HPRAC

HEALTH PROFESSIONS REGULATORY ADVISORY COUNCIL

ADVICE TO THE MINISTER OF HEALTH

Form and Content of a Regulation Respecting "Prescribed Diseases" under the Optometry Act, 1991.

March 1995

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EXECUTIVE SUMMARY

Introduction

On January 26, 1994, Health Minister, Ruth Grier, requested HPRAC to advise her on the issue of "prescribed diseases" as found in ss. 3 and 4 of the *Optometry Act, 1991*. Based on the Minister's Referral, HPRAC addressed two fundamental questions pertaining to "prescribed diseases": (1) what form a regulation(s) should take; and (2) what its content should be. This Advisory Memorandum answers these questions in the context of the Referral's Terms of Reference: (1) protection of the public interest; (2) the statutory language within the *Optometry Act, 1991;* and (3) the historical context and current professional practice of optometry.

Process

HPRAC offered a wide range of groups and individuals an opportunity to express their views on the matter of a regulation respecting "prescribed diseases" for the practice of optometry. The review process itself extended for more than six months, during which time interested parties developed, refined, and communicated their respective positions to HPRAC. Communications took the form of 24 written and 12 oral submissions and numerous pieces of correspondence.

HPRAC believes that the public interest is promoted by adhering to the following principles which underlie the *Regulated Health Professions Act*. These principles therefore, formed the basis for HPRAC's analysis and final recommendations: (1) risk of harm , (2) quality of care (3) accountability, (4) accessibility (5) equity and (6) equality.

Recommendations

1. HPRAC recommends, with respect to form:

A regulation concerning "prescribed diseases" should be specific rather than general and must be able to identify which *diseases optometrists are capable of communicating to a patient as a diagnosis*.

2. HPRAC recommends, with respect to content:

In providing maximum protection of the public interest, at this time there be no diseases specified for purposes of defining "prescribed diseases."

3. HPRAC recommends that:

The College of Optometrists be invited to propose a specific regulation. In justifying the regulation the College:

1. Name the disease
2. Identify the cause of the disease
3. Identify how the cause is determined
4. Identify the training, education and clinical experience that allow the above to be answered

In preparing the specific regulation, the College should adhere to the following parameters: the regulation must exclude systemic diseases and any other diseases for which testing is required that is beyond optometry's scope of practice.

I. INTRODUCTION

1.0 The Role of HPRAC

In interpreting its role and responsibilities, the Health Professions Regulatory Advisory Council (HPRAC) understands that its duties as outlined in Section 11 of the *Regulated Health Professions Act, 1991* (*RHPA*), are carried out in order to assist the Minister of Health in ensuring regulation and coordination of the health professions in the public interest (*RHPA*, Section 3). For purposes of this Referral on "prescribed diseases" for optometry, HPRAC further believes that the public interest is promoted by adherence to the principles which underlie the *RHPA*:

- protection from harm (minimize the risk of harm)
- quality of care (as related to standards)
- accountability (through effective structures and mechanisms)
- accessibility (in each of its forms: geographic, linguistic, barrier-free, etc.)
- equity (in the availability of opportunities for choice of health care provider)
- equality (among health professions)

The advice which follows is based upon these principles and upon HPRAC's responsibility to promote the public interest.

2.0 The Public Interest Discussed

The fundamental axiom which underlies the regulation of health professionals is that they are to be regulated in the public interest. Indeed, the six principles identified above are themselves reflections of that public interest. Because the public interest is so important, HPRAC believes that it would be helpful to discuss our views in some detail, with respect to what the public interest requires in the context of the *RHPA* as a whole. This discussion is necessary to better understand how the public interest is manifested and can be promoted in the context of a regulation respecting "prescribed diseases" under the *Optometry Act, 1991.*

2.1 Protection from Harm

HPRAC believes the overriding principle of the *RHPA* is the protection of the patient/client from harm in the delivery of health care services. Protection from harm is based upon well accepted moral and legal obligations of health care practitioners to their patients/clients to avoid doing intentional or unintentional harm of any variety. HPRAC understands harm to mean any kind of hurt, damage or injury which results in a number of consequences.

The *RHPA* evolved from the Health Professions Legislation Review, (*HPLR*) which began its review of the health professions in 1982. In the words of the *HPLR* the paramount objective of the *RHPA* was to advance and protect the public interest. To achieve this objective, the *HPLR* recognized that the "public must be protected from unqualified, incompetent and unfit health care providers to the extent possible." The legislature, when enacting the *RHPA*, upheld the principle of protection from harm in a number of specific statutory provisions which will be discussed below.

The *RHPA* embodies the protection from harm principle in a number of key provisions and mechanisms. First and foremost is the "harm clause", being s. 30(1) of the *RHPA* which provides:

> No person, other than a member treating or advising within the scope of practice of his or her profession, shall treat or advise a person with respect to his or her health in circumstances in which it is reasonably foreseeable that serious physical harm may result from the treatment or advice or from an omission from them.

Section 40(1) of the *RHPA* makes it an offense to contravene s. 30, and a person, if convicted, is liable to a fine of not more than $25,000.00 and/or a term of imprisonment of not more than six months.

The scope of practice section contained in each regulated health profession Act is also an important indicator of how the *RHPA* regime protects the public from harm. The scope of practice provisions provide three pieces of descriptive information about a profession that assists the public and the practitioner in understanding:

- what the profession does
- the methods it uses
- the purpose for which it does it. (*HPLR*, p. 15)

In addition to scopes of practice statements, the *RHPA* regime identifies thirteen potentially harmful acts and procedures in s. 27 of the *RHPA*. This section also specifies provisions prohibiting performance of these "controlled acts" by anyone other than a health professional authorized to perform them. Each professional act then specifies which controlled acts members of that profession may perform. For example, the *Medicine Act, 1991* authorizes its members to perform 12 out of the 13 acts. By way of contrast, five professional Acts authorize no controlled acts. These are: the *Dental Technology Act, 1991,* the *Dietetics Act, 1991,* the *Massage Therapy Act, 1991,* the *Occupational Therapy Act, 1991, and t*he *Audiology and Speech Language Pathology Act, 1991*, with respect to speech language pathologists.

Taken together, the harm clause, the scope of practice statements, the controlled acts, the authorized acts and the regulations made under the *RHPA* provide a College with the authority to govern and hold its members accountable, provide members of the profession with the guidance they need to practice safely, and provide the public with sufficient assurance that they are protected from harm.

2.2 Quality of Care

HPRAC believes that although quality of care is a standard which may be difficult to measure, it can, nevertheless, be used to indicate or gauge the effectiveness and safety associated with the delivery of health care services. In its most succinct form, quality of care means the right care to achieve the right outcome. The right care/right outcome balance is affected by a number of factors; i.e., consumer choice, standards of practice and costs. For example, consumers of health care services are concerned about choices. Consumers are becoming increasingly knowledgeable and seek greater options for their health care. This means that they must make informed choices in choosing both the right practitioner and the right treatment. From the perspective of the health care practitioner, the standards of practice of their respective health care profession will play an important part in ensuring that the right care is received in terms of treatment that is both effectively and safely delivered. From the viewpoint of the public, who is increasingly asked to "pay the bill", the right care/right outcome balance must be tempered with the additional realization that that balance must be achieved "at the right cost".

HPRAC believes that the public interest is protected and promoted by the quality of care principle, which means the right care to achieve the right outcome. This principle has been codified in the *RHPA* through numerous mechanisms and structures. Specifically these are: the Complaints and Discipline Committees; the Quality Assurance Committee; and the Patient Relations Committee. As well, College Councils have the authority: to make Codes of Ethics for their members; to make regulations about standards of practice and to define "professional misconduct". Finally, the quality of care principle is embodied through the provision of external evaluations of the effectiveness of many College programs.

2.3 Accountability

HPRAC believes the public interest requires that the law, whether it is the *RHPA* itself or regulations made thereunder, be sufficiently clear to give unequivocal guidance to individual members of their obligations and consequential liabilities. The law must also be accessible and understandable to the public so they may identify their rights of recourse against a health care practitioner who breaches the required standards of practice. And finally, the regulations must also be administratively feasible for the College and/or the courts in order to hold its members accountable.

In HPRAC's view the principle of accountability ensures that the public interest is protected and promoted through self-governance. First and foremost it must be recognized that Colleges, in carrying out their objectives, have a "duty to serve and protect the public interest" (s. 3(2) of the Health Professions Procedural Code, (HPPC), Schedule 2 of the *RHPA*, which is deemed to be part of each health profession Act). The College objectives are themselves further reflections of the public interest and are found in s. 3(1) of the HPPC.

The accountability principle also helps to ensure protection of the public interest by regulating the relationship: 1) between the health care provider and the patient/client; 2) between the practitioner and their respective health profession College and 3) between the health profession College and the public.

It is through accountability that an individual health care practitioner's competency and obligations to his or her patients/clients are assessed. As well, accountability mechanisms assure that the profession's scope and standards of practice are applied to the membership. Finally, a College relies on accountability not only to hold its members accountable, but also to fulfill its obligations to the public in whose interests they govern themselves.

2.4 Access

In HPRAC's view, it is clearly in the public interest that the principle of access be understood as requiring that health care providers be readily available and that patients/clients are not restricted in their access to safe health care. The access principle manifests itself under the *RHPA* in a number of different ways. For example, the *RHPA* makes it very clear that access to health services is of prime importance, and the Act imposes a duty on the Minister of Health to further this goal. Section 3 of the *RHPA* states:

> It is the duty of the Minister to ensure ....that individuals have access to services provided by health professions...

Access to services is further provided in the *RHPA* by the enhanced statutory provisions for delegation of controlled acts and by the exemption of certain categories of individuals, such as aboriginal healers and aboriginal midwives, from the *RHPA*.

HPRAC believes such considerations as financial means, geography, language, physical barriers, *etc.*, should not preclude access to safe, affordable health care services. The public interest is best protected by the promotion of access to safe, affordable health care.

2.5 Equity

The principle of equity applies to the issue of not only the availability of health care services to all residents of Ontario, but also that such health care services ought to be delivered in such a way that residents are not discriminated against. In HPRAC's view, protection of the public interest is achieved in the context of the principle of equity at three levels. First, equity implies there is recognition and respect for personal choice of safe health care opportunities. This means that each individual ought to have freedom of choice of health care provider. Second, equity means that health care services are delivered in a fair and open manner. Third, that fairness comes about through a sensitive and professional relationship between the patient/client and the health care practitioner. The Minister has specific duties to guarantee that the principle of equity is achieved by ensuring:

> ... that the health professions are regulated and co-ordinated in the public interest, that appropriate standards of practice are developed and maintained and that individuals have access to services provided by the health profession of their choice and that they are treated with sensitivity and respect in their dealings with health professionals, the Colleges and the Board. (*RHPA*, s. 3)

2.6 Equality

HPRAC believes the public interest is protected and promoted by treating each health care profession as an autonomous, self-regulating profession equal to any other health care profession relative to its respective scopes of practice and authorized acts. A legitimate differentiation between professions is found in recognizing the limits of each profession through its respective scopes of practice and authorized acts

Furthermore each profession has unique education and training requirements that establish qualifications for entry to practice. Appropriate education and training provide the skills and clinical experience necessary for practitioners to exercise the authority given to them through their scope of practice and authorized acts.

