ONTARIO PHARMACISTS ASSOCIATION

April 13, 2018

The Hon. Dr. Helena Jaczek
Minister of Health and Long-Term Care
c/o 8th Floor, Hepburn Block
80 Grosvenor Street
Toronto ON M7A 1R3

Dear Minister Jaczek,

Re: Proposal Number 18-HLTC017 – Health Sector Payment Transparency Act, 2017 - New Regulation

On behalf of the province's pharmacy professionals – pharmacists, pharmacy students and pharmacy technicians – the Ontario Pharmacists Association ('OPA', the 'Association') submits its comments, concerns and recommendations related to the proposed regulations to the *Health Sector Payment Transparency Act, 2017* ('HSPTA', the 'Act'). We understand that the intent of the HSPTA and its regulations are to strengthen transparency about financial relationships that exist within Ontario's health care system and increase public trust and confidence. The Association also acknowledges that transparency is critical to ensure that all health stakeholders commit to maintaining objectivity in the delivery of patient care so that commercial practices do not unduly influence care.

The Ontario Pharmacists Association is committed to evolving the pharmacy profession, and advocating for excellence in practice and patient care. As the largest provincial pharmacy advocacy organization and Canada's largest continuing professional development and drug information provider for pharmacists, OPA represents the views and interests of pharmacy professionals (including pharmacists, pharmacy students, and pharmacy technicians) in all practice settings across Ontario. By leveraging the unique expertise of pharmacy professionals, enabling them to practise to their fullest potential, and making them even more accessible to patients, OPA is working to drive the efficiency and effectiveness of the healthcare system.

As currently written, the proposed regulations have very far reaching and complex implications to the pharmacy profession as well as to other stakeholders and it is critical that any unintended consequences are fully considered. Based on verbal discussions and pre-regulatory consultations with the Ministry of Health and Long-term Care ('MOHLTC', the 'Ministry') in mid-2017 and early 2018, OPA has been advised that there are multiple stakeholder groups simply within the pharmacy profession that will be impacted to varying degrees by mandated transparency reporting either as payors, intermediaries or recipients, if not all three. This submission considers the impact of transparency legislation and regulation on the various stakeholders that comprise the broader pharmacy sector, which includes, but is not limited to, the categories of individuals and groups listed in the table below:

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Table 1: Pharmacy Stakeholder List

Pharmacy Stakeholders Impacted	Examples *(not exhaustive)*
Pharmacy Professionals (Recipients)	• Pharmacists • Pharmacy students/interns • Pharmacy technicians
Corporate Pharmacy Organizations (Payors, Intermediaries, &/or Recipients)	• Chains • Banners • Franchises • Mass merchants • Grocery
Independent Owners (Payors, Intermediaries, &/or Recipients)	• Many
Buying Groups (Payors, Intermediaries, &/or Recipients)	• Numerous
Pharmacy Professional Associations (Payors, Intermediaries &/or Recipients)	• Ontario Pharmacists Association ('OPA') • Canadian Society of Hospital Pharmacists-Ontario Branch • Canadian Pharmacists Association ('CPhA')
Pharmacy Business Associations (Payors & Recipients)	• Neighbourhood Pharmacy Association of Canada
Academia (Payors, Intermediaries, &/or Recipients)	• Leslie Dan Faculty of Pharmacy at the University of Toronto • School of Pharmacy at the University of Waterloo • Humber College • Lambton College
Not-for-Profit Education Providers - non-academia (Payors, Intermediaries, &/or Recipients)	• OPA • CPhA
For Profit Education Providers - non-academia (Payors, Intermediaries, &/or Recipients)	• Several

The Ontario Pharmacists Association acknowledges the importance of transparency related to transfers of value ('TOV') within the health sector to ensure that such transfers between payors, intermediaries and recipients do not influence decisions on the provision of care to patients. However, there are various details that need to be carefully considered prior to the passage of the proposed regulations, most of which are related to administrative complexity of the regulations.

