



*Working to keep our health care system healthy™*

**THE ONTARIO ASSOCIATION OF MEDICAL LABORATORIES**  
**COMMITMENT TO THE FUTURE OF MEDICARE ACT, BILL 8/2003:**  
**THE COMMUNITY LABORATORY PERSPECTIVE**

January, 2004



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## Preamble

The Ontario Association of Medical Laboratories is supportive of the creation of a quality council to provide the people of Ontario with an assessment of the performance of the health system as a whole. The OAML agrees with the principles of accountability and transparency in the health system but, we do not believe that this bill achieves those principles.

The OAML has, for twenty-five years, served as the representative organization of Ontario's community laboratories. As the health system has evolved and, most particularly, since the early 1990's, the OAML has worked closely with the Ministry of Health and Long Term Care to develop a co-management role with the Ministry. Since 1992, the OAML and the Ministry have negotiated agreements that have served as the foundation for our relationship.

In 1996 the Ministry, in consultation with the OAML, put in place regulations that imposed a "cap" on payments to community laboratories for all services provided. As well, individual corporations were "capped", based on their market share at the time the regulation came into effect. Since that time, the OAML and the Ministry have negotiated a series of two-year agreements that not only set the global funding for community laboratory services for the term of each agreement but, also establish the accountability of both parties for deliverables to be achieved within the agreements' terms.

The impact of these "accountability agreements" has been to establish stability of revenues that laboratories may expect, in any given year, from billings for insured services<sup>1</sup> and the development of OAML programs that have added tremendous value to the system; these include the Quality Assurance of Clinical Laboratory Practice Program and the OAML Human Resources Program.

Working with the Ministry, the OAML has also participated as an active partner in the process of laboratory reform and we bring to these discussions our own experience of reform and restructuring, which community laboratories underwent throughout the 1990's. We remain hopeful that current laboratory reform initiatives will bring the same rigour to the examination of public health and public hospital-based laboratory services.

Our experience tells us that the most fruitful relationship between the Ministry and health services providers is one that is based on respect, explicit expectations mutually agreed upon and a collaborative approach to the management of the sector.

Community laboratories demonstrated, during the SARS outbreaks of 2003<sup>2</sup>, our agility and responsiveness. As hospitals shut down their outpatient clinics, the Ministry asked that community laboratories step into the breach and provide laboratory testing to hospital outpatients. Community laboratories did so. Despite the communications difficulties that were so much a feature of the first few weeks of the outbreaks, community laboratories demonstrated their ability to serve as necessary "surge capacity" in a health crisis.

It is in this spirit that we have reviewed and commented on the current bill. We have concerns with the legislation as currently drafted and these are made clear in the analysis that follows. However, the OAML and Ontario's community laboratories believe that the relationship we have fashioned, with the collaboration of the Ministry, and the agreements we have negotiated can serve as a model for other health services sectors. Our history over the past ten years convinces us that open communication and a conciliatory approach can produce mutually gratifying results. We look forward to a continuing, productive relationship with the Ministry.

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<sup>1</sup> In the capped environment community laboratories have often been in the position of providing ten of millions of dollars worth of services for which they do not receive compensation.

<sup>2</sup> The OAML's report on SARS 2003, The Community Laboratory Perspective is available at [http://www.oaml.com/PDF/sars\\_report.pdf](http://www.oaml.com/PDF/sars_report.pdf)

## Executive Summary

The Ontario Association of Medical Laboratories has reviewed Bill 8, 2003, as it was tabled for first reading in the Legislature on November 27, 2003.

The implications of the Bill for the community laboratory sector are serious. We provide section-by-section analysis and comment in the body of this report but, we are extremely uncomfortable with the Bill in its present form and are deeply concerned that this piece of legislation indicates the nature of the relationship that the Minister might wish to have with the health services sector.

We have undertaken in our section-by-section analysis and comment, to provide an alternative approach; one that is both more conciliatory and allows for the meaningful input of service providers into a model of health care delivery.