The scope of practice statements with associated controlled acts have replaced the earlier licensing arrangements that gave each profession the exclusive right to practice. Currently, under the *RHPA*, it is recognized that even though members of a profession are limited in what they can do there is also recognition that there is some overlap in some professional practices. In addition, HPRAC recognizes that equality between professions is further enhanced by the fact that all regulated health professions are regulated under one comprehensive *Health Professions Procedural Code*. Thus, the same rules are applicable to all Colleges and its members regardless of the College's size, membership composition or scope of practice.

It is against these *RHPA* principles which reflect, protect, and promote the public interest that the Referral has been considered.

3.0 The Referral

On January 26, 1994, the Minister of Health, Ruth Grier, requested HPRAC's advice on the issue of "prescribed diseases" as found in sections 3 and 4 of the *Optometry Act, 1991*. (The complete Referral letter is reproduced in Appendix A). The Minister also mentioned another issue concerning the regulation and restriction of diagnostic drugs that optometrists may use in their practice. The Minister held out the possibility of linking diagnostic drug use with therapeutic drug use. Subsequently, a specific Referral was given to HPRAC dealing with the question of which therapeutic pharmaceutical agents optometrists would be permitted to use. Although in HPRAC's view "prescribed diseases" and therapeutic pharmaceutical agents are related, the subject of this advisory memorandum is restricted to "prescribed diseases." The issue of

therapeutic pharmaceutical agents will be dealt with subsequent to "prescribed diseases" in a separate advisory memorandum.

In prefacing the Referral's Terms of Reference, the Minister stated:

> As you know, the College has the authority to make regulations setting out what constitutes "prescribed diseases" for the purpose of sections 3 and 4 of the *Optometry Act, 1991*. It is the Ministry's position that this regulation (or regulations, since it may be possible to consider a regulation related to the scope of practice statement and another related to the authorized act of diagnosis) should specifically set out in some manner, such as a list, which diseases are "prescribed". The College has rejected this approach, favouring a broad statement which would, it argues, be more flexible and responsive to the actual practice of the profession.

The specific Terms of Reference respecting the issue were:

> Considering the protection of the public interest, the statutory language within the *Optometry Act, 1991*, the historical context and current professional practice respecting the diseases that optometrists now diagnose, treat and prevent, how should a regulation(s) respecting "prescribed diseases" be framed, in form and content.

In formulating its advice, the Minister asked HPRAC to consider the following sources of information:

i. Relevant correspondence between the Ministry and the College on this matter;

ii. The work of the Health Professions Legislative Review with respect to the scope of practice of optometry

iii. Records of debate of the Standing Committee on Social Development prior to the passage of the *Regulated Health Professions Act* (*RHPA*) and the *Optometry Act, 1991*

iv. Consumer needs

v. The views of other regulated or unregulated professions

vi. Other *directly* relevant research and information available to HPRAC.

Based upon the Minister's Referral, HPRAC has viewed its mandate as addressing two fundamental questions pertaining to "prescribed diseases": (1) what form a regulation(s) should take; and (2) what its content should be. This Advisory Memorandum will answer these questions in the context of the Referral's Terms of Reference: (1) protection of the public interest; (2) the statutory language within the *Optometry Act, 1991;* and (3) the historical context and current professional practice of optometry.

4.0 The Proposed General Regulation

Prior to proclamation of the *RHPA* on December 31, 1993, the College of Optometrists prepared and submitted a regulation to the Ministry of Health's Professional Relations Branch which was intended to satisfy the need to

clarify and interpret the reference to "prescribed diseases" in sections 3 and 4 of the *Optometry Act, 1991.* The general regulation was proposed because, in the view of the College of Optometrists, it represented the manner in which optometry was practiced under the *Health Disciplines Act (HDA).* The proposed regulation read:

> For the purposes of this Act "diseases" means diseases of the eye and vision system that can be determined by way of an oculo-visual assessment.

During this review, HPRAC and the participants have focused primarily on *the* general regulation proposed by the College of Optometrists. HPRAC wants to be clear however, that the Minister's Referral has been interpreted as referring to *a* regulation and determining how it should be framed in form and content. One can consider a continuum for a regulation that ranges from general to specific. In HPRAC's view, the analysis that follows is concerned with the form and content of *a* regulation rather than on *the* regulation that was proposed by the College.

5.0 The Process

HPRAC's review process for this Referral offered a wide range of groups and individuals an opportunity to express their views on the matter of a regulation respecting "prescribed diseases". The review process itself extended for more than six months, during which time interested parties were given the opportunity to develop, refine, and communicate their respective positions to HPRAC . Communications took the form of written and oral submissions and numerous pieces of correspondence. The review process consisted of several steps and these are discussed below.

5.1 Background Information and Participants

HPRAC initially reviewed a package of correspondence supplied by the Professional Relations Branch, which included all relevant correspondence between the College of Optometrists and the Ministry of Health on "prescribed diseases." The Ministry noted that this material included everything from their files that met the criteria in the Minister's Referral. The correspondence covered the period from November 1993 to February 1994. (Copies of this package were distributed to the groups and individuals who expressed interest in actively participating in this review. These participants are identified below.)

HPRAC used the background information contained in the correspondence to develop seven questions for response by the College of Optometrists. These questions focused on:

1) the benefits to the public from optometrists diagnosing "prescribed diseases"

2) the diseases or classes of diseases optometrists propose to diagnose

3) optometrists' clinical education and training

4) separating diagnosis from treatment

5) understanding the Guide to the Clinical Practice of Optometry and how it relates to diagnosis

6) specific wording for the proposed regulation

7) public understanding of what diseases optometrists diagnose.

These questions were designed to provide the College with the opportunity to explain and justify its rationale for proposing a general regulation with respect to "prescribed diseases."

HPRAC understood from the Minister's Referral letter that there were two differing views with respect to the form a regulation might take: the College of Optometrist's view was that the regulation in question should be general in nature; the Ministry of Health's view was that such a regulation ". . .should specifically set out in some manner, such as a list, which diseases are 'prescribed'." Therefore, a request was also sent to the Minister of Health asking for her rationale for this view.

HPRAC solicited participation in this review by sending notice of the Referral to its mailing list and asking recipients to indicate their interest and degree of anticipated interest. Eleven groups expressed a desire to participate in the review and provide written and/or oral submissions. (Subsequent to this formal request for participation, one individual and one organization also expressed their desire to participate). The fourteen participants who took part in this review are listed in Appendix B.

5.2 College of Optometrists' Response

The College of Optometrists responded to the questions posed by HPRAC and provided their first submission on March 14, 1994. This submission was subsequently distributed to all participants. The participants were invited to respond to two specific questions and to comment on the submission by the College of Optometrists. The two specific questions were:

> 1. What do you see as the benefits to the public and the effects on the health care system of optometrists diagnosing "prescribed diseases"?
> 2. Do you favour a general statement respecting "prescribed diseases" as proposed by the College of Optometrists or a list of specific diseases? What is the rationale for your choice? How will the public interest be served by your approach? Explain your answers.

Eleven submissions were received in addition to one from the College of Optometrists. Respondents included: the College of Physicians and Surgeons of Ontario; the School of Optometry, University of Waterloo; the Opticians Association of Canada; the Ontario College of Family Physicians; the Ontario Association of Optometrists; the Vision Council of Canada; the Vision Institute

of Canada; the Ontario Medical Association, Ophthalmology Section and Section on Family Practice; Dr. Bruce Hawkins; the Chinese Medicine and Acupuncture Association of Canada; and the Union of Ontario Indians. (See Appendix C for a listing of all submissions.)

HPRAC followed up with the College of Optometrists' initial submission by asking them on March 25, 1994 to provide a supplementary submission to address a number of outstanding questions identified by HPRAC . The purpose of the supplementary submission was to encourage the College to clarify what diseases optometrists are capable of diagnosing and to link optometry's education process directly to their diagnostic capabilities. Specifically, HPRAC asked for:

1. A clearer indication as to what diseases optometrists diagnose based on the *RHPA* and the language therein; and
2. An explanation of the material on education and training to better understand the connection of training to diagnosis of diseases.

5.3 Public Meeting

Early in the process HPRAC planned to hold a public meeting where all interested parties would be given an opportunity to make a presentation. The purpose of the meeting was:

1) for HPRAC to hear the viewpoints expressed by all participants and to provide an opportunity for HPRAC to question the participants
2) for participants to hear each other's viewpoints
3) for the general public to hear the variety of positions held by the participants.

The College of Optometrists and the Ministry of Health were invited to make opening statements supporting and explaining their respective positions. The Ministry of Health chose not to make a presentation at this meeting. The open meeting was held on June 6, 1994 at the Macdonald Block in Toronto. More than 50 people attended. Presentations were made by eleven groups: the College of Optometrists of Ontario; the College of Physicians and Surgeons of Ontario; the School of Optometry, University of Waterloo; the Opticians Association of Canada; the Ontario College of Family Physicians; the Ontario Association of Optometrists; the Vision Council of Canada; the Vision Institute of Canada; the Ontario Medical Association-Ophthalmology Section and Section on Family Practice; Dr. Bruce Hawkins; and the Union of Ontario Indians.

5.4 Round Two Submissions

Following the public meeting of June 6, participants were invited to provide additional submissions based on any new arguments or information raised by presenters at the public meeting. The request for a second round of

submissions was specific, with sufficient time permitted to allow participants to study the first round submissions, review the transcript of the public meeting and to consider their own positions. Participants were asked by HPRAC to specifically address:

1. How the public interest would be protected by a general regulation; and
2. To provide the names of the specific diseases optometrists currently diagnose.

The second round of submissions was requested by July 15, 1994. Five of the twelve participants provided additional submissions (the College of Optometrists; the College of Physicians and Surgeons of Ontario, the Ontario Medical Association—Section on Ophthalmology; the Ontario Association of Optometrists and the Vision Institute of Canada).

5.5 Round Three Submissions

HPRAC reviewed the five second round submissions and concluded that there was sufficient new information and argument contained in them to warrant a third round of submissions. Accordingly, HPRAC invited participants to become even more specific by focusing their attention on the content of a regulation, and not only on its form.

HPRAC noted that its concern about a general regulation was growing because the submissions and discussions to date had generally failed to adequately address several points: no solid evidence was provided supporting the claim that a general regulation would permit the College to better protect the public; the diseases optometrists diagnose had not been identified; the discussions surrounding the general regulation were primarily concerned with optometry's scope of practice; and no consensus had been reached on what optometry's scope of practice is that would allow for a general regulation.

The second round submissions were distributed at this time to the participants with an invitation to be more specific in their responses. Participants were asked to express their views on examples of lists that were provided and to consider whether a classification scheme would be feasible. Participants were also invited to provide their own lists of diseases and to include their rationale for the inclusion of a given disease as a "prescribed disease". In identifying diseases, participants were asked to link education, training and diagnostic tools or tests with the specific diseases optometrists are capable of diagnosing. The purpose of this degree of specificity was to permit HPRAC to assess the merits of a specific regulation versus a general one.