CONSIDERATION OF AN EXTENSION OF THE CONSULTATION DEADLINE

The Association was pleased to receive the update message from Assistant Deputy Minister Patrick Dicerni on April 4, 2018 announcing that the government will not be proceeding with the final regulation approvals before the writ period begins and that this will be revisited in Fall 2018. Mr. Dicerni's statement validates OPA's position that the HSPTA and the draft regulations are landmark in nature, both provincially and nationally. Given the complexity of the proposed regulatory framework, with its potential for various intended and unintended impacts and consequences, OPA is encouraged that government has opted to give itself an extension in finalizing the regulations so that it can carefully consider all stakeholder feedback. Hopefully, this will afford government the time to ensure whether the regulations are in alignment with the *Reducing Regulatory Costs for Business Act, 2017* ('RRCBA').

Under the RRCBA O. Reg 491/17, section 4(1) states that "*a prescribed offset in respect of the administrative cost resulting from a specified regulation shall achieve an average annual reduction in costs of an amount*

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equal to 125 per cent of the administrative cost". There remains much work to be done to understand and predict the administrative costs to payors, intermediaries and recipients from the HSPTA. Therefore, more time will be required for the Ministry to conduct an analysis of these regulatory impacts and to make the estimated administrative costs available to the public (See Appendix). The Association believes that all health stakeholders would appreciate a similar extension that they might continue their respective analyses of the draft regulations through to the Fall of 2018, at which time they would hope to have another opportunity for a public consultation prior to the finalization of the regulations.

CONSIDERATION OF OPERATIONAL IMPACTS OF HSPTA

The broad reaching nature of the Act and of the proposed regulations will introduce significant levels of confusion and intrusion into day-to-day operations as payors, intermediaries and recipients attempt to comprehend and navigate the varying inclusions and exclusions for reporting, tracking and validation of TOV.

Table 2: List of Common Pharmacy Activities Subject to Disclosure

COMMON DISCLOSURE ACTIVITIES FOR PHARMACY BUSINESSES AND ORGANIZATIONS *(not an exhaustive listing)*	
• Ontario College of Pharmacists license fees	• Corporate sponsorships of miscellaneous events
• Professional liability insurance	• Staff social events
• Corporate conference participation and related expenses	• Shipping costs
• Conference vendor payments	• Shipping supplies
• Professional association fees	• External consultants not related to conferences
• Continuing education activities	• Funding for research initiatives
• Operational training	• Drug Information Subscription Service
• Expenses for attendance of internal or external meetings	• Patient information books, other reference materials
• Education sponsorships	• OTC drug
• Payments for service delivery	• OTC medical devices
• Student recruitment and retention events	• Engagement-related Activities and Rewards Programs
• Meals with colleagues that are members of the Ontario College of Pharmacists	• In-kind items or services provided by corporate head offices
• In-kind items or services by other staff that are members of the Ontario College of Pharmacists	

While these activities comprise a comprehensive list of activities that will require disclosure by payors in the broader pharmacy sector, they are projected to be significantly impactful and intrusive to business. In particular, community pharmacy owners (corporates and independents alike) are already heavily regulated in all aspects of business and the delivery of care to patients. Most notable in this regard are the existing prohibitions on rebates as transfers of value outlined in both the *Drug Interchangeability and Dispensing Fee Act, 1990* ('DIDFA') and the *Ontario Drug Benefit Act, 1990* ('ODBA'). The Association believes these prohibitions sufficiently restrict and regulate TOV made to pharmacy businesses ('community pharmacies') and pharmacist practitioners, warranting their exclusion from the list of recipients in the proposed HSPTA regulations.

The OPA has considerable concern on the impact of reporting TOV payments to the competitive nature of the pharmacy business model. Insofar as the disclosure of reported TOV payments will be public, negotiated terms between payors and providers may significantly compromise the business model which could translate into higher costs for services and could ultimately result in an inability to sustain the continued provision of those services.

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Community pharmacy owners have conveyed their concern as to the operational costs required to report, track and validate payments of TOV. Many pharmacy owners anticipate the need to hire additional staff simply to administer the paperwork related to reporting, tracking and validation of TOV payments related to the many activities listed in Table 2.