We note that, this bill includes **uninsured services**. In the case of laboratories, these are services that we are licensed to provide but, for which OHIP makes no payment. One example is PSA screening for men. Our analysis and commentary of section 14 is in the body of the report but, we are deeply concerned that there should be **no limitation on the generality of the power delegated to the General Manager of OHIP**. He or she could demand submission of proprietary information and with no purpose stated. Uninsured services, by their very definition, do not fall within the bailiwick of the General Manager of the Ontario Health Insurance Plan.

We are disturbed at the extent to which the Bill seeks to impose **ministry micromanagement of health care**.

We are not offended by the principle of accountability. Every two years the community laboratory sector negotiates a funding agreement with the Ministry of Health that sets the maximum amount of monies to be paid during the term of the agreement, for all insured laboratory services, provided by the community sector. The agreements often include obligations to which the OAML and the community laboratories must respond. This has been the case since 1992-93. We perform millions of dollars worth of insured testing each year for which we do not get compensated. Our billings are submitted to OHIP. Our OHIP claims are subject to Ministry of Health audit, our laboratories and specimen collection centres are subject to Laboratories Branch inspection. We are subject to licensing for every test we perform. We deal with Ministry staff at all levels several times a week and are also subject to accreditation by the Ontario Laboratory Accreditation process of QMP-LS, a joint Ministry/OMA initiative.

We feel the community laboratory sector is also accountable to our ordering physicians, to the clients who use our services, to a code of ethics and to the Ministry of Health through a number of mechanisms, including our negotiated agreements. We would hope that revised legislation would allow for negotiated agreements for service provision with terms with which all parties can abide, rather than imposed **“accountability agreements.”**

We are concerned at the idea of **compliance directives** and the penalties attached thereto. The power, as described in the Bill, is draconian. **There is no limitation on the generality of the Ministerial power**. We have reviewed these sections of the Bill and have provided some commentary that may add meaningfully to the conversation.

We are partners in the laboratory reform process, having been the first sector to undergo restructuring in the 1990's. We are hopeful that the current process will bring meaningful change to hospital and public health laboratories too. We have worked with successive Ministers of Health to ensure that the laboratory services, available to patients in their own communities, are of high quality, reliable and, in our capped billing environment, less expensive than similar services provided elsewhere in the system. We are partners in the delivery of health services.

We look forward to further developing that partnership.

## Analysis of Bill 8

### Short Title, Commitment to the Future of Medicare Act

There are several important implications for community medical laboratories of the bill in its current state. We have prepared our submission in a timely fashion, so as to ensure our voice is heard **before** redrafted legislation is returned from committee. Specific sections to which we would draw your attention are as follows:

#### PART II HEALTH SERVICES ACCESSIBILITY

##### Section 9 - Persons not to charge more than OHIP

Section 9 codifies what has been community laboratory practice for decades.

##### Section 10 - Agreement for determining amount

- (3) The Lieutenant Governor in Council may make a regulation providing that the Minister may enter into an agreement under subsection (1) with a specified person or organization...

##### Comment:

It has been the case since 1992-93 that the Minister and the OAML have entered into such agreements.

##### Section 14 - Disclosure of Information to the General Manager

- (1) At the request of the General Manager, any person or entity that provides a provincially funded health resource or that renders an uninsured health service to an insured person shall submit information to the General Manager and disclose information to persons specified by the General Manager for purposes related to the administration of this Part, the *Health Insurance Act*, or the *Independent Health Facilities Act* or for other prescribed purposes.
- (2) The information mentioned in subsection (1) may be any information that the General Manager reasonably considers that he or she requires.
- (3) Subject to the regulations, the information shall be provided and disclosed in the form and at the times required by the General Manager.

##### Comment:

Ontario's community laboratories currently submit all required information respecting insured services delivered to insured people. We also, as a condition of licensing for uninsured services, provide annual reports of the total numbers for each uninsured test performed to the Laboratory Licensing and Inspection Branch. Section 14 is overly intrusive and will not improve the quality of services provided. The import here is that, under the Act, laboratories would be required to report not just numbers of uninsured services rendered to "insured persons" but, also any other information the General Manager of OHIP deems reasonably necessary, to the General Manager or any other persons specified by the General Manager for purposes related to the administration of the *Health Insurance Act*, the *Independent Health Facilities Act* or any other prescribed [in regulation] purpose.

