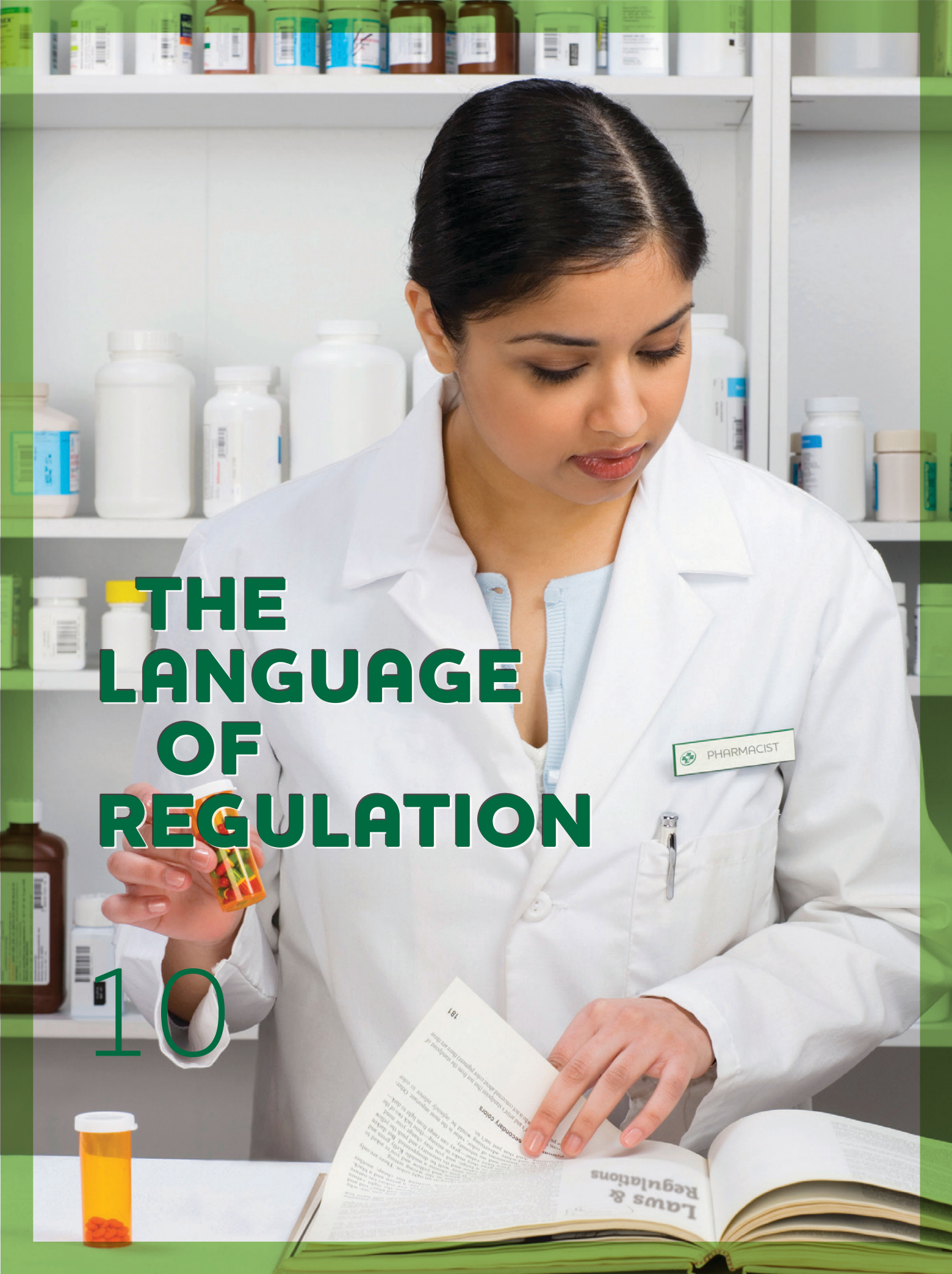
When Do Regulations Take Effect?