CONSIDERATION OF UNINTENDED CONSEQUENCES

OPA is concerned regarding the potential for unintended consequences associated with reporting of payments of TOV. Notwithstanding the valid concerns of bias associated with some TOV and the provision of care to patients, there are many instances whereby TOV are completely separated and unrelated to the promotion of a product or other proprietary self-interests of the payor and serve instead to enhance and/or advance healthcare, professional development, patient engagement and general health literacy. Many TOV that are related to these types of initiatives or programs are frequently offered by payors as competitive investments toward practice and healthcare excellence with no product biases, with dollar amounts committed confidentially to enhance their corporate image and to offer broad-based support for health system advancement. Often, these TOV significantly subsidize costs of professional development and training for healthcare professionals, and the Association is concerned that mandatory reporting might disincentivize such investments by payors in the Province of Ontario, thereby stifling their important and essential contributions toward professional development and health system growth.

CONSIDERATION OF TECHNOLOGICAL AND OTHER RESOURCES FOR IMPLEMENTATION

To accommodate the complexity of reporting, tracking and validating TOV, technological changes will need to be incorporated at the payor, intermediary and recipient levels. While section 10(2) of the proposed regulations stipulates that "payor[s] shall report all transfers of value through an electronic data collection platform created and maintained by the Minister", payors will need to ensure this platform functions well and accurately with their existing systems. In addition, there is no reference in the draft regulations of any technological solutions for either intermediaries and recipients to track and validate any TOV, and this needs to be considered.

Finally, there has been no consideration of costs and time related to training on reporting, tracking and validating TOV. As referenced earlier in this submission, the Association expects that the HSPTA regulations, once passed, will have been constructed in full alignment with the RRCBA and its regulations so that administrative costs (including technological) that accrue to payors, intermediaries and recipients from transparency legislation are not only considered but also offset by 125 percent.

REDEFINING THE TERM "DRUG" FOR THE PURPOSES OF TRANSPARENCY REPORTING

As it relates to the term "drug" in section 3 of the proposed HSPTA regulations, OPA believes that the definition applied for purposes of tracking payments of TOV is far too broad with its inclusion of Schedule II and III drug products as listed in the *Drugs and Pharmacies Regulation Act, 1990*. The Association suggests that inclusion of traditional over-the-counter products in the definition is unwarranted since, in most cases, neither public nor private plans cover such products. Furthermore, OPA is unaware of another situation whereby non-health retail entities that derive revenues from the sale of products to the general public face such scrutiny of revenues by either government or private policy makers. As such, the draft regulations to the HSPTA would unduly restrict competition in Ontario, while competition in other provincial jurisdictions would remain unrestricted. Furthermore, the proposed HSPTA regulations seems wholly unbalanced and insufficiently considered given the current inclusion of Schedule II and III products and exclusion of

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traditional Chinese medicines, medical devices, health aids (e.g., dosing cups and syringes, pill splitters, measuring cups, compounding supplies, placebo training devices, etc.), natural health and, eventually, recreational cannabis products.

The Association understands the desire of the Ministry to demand transparency in the provision of drug products for the public drug plan for which it serves as the payor for eligible recipients. To apply a broader definition of "drug" for the proposed HSPTA regulations that extends beyond the parameters of the ODBA would be an intrusion into business transactions that fall outside of the government's purview. Therefore, it is the position of OPA that, as it relates to its definition within the HSPTA and section 3 of the draft regulations, the term "drug" should be amended to exclude products listed in Schedules II and III and be further restricted to Schedule I products that have been designated as eligible benefits in the Ontario Drug Benefit Formulary under the ODBA.

RECONSIDERATION OF THE BREADTH OF THE LIST OF RECIPIENTS

The Association recommends that the Ministry should reconsider both the overly comprehensive list of recipients. Specifically, OPA believes that reporting of payments of TOV should be linked to the purpose of the payment itself, whereby:

- TOV are directly linked to the provision of care to patients,
- TOV are directly influencing the sale of a product, or
- TOV are otherwise preferentially promoting matters of proprietary self-interest for the payor.