The General Manager of OHIP decides what is appropriate information to be requested to disclose. This is worrisome as the scope of inquiry does not exclude proprietary financial information. The intent of this section remains unclear.

The penalty for failure to comply with this section is a suspension of payments under OHIP.

Sections 14 applies even if the information is confidential, privileged and despite any Act, regulation or other law prohibiting disclosure of information (except the privilege that may exist between a solicitor and his or her client). The privilege that may exist between a provider and a patient is given short shrift. We are informed that Bill 31 might contradict this provision of Bill 8.

Nothing in this section explains the necessity of collecting information about the delivery of uninsured services, nor does the section specify the purposes to which such information may be used. It is an instance where there is **nothing that limits the generality of the power delegated to the General Manager**. Uninsured services, by definition, clearly fall outside the bailiwick of the General Manager of the Ontario Health Insurance Plan.

There will be costs involved in complying with this section. Who will bear the expense?

### Part III - ACCOUNTABILITY

#### Sections 19-32

This Part is troublesome. Community laboratories are clearly included under this section as health resource providers. Executives could be held personally liable by the government for the performance of the laboratory. Part III gives the Minister extraordinary powers to direct an organization to fire, demote or otherwise sanction any person within the organization without any right of recourse. Laboratory corporations could be forced into individual “accountability agreements” with the Ministry. The Minister has the sole right to determine the contents of such an agreement and to enforce compliance. This is micromanagement of the health system.

**Section 19** defines terms that apply from section 20 to section 32.

**Section 20** lists those matters that the Minister may consider as being within the scope of “accountability agreements.”

**Section 21** provides for the entering into accountability agreements by the Minister and any one or more persons, agencies or entities, as directed by the Minister.

#### Comment

Apart from its implications for forced accountability agreements between the Minister and the corporations, deemed, by Ministerial fiat, to be mutually agreed, the Bill would allow the Minister to force anyone to enter into an accountability agreement with anyone else! This section also allows the Minister to vary private employment contracts retroactively and specifies that such variations, arrived at unilaterally, would be deemed to have been mutually agreed. This is a rebuke of Ministry/Provider consultation as a means of arriving at a satisfactory arrangement for the supply of and payment for services and further reinforces the perception that **the intent of the Bill is to support Ministry micromanagement of the health care system**.

The example of the negotiated agreements between the Ministry of Health and the OAML, representing the community laboratory sector, might serve as a model for accountability agreements. They contain no specific check lists but do impose obligations on the OAML and the community laboratories and on the Ministry of Health for the term of the agreement. The inclusion of specific accountability markers actually mutually agreed upon, would provide the Ministry with the reassurance needed, while leaving community laboratories to manage their own affairs in the best interests of physicians, patients and the sector.

One of the elements to be considered in the proposed “accountability agreements” is quality improvement. The OAML’s Quality Assurance of Clinical Laboratory Practice has issued guidelines to physicians encouraging the appropriate ordering of laboratory tests for almost a decade and the result has been massive savings to the health care system. A 1998 study published in the Journal of the American Medical Association

demonstrated reductions of 62,500,000 tests and savings to the system of \$21,040,000 in the first two years of the program's operation.<sup>3</sup>

The quality management systems in place in Ontario's community laboratories meet or exceed those demanded for QMPLA - OLA accreditation.

Another proposed element of an accountability agreement is "trust". OAML member laboratories have demonstrated a willingness to abide by our negotiated agreements and we would hope that nothing in this bill will undermine the trust that we have worked so diligently to establish between the sector and the Ministry.

**Section 22** provides for the Minister to issue compliance directives to any health resource provider or any other prescribed person, agency or entity and to prescribe the time the directive takes effect and period within which the directive will be in place.

