) in the draft regulation.

Recommendation 2. Proceed with the definition of "transfer of value" as it appears in Section 2 (Transfer of value) of the draft regulation.

Recommendation 3. Make the reporting threshold for transfer of value $0.

Recommendation 4. Include in the public database under the Act all recipients of transfers of value who are deemed to be employees of payors, with the same identifying information on the recipient and the payor as is reported for payors and recipients who are not exempted from reporting.

Recommendation 5. Report in the public database all employment income received by recipients from payors.

Recommendation 6. Include a provision in the regulation requiring verification that drugs are given free of charge to patients.

Recommendation 7. Include in the regulation a requirement that all educational materials and items used in a clinical setting and donated by payors be clearly labeled so that users are aware of the donor's identity.

Recommendation 8. Include in the public database under the Act all recipients who are paid for expert testimony or other services with respect to a legal proceeding, with the same identifying information on the recipient and the payor as is reported for payors and recipients who are not exempted from reporting.

Recommendation 9. Do not exempt benefits provided by a drug manufacturer in accordance with ordinary commercial terms as set out in the regulations under the *Ontario Drug Benefit Act*. If these benefits are exempted, include in the public database under the Act all recipients of these transfers of value, with the same identifying information on the recipient and the payor as is reported for payors and recipients who are not exempted from reporting.

Recommendation 10. Report in the public database all payments to recipients for expert testimony or other services with respect to legal proceedings.

Recommendation 11. Proceed with prescribing pharmacies, laboratories and specimen collection centres as payors under the Act.

Recommendation 12. Proceed with the specification of reporting obligations on identification of businesses, identification of individuals, and transfers of value, as in section 7 of the draft regulation.

Recommendation 13. Proceed with the proposed timeline of Jan. 1, 2019 for the regulation and Act to come into force, and with annual reporting to start June 30, 2020 for 2019.

Recommendation 14. Ensure a reasonable process for recipients to review and correct information about transfers of value they are reported to have received, under the regulation.

Introduction

The Registered Nurses' Association of Ontario (RNAO) is the professional association representing registered nurses (RN), nurse practitioners (NP), and nursing students in all settings and roles across Ontario. It is the strong, credible voice leading the nursing profession to influence and promote healthy public policy.

RNAO is pleased to offer its submission on the draft regulation[1] [2] under the *Health Sector Payment Transparency Act, 2017*,[3] (HSPTA) posted to Ontario's Regulatory Registry on Feb. 21, 2018.[4] The *Health Sector Payment Transparency Act, 2017* was created by Schedule 4 of Bill 160, *the Strengthening Quality and Accountability for Patients Act, 2017*.[5] According to the Ministry of Health and Long-Term Care (MOHLTC), the latter was designed to support *Ontario's Patients First: Action Plan for Health Care.*[6]

RNAO welcomed Bill 160's objectives of strengthening transparency, accountability, and quality of care in a person-centred health system.[7] RNAO's submission recommended the government "proceed to require public disclosure of payments and transfers of other value from the medical industry to health-care professionals and to organizations. Ensure that the reporting threshold is very low and that there are few exemptions."[8] The submission went further, urging the government to "[b]an the practice by the medical industry of providing payments and transfers of other value to health-care professionals and to organizations."[9] Bill 160 did not go that far, but it did require payors from the medical industry to report direct or indirect transfers of value beyond a prescribed threshold.[10] That was an important step forward.

The draft regulation details which recipients of transfers of value are included; the definition of transfer of value; exemptions from reporting requirements; which payors are included; which intermediaries are included; the information that is to be reported; the manner and frequency of reporting; the date the regulation would come in force; the procedure for payors to correct information provided by payors; record retention requirements; exclusion of non-medical cannabis; and the method of serving compliance orders.

RNAO's general comments

RNAO recommended a complete ban on transfers of value to health professionals and other recipients,[11] as this approach would have the greatest impact in reducing the influence of transfers of value on health professionals' practice (e.g., prescribing a drug from a supplier who donates generously). While the legislation did not reflect this recommendation, RNAO recognizes that providing clear reporting on transfers of value will go a long way to increase transparency concerning the links between health-care professionals receiving transfers of value and those entities providing transfers of value. This will allow users of the health system to be better informed on the influences on health professionals' practices, and will deter inappropriate transfers that must now be disclosed.