HPRAC also reviewed its understanding of the controlled act of diagnosis, contained in s. 27(2)1 of the *RHPA*. In doing so HPRAC intended to clarify the link between the legal meaning of the controlled act of diagnosis and the list of diseases requested. HPRAC also stated its view that communicating the results of assessments with statements such as "I think you have ....." is in the public domain and not a controlled act.

5.6 Conclusion of Process

Five third round submissions were received from the following participants: the College of Optometrists, the Ontario Association of Optometrists, the Vision Institute of Canada, the Ontario Medical Association-Section on Ophthalmology and the Chinese Medicine and Acupuncture Association of Canada. HPRAC determined that the information in them did not warrant a fourth round of submissions. The final submissions were circulated to the 12 participants and HPRAC indicated it would be moving toward its final report with recommendations to the Minister.

5.7 Field Trips

During the course of conducting its review, and in accordance with the Minister's Referral, HPRAC determined that additional research into background information on the educational curricula of optometrists, ophthalmologists and family practitioners was needed. Accordingly, informational visits were arranged to: (1) the School of Optometry, University of Waterloo; (2) the Department of Ophthalmology, Faculty of Medicine, University of Toronto; and (3) the Department of Family and Community Practice, Faculty of Medicine, University of Toronto. These meetings permitted HPRAC to gain a basic understanding of the educational process and a limited understanding of the linkage between didactic course work and clinical experience in diagnosing and treating eye conditions which optometrists, ophthalmologists and family practitioners obtained during their university education.

5.8 Research

HPRAC conducted a search of current literature surrounding the diagnosis of diseases of the eye. This literature search uncovered no Canadian research that specifically addressed the diseases optometrists are capable of diagnosing. Two American studies, however, were reviewed that dealt with diagnosis of ocular diseases.

In 1979 a study of optometrists' competency to diagnose ocular diseases was conducted in a Veterans Administration Hospital. Newcomb and Potter studied 410 Referrals made by hospital optometrists to other departments for consultation or treatment. Comparisons of the consulting physicians' diagnoses to the referring optometrists' diagnoses showed 85 percent of the optometrists' diagnoses were fully confirmed. The remaining 15 percent of findings were confirmed by the consulting physicians but the diagnosis of the condition was not the same as the optometrists' diagnoses. (Newcomb and Potter, 1979)

A study conducted by Wang, et. al., at the Johns Hopkins Internal Medicine Associates Clinic at Johns Hopkins University found that 50 percent of the sample patients had clinically important ocular disease and one third of those were unaware of their eye disease. Among several findings, one stands out

for our purposes: the study participants with eye disease were seven times more likely to be unaware of their eye disease when their last exam was conducted by an optometrist. Although the purpose of this study was not to determine the ability of optometrists to diagnose eye disease, this finding, nevertheless, led the authors to conclude that more research was needed with respect to this finding (Wang, Ford, Tielsch, Quigley and Whelton, 1994).

HPRAC finds the value of this literature review is limited because only two relevant articles were found that were related to the Referral and that in any event, specific conclusions from these two studies would be preliminary and speculative at best.

II. SUMMARY OF PARTICIPANTS' POSITIONS

Altogether, 24 written submissions were received during the review plus a transcript prepared of the June 24, 1994 public meeting. Although these submissions covered a range of topics, the intention of this section is to provide a summary of what HPRAC understood the position of the participants to be with respect to the specific terms of reference laid out by the Minister in the Referral. For ease of reference, the Minister asked:

> Considering the protection of the public interest, the statutory language within the *Optometry Act, 1991*, the historical context and current professional practice respecting the diseases that optometrists now diagnose, treat and prevent, how should a regulation(s) respecting "prescribed diseases" be framed, in form and content.

Specifically, the position of each participant will be summarized with respect to their consideration of: (1) the protection of the public interest; (2) the statutory language; and (3) the historical context and current professional practice of optometry.

1.0 Submissions

1.1 The College of Optometrists of Ontario

The College's first submission emphasized the historic practice of optometry by providing a summary of, and background on, the *Health Disciplines Act*, (*HDA*). This review included the scope of practice for optometry and its associated regulations. This setting was provided to link the past practice of optometry under *HDA* to the current practice under the *RHPA.* The College's position was that the practice of optometry under *RHPA* would be the same as under the *HDA*: neither expanded nor narrowed.

The College's submission responded to several questions posed by HPRAC that were designed to encourage the College to explain its rationale for a general regulation. The College stated that the benefits to the public by such a regulation are "self-evident". (COO1, pp. 13-14) The College defended its proposed general regulation on the basis that:

> ...it represented the manner in which optometry was (is) practiced under the *Health Disciplines Act*, Part V-Optometry and the regulations thereto and members would continue to be held to the same level of accountability as they were under the *HDA*. (COO1, p. 19)

Furthermore, the College concluded that as the public interest was served under the *HDA* there was no reason to change anything that had worked, under the *RHPA.*

Although the submission discussed the historical practice of optometry and linked it to current practice, it did not address the College's proposed general regulation in terms of the statutory language of *RHPA*. The College did not address the protection of the public interest other than by asserting that the

College had always governed its members in the public interest and would do so in the future.

The College's second submission supplemented its first by including portions of a publication titled: "The Educational Annotation of ICD-9-CM", 4th Edition, Diseases of the Nervous System and Sense Organs, Disorders of the Eye and Adnexa (360-379). Channel Publishing Limited, Reno, Nevada. The ICD-9 listing is a World Health Organization classification system and is found in all hospitals in Ontario.

The ICD-9 is a "definitive listing of classifications of morbidity states to describe the clinical picture of the patients." (COO2, p. 1) The College stated that in protecting the public interest a list of diseases would be inappropriate because:

- such a list at best would be arbitrary;
- no list is ever complete; and
- a list of any kind viz. disease, dysfunction, disorder would make the administration of the Act and consequently the protection of the public more difficult and less effective. (COO2, p. 2)

The College addressed the current practice of optometry via the ICD-9 list and referred HPRAC to the professional misconduct regulation; i.e., the statutory language (Ont. Reg. 859/93), as the means for the College to regulate the profession:

> The College's proposed general regulation is not intended to include or exclude. Rather it provides the framework within which the College may appropriately administer the Act applying **'standards of practice'** and the regulations that define **'professional misconduct'**. [Emphasis in original] (COO2, p. 2)

The College's third submission pointed out how the public would be protected by its proposed general regulation. The College recognized that:

> ...the word "prescribed" placed as it was before the word "diseases" in the statute is understandable and suggests elaboration by regulation. If the word was not present, optometrists would be unlimited in offering patients' diagnoses, treatment, and prevention of any and all diseases of the human condition. The Legislature and the Standing Committee rightly understood that the unique expertise and the scope of practice of optometry is limited to the eye and visual system and the diseases of that system, and that a regulatory limitation needed to be placed on the word "diseases". (COO3, p. 2)

The College stated that the proposed general regulation in conjunction with the professional misconduct regulations would appropriately and adequately set the boundaries and provide for the College's authority to protect the public. (COO3, p. 4)

The fourth submission from the College stated that the general regulation respecting "prescribed diseases" is

> ...relevant to the welfare and protection of the public... (COO4, point 3)

Furthermore, in summary, a general regulation:

> ...maintains the status quo of the practice of optometry and is optimally protective of the public welfare even in the worst case scenario viz. a civil suit for malpractice.
>
> The general regulation clearly establishes:
>
> - the necessary legal linkage between S. 3 [sic] of the *Optometry Act, 1991* and the professional misconduct/standards of practice regulations.
> - the appropriate requirements for the College's administration of the *Act* and governance of the profession; and
> - it avoids any semantic arguments.
> - it affords the College system an understandable law when an incident is brought before the Complaints and Discipline Committees; and
> - it affords the judicial system an understandable law when a case is brought before the Courts. (COO4, point 24)

The College's final submission also contained a legal opinion from the law firm, Sawers Liswood Hickman. The legal opinion discussed, among other things, that the problems associated with a list were such that a list would work to the detriment of consumer protection. This was thought, in the solicitor's opinion, to occur because the College would be impaired in its ability to hold its members accountable because they could only diagnose, treat and prevent those diseases that may be on the list. (COO4, Appendix A, p. 8)

The College steadfastly supported its proposed general regulation throughout the review. In its submissions and presentation, the College asserted that the public interest had always been served and would be in the future. The College discussed the statutory language of the *HDA*, but little of the *RHPA*. The College discussed the historical context of the practice of optometry and suggested that the current practice is the same as in the past.

1.2 The Ministry of Health

The Deputy Minister of Health wrote to HPRAC on September 14, 1994 (in response to HPRAC's request) and outlined the Ministry's rationale on the matter of "prescribed diseases" for purposes of the *Optometry Act, 1991*. The Deputy Minister stated in part:

> ...the Health Professions Legislation Review did not envisage diagnosis of diseases as being within the scope of practice of Optometry. Legislators involved in framing the *Optometry Act, 1991* amended the original Bill during third reading to include the "controlled" act of diagnosis of "prescribed diseases" as one of the acts authorized to Optometrists. It appears clear that it was their intention that some kind of list or other manner of designating which diseases optometrists were to be allowed to diagnose, was necessary to safeguard the public interest. (MOH, p. 2)

In terms of the public interest, the Ministry stated its position as follows:

> As well it is the Ministry's view that to ensure the protection of the public interest any regulation must provide a clear and unequivocal means for discerning whether a particular disease is one that is "prescribed" for the purposes of sections 3 and 4 of the *Optometry Act, 1991*. (MOH, p. 1)

The Ministry explained its view of the historical context for the practice of optometry by referencing the recommendations of the *HPLR* and the debates of the Standing Committee on Social Development (*SCSD*). The *HPLR* did not include diagnosis of "prescribed diseases" in the scope of practice for optometry. This was added later during the debates of *SCSD*. During the debates of the *SCSD*, both Paul Wessenger, MPP and J. Wilson, MPP made statements that made it appear clear that some kind of list or other manner of designating which diseases optometrists were to be allowed to diagnose was necessary to safeguard the public interest.

The Ministry's position was that in its view, the legislation was intended to include a regulation that would set out in some appropriate way the diseases that are "prescribed". A "list" was one example of doing this; a regulation might also describe classes of diseases. The Ministry's submission primarily addressed the statutory requirement of a regulation but did not address the current practice of optometry.

1.3 The Ontario Association of Optometrists

The OAO submitted three briefs and made a presentation at the public meeting in June. The Association's oral presentation included a video depicting the clinical practice of optometry.

The Association's first submission provided the historical context in which the *Optometry Act, 1991* was developed by referring to the *HPLR* and the debates of the *SCSD* in the fall of 1991. The Association outlined benefits to the public from diagnosing prescribed diseases and provided its interpretation of the statutory language in the *RHPA* contained in section 27(2)1, the controlled act of diagnosis. (OAO1, pp. 1-8) In concluding, the OAO noted that a "list" of diseases creates more problems than it solves and stated its support for the proposed general regulation. In the OAO's view such a regulation provides for the necessary protection of the public interest and would preserve the scope of optometric practice.

