

Guideline regarding Conflict of Interest when Providing Laboratory Service

Revised September, 2019

Introduction

The Ontario Association of Medical Laboratories (“OAML”) seeks the highest level of professionalism, accountability, and technical excellence in the provision of laboratory services for the benefit of people in Ontario. To this end, the OAML has developed this guideline to promote ethical behaviour in the relationships between laboratories and authorized health care practitioners when ordering laboratory services.

This guideline is based on, and intended to be in compliance with:

- Ontario’s statutes and regulations
- Ontario Health Regulatory Colleges’ policies, rules of conduct and guidelines for health practitioners; and
- Ontario Ministry of Health policies

These are more particularly described in Appendix A.

Intent

This guideline is intended to assist in the establishment and maintenance of relationships between laboratories and authorized health care practitioners and specifically to help ensure the following:

- laboratories do not confer directly or indirectly an incentive or benefit to practitioners in exchange for ordering laboratory services
- health care practitioners and laboratories recognize that there is a conflict of interest whenever a laboratory confers a benefit, directly or indirectly, to a health care practitioner from whom the laboratory receives referrals or specimens.

Specimen Collection Locations

At the request of an authorized health care practitioner, specimens may be taken or collected from a patient in four types of locations:

1. A licensed specimen collection centre – O. Reg. 683 under the Laboratory and Specimen Collection Centre Licensing Act (LSCCLA)
2. An established temporary specimen collection centre – as authorized under O. Reg 683 subsection 7(1) of the LSCCLA
3. A place where a physician, nurse practitioner, or midwife practices their profession – O. Reg. 682 under the LSCCLA
4. A place where the operator of a licensed laboratory provides mobile collection services (i.e. private residence, retirement/nursing home, etc.)

Conflicts of Interest Circumstances

The categories in the table below describe examples of events or activities that may give rise to an actual or perceived conflict of interest situation. The guiding principles listed beside each category clarify the parameters of appropriate interactions that should be applied to avoid an actual or perceived conflict of interest.

Circumstance	Guiding Principles & Relevant Regulatory Provisions
<p>Payment of Rent</p>	<p>It is a conflict of interest for a physician (or a member of his/her family or an associated corporation) to rent premises to a supplier to whom the physician refers his/her patients or their specimens, except when the rent is based on market rent having regard to the area, and the amount of rent is not related to the volume of services.*</p> <p>Market rental rate should consider such factors as:</p> <ul style="list-style-type: none"> a) Physician and other medical-services rental rates in the area; b) Office rents in the area; c) Commercial rents in the area for both medical and non-medical space; d) Rents appropriate to location within a building; and e) Reasonable square footage for services provided. <p>Additionally, guiding principles for evaluating rental rates include ensuring there is no benefit to health care practitioners resulting from inflated rents or volume-based correlations. The amount of space leased by a laboratory should also conform to the general amount of space a laboratory would reasonably need to provide laboratory services.</p> <p><i>*Under Part IV Conflicts of Interest in Ontario Regulation 114/94 made under the Medicine Act 1991.</i></p>
<p>Collection of specimens in the offices of a physician, nurse practitioner or midwife</p>	<p>Further to Ont. Reg 682, a specimen collection license is not required when specimens are collected in the offices of a physician, nurse practitioner or midwife, if:</p> <ul style="list-style-type: none"> a) The practitioner, or group of practitioners are responsible for the costs of the leased facilities; b) The place where the specimens are taken or collected is part of the practitioner's practice (i.e. not operated separately from his/her practice); c) The place where the specimens are taken or collected is under regular supervision of the practitioner(s); and d) Patients from whom specimens are collected are patients of the supervising practitioner or a group of practitioners