**Comment:**

This element is troublesome in that it is general, vague, ambiguous and uncertain. There is **nothing that limits the generality of the ministerial power**. The inclusion of agencies and entities extends the Ministerial power beyond the health resource providers already defined.

One would hope that such powers might be invoked only in situations of local or provincial emergency and that the legislation would define and delimit the scope of Ministerial power. Ministerial transparency is an important element in maintaining the trust and co-operation of health providers.

**Section 24** allows the Minister to terminate any "accountability agreement" or to vary its terms.

**Comment:**

Agreement requires mutually arrived at conclusions. Agreements may be "deemed to have been mutually agreed" in regulation but such an approach can only lead to a deleterious breakdown in the relations between government and health providers. Further alienation of the people who staff the health system is not a constructive answer to the problems that beset the health care system.

Again we would emphasize the importance and benefit of the consultative process of negotiation which has served the Ministry and the community laboratory sector so well over the last decade and encourage a similar, mutually agreed model for all sectors of the health system.

**Section 26** allows the Minister to take prescribed measures against any person, agency or entity who fails to comply with the terms of an accountability agreement or a compliance directive.

**Comment:**

Any person, agency or entity that fails to abide by actual, negotiated, mutually agreed accountability agreements ought to be held accountable. As we are unsure of the intent of "compliance directives" and until this is more clearly enunciated we can only reiterate our concern that there is **no limitation of the generality of the Ministerial power**.

**Sections 27 and 28** speak to material changes in a person's employment terms as a result of an order made by the Minister and essentially allow for the ability to reallocate executive health human resources without the agreement of the employee or any compensation for any loss sustained.

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<sup>3</sup> Carl van Walraven, Vivek Goel, Ben Chan, "Effect of Population-Based Interventions on Laboratory Utilization - A Time Series Analysis", *JAMA* 1998;280:2028-2033.

**Comment:**

These sections will apply not just to executives already included in the term “health resource provider” but, to anyone described in a regulation under the Act. Again the concern is that there seems to be **no limitation to the generality of the Ministerial power.**

**Section 29** (1) speaks to the disclosure of any information, excepting personal health information, but including all other personal information (as defined in the *Remedies for Organized Crime and Other Unlawful Activities Act*, 2001) in such form and at such times as the Minister may require.

**Comment:**

The Bill refers to the *Remedies for Organized Crime or Other Unlawful Activities Act, 2001*, as the source of the definition of “personal information”. The latter act refers to the *Freedom of Information and Protection of Privacy Act, 1990* for a definition of “personal information”. It would be less confusing were the Bill to refer directly to *FIPPA* for a definition of “personal information”.

**Section 29** (2) compels any health resource provider to post in a conspicuous place all or part of any accountability agreement, compliance directive or other measure taken under section 26, even if this results in disclosure of personal information.

**Section 29** (3) allows the Minister to disclose publicly the terms of any accountability agreement or compliance directive.

**Section 29** (4) provides that any agency, person or entity who fails to disclose information or post a notice under subsections (1) and (2) is guilty of an offence and, upon conviction, subject to fine of not more than \$50,000.

**Comment**

The tenor of this Bill with respect to personal information runs counter to current and pending legislation and the rulings of privacy commissioners in the two senior levels of government.

Section 29 would seem to allow for the collection and disclosure by the Minister of proprietary financial information. This would be seen as a counter-productive move, by community laboratories.

The health services sector is undergoing massive expense and restructuring to protect the privacy of personal information and personal health information. This Section would seem a retrogressive and invasive step in the opposite direction.

**Section 30** absolves the Ministry of any liability with respect to anything done or purported to be done under Part III or regulations.

**Comment:**

Section 30 begs the question, “To what extent is the Minister accountable?” Accountability is necessarily a two-way street. If the Minister may, with no regard to consequences, impose her or his will on the health services sector and stand absolved of responsibility for any harm done, as a result of such imposition, we will have moved into a new paradigm for delivery of health services in Ontario; one that bodes not well for the future of service provision. Health care workers are already voting with their feet and leaving Ontario for other jurisdictions. Conciliation is required. The relationship between the Minister and health services providers ought to be one of co-operation, in the most exact sense of that word. There should exist a partnership between provider and payer. An adversarial approach may elicit any number of responses, none of them likely to be productive.