The second submission responded to issues that were brought forward in the public meeting of June 6. The Association explained that a general statement is consistent with public expectations and trust between optometrist and patient. Furthermore any list of diseases would not be helpful to a patient as they would not know whether they had a disease on the list or not. Professional misconduct regulations provide the necessary legislative framework to enable the College to govern its members and the necessary assurance to the public that optometrists must refer all conditions of the eye and vision system that they cannot diagnose or manage. (OAO2, pp. 2,3)

The Association explained the pitfalls and shortcomings of a list. It concluded that if the College were compelled to provide a list, then the principle of self regulation would be violated because HPRAC would invite input from interested, including non-optometric, groups. (OAO2, p. 11)

The OAO discussed its view of the difference between assessment and diagnosis. This was raised as a result of a question at the public meeting in June. The Association explained that assessment is the examination process optometrists perform in arriving at their diagnosis. (OAO 2, p. 14) Furthermore, in its view, the controlled act of diagnosis is really about communication with a patient. Because the public interest demands that a patient rely on the diagnosis to point to an appropriate course of action, diagnosis is considered a controlled act. Based on this reasoning, the Association concluded that:

> It therefore seems reasonable to include as possible diagnoses all diseases that optometrists can diagnose by way of the oculo-visual assessment they perform on their patients. (OAO2, p. 14)

The Association's brief also gave attention to systemic diseases and their ocular manifestations. The Association stated:

> There is no question that optometrists do not diagnose systemic disease upon completion of an oculo-visual assessment. There is not a single systemic disease that can be diagnosed on the basis of an oculo-visual assessment alone. However, optometrists have the ability and responsibility to diagnose the ocular manifestations of systemic disease. (OAO2, p. 24)

The Association's third submission demonstrated how a listing of categories of ocular diseases could be constructed. The proposed listing was drawn from the ICD-9 listing of diseases of the eye and adnexa. In the OAO's view these categories and a listing of exclusions could be used to define prescribed diseases. The Association indicated:

> To illustrate, existing practice restrictions exclude systemic diseases, cancers and all other diseases which require as part of their diagnosis specific tests or procedures which lie outside the scope of optometric practice; including for example fluorescein angiography, blood tests, tissue tests (biopsy) and imaging (x-ray, C.T. scan, MRI)... (OAO 3, p. 1)

The Association noted the relevant professional misconduct regulations (Ont. Reg. 859/93) which provide the regulatory control for the practice of optometry. The Association concluded that the same inclusions and exclusions of diseases exist whether represented as a general statement or broken down into categories. Furthermore, a list of categories suffers from the same problems as a list of diseases; i.e., always out of date. The Association continued its support of the College of Optometrists which has noted that their task of administering the regulation would be best served by a general statement and ill served by a list. (OAO3, p. 2)

The OAO consistently supported the general regulation proposed by the College. During the review, the Association presented arguments respecting the public interest aspects of the general regulation. The OAO's submissions

also discussed the statutory language and the historical and current practice of optometry.

1.4 The School of Optometry

The School of Optometry, University of Waterloo, provided one submission and made a presentation at the public meeting in June. The School strongly supported the College's proposed general regulation, based on four reasons that in their view would support the public interest:

> 1. Every patient must be suspected of having every disease in the book. Any limitation on diagnostic possibilities i.e., diseases, would limit an optometrist's ability to care for the public.
> 2. The degree of precision of diagnosis will vary according to the level of the practitioner involved and their area of expertise.
> 3. Patients would not benefit by having a list of diseases optometrists can diagnose.
> 4. Using a list would mean the public would have a lower standard of care than elsewhere in North America, which is ethically unacceptable. (SoO, p. 2)

The School noted six ways in which the public would benefit as a result of optometrists' diagnosing prescribed diseases:

(1) ready public access
(2) public routinely seeks eye examinations
(3) establishing baseline findings and departures from them
(4) provision of timely Referrals
(5) optometrists spend time with patients and explain reports; and
(6) involvement with management and monitoring of patients' progress. (SoO, p. 3)

The School also linked optometrists' education and their competence to diagnose diseases by outlining the courses optometric students take that are related to pathology and disease: one year of general pathology and three one-term courses in ocular pathology. During third and fourth years, students examine patients in the University's Optometry Clinic; they participate in grand rounds; and they rotate through the clinic's specialty areas and through external clinics.

The School provided information on the current practice of optometry by including a detailed listing of the diagnoses recorded in the Optometry Clinic between January 1992 and March 1994. The listing summarized the diseases observed in 44,384 patient visits. The total number of codes recorded was 95,030. These numbers differed because some patients presented with more than one disease or disorder which was coded against their visit.

The diseases encountered at the clinic were recorded and coded using the ICD (International Classification of Disease, World Health Organization

classification system) code(s) appropriate for each patient following examination. The School noted that the listing covered patient conditions recorded during that particular time period. This was significant, for the School indicated that a different listing of diseases or disorders was likely to occur during a different time period. The listing included ocular diagnoses as well as conditions (diseases or disorders) that were not diagnosed by the staff optometrists. For example, "mental retardation" was included in the list, although it was made clear that this was not a diagnosis that an optometrist would make. It was not made clear which diseases on the list optometrists could diagnose.

The School's submission supported the proposed general regulation by arguing that a general regulation best protects the public interest. It also explained the current clinical practice of optometry as carried out at the School's clinic. The School did not develop its arguments in the context of the statutory language of either the *RHPA* or of the *Optometry Act, 1991.*

1.5 The Vision Institute of Canada

The Vision Institute (VIC) submitted three briefs and made a presentation at the public meeting in June.

The first submission of the VIC reviewed the practice of optometry in a clinic in Toronto. The brief addressed issues around the health care system and the public interest. The Institute explained that problems (such as patient counselling, disease monitoring and patient Referrals) would be exacerbated should the traditional practice of optometry be restricted. (VIC1, pp. 6-13). The Institute noted that optometrists have successfully diagnosed and co-managed patients along with physicians, and that the judicial system has also recognized optometrists' capability and responsibility to diagnose diseases of the eye and vision system. (VIC1, p. 15)

This brief provided argumentation on the public interest, but no interpretation of the statutory language of *RHPA* or the *Optometry Act, 1991* and simply stated its support for the general regulation proposed by the College of Optometrists.

The second submission from the Institute provided more explanation of the diagnosis of eye diseases and stated:

> A part of our role in the examination of the eye and visual system is to diagnose any ocular disease that a patient may have, whether or not related to any systemic condition (e.g. diabetes, hypertension). Where ocular manifestations of systemic disease exist, we will discuss the ocular diagnosis and its systemic relationship with the patient. A report is sent to their family practitioner for further follow-up of the systemic condition. (VIC2, pp. 3,4)

The Institute organized much of its submission under the headings of: minimized risk of harm, quality of eye care, accessibility, accountability, equality between professions and practicality of administration of regulations. The discussion showed, from the Institute's point of view, that patients are

protected by the diagnostic acumen of optometrists which is facilitated by a close working relationship between optometrists and ophthalmologists. Furthermore, optometrists have been successful in meeting the needs of their patients and in providing quality eye and vision care. (VIC2, pp. 5-12)

The third submission from the Institute discussed classification of eye disease and concluded that the class of diseases optometrists diagnose is of the "eye and vision system". Furthermore, "Optometrists, because of their education and clinical training, have the same knowledge and skill physicians use to diagnose diseases of the eye and vision system". (VIC3, p.4) Reference was made to the protection of the public that had been afforded patients under the *HDA* and that the performance of optometrists in diagnosing diseases of the eye and vision system had become a clinical standard. (VIC3, p. 5)

The Vision Institute supported the College's proposed general regulation throughout the review. The Vision Institute addressed the public interest protection afforded by implementing the proposed general regulation. The submissions reviewed the current practice of optometry, but did not address the statutory language of the Act.

1.6 Individual Optometrist—Dr. Bruce Hawkins

Dr. Hawkins submitted a brief and made a presentation at the public meeting in June. His paper pointed out that an optometrist's practice was such that they historically diagnosed both ocular and systemic disease. The standard practice is to follow the oculo-visual assessment as laid out in the College's *Guide to the Clinical Practice of Optometry* (especially pp. 11-12). Any portion of the assessment may yield clues to the presence of ocular or systemic disease.

Dr. Hawkins stated that the proposed general regulation would be more in the patient's interests and would not represent a change in the scope of practice, as that is what optometrists now do. Dr. Hawkins pointed out the problem that would result if the proposed general regulation were not adopted. That problem is that if a disease condition was encountered that was not on a list, then an optometrist would be unable to manage the patient and his/her disease. (Hawkins, p. 4)

Dr. Hawkins' submission and presentation supported the proposed general regulation. His supporting statements were based on the historical practice of optometry and protection of the public interest primarily based on accessibility and quality of care. He did not address the statutory language of the Act.

1.7 The College of Physicians and Surgeons of Ontario

The CPSO submited two briefs and made a presentation at the public meeting June 6. The CPSO provided its views in the context of its understanding of the scope of practice statement defined in s. 3 of the *Optometry Act, 1991* and the regulatory scheme in the *RHPA*. The

significance of s. 3 is to: ensure consistency with the controlled acts; clarify application of the harm clause; provide consumers with a description of the profession's activities; and link with the definition of misconduct. This understanding permitted the CPSO to make the point that if a controlled act is granted, i.e., diagnosis and treatment, then it should be reflected in the scope of practice. The CPSO made it clear, however, that the converse is not true, i.e., if an act (diagnosis and treatment) is in the scope of practice, then it should be granted as a controlled act. (CPSO1, pp. 1,3)

The point of this argument was that any authorization to diagnose diseases should not be linked with authorization to treat. In CPSO's view, diagnostic skills are not the same as treatment skills.

The CPSO proposed a regulation for the purpose of s. 3, that restricts "diseases" to relate only "...to diagnosis and prevention of diseases of the eye and vision system ...". Similarly, CPSO proposed that "for the purpose of s. 4, "diseases" means diseases of the eye and vision system ...". (CPSO1, p. 3)

The CPSO recognized that optometrists are able to identify a wide range of abnormalities of the eye. In CPSO's view, treatment is far more harmful than diagnosis. Therefore optometrists should not be restricted in communicating their findings to patients. The CPSO stated:

> In conclusion, CPSO is of the view that optometrists should be authorized to communicate the diagnosis of those eye diseases that can be determined by way of an oculo-visual assessment. (CPSO1, p. 4)

In its second submission the CPSO responded to the questions raised by HPRAC . CPSO questioned whether the public interest is protected by limiting optometrists' diagnoses because they are required by their regulations to refer patients they are not qualified to treat. As well, determining the diseases or disorders that optometrists have the ability to identify could be time consuming and would not further protect the public. Reference could perhaps be made to the ICD-9 list of disorders of the eye and adnexa for such a list of diseases. CPSO declined to select such diseases from that list. (CPSO2, p. 2)

The CPSO addressed the public interest and supported a general regulation respecting "diagnosis"; addressed and analyzed the statutory language of the *RHPA* and the *Optometry Act, 1991*. CPSO did not address the historical and current practice of optometry.