<p>Phlebotomists in physician’s offices</p>	<p>Where a laboratory enters into an arrangement with a physician to place a phlebotomist employed by the laboratory within their office to collect specimens, or an arrangement to reimburse the practitioner for phlebotomy services, the following conditions must apply to avoid conferring a benefit:</p> <ul style="list-style-type: none"> a) The specimen is drawn in a place where a legally-qualified medical practitioner(s) practices medicine and the place is under the control of a legally-qualified medical practitioner(s); b) The space used for drawing specimens must be leased by the physician(s); c) The phlebotomist is paid by the laboratory or the practitioner; d) Where employed by the laboratory, the remuneration paid to the phlebotomist must relate only to the provision of phlebotomy services; e) Where the practitioner is reimbursed by the laboratory, the reimbursement must relate only to the portion of the physician’s employee’s salary that relates to the provision of phlebotomy services; f) The laboratory does not pay for the use of space within the physician’s office for the phlebotomy service;
<p>Supplies, Equipment and other Services</p>	<p>Supplies and Equipment - Laboratories should only supply a practitioner with items that are directly connected to the collection and/or maintenance of the specimen until picked up by the laboratory.</p> <p>Table A- Equipment & Supplies below lists acceptable supplies and equipment that can be provided based on the type of specimens collected.</p> <p>Services – Laboratories should not pay any fees associated with the management/operation of the practitioner’s office (i.e. EMR licensing fees).</p>
<p>Educational & Consulting and advisory fees</p>	<p>Laboratories may approach physicians to become advisors, members of advisory boards, educators or consultants.</p> <p>While there is a legitimate role for physicians to play in these capacities, as outlined in the ‘<i>CMA Guidelines for Physicians Interactions with Industry</i>’, physicians should be mindful of the potential for this relationship to unduly influence their clinical decision-making.</p> <p>The following principles should be observed by laboratories in such relationships:</p> <ul style="list-style-type: none"> a) The exact deliverables of the arrangement should be clearly set out and put in writing in the form of a contractual agreement.

	<ul style="list-style-type: none">b) The purpose of the arrangement should be exclusively for the physician to impart medical knowledge that could not otherwise be acquired by the laboratory.c) Remuneration of the physician should be reasonable and take into account the extent and complexity of the physician's involvement.
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Note

This guideline provides laboratories and practitioners with a framework within which to govern their relationship. The OAML remains committed to ensuring that this guideline remains current and relevant – as such, this guideline will be periodically reviewed and amended as may be required.

Table A

Supplies permitted to take or collect specimens in practitioners' offices

Blood Collection	Urine Collection	Other Collections
Gloves	24-hour urine containers, plus additives	Scalpels
Vacutainers	Sterile urine, sputum containers	Chlamydia Kits
Multi-sample needles	Pediatric urine collectors	Pinworm Kits
Alcohol Swabs	Castille Soap Towelette (Urine C&S)	Pap Kits
Cotton balls		HPV Kits
Band-aids-Millipore tape		Semen Analysis Kits
Tourniquets		Snares
Sharps Containers		Forceps
Patient take-home kits		Biopsy Needles
Centrifuges		Endo-loops
Lancets		Swabs
Ziplock bags		

Appendix*

Laboratory and Specimen Collection Centre Licensing Act R.S.O. 1990, c. L.1

www.ontario.ca/laws/statute/90l01

R.R.O 1990, Reg. 683 Specimen Collection Centres

www.ontario.ca/laws/regulation/900683

R.R.O 1990, Reg. 682 Laboratories

www.ontario.ca/laws/regulation/900682

Medicine Act, 1991, S.O. 1991, c. 30 S

Ontario Regulation 114/94 Part IV Conflicts of Interest

www.ontario.ca/laws/regulation/940114#BK1

Canadian Medical Association, Code of Ethics Updated, 2004 (last reviewed March 2018)

<https://policybase.cma.ca/documents/policypdf/PD04-06.pdf>

Canadian Medical Association, 2007

Policy Guidelines for Physicians in Interactions with industry

<https://policybase.cma.ca/documents/policypdf/PD08-01.pdf>

College of Physicians and Surgeons of Ontario

The Practice Guide – Medical Professionalism and College Policies (Section 5 – Managing Conflicts of Interest)

<https://www.cpso.on.ca/admin/CPSO/media/Documents/physician/polices-and-guidance/practice-guide/practice-guide.pdf>

*All links were active as of date of issue of this Guideline