**Section 31** provides that everyone who fails to comply with the terms of an accountability agreement or a compliance directive is deemed to be guilty of an offence and to be subject, upon conviction, to a fine of not more than \$100,000.

**Section 32** provides for the making of regulations under this part of the Act.

**Section 33** speaks to who may bill the plan.

**Comment:**

Section 31 reinforces our concern with the issue of compliance directives and the absence of limitations on Ministerial power.

Section 33 codifies current practice.

**Section 40** This section amends the *Health Insurance Act* in a number of way but, perhaps the most significant is the following:

**Ministerial Order**

(2.1) Upon the advice of the General Manager, and where the Minister considers it to be in the public interest to do so, the Minister may make an order amending a schedule of fees referred to in subsection (2) in any manner the Minister considers appropriate. The order remains in effect until either it is rescinded, a regulation is put in place which renders the order redundant or twelve months have elapsed.

**Comment:**

The import for the Community Laboratory Sector is that our fee schedule can, without any consultation with the sector, be changed; tests may be added without an increase to our “capped” revenues, prices may be arbitrarily reduced or, in the case of a new test, added as determined by the Minister arbitrarily. We experienced the consequences of similar action in the early to mid-1990’s and have only now recovered. The implications are that jobs may be lost in a field of health care that already faces critical shortages of scarce skills.

Community Laboratories have already undergone the laboratory reform so desperately needed in the public sector. We have consolidated resources, necessarily eliminated hundreds of jobs and with them lost the health human resources and the scarce skills the system now cries out for. To be subjected to this kind of action again will have serious consequences for the community laboratory sector and may further aggravate the already looming crisis of scarce skills in health services.

Sector-by-sector negotiation of agreements, mutually agreed by the parties, and not subject to Ministerial fiat are the most effective means to win acceptance of a form of “accountability agreement” that may vary from sector to sector but which can still provide the Ministry, over time, with the assurance that the quality of the services delivered remains high, the costs reasonable and roles clearly delineated.

## Conclusion

Our analysis of Bill 8, as presented to the legislature for first reading, leaves us disturbed. Some of the measures included in the Bill would, in our assessment, have a deleterious effect on the nature of the relationship between the Minister/Ministry and service providers.

However, we are supportive of the principles which the Bill seeks to codify. We think that accountability is necessarily a two-way street and are, therefore, disturbed at the possibility of arbitrary actions on the part of the Minister to impose and enforce mock accountability agreements. Trust is not something that can be legislated. We have argued in our preamble that agreements between the OAML and the Ministry might serve as a model for real accountability agreements. The elements may vary but the essentials would remain the same.

Transparency is crucial to the health of our health care system. But transparency requires a structure that allows for open communication and the development of a level of trust that does not now exist in many sectors. Current funding structures for some sectors militate against transparency.

We are concerned that elements of this Bill reflect the nature of the relationship between providers and government that the Minister would like to see develop over the next four to five years. It is an adversarial relationship, as defined in this legislation. The OAML is proud of the relationship we have developed with the Ministry under successive Ministers. We would be loath to see what has taken such commitment to build destroyed by misguided legislation. We are not adversaries; we are partners. We are not stakeholders; we are service providers and participants. The vocabulary of the discourse can very much influence the outcome.

We appreciate that the government has indicated its willingness to seek advice and input before submitting the bill for second reading and value the opportunity to provide our assessment and suggestions.

We are encouraged that the Minister may, in this and in all things, seek to build the broadest consensus possible, through a consultative process with providers and citizen representatives, to support him in his difficult task.

Ontario's community laboratories would like to see recognition, in the bill, of "accountability agreements" that already exist. The Bill might permit a review of existing agreements to determine that they meet requirements, contemplated in the bill, and that they achieve the intent of the legislation.

We would, further, encourage the Minister look to those areas of the health system that function well for remedies for those areas that do not.