1.8 Ontario Medical Association – Section on Ophthalmology

The OMA-Section on Ophthalmology submitted three briefs and made a presentation at the public meeting in June. In its first submission, the Section took the view that the regulations should separate diagnosis and prevention from treatment with respect to "prescribed diseases". The Section proposed a regulation that distinguished between "prescribed diseases" for purposes of diagnosis and prevention and those identified for purposes of treatment.

In its review of the historical context of the practice of optometry, the Section on Ophthalmology noted that under the *Health Disciplines Act*, optometrists had identified abnormal signs in patients' eyes. Optometrists have not been diagnosing medical eye diseases as optometrists' training has never been sufficient in the area of medical eye disease to permit them to diagnose as physicians would. (OMA1, p. 5)

The first submission reviewed the statutory language of ss. 3 and 4 of the *Optometry Act, 1991* and concluded that safeguarding the public, maintaining the status quo in optometric practice and permitting the College to govern its members can only be achieved by separating diagnosis and prevention from treatment. (OMA1, p. 5)

Furthermore, in the Section on Ophthalmology's view, failure to separate diagnosis and prevention from treatment :

> ...will alter fundamentally the manner in which optometry is practiced in Ontario and will prejudice the public interest by giving optometrists a scope of practice far exceeding optometric training and experience. (OMA1, p. 6)

In line with this reasoning, the Section supported a general regulation and proposed how such a regulation that separated diagnosis and prevention from treatment could be framed.

The Section on Ophthalmology provided a second submission in which it explained in more depth its understanding of the language used in the *RHPA* and the *Optometry Act, 1991*. In so doing, the Section defined "assessment", "diagnosis" and "disorder, dysfunction and disease" as used in the statutory language of *RHPA*. (OMA2, pp. 3-5)

In this second submission, the Section revised the position taken in its first submission respecting the diseases optometrists can diagnose and in the end concluded that:

> ... optometrists cannot, within their present scope of practice, investigate eye disease to determine its cause. Accordingly, the public cannot safely rely upon optometrists to ascertain, that is to say diagnose, the cause of their disease. The public can and should rely on optometrists to assess the eye for abnormal signs, and optometrists may certainly then communicate any abnormal signs they find on their assessment and suggest to the patient those signs they feel need further investigation to arrive [at] an accurate diagnosis. [Emphasis in original] (OMA2, pp. 10, 11)

In the Section's view, the legislature never envisioned a long list of diseases, or even any at all. In any event, the Section concluded that, if it is necessary to include something on the list, then four "conditions" can be safely diagnosed by optometrists: (1) non-penetrating corneal foreign body (a form of Keratitis-370); (2) pinguecula and conjunctival foreign body (forms of Disorders of Conjunctiva-372); and eyelid foreign body (a form of Other Disorders of the Eyelid-374). Note 370, 372 and 374 are the relevant ICD codes. (OMA2, p.11)

Finally, the second submission reviewed how the public could be harmed through inappropriate diagnoses. If either a false negative diagnosis or a false positive diagnosis is made, patients and/or their families may suffer mental or physical distress. (OMA2, pp. 11,12)

The Section on Ophthalmology's third submission reaffirmed its position made in its second submission and indicated partial agreement with the College of Optometrists and the OAO over what diseases optometrists 'can' or cannot diagnose:

> As set out in the Section's Further Submission, at Pages 6 to 11, [OMA2] there are virtually no "diseases" which optometrists are competent, by reason of their training, experience, expertise and controlled acts, to diagnose. Indeed, both the College of Optometrists and the OAO concede in their latest submissions that optometrists are not capable of diagnosing any systemic disease. (OMA3, p. 2)

The Section on Ophthalmology addressed the public interest, the statutory language and the historic and current practice of optometry.

1.9 The Ontario Medical Aassociation – Section on General and Family Practice

The Section on Family Practice expressed its views on protection of the public interest, in the context of eye care conducted by family physicians. There are some 9,000 family practice members in Ontario. The brief stated that they are readily available and carry out the majority of primary medical eye care delivery. The Section stated that broad medical training plus knowledge of pharmaceuticals allows family physicians to integrate eye care into the care of the whole person and to relate conditions of one organ system to another. Physicians are trained in collaboration with ophthalmologists and support strong working relations with other professions based on scopes of practice consistent with each profession's training. (OMA1, Appendix A).

The Section indicated that optometric education and training is limited with respect to diagnosis of disease:

> When considering this regulation on "prescribed diseases", the safety of the public must clearly be a primary consideration...Anyone providing medical care for their eyes must be adequately and safely trained to recognize disease states and make a medical diagnosis based on this training. (OMA1, Appendix A).

HPRAC drew from this submission that the Family Practitioners would not support the proposed general regulation.

Although the Section commented on protecting the public interest the Section did not comment on either the statutory language or historical context of the practice of optometry.

1.10 The Ontario College of Family Physicians

The OCFP submitted one brief and made a presentation at the public meeting in June. The College believes:

> that the general public currently enjoys excellent access to quality health services which can readily diagnose and treat eye disorders. (OCFP1, p. 5)

The College noted its concern with respect to developing a parallel process by which individual diseases are diagnosed and treated without any attention paid to comprehensive health care. Such a parallel process represents a fragmentation of the health care system. It was the College's view that this would ultimately lead to more costly and less effective services. (OCFP, p. 5)

The College presented discussion in terms of public interest issues especially timely treatment and accessibility of physicians to the public. The College did not address the statutory language or the historical context of the practice of optometry.

1.11 The Vision Council of Canada

The VCC submitted one brief and made a presentation at the meeting in June. VCC believes that it would be inappropriate for opticians to comment on, if, or how "prescribed diseases" should be addressed in optometry's regulation.

The VCC stated that giving optometrists the right to diagnose and treat diseases is a significant increase in their scope of practice. Any such changes have implications for how several professions work together for the provision of quality eye care services to the public. (VCC, p. 2)

1.12 The Opticians Association of Canada

The OAC submitted one brief and made a presentation at the public meeting in June. The OAC believes that the language used in the *Optometry Act, 1991* clearly expands the scope of practice for optometrists. Optometrists will be allowed to practice in a manner similar to ophthalmologists. If this is to occur then optometrists' training should be equally as rigorous as for physicians.

The OAC pointed out that the public has not asked for this increase in the scope of practice and that optometrists are not the "only source of vision care in many communities." Family physicians are widely distributed. In the OAC's view, the health care system will be negatively affected if the proposed general regulation is accepted. (OAC, pp. 1,2)

OAC believes that a general regulation will increase the risk of harm to consumers. (OAC1, pp. 2)

The OAC stated that the proposed general regulation was not in the public interest; referenced the statutory language in the *Optometry Act, 1991* but did not develop a view of the historic/current practice of optometry.

1.13 The Union of Ontario Indians

The UOI made a presentation at the public meeting in June. The UOI's argument supporting the proposed general regulation was framed in terms of quality of care and accessibility

The UOI discussed seven points that reflected its views of the scope of duties of optometrists in Ontario. The UOI noted that the scope of practice should not be reduced over the present practice and in fact should be expanded where feasible to provide more eye care service. Optometrists should form the first line of care by the diagnosis of eye problems. Optometrists should be encouraged to continually upgrade their skills and the Ontario government should provide more recognition of optometrists' value to society. Last, "turf disputes" between optometrists and other specialist physicians should not be tolerated when these can affect access of patients to optometric services.(UOI, pp. 1,2)

The UOI supported the College's proposed general regulation. The UOI did not address the statutory language or the historical context of the practice of optometry. It did address the current practice in terms of quality and accessibility.

1.14 Chinese Medicine and Acupuncture Association of Canada

CMAAC submitted two briefs. CMAAC supported the proposed general regulation because "a list of specific diseases would create limits on oculo-visual conditions that could be assessed, diagnosed, treated and clinically managed by optometrists." [emphasis in original] (CMAAC1, p. 1)

CMAAC states that optometrists are able to:

1. assess disease, dysfunction and disorders of the eye and visual system
2. communicate a diagnosis to the patient or respective significant other
3. determine and implement an appropriate modality of treatment and management
4. recommend alternatives or refer for further investigation. (CMAAC2, p. 2)

CMAAC submitted that the professional misconduct regulations provide the necessary legislative authority to establish accountability. Its arguments were framed in the public interest context and did not focus on the statutory language nor on the historical context or current practice of optometry.

2.0 Conclusions from the Review of Participants' Positions

HPRAC received comments and arguments on all aspects of the Minister's Terms of Reference: protection of the public interest, the statutory language and the historical and current professional practice of optometry. Not all participants, however, commented on all three aspects. Relevant arguments from the submissions will be analyzed in Sections III.2 to III.5 in this advice memorandum. The next section, III.1, outlines the framework adopted for conducting that analysis.

III. ANALYSIS

1.0 Introduction

The first part of this Section will outline the analytical framework that HPRAC has applied in considering the submissions received from the respective participants. This framework is largely derived from the Terms of Reference contained in the Minister's Referral letter of January 26, 1994 and the public interest principles articulated in Section I.2 of this advice memorandum.

For ease of reference the Terms of Reference are:

> Considering the protection of the public interest, the statutory language within the *Optometry Act, 1991*, the historical context and current professional practice respecting the diseases that optometrists now diagnose, treat and prevent, how should a regulation(s) respecting "prescribed diseases" be framed, in form and content.

HPRAC has used these Terms as a foundation for constructing an analytical model. The Minster, in effect, has asked for HPRAC's advice with respect to three separate, but related questions:

1. Considering the protection of the public interest, how should a regulation(s) respecting "prescribed diseases" be framed in form and content?
2. Considering the statutory language within the *Optometry Act, 1991* , how should a regulation(s) respecting "prescribed diseases" be framed in form and content?
3. Considering the historical context and current professional practice respecting diseases that optometrists now diagnose, treat and prevent, how should a regulation(s) respecting "prescribed diseases" be framed in form and content?

It is these three questions which form the basis of an analysis.

Although each question represents a separate line of inquiry, HPRAC understands that they are related to each other at a number of levels. Moreover, HPRAC believes that each question, i.e., protection of the public interest, statutory language and historical context/current professional practice, should be explained and understood in the context of the principles underlying the *RHPA* as a whole.

The six principles underlying the *RHPA* were enumerated and expanded upon in Section I of this memorandum. For ease of reference, these principles are:

- *protection from harm (minimize the risk of harm)*
- *quality of care (as related to standards)*
- *accountability (through effective structures and mechanisms)*

- *accessibility (in each of its forms: geographic, linguistic, barrier-free, etc.)*
- *equity (in the availability of opportunities for choice of health care provider)*
- *equality (among health professions)*

In the following sections of this memorandum HPRAC will analyze the arguments, statements and assertions made by the participants. This analysis will be accomplished in the context of the three questions derived from the Minister's Referral. These questions will be addressed in reverse order for sake of analytical clarity. In the course of this review HPRAC will refer to the general regulation proposed by the College of Optometrists and the support, for or against, this proposal, as an example only of a general regulation.

2.0. Considering the Historic Context and Current Practice of Optometry, How Should a Regulation be Framed in Form and Content?

Issue

The fundamental question throughout this Referral has been to identify what it is optometrists actually do, and what it is they are qualified to do i.e., scope of practice.