As the association that advocates for the interests of pharmacy professionals and for practice excellence, the Ontario Pharmacists Association neither delivers direct patient care nor provides biased, product-focused programming to its member constituents. Monies received by OPA from pharmaceutical manufacturers are designated as "unrestricted educational grants" that support the development and delivery of unbiased professional development material that are aimed solely at providing health and disease-specific information. The Association's educational programs are fully accredited by the Canadian Association of Continuing Education in Canada ('CCCEP')[1], which stipulates that OPA will ensure that sponsored learning activities meet the rigid standards established for CCCEP accreditation and will guarantee independent control of the learning activity content along with clear and transparent sponsorship agreements. This means that sponsors (e.g., pharmaceutical manufacturers and others who provide unrestricted educational grants to the education provider) are appropriately identified and that there is no evidence of bias in the content of the program or any promotional materials towards the sponsors or their products. The Association is concerned that mandatory reporting under HSPTA regulations of unrestricted educational grants for accredited programs will stifle a manufacturer's competitive investment in the profession of pharmacy and in unbiased promotion of disease awareness and general health and wellness strategies. Based on this, OPA contends that a payor's financial support of an accredited educational program through unrestricted educational grants be exempted from the reporting process.

RECOMMENDATION TO EXEMPT CERTAIN FORMS OF TRANSFERS OF VALUE

Similar to payments of unrestricted educational grants mentioned above, provisions of TOV for event sponsorships (e.g., conferences and professional symposia) made to professional associations such as OPA that are not involved in the provision of direct patient care ought to be excluded from the reporting process.

[1] Canadian Council of Continuing Education in Pharmacy website http://www.cccep.ca

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Not-for-profit associations like the OPA rely heavily on the financial contributions of pharmaceutical manufacturers, distributors, pharmacy organizations and individuals to support the necessary work done by these associations on behalf of their respective members. Once again, such contributions are deemed by the payor to be competitive investments in healthcare, with specific dollar amounts committed in confidence, and are completely unrelated to promotion of products for patient care or to influencing prescribing and dispensing patterns. Once again, mandatory reporting might serve to stifle investments such as these that are so critical in the coordination of expensive yet needed educational events.

With the addition of section 5, paragraph 1 in the draft regulations calling for the inclusion of holders of a certificate of accreditation for the operation of a pharmacy as payors, the Association is disappointed to see inclusion of payments of professional membership fees on the TOV listing. It remains wholly unclear as to how payments made by pharmacies of professional membership fees for its staff will influence the provision of care provided by healthcare professionals. Furthermore, while not specifically identified as TOV in the draft regulations, it is reasonable to assume that similar types of non-patient related payments may get captured in the reporting framework. These might include, but would not be limited to, payments related to mandatory coverage of professional liability insurance premiums, professional licensure fees and other human resource related initiatives such as staff holiday events and funded professional development training programs. Once again, OPA asks government to carefully reconsider the impacts of such broad-based reporting, most of which have no bearing or influence on the provision of care to patients.

RECONSIDERATION OF THE $10 REPORTING THRESHOLD

Notwithstanding pre-regulatory stakeholder consultations that included discussions related to a reporting threshold, OPA remains unconvinced that a threshold of $10 is both realistic and practical. As an example, payment by a pharmaceutical sales representative of two cups of coffee for two pharmacists in a pharmacy – a scenario that in any other market would be viewed and accepted as nothing more than a courteous gesture between business colleagues – can easily put the payor over the threshold and cause undue reporting, tracking and validation headaches for payors, intermediaries and recipients alike. This would also be a tremendous administrative burden to Ministry staff responsible for tracking payment trends with little if any real value to that information. It is understandable that a threshold needs to be established, but it must be both reasonable and respectful of the administrative burden being added to payors, intermediaries, recipients and government staff, and that is time that could be much better spent on more important matters.