Over the past several years, College Council has approved several regulations under the *Drug and Pharmacies Regulation Act* and the *Pharmacy Act*. Most recently, Council approved a revised regulation on professional misconduct. So what happens next? Have the rules on professional misconduct changed? Is this regulation now in effect?

In a word, NO.

A regulation is not in effect until it is filed with the Registrar of Regulations and published on the Government of Ontario's e-Laws website and in the print version of *The Ontario Gazette*. When College Council approves a regulation, it is an approval to submit the regulation to government for review. Prior to filing and publication, the regulation is scrutinized by both bureaucrats and government members to ensure it fits in with the overall rules and principles of government. The overall impact of the regulation is assessed, as are projected costs and benefits. This process usually involves engagement with College staff to clarify the intent and impact of the regulation on member practice, and may lead to revisions of the regulation itself.

In this issue of *Pharmacy Connection* are two articles related to regulating member practice (*The Language of Regulation* on page 10 and The *Role of Supervision in Professional Training* on page 14). It should be noted, that the articles refer to the "draft revised professional misconduct regulation" and "the College's proposed *Professional Misconduct Regulations*". The regulation is "draft" and "proposed" because, while Council has approved it, the full process is not yet complete so the regulation is not yet in effect. Once it has been approved, members will be advised and directed to the new regulation. Until then, the current rules are the ones that govern practice.



THE LANGUAGE OF REGULATION

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THIS ARTICLE WILL EXPLORE SOME OF THE TERMS USED IN THE COLLEGE'S PROPOSED PROFESSIONAL MISCONDUCT REGULATIONS AND THE ADVANTAGES IN USING OPEN-ENDED LANGUAGE.

As regulated health professionals, pharmacists and pharmacy technicians are required to practice within the parameters established by legal and ethical frameworks. However, the formal language used in laws and regulations can appear imprecise. For example, regulations may contain words and phrases that seem general and/or euphemistic, meant to guide professional behaviour, rather than prohibit it. Yet somehow, within the vagaries of language, the member needs to parse out what is meant and then practice accordingly. This article will explore some of the terms used in the College's proposed *Professional Misconduct Regulations* and the advantages in using open-ended language.

Taken together, laws and regulations create duties, obligations and responsibilities that are binding on the member and address the overall delivery of patient care. Health practitioners, as accountable self-regulating professionals, must be prepared to justify clinical decision-making within the context of this framework. Given that these rules of practice guide professional behaviour across a range of settings, they are articulated in general terms, rather than in regard to specific circumstances. Since both practitioners and members of the public should be equally able to understand what is meant by a regulation, basic phrases and terms are used. This approach may result in such vague language that it creates difficulties for the individual member who looks to regulations for guidance over what is acceptable in his or her practice.

There are both pros and cons to drafting regulations in a more or less precise fashion. The advantage of detailed regulations is that they are clear and easily enforced; however, they may end up being too narrow to really

get at the behaviour they are intended to address. Rules that are generally stated, on the other hand, are flexible and easily applied to a variety of circumstances. As their meaning is somewhat negotiable, they can support innovation and creativity in practice and permit the health professional latitude in making clinical decisions in the context of individual patient needs. A drawback, however, is that if the wording used is too vague, they may be unenforceable. Therefore, it is necessary to find a balance between clarity and generality.

> "... context and judgment are key elements in making that determination."

The draft *Professional Misconduct Regulations* recently approved by College Council for submission to government contain several words and phrases that may be viewed as imprecise and which illustrate the issues raised above. The draft regulation includes terms such as "excessive" and "reasonable" along with phrases like "not of good quality" or "knows or ought to know". While these are words and expressions that can be found in many health professional regulations, how does the individual member apply them to practice? As will be illustrated below, both context and judgment are key elements in making that determination.