There are two reasons for this question remaining central to this inquiry. First, HPRAC accepts the premise that optometry's scope of practice is to remain the same under the *RHPA* as it was under the *HDA*. Second, the public interest requires that there be sufficient and accurate information about the nature and scope of professional services available to the public in order for them to make informed decisions regarding their heath care options. It is, therefore, important for HPRAC to understand the historical, as well as the current practice of optometrists.

In the following section, HPRAC will examine the practice of optometry as it relates to the issue of "prescribed diseases" and consider how the historical /current practice identifies what diseases optometrists diagnose. This exploration takes into account the appreciation that the *RHPA* represents a different regulatory model from that under the *HDA*.

Under the *HDA,* physicians, dentists, optometrists and pharmacists were granted an exclusive scope of practice by virtue of the Act and the regulations made thereunder. In contrast the *RHPA* has rejected the licensure model in favour of a broad descriptive scope of practice statement and the authorization of certain controlled acts within each health profession Act. With the introduction of a descriptive scope of practice statement under the *RHPA*, the actual "regulation" of a profession is accomplished through the mechanisms of controlled acts, authorized acts and regulations.

With respect to the *Optometry Act, 1991,* section 3 provides the scope of practice statement for optometry and section 4 specifies the controlled acts that a member is authorized to perform.

The scope of practice is a description of the profession's activities. Section 3, the scope of practice statement, provides protection for the public by outlining what the profession does, the methods it uses, and the purpose for which it does it. Section 4, the statement on controlled acts, is permissive. It outlines which of the 13 controlled acts this profession is permitted to perform.

Sections 3 and 4 are closely linked. The two sections support each other. When taken together, they give notice to other professions; to their own practitioners; and to the public about the nature of the services optometrists are expected to provide; i.e., the scope of practice.

Discussion

Under the *HDA*, optometry's scope of practice statement provided:

> "practice of optometry" means *the services usually provided by an optometrist*, including the measurement and assessment of vision, other than by the use of drugs, except such drugs for such purposes as are prescribed by the regulations, the prescribing and dispensing of ophthalmic appliances, and prescribing and providing orthoptics for the relief or correction of any visual or muscular error or defect of the eye. (*HDA*, s. 89.(1)(F)) [emphasis added]

In addition to this licensing statement, the *HDA* also supported a number of regulations which informed the nature and scope of "services usually provided by an optometrist".

A number of participants provided submissions with respect to their own understanding of optometrists' historical scope of practice.

The OMA Section on Ophthalmology noted that under the *HDA* and accompanying regulations there was no mention of diagnosing "underlying medical diseases". However, optometrists were able to identify "abnormal signs" and were obligated to make the appropriate Referral upon such findings. (OMA1, p. 4)

The Vision Institute of Canada submitted that under the *HDA* the practice of optometry consisted of diagnosing any ocular disease whether systemic in nature or not. The Institute stated that where an ocular manifestation suggested a systemic disease, the optometrist would discuss the finding with the patient/client and make the appropriate Referral. In making findings the VIC was of the view that the *HDA* never imposed any limitations upon optometrists with respect to diagnosis of diseases of the eye and vision system. (VIC2, p. 3).

Dr. Bruce Hawkins, a practising optometrist since 1970, submitted that optometrists since 1970 have been making diagnoses "of ocular and

systemic disease ranging from cataracts, glaucoma, diabetic retinopathy, retinal detachment to thyroid malfunction and hypertension". (Hawkins, p.1)

The OAO stated that the *HDA* allowed optometrists based on the standards of practice, to treat, monitor or refer any disease, disorder or dysfunction. (OAO1, p. 5).

The COO submitted that the *HDA* and the relevant optometry regulations were the means by which the profession was governed prior to the *RHPA* and that these legislative provisions accurately reflected the practice. (COO1, p.5)

HPRAC has reviewed the relevant legislation, together with the above submissions and other submissions. The only certainty this review revealed was the fact that there was no consensus between the experts within the eye care community on what optometry's scope of practice had been under the *HDA*. Given this lack of agreement it was impossible for HPRAC to conclude with any satisfactory sense of accuracy the exact nature and extent of the "services usually provided" by optometrists under the *HDA*.

The *HPLR* concluded that optometry's scope of practice was and should be for purposes of new legislation:

> The practice of optometry is the assessment of the eye and visual system and the diagnosis, treatment and prevention of visual and oculomotor dysfunctions of the eye. (*HPLR*, p. 282)
>
> In the course of practising as an optometrist, a member may perform the following licensed acts:
>
> 1. Diagnosis of visual and oculomotor dysfunctions of the eye.
> 2. Using drugs as specified by regulation.
> 3. Prescribing ophthalmic appliances.
> 4. Dispensing ophthalmic appliances.

When Bill 60 was introduced into the legislature for first reading on April 2, 1991, the scope of practice was essentially the same as the one posed by the *HPLR* in 1989.

Dissatisfaction with this scope of practice definition led to a series of debates before the *SCSD* during the *RHPA*'s passage. Various groups, including some of the participants in this Referral, made submissions to the Standing Committee proposing amendments to optometry's scope of practice statement. In the end, the Standing Committee recommended amending the proposed legislation to allow optometrists to "diagnose, treat and prevent prescribed diseases."

In arriving at this conclusion members of the Standing Committee noted during their proceedings that:

> The effect of this amendment is to add a new class of authorized practice for the practice of optometry, and that is "prescribed diseases." What that in effect means is that the College of Optometrists of Ontario would have the

> right to pass regulations pertaining to designating the diseases it could diagnose. Those regulations would then, in the normal course, be circulated among all the health professions. It would then go to the Health Professions Regulatory Advisory Council for approval. If approved, the advisory council would then submit it to the minister for approval in the normal course of regulatory procedure. (P. Wessenger, Hansard, 5 November 1991, p. s-919)

Further, Mr. J. Wilson, in proposing an amendment stated:

> The purpose [of the amendments] is to make sure that we are absolutely clear that the list of prescribed diseases will be set out in the regulations...(J. Wilson, Hansard, 5 November 1991, p. s-919)

Mr. Callahan supported an amendment that added "diseases" to the items that optometrists diagnose. In defense of the motion, Mr. Callahan stated:

> ... this legislation was commenced with a view to being consumer legislation which was to define the product the public could expect to receive, and at the same time ensure the product was being provided in a sensitive and professional way. If that is the case and I believe that to be the case, then it is absolutely essential that the governing body has the clarity of definition to be able to determine whether or not an individual practising in this field is doing it in such a way that he deserves not to be sanctioned, and in addition to that, that it be available to the public, that they can prove in a very definite way that this person has exceeded or gone beyond the bounds of his capability. (R. Callahan, Hansard, 5 November 1991, p. s-925,926)

In the aftermath of the Standing Committee debates the *Optometry Act, 1991* was amended to its current wording which is:

> 3. The practice of optometry is the assessment of the eye and vision system and the diagnosis, treatment and prevention of,
>
> a) disorders of refraction;
>
> b) sensory and oculomotor disorders and dysfunctions of the eye and vision system; and
>
> c) prescribed diseases.
>
> 4. In the course of engaging in the practice of optometry, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:
>
> 1. Communicating a diagnosis identifying, as the cause of a person's symptoms, a disorder of refraction, a sensory or oculomotor disorder of the eye or vision system a prescribed disease.
> 2. Applying a prescribed form of energy.
> 3. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses.

HPRAC understands the current wording contained in the *Optometry Act, 1991* as being necessitated by the unresolved debate about what it is optometrists do and what diseases they are capable of diagnosing. In choosing to resolve

this debate through the mechanism of "prescribed diseases", the legislature has clearly shown that its intention was to conclude the discussion via the regulations process.

Following the *Optometry Act, 1991* receiving Royal Assent on November 25, 1991, the Ministry of Health made available a "Fact Sheet" outlining significant amendments to the Act. with respect to the addition of "prescribed diseases" the Ministry noted that such diseases would: "be listed in regulations .... [and that the] regulations listing diseases will be developed by the COO."

The Ministry also stated that the regulation would be "vetted" by HPRAC and that:

> Optometrists will continue to assess and monitor the condition of their patients' eyes and vision and to communicate their findings to them and to other caregivers. As well, they will continue to inform patients of diagnoses of disorders of refraction, sensory and oculomotor disorders and dysfunctions of the eye and vision system, and diseases prescribed (listed) in the regulations. (MOH, Fact Sheet, December 16, 1991)

The unresolved debate concerning "prescribed diseases" continued throughout the course of the Referral. HPRAC made repeated attempts to learn and understand from the participants what specific diseases of the eye and vision system optometrists, based on their knowledge, skill and training, are capable of diagnosing.

HPRAC was presented with various "lists" throughout its review, which attempted to answer the question of what diseases optometrists are capable of diagnosing. As previously noted, the College supplied an extensive listing. This listing was the ICD-9 list, "Disorders of the Eye and Adnexa (360-379)." (COO2, p. 1)

The College also provided "Optometric Diagnostic Codes, Ontario Association of Optometrists, 1994." This listing is a simplification of the ICD-9 coding scheme. Starting on May 1, 1994, completion of diagnostic codes was an OHIP requirement for optometrists. (COO2, p. 1).

The Ontario Association of Optometrists provided detailed discussion with examples of their attempts to arrive at lists of diseases or classes of diseases that optometrists diagnose. The OAO provided three examples of lists of diseases they had developed following a systematic, four-step process: identify a source for the disease, i.e., the ICD-9 listing; identify the procedures required for diagnosis; determine if these procedures are available to optometrists; and last determine if the condition can be diagnosed by optometrists. The OAO concluded that this procedure is unacceptable because: (1) in many cases the testing procedures necessary to identify to the underlying cause of some diseases lies outside the scope of practice of optometrists; and (2) lists are always incomplete. Based on this reasoning OAO abandoned the exercise and restated its support for the proposed general regulation.

The OAO also provided examples of categories of diseases that optometrists diagnose. These categories were based on the 19 major headings of classes of conditions listed in the ICD-9 listing of "Disorders of the Eye and Adnexa (360-379)" (discussed above). These categories are the same categories that make up the "Optometric Diagnostic Codes" list of codes used for OHIP recording.

The categories of diseases identified were based on the reasoning "that optometrists can definitively diagnose all of those ocular conditions when a definitive diagnosis can be made by a health care practitioner with the training, procedures and instruments available to optometrists". Furthermore, it was OAO's opinion that diseases that optometrists do not diagnose include:

- all systemic disease
- cancer
- all ocular diseases which require as part of their diagnosis, specific tests and/or procedures which are not part of an optometric examination. (OAO3, Attachment1)

The OMA-Section on Ophthalmology provided a discussion of the process that it when through to arrive at its list of four "diseases". The Section divided diseases into three broad categories: systemic disease, extrinsic disease and intrinsic disease. The Section used this structure to identify three extrinsic diseases and one intrinsic disease that can safely be diagnosed by optometrists: (OMA2, pp. 8-10)

Keratitis:

- Non-penetrating corneal foreign body

Disorders of Conjunctiva (excludes keratoconjuntivitis):

- Pinguecula
- Conjunctival foreign body

Other Disorders of the Eyelid:

- Eyelid foreign body

Despite the various "lists" being circulated to the participants no consensus or agreement could be reached within the eye care community, in particular within the optometric community, and government as to the nature and extent of optometry's scope of practice respecting the diseases optometrists are capable of diagnosing either under the *HDA* or currently under the *RHPA*.