RECONSIDERATION OF THE EXCLUSION OF MEDICAL SAMPLES FROM REPORTING

With reference to section 6, paragraph 3 of the HSPTA draft regulations, OPA is disappointed in the unreasonable exemption of “medical products that are provided to a recipient that are intended to be given to patients by the recipient free of charge”. During the pre-regulatory consultation phase for the HSPTA, OPA raised the matter of marketing programs with Ministry staff that included provision of free physically produced medical samples as well as virtual drug sample and discount cards that cover a portion of drug costs for the patient. At that time, OPA was informed that such pharmaceutical marketing practices, which constitute obvious forms of product influence and prescriptive bias, were too complex to be fully understood for preliminary inclusion in the regulations and were therefore exempted pending further discussion. This underscores government’s recognition of the complexity associated with these regulations. Furthermore, upon seeing the complete imbalance and illogic between exclusions from the TOV list of blatant marketing tactics such as samples and discount cards but inclusion of payments of staff pharmacists’ professional fees by pharmacies that have no bearing at all on dispensing influences, it is quite clear that a

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complete reconsideration of the TOV list is required and that this ought to involve more fulsome dialogue with all impacted stakeholders.

OTHER MISCELLANEOUS CONSIDERATIONS AND RECOMMENDATIONS

- OPA requests that section 6 paragraph 2 be reworded in a way that adds "honoraria" paid to pharmacy students and interns in lieu of salary or wages for interim work placements as an exclusion to reporting. Similarly, wording for section 2(1)(e) should be modified to read, "*honoraria, except where they are paid to students and/or interns in lieu of salary or wages for interim work placements*".

CONCLUSION

The Ontario Pharmacists Associations appreciates the opportunity to provide fulsome commentary to the Ministry of Health and Long-Term Care on the draft regulations for the *Health Sector Payment Transparency Act, 2017*. OPA also acknowledges and supports the comprehensive submissions provided to the Ministry by the Neighbourhood Pharmacy Association of Canada and by Shoppers Drug Mart Inc./Loblaw Inc. As this is truly landmark legislation provincially and nationally and introduces unprecedented oversight on payments of transfers of value in a highly complex and competitive sector, it is imperative that stakeholders, government, and the general public completely understand the implications (intended or otherwise) of this legislation and proposed regulations. Otherwise, they could disrupt the flow of much needed investment dollars and equivalent forms of support from industry to healthcare providers and associations.

Notwithstanding this submission, OPA is committed to continue working internally and with its sector partners to identify and more fully understand the many costs (real and potential) associated with the proposed transparency regulation. We therefore reserve the right to supplement and/or amend this submission as more information on costs and impacts become known. We will remain in contact with the Ministry on any such supplements and/or amendments and look forward to continued discussions on this matter in the Fall of 2018.

Should you have any questions or concerns related to this submission, please do not hesitate to contact me at your earliest convenience either by email at agall@opatoday.com or by phone at 416-441-0788.

Yours sincerely,

Andrew D. Gall
Chief Executive Officer

cc: Patrick Dicerni, Assistant Deputy Minister, MOHLTC
Suzanne McGurn, Assistant Deputy Minister and Executive Officer, MOHLTC
Mike Cavanagh, Chair, Board of Directors, Ontario Pharmacists Association
Justin Bates, CEO, Neighbourhood Pharmacy Association of Canada
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APPENDIX – REDUCING REGULATORY COSTS FOR BUSINESS ACT, 2017

OPA believes a more fulsome review of transparency practices (nationally and internationally) be undertaken to explore best practices as well as lessons learned.

Ontario's 7 Regulatory Modernization Principles

1. **Use industry standards or international best practices** to eliminate redundant reporting requirements and facilitate harmonization
2. **Apply a small business lens** by setting different compliance paths to achieve desired outcomes, rather than using a one-size-fits-all approach
3. **Go digital** by delivering simple and straightforward digital services and products that will modernize public service delivery and make government work better for businesses
4. **Strengthen risk-based inspections** to recognize businesses with a strong safety and compliance record, using accreditation to distinguish good actors from high-risk targets and better coordinating inspections among ministries and agencies
5. **Create a "tell us once" culture** with ministries that interact with business by ensuring all ministries that interact with business use the Business Number to avoid having businesses provide the same information to government repeatedly
6. **Focus on the user** by writing in plain language and creating a single point of contact for businesses to access government information and services
7. **Facilitate equivalent means of regulatory compliance** where a business can demonstrate an alternative approach that meets or exceeds the requirement of the regulation, where appropriate