The draft regulation

The draft regulation casts its net widely, and we applaud that approach. In particular, the definitions of recipients, and of transfers of value, are designed to capture the full range of each. RNAO has concerns about some of the exemptions, which would afford opportunities to circumvent the transparency which the Act is designed to deliver. We welcome the inclusion of pharmacies, laboratories and specimen collection centres as payors in the draft regulations; the failure to do so would be a significant omission. The draft regulation also spells out the information which must be provided; that information is essential for any health system user to judge the relationship between a providing entity and the medical industry.

Definition of recipients (Section 1)

The MOHLTC proposes a broad definition of recipients within the health sector:[12]

- member of a health regulatory college
- hospital or 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

If there are other health sector entities not yet listed, we would welcome their addition. We note that our association and all of our members in the nursing workforce would be included, and that is appropriate.

Recommendation 1. Proceed with prescribing recipients under the Act, including the list of individuals and organizations appearing in Section 1 (Recipients) in the draft regulation.

Definition of transfer of value (Section 2)

Similarly, the draft regulation seeks to include fair market value of any benefit transferred from a payor to a recipient. Again, the list is extensive, as it should be:[13]

- 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 reprints
- 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
- charitable contributions made in the name of a recipient within the meaning of the Act

Excluded are goods sold at fair market value. As with the definition of recipients, RNAO supports the above broad definition of transfers of value, and would support the addition of other reasonable benefits not already included in the list.

Recommendation 2. Proceed with the definition of transfer of value as it appears in Section 2 (Transfer of value) of the draft regulation.

Exemptions (Section 6)

RNAO urges minimal use of exemptions in reporting transactions. We are concerned that the intent of the Act and the regulation could be undermined. Proposed exemptions are as follows:

Transactions valued under $10. RNAO recommends a $0 threshold.

Salary and benefits provided as part of employment. People should be afforded the opportunity to know if a health professional is employed by the medical industry, particularly if that person is also providing health-care services – even if the amounts paid to the employee are not reported. The regulation should ensure that health system users are aware that a health-care provider is receiving consideration from the medical industry, and they should know which payor that is, irrespective of whether the benefits are payments or salary. One obvious concern is that a payor could circumvent the intent of the Act and the regulation by simply entering into an employer-employee relationship with the recipient.

Medical products intended to be provided to patients free of charge. RNAO agrees that this is a reasonable exemption, so long as it is verified that the drugs are provided to patients free of charge.

Education materials and items intended for use within a clinical setting. RNAO insists that the regulation must ensure that all educational materials and items are labeled so that users are aware of who provided them.

Compensation for expert testimony or other services with respect to a legal proceeding. RNAO asserts that if this exemption is allowed to stand, the regulation must ensure that health system users are aware that the recipient is being paid by the named payor for these services.

Benefits provided by a drug manufacturer in accordance with ordinary commercial terms as set out in the regulations under the *Ontario Drug Benefit Act*. RNAO asserts that, even if benefits are in accordance with ordinary commercial terms, these benefits must be reportable. If these benefits are exempted under the regulation, the public must be informed of the identities of the payor and the recipient, and of their relationship.

Recommendation 3. Make the reporting threshold for transfer of value $0.

Recommendation 4. Include in the public database under the Act all recipients of transfers of value who are deemed to be employees of payors, with the same identifying information

on the recipient and the payor as is reported for payors and recipients who are not exempted from reporting.

Recommendation 5. Report in the public database all employment income received by recipients from payors.

Recommendation 6. Include a provision in the regulation requiring verification that drugs are given free of charge to patients.

Recommendation 7. Include in the regulation a requirement that all educational materials and items used in a clinical setting and donated by payors be clearly labeled so that users are aware of the donor's identity.

Recommendation 8. Include in the public database under the Act all recipients who are paid for expert testimony or other services with respect to legal proceedings, with the same identifying information on the recipient and the payor as is reported for payors and recipients who are not exempted from reporting.

Recommendation 9. Report in the public database all payments to recipients for expert testimony or other services with respect to legal proceedings.

Recommendation 10. Do not exempt benefits provided by a drug manufacturer in accordance with ordinary commercial terms as set out in the regulations under the *Ontario Drug Benefit Act*. If these benefits are exempted, include in the public database under the Act all recipients of these transfers of value, with the same identifying information on the recipient and the payor as is reported for payors and recipients who are not exempted from reporting.