Conclusion

Given the lack of consensus with respect to the historic context and the current practice of optometry, HPRAC is not in a position to recommend how a regulation respecting "prescribed diseases" should be framed in form and content.

3.0 Considering the Statutory Language, How Should a Regulation be Framed in Form and Content?

Issue

HPRAC acknowledges that any regulation regarding "prescribed diseases" must be made in accordance with the beneficial and protective spirit of the *RHPA*. Moreover, that spirit is reflective of the public interest which animates the legislation and ensures that health professions provide safe health care services. In HPRAC's view the public interest is promoted in the *RHPA* through a number of express statutory provisions.

In the following section HPRAC will examine two important provisions which safeguard the public interest and protect the public from harm. They are: (1) the controlled act of "diagnosis"; and (2) "prescribed".

Discussion

- *The Controlled Act of "Diagnosis"*

Throughout the Referral HPRAC has been concerned with understanding what is meant by "diagnosis". This term not only appears in ss. 3 and 4 of the *Optometry Act, 1991*, but also is one element of the controlled act contained in s. 27(2)1 of the *RHPA*, which provides:

> communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.

During the review it became clear that "diagnosis" had a variety of interpretations among optometric practitioners as well as those outside the practice. Some took a broad interpretation, some held a narrower view.

The OAO provided its understanding of "diagnosis" in both its first and second submissions. In its first submission, the OAO stated that every optometric eye examination will result in the communication of a "diagnosis" of the problem to the patient and it [the eye examination] will ensure that the patient receives proper care. (OAO1, p.4)

In its second submission, the OAO noted that "assessment" is the process of arriving at a conclusion. The "assessment" process is called an "oculo-visual assessment" and the conclusion is the "diagnosis". The Association noted that "diagnosis" was a controlled act because the public demands that a patient can rely on the "diagnosis" to point to an appropriate course of action. (OAO2, p. 14)

The COO stated in its fourth submission that s. 27(2)1 of the *RHPA* is not relevant to "prescribed diseases" and furthermore does not apply to s. 3 of the *Optometry Act, 1991*. The College stated that "it is not relevant since if a 'disease' was present in the eye and vision system and the 'disease' was not on a list, and as a result of the 'disease' the patient suffered harm a member

could argue that he/she has no requirement to advise the patient and furthermore could not be held accountable to "assess" and "diagnose" that 'disease' since it is not within s. 3 of the *Optometry Act.*" (COO4, pt. 11).

The OMA-Section on Ophthalmology outlined its understanding of the terms "assessment" and "diagnosis" as used in the *RHPA*. "Assessment" is viewed by the Section as a process of interaction between patient and health care provider in conducting a physical examination. This would imply that all ocular findings detected by an optometrist during an "assessment" could be communicated to the patient. "Diagnosis" as physicians use the term, however, is broader and more complex than describing abnormal signs. "Diagnosis" as physicians understand it means that the cause of the abnormalities must be determined. (OMA2, p. 4)

In HPRAC's view Section 27(2)1 of the *RHPA* contains four crucial elements :

1. **Communication** to an individual or their personal representative;
2. of a **diagnosis** which **identifies a disease or disorder** as the **cause of symptoms;**
3. in circumstances in which it is **reasonably foreseeable** that;
4. the individual or personal representative will **rely on the diagnosis**.

The four elements therefore are: communication, diagnosis, reasonable foreseeability and reliance. Thus the controlled act of diagnosis is broader than just "diagnosing" or arriving at a conclusion. "Diagnosis" plus the other three elements must be present to fulfill the controlled act of diagnosing under the Act.

HPRAC believes that the public is best protected and the public interest enhanced by a regulation which furthers the intent of the Act. Clearly, the controlled act of diagnosis contemplates, as part of its structure, the ability to identify a specific disease as being the cause of symptoms. The controlled act, at the very least, suggests that identification of disease is possible and can be named in a regulation.

HPRAC notes that its views about the controlled act of diagnosis are synonymous with those that were expressed by the government's counsel during *SCSD* proceedings. Ms. Bohnen stated that while there were various philosophical approaches to understanding "diagnosis", the *RHPA* was using "diagnosis" in the controlled act:

> in the traditional , conventional ,western medical way of thinking, which is to say yes we know people exist in an environment, but the diagnostic process is a process of finding out the specific cause of a particular set of symptoms. (L. Bohnen, Hansard, August 7, 1991, s-279)

HPRAC feels it is important to point out that whether or not optometrists are capable of diagnosing diseases, prescribed or otherwise, they are capable, of and required to, make assessments of a patient/client's ocular and visual health. Such assessments are a necessary component of their obligation "to recognize and refer any condition of the eye and vision system that appears

to require such a Referral and examination by another regulated health professional" (Ont. Reg. 859/93 s. 1(1)(13))

"Assessment" is not a controlled act and as such is in the public domain. This means that anyone can perform an assessment and communicate the results or findings from the assessment to the patient/client without violating the *RHPA*.

HPRAC is concerned that some optometric groups have taken the position that should optometrists be restricted in their ability to "diagnose diseases" they will not be able to fully practice to sufficiently meet the needs of their patients/clients. In response, unequivocally believes that optometrists would not be hampered in their practice in communicating findings to their patients via assessments. Optometrists would be expected to communicate their findings in such a way that patients are absolutely clear that they must not rely on an assessment as a diagnosis. Optometrists would, therefore, be permitted to communicate their assessments to patients using terminology such as: "I think you have..." or "You may have...".

P "Prescribed"

Section 1 of HPPC defines "prescribed" in the following way:

> 1.--(1) In this Code,
> "prescribed" means prescribed in the regulations.

Section 95(1)37 of the HPPC gives the following regulatory power to the College with respect to "prescribing":

> Subject to the approval of the Lieutenant Governor in Council and with the prior review by the Minister, the Council may make regulations,
>
> . . .
>
> 37. Prescribing anything that is referred to in the health profession Act or this Code as being prescribed;

During this review HPRAC has attempted to understand the significance, if any, of the use of the word "prescribed" before "diseases" in ss. 3 and 4 of the *Optometry Act* and the word's impact on protecting the public from harm.

This issue was brought to HPRAC's attention through correspondence between the College and its solicitor, Mr. Arthur Stone. HPRAC found Mr. Stone's comments both useful and enlightening.

The College had asked for a legal opinion on the significance of "prescribed". Mr. Stone advised the College that "prescribed" has meaning and that "the reader must be able to determine, from the words used only, what the law is." In addition, Mr. Stone also warned the College that it had a potential problem with their then proposed regulation in so far as the definition of disease was circular and thus "borders on subdelegation".

It is clear that Mr. Stone was alluding to the fact that the College's proposed regulation did nothing more than allow either the individual optometrist or the

College to decide what was or was not within their scope of practice at any given moment (Letters dated February 15 and March 25, 1993).

The College of Optometrists noted its understanding of "prescribed" in its third submission. The College stated that "prescribed" suggests "elaboration by regulation". In the College's view the presence of the word precludes optometrists from offering unlimited diagnosis, treatment and prevention of all diseases of the human condition because the practice of optometry is limited to the eye and vision system. This viewpoint is substantiated, in the College's view, by the legislature who, in the College's words, "rightly understood ... that a regulatory limitation needed to be placed on the word "diseases"." (COO3, p. 2,3)

In addition, the College was of the view that their proposed regulation was not subdelegation because the individual optometrist would know that only diseases of the eye and vision system could be diagnosed. (Letter, COO to HPRAC , July 26, p. 2)

It was the Ministry's view that in order to safeguard the public interest, the regulation must set out in some kind of list or other specific manner appropriate information designating which diseases optometrists diagnose (MOH, p. 1)

Apart from the above submissions, HPRAC received no other submissions which dealt with the technical meaning and implications for the use of the word "prescribed". However, HPRAC did find the material in the Standing Committee proceedings to be very helpful in understanding what the legislature intended by using the word "prescribed".

When the *Optometry Act, 1991* was amended to its current form to include the words "prescribed diseases" the Standing Committee considered how this wording would be accomplished. It is very clear that the intention was: (1) that the College Council itself would be deciding which diseases could be prescribed; and (2) that the College Council would propose regulations "listing the diseases" that optometrists could diagnose. (L. Bohnen, Hansard, *SCSD*, November 5, 1991 p. s-919-922)

In looking at this material HPRAC came to the common-sense conclusion that "prescribed diseases" did a have a meaning and that that meaning suggested something specific or designated.

Indeed, HPRAC notes that the OMA's first submission contained a legal opinion which considered the specific question of whether "in defining those 'prescribed' diseases, the government is obliged to stipulate a single set of 'prescribed' diseases for purposes of 'diagnosis', 'treatment' and 'prevention' or whether in the alternative, different diseases may be prescribed for each of the three processes" (OMA1, Appendix D, p. 1-2). In concluding that the Ministry could stipulate different categories of prescribed diseases for each process; the OMA solicitor inferred that a "prescribed" disease is something listed or listable.

Nevertheless, HPRAC sought its legal opinion respecting the meaning of "prescribed diseases". The following comments are based upon that legal opinion, a copy of which is attached as Appendix D.

In HPRAC's view, the College has been given (delegated) a legislative power to "prescribe" or define certain specific terms. In this case the term or item to be "prescribed" is "diseases." In its ordinary interpretation "prescribed" or "prescribing" must have a specific meaning, such as "to specify", otherwise the language of the *Optometry Act, 1991* would not have used such terminology.

Based on the language of the Act, HPRAC is of the view that the power to "prescribe" diseases has been given, or delegated, to the Council of the College, and not to anyone else. Accordingly, HPRAC believes that by using the word "prescribed" the legislature has clearly indicated that, at the very least, the diseases which optometrists are capable of diagnosing must be specified. Whether such specificity requires a list or some other way of making the identification will be dependent upon a proper appreciation of optometry's scope of practice.

HPRAC also believes that by using the word "prescribed" to describe the nature of the delegated legislative authority the legislature has given a narrow power to the College Council. In this context HPRAC understands that the meaning of "prescribed" as elaborated in the previous sections is closely linked with the concept of subdelegation. This linkage stems from the view that the power to "prescribe" is a narrow power that is delegated to the Council of the College. Furthermore, HPRAC believes that that delegated power must be exercised by the authority to whom it is given (i.e., cannot be delegated to someone else) and cannot be exercised in a general way.

HPRAC has concluded that delegation of authority is very important and ought to be kept in mind when assessing a regulation that leaves it up to the individual practitioner to determine which diseases he/she can diagnose. In HPRAC's view, the understanding of subdelegation has pivotal significance respecting both the regulation in question and the overall scope of practice of optometry and even for the *Optometry Act, 1991* itself. In choosing the word "prescribed", the legislature has suggested that the public will be best protected from harm by a specific regulation , made specifically by the College Council.

Conclusion

Based on HPRAC's understanding of the controlled act of "diagnosis" and the meaning of the term, "prescribed" HPRAC has concluded that the statutory language requires that a regulation be specific in form and content. Therefore, the College's proposed regulation is not acceptable.