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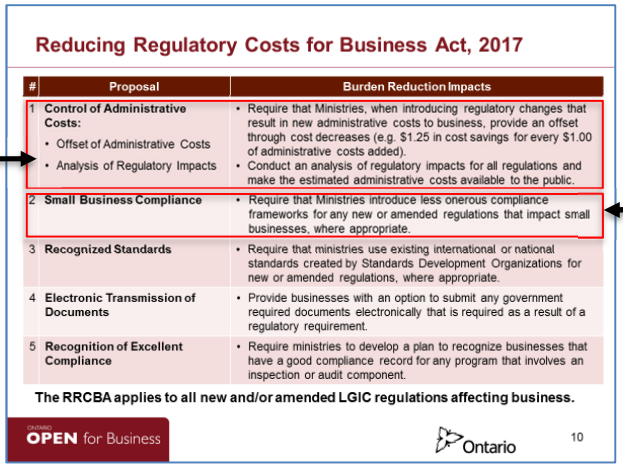
OPA believes the HSPTA does not differentiate between the unique challenges faced by corporate and independent pharmacies.



Reducing Regulatory Costs for Business Act, 2017

#	Proposal	Burden Reduction Impacts
1	**Control of Administrative Costs:** • Offset of Administrative Costs • Analysis of Regulatory Impacts	• Require that Ministries, when introducing regulatory changes that result in new administrative costs to business, provide an offset through cost decreases (e.g. $1.25 in cost savings for every $1.00 of administrative costs added). • Conduct an analysis of regulatory impacts for all regulations and make the estimated administrative costs available to the public.
2	**Small Business Compliance**	• Require that Ministries introduce less onerous compliance frameworks for any new or amended regulations that impact small businesses, where appropriate.
3	**Recognized Standards**	• Require that ministries use existing international or national standards created by Standards Development Organizations for new or amended regulations, where appropriate.
4	**Electronic Transmission of Documents**	• Provide businesses with an option to submit any government required documents electronically that is required as a result of a regulatory requirement.
5	**Recognition of Excellent Compliance**	• Require ministries to develop a plan to recognize businesses that have a good compliance record for any program that involves an inspection or audit component.

The RRCBA applies to all new and/or amended LGIC regulations affecting business.

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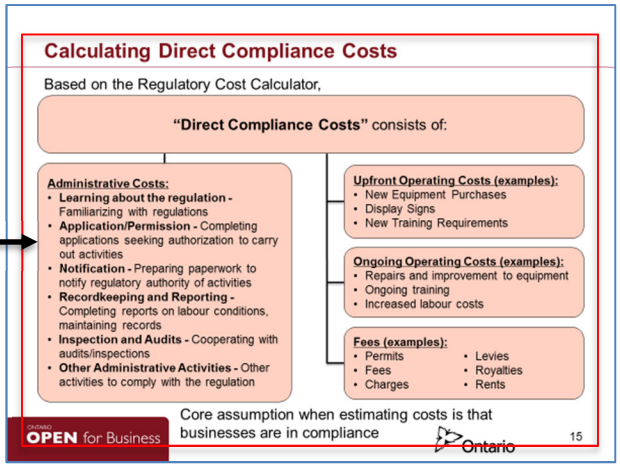
OPA requests that the MOHLTC undertake a full regulatory impact assessment prior to finalization and implementation of the regulations to ascertain the costs to stakeholders from intended and unintended consequences of the HSPTA.



Calculating Direct Compliance Costs

Based on the Regulatory Cost Calculator,

"Direct Compliance Costs" consists of:

Administrative Costs:
- **Learning about the regulation -** Familiarizing with regulations
- **Application/Permission -** Completing applications seeking authorization to carry out activities
- **Notification -** Preparing paperwork to notify regulatory authority of activities
- **Recordkeeping and Reporting -** Completing reports on labour conditions, maintaining records
- **Inspection and Audits -** Cooperating with audits/inspections
- **Other Administrative Activities -** Other activities to comply with the regulation

Upfront Operating Costs (examples):
- New Equipment Purchases
- Display Signs
- New Training Requirements

Ongoing Operating Costs (examples):
- Repairs and improvement to equipment
- Ongoing training
- Increased labour costs

Fees (examples):
- Permits
- Fees
- Charges
- Levies
- Royalties
- Rents

Core assumption when estimating costs is that businesses are in compliance

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