Additional payors (Section 5)

As the summary of the draft regulation notes, "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."[14] The draft regulation proposes adding pharmacies and laboratories and specimen collection centres. RNAO supports this expansion of the definition of payor.

Recommendation 11. Proceed with prescribing pharmacies, laboratories and specimen collection centres as payors under the Act.

Intermediaries (Section 4)

The draft regulation defines an intermediary as an individual or entity providing or facilitating transfers of value to recipients on behalf of payors. The inclusion of reporting on intermediaries is supported, as they can be important agents of transfers of value.

Information to be reported (Sections 7 and 8)

The Act already requires the payor to report: "individual [recipient]'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 draft regulation provides greater detail on reporting obligations as related to identification of businesses, identification of individuals, and transfers of value.

Recommendation 12. Proceed with the specification of reporting obligations on identification of businesses, identification of individuals, and transfers of value, as in Section 7 of the draft regulation.

Manner and frequency of reporting, and commencement (Section 10)

The regulation and Act would come into force on Jan. 1, 2019, with annual reporting starting June 30, 2020 for the 2019 year. That is a reasonable period of time for payors to comply, therefore RNAO supports this recommendation.

Recommendation 13. Proceed with the proposed timeline of Jan. 1, 2019 for the regulation and Act to come into force, and with annual reporting to start June 30, 2020 for 2019.

Corrections (Section 12)

The draft regulation provides a process for recipients to review and correct information about transfers of value they are reported to have received. It is important for recipients to have the ability to correct such information.

Recommendation 14. Ensure a reasonable process for recipients to review and correct information about transfers of value they are reported to have received, under the regulation.

Conclusion

RNAO welcomes the The *Health Sector Payment Transparency Act, 2017* and the draft regulations. This is an important step to enhance accountability in health care. Our only concern is with the exemptions under the draft regulation. If exemptions are made for the reporting of amounts transferred (as with payments to employees), it is important to inform the public that these transfers have taken place. There is a compelling public need for the regulation to ensure that this critical information is publicly available.

References:

[1] Ontario Ministry of Health and Long-Term Care. (2018). *Consultation Draft: Ontario Regulation to be made under the Health Sector Payment Transparency Act, 2017.*

[2] Ontario Ministry of Health and Long-Term Care. (2018). *Proposed new regulation made under the Health Sector Payment Transparency Act, 2017* [summary].

[3] Ontario Government. (2018). *Health Sector Payment Transparency Act, 2017.* https://www.ontario.ca/laws/statute/17h25?_ga=2.208005714.130236814.1519740210-1660841978.1504716390.

[4] Ontario Ministry of Health and Long-Term Care. (2018). *Health Sector Payment Transparency Act, 2017 – New Regulation.* http://www.ontariocanada.com/registry/view.do?postingId=26846&language=en.

[5] Legislative Assembly of Ontario. (2017). Bill 160, Strengthening Quality and Accountability for Patients Act, 2017. http://www.ontla.on.ca/web/bills/bills_detail.do?locale=en&BillID=5096&detailPage=bills_detail_status.

[6] Ontario Ministry of Health and Long-term Care. (2017). *Ontario's Patients First: Action Plan for Health Care*. July 12. http://www.health.gov.on.ca/en/ms/ecfa/healthy_change/.

[7] Registered Nurses' Association of Ontario. (2017). *RNAO submission on Bill 160: Strengthening Quality and Accountability for Patients Act, 2017*, http://rnao.ca/policy/submissions/rnao-submission-bill-160-strengthening-quality-and-accountability-patients-act-2.

[8] Ibid.

[9] Ibid.

[10] Ontario Government. (2018). *Health Sector Payment Transparency Act, 2017.* Section 4.

[11] Registered Nurses' Association of Ontario. (2017). *RNAO submission on Bill 160: Strengthening Quality and Accountability for Patients Act, 2017*, http://rnao.ca/policy/submissions/rnao-submission-bill-160-strengthening-quality-and-accountability-patients-act-2.

[12] Ontario Ministry of Health and Long-Term Care. (2018). *Proposed new regulation made under the Health Sector Payment Transparency Act, 2017* [summary].

[13] Ibid.

[14] Ibid.