USE OF THE TERM "EXCESSIVE"

The proposed regulation contains a provision making it professional misconduct to charge a fee or amount that is excessive in relation to the service or product provided. Accordingly, there must be a clear rationale for the amount charged for a product or service. Many health professional colleges in Ontario have exactly the same provision in their regulations, as it is clearly in the public interest that patients are not denied access to health-related products or services due to unreasonable fees. The College of Nurses of Ontario, for example, indicates to their members that, in setting a fee, a nurse should consider the nature and complexity of the nursing service rendered, including the time spent with or on behalf of the client, and the cost of materials.[1] In 2010, in anticipation of an expanded scope of pharmacy practice, Council approved a policy on *Fees for Professional Pharmacy Services* (http://www.ocpinfo.com/regulations-standards/policies-guidelines/fees/). The policy establishes principles that members are encouraged to use when establishing a fee schedule for professional services, including transparency, ethics and fairness.

WHAT IS "REASONABLE"?

In the context of health professional practice, what is considered to be "reasonable" is based on the role of the individual and the generally accepted standards in similar circumstances. The term is both generic and relative, and is meant to apply to whatever is appropriate in a particular situation. In the four areas where it is used in the draft professional misconduct regulations, additional qualifying detail is provided to illustrate what is meant in the circumstances. The new section defining what is, and what is not, considered to be a conflict of interest qualifies the concept based on what "a reasonable person knowing the relevant facts would conclude or perceive in the circumstances." A health professional is expected to use his or her professional judgment to assess what is appropriate behaviour and what may constitute misconduct.

NOT OF GOOD QUALITY

The use of this broadly stated phrase is not meant to imply that a member is required to test the make up of drugs via a chemical analysis at the pharmacy. The phrase "not of good quality" is meant broadly to include drugs that are past expiry, counterfeit drugs and drugs that have been exposed to conditions which alter the effectiveness of the drug; for example, if a pharmacy discovers a cold chain breach but sells or administers the drugs anyway. Listing everything that would make a drug "not of good quality" would require a very precise list and some scenarios may be missed. Sourcing drugs through reputable distributors, storing them according to manufacturer requirements, and evaluating the information provided on the label, including for example that there is a valid drug information number or natural product number, supports the member in ensuring that they meet appropriate standards and are of good quality.

In addition to the methods indicated above, there are tools that can be adapted to the specific pharmacy practice. Many organizations have developed systems to detect potential quality issues including, for example, the use of

a standardized checklist to identify problems with product orders. One version in use at an Ontario hospital prompts a review of the packaging and/or product label and utilizes criteria to evaluate product characteristics including dosage/strength and formulation and to check and compare against the product already in use.[2] Staff information and training are keys to ensuring an efficient and effective approach to protecting patient safety.

KNOWS OR OUGHT TO KNOW

A search of regulations across many professions, in addition to health professions, shows that the notion of using a phrase applying to what a professional "knows or ought to know" is common. Initially trained to a set of established competencies at entry to practice, professionals are expected to have mastered basic skills, and then continue to learn through practice, professional development, and by applying evidence-informed decision-making. What a professional knows, or ought to know is therefore relative and can be expected to change over the course of a life of practice.

While it may seem ambiguous to refer to what a member knows or ought to know, essentially the meaning is subject to evaluation in the event of a complaint taking into account the duties of the member and the circumstances being evaluated. For example, Designated Managers have specific duties and obligations inferred through the legislative framework and reinforced by policy, which would be taken into account in the event of a complaint.

LOOKING FORWARD

Regulators require health professionals to continuously evaluate their own knowledge, skills and abilities. As reported in the article *A Futurist Looks at Professional Regulation* (http://www.sml-law.com/wp-content/uploads/2013/11/Greyar180.pdf) regulating health professional practice is due to shift in substantial ways. With time, new approaches will be introduced to better assist an individual member to assess his or her professional practice. There will always continue to be, however, an onus on the member to apply professional judgment in the evaluation of his or her practice against the accepted standards of the profession. PC

Referencs

1 College of Nurses of Ontario: Professional Conduct/ Professional Misconduct. p. 14 http://www.cno.org/Global/docs/ih/42007_misconduct.pdf

2 Fraser, Kelly. Pharmacy Checklist for New or Replacement Products. Windsor Regional Hospital Pharmacy Services, 2013.