4.0 Considering the Public Interest, How Should a Regulation be Framed in Form and Content?

Issue

Given the conclusions reached in response to the minister's questions concerning the historical/current practice and statutory language, HPRAC is of the opinion that the answer to the present question must be that the public interest is best protected by a specific regulation. Having reached this conclusion, however, HPRAC still feels that it is important to address a number of arguments raised by the participants relating to the *RHPA* principles of protection from harm, accountability and access outlined above. In doing so, HPRAC recognizes that serious issues have been raised and require a response independent of any conclusion reached regarding the first two questions.

Discussion

- *Protection from Harm*

Implicit in the discussions on historical/current practice of optometrists and statutory language has been the issue of "harm".

HPRAC is of the view that for purposes of this matter on "prescribed diseases", the very real and ultimate risk of harm is loss of sight. HPRAC therefore supports any efforts to maintain, enhance, and/or improve vision.

It is important, however, to recognize that in addition to visual impairment, other types of harm may result where either a diagnosis is erroneous or simply missed.

The Ontario Medical Association-Section on Ophthalmology outlined how harm can be extended to patients. First of all, it is fairly obvious to all that harm can result when a correct diagnosis is made, but an inappropriate treatment is administered. Second, harm can result when a wrong diagnosis is made. A wrong diagnosis could be in the form of either a false negative diagnosis or a false positive diagnosis. If a false negative diagnosis is made the patient's health may be prejudiced because the patient may not seek future input respecting the condition identified. Such condition, if left untreated, could deteriorate to the point that treatment could be rendered ineffective.

Similarly, if a false positive diagnosis is made, the patient may suffer substantial and unnecessary mental and psychological stress. For example, if a patient were diagnosed as having diabetes, without the practitioner having carried out the appropriate tests to determine this condition, and it turns out that the diagnosis is wrong, the patient and his/her family could experience significant anxiety as a result of this wrong diagnosis. (OMA2, p. 11,12)

Other submissions, however, arrived at the opposite conclusion. For example, the College of Physicians and Surgeons of Ontario took the position that

diagnosis is not harmful. The CPSO made it very clear that, in its view, the real harm to a patient comes about through treatment. Therefore, in addressing how a regulation respecting "prescribed diseases" should be framed, the CPSO clearly stated that a regulation should be written that addressed "diseases" that could safely be diagnosed and prevented in terms of s. 3 of the *Optometry Act, 1991* and another regulation should be written that addresses "diseases" that could be treated in terms of s. 4 of the *Optometry Act, 1991*. (CPSO1, p. 2)

It is HPRAC's opinion that the better view is that real harm can result from a wrong diagnosis. This can be manifested in several ways. First harm can result because the wrong, or no treatment, may be rendered. Second, harm can result from a failure to refer a patient to an appropriate medical practitioner. Third, harm can be extended to others, beyond the patient. For example, hemorrhaging may be observed in the eye. Although an optometrist might diagnose diabetic retinopathy, without further testing this could be a sign of other serious diseases: i.e., leukemia or even AIDS. Clearly, a patient with undiagnosed AIDS could unknowingly put others at risk.

HPRAC believes that significant psychological and mental harm could be rendered to an individual and/or his/her family if a diagnosis is made, when, in fact the patient does not have the diagnosed condition. HPRAC also believes that harm can result from lack of a timely Referral.

Furthermore, HPRAC believes that the notion among some practicing optometrists that a diagnosis must be rendered in every case is potentially very harmful to the public. (OAO1, p. 4)

HPRAC has concluded that diagnosis in and of itself is potentially harmful. Therefore, HPRAC does not support the proposal held by some that separating diagnosis from treatment and prevention will adequately ensure the public is protected from harm.

Accountability

As previously discussed, HPRAC believes that it is through accountability that an individual health care practitioner's competency and obligations to his or her patients/clients are assessed. As well, accountability mechanisms assure that the profession's scope of practice and standards of practice are applied to the membership and that a College focuses on accountability not only to hold members accountable, but also to fulfill its obligations to the public.

HPRAC believes that the *RHPA* and the regulations made thereunder must be: (1) clear to give guidance to members; (2) accessible and understandable to the public so they may identify their rights; and (3) administratively feasible.

Feasibility

Many groups questioned the administrative feasibility of a list. It was submitted that a list was: never complete, arbitrary, and difficult to administer. (COO1, p. 6; COO2, p.2; OAO1, p.8-9; OAO2, p.8-9; VIC2, p. 10)

In response, HPRAC acknowledges that with an evolving or expanding scope of practice, there may be need to revise any "list" with respect to "prescribed diseases". However, HPRAC does not believe that the possibility of such revision is sufficient to make a "list" impractical or undesirable.

The Advisory Council also notes a list, by definition, which identifies the diseases an optometrist is capable of diagnosing is not arbitrary but rather reflects a methodology based on reason and justification.

Finally, in HPRAC's view a listing of those diseases which optometrists can diagnose adds to administrative feasibility because it gives clear notice to those who are regulated, and those who regulate, of optometry's scope of practice. This notice provision in the context of optometry is no different from the notice given in any number of regulatory regimes that use lists to administer complex and evolving regulatory environments, e.g., the *Drug and Pharmacies Regulation Act;* the *Food and Drug Act*; the *Customs and Excise Act*; the *Narcotic Control Act* and the *RHPA* itself.

The Relationship Between Scope of Practice, Standards of Practice and Professional Misconduct

The College submitted that, in essence, the proposed general regulation provided nothing more that a framework within which the College would administer its Act by applying "standards of practice" and "professional misconduct" to clinical situations. As a framework the College stated that "the proposed general regulation is not intended to include or exclude" (COO2, p.2).

It was the College's view that this trinity of general regulation, standards of practice and professional misconduct adequately "set the boundaries and would provide for the College's authority to protect the public". (COO3, p. 4). The OAO supported the College's views. (OAO1, p. 11).

HPRAC agrees that it is important to set boundaries, that they be known and knowable, and that they are established through the scope of practice, standards of practice and professional misconduct regulations.

In the context of standards of practice HPRAC has reviewed the College's *Guide to the Clinical Practice of Optometry* and understands from the College that one of its purposes is to "inform the profession of the principles and criteria which would guide committees of the College in their assessment of diagnostic and treatment services which are now provided by members of the College and by extension how this clinical performance would be assessed, i.e. standards of practice". (COO1, p.18)

In HPRAC's view the *Guide* provides a clinical framework in which assessment /management/Referral processes are outlined. The *Guide* reflects certain minimal standards of practice which by their nature are general and need to be informed and defined by, amongst other things, the profession's scope of practice.

HPRAC has also reviewed optometry's professional misconduct regulation including those specific provisions which the College made reference to:

> 2. Exceeding the scope of practice of the profession.
>
> 12. Treating or attempting to treat an eye or vision system condition which the member recognizes or should recognize as being beyond his or her experience or competence.
>
> 13. Failing to refer a patient to a regulated health professional when the member recognizes or should recognize a condition of the eye or vision system that appears to require such Referral and examination.
>
> 17. Failing to maintain the standards of practice of the profession.
>
> 19. Performing a controlled act which has not been delegated to the member in accordance with the regulations. [O.Reg. 859/93 S.1(1)] (COO3- enclosure)

In HPRAC's view, these regulations provide some clarity in terms of identifying what types of conduct will attract professional liability. However, many of the regulations require additional information to be applicable in different situations.

Given HPRAC's observations about the College's *Guide* and professional misconduct regulations HPRAC has grave concerns about whether a general regulation respecting "prescribed diseases", which is not intended to "include or exclude", can adequately inform standards of practice and professional misconduct regulations which are themselves general. These concerns regarding generality are exemplified by the situation of an optometrist who was found guilty prior to the *RHPA* by the court, of negligence and failing to meet the profession's standards of practice but was not disciplined by the College, under the *HDA*, because he did not "globally fail[ed] to meet the standards of practice" and because there were "no significant deficiencies". (*Semple* v. *Conron* (1993), 41 A.C.W.S.(3d) (472); (COO, Letter to HPRAC , August 19, 1994, p.2).

Accordingly, HPRAC is unable to agree with the College's proposition that a general regulation respecting "prescribed diseases", which does nothing more than establish a framework within which the College applies standards of practice and professional misconduct regulations, is sufficient.

Governance

The College made several submissions with respect to the relationship between the general regulation and self-governance. It was the College's position that a general regulation was necessary to: (1) allow it to be self-governing; (2) allow it to protect the public through governing their members; and (3) facilitate peer review which the College understood to be the very 'essence of self-governance' (COO1 p. 7, 9, 18)

HPRAC notes that there is nothing inconsistent with self-governance by requiring that a regulation respecting "prescribed diseases" be in the form of a list. Indeed the College, by proposing a specific regulation, would be

exercising one of the hallmarks of self-governance by fulfilling its statutory obligation to "prescribe in regulation".

With respect to the issue of peer review, HPRAC notes that with the advent of increased public representation on College Council and Committees, the concept of "peer review" has been expanded to better incorporate "public review". Therefore, any specificity which can be included in a regulation respecting "prescribed diseases" actually facilitates a greater degree of self-governance by making the profession's scope more accessible to public members.

Access

A number of submissions received by the Advisory Council addressed the issue of prescribed diseases from the perspective of access. The College noted that optometrists are generally distributed across the province and therefore accessible. The College also submitted that optometrists are the only source of vision and eye care in many communities. (COO1, p.13)

The OAO submitted that optometrists provided widely available and easy access to eye care services. In addition, the OAO stated that they were the only providers of eye and vision care in more than 75 percent of the communities in which they practice. Easy access to optometrists allows for prompt appointments and the ability to make timely Referrals to other health care professionals. Thus, the OAO was of the view that any definition of "prescribed diseases" must preserve patient ease of access. (OAO1, pp. 5,6)

The Union of Ontario Indians made a number of submissions dealing with access; they noted that native patient/clients face several difficulties in accessing health care professionals, including, their geographical dispersion in the North and language barriers. It was the UOI's submission that the native community was well served by the optometrists insofar as they were readily available in the smaller communities and were also available to "fly-in communities" in the far North. Optometrists provided a good quality of care to native communities and regulations should not jeopardize that access. (UOI, Transcript of Public Meeting, p. 56-64).

The OMA-section on Ophthalmology stated that ophthalmologists are involved with serving northern areas of the province, including native communities. They also noted with respect to primary eye care in the province, there were more than 9,000 family-physicians compared with 916 optometrists, and that family -physicians are widely distributed in the province providing health care services covering a wide range of diseases including diseases of the eye. (OMA2, p.1; OMA1, p. 6)

The Ontario College of Family Physicians stated that 7, 000 general practitioners are widely distributed throughout the province and are therefore, arguably far more accessible than optometrists. Further, they provide ready access to comprehensive health care. (OCFP, p. 2-3).

HPRAC agrees in principle with the submissions that any regulation governing "prescribed diseases" ought not to limit access to optometrists. However, it should be remembered that regardless of any regulation, optometrists will continue to assess their patients and communicate those assessments to patients. In HPRAC's view, the public interest is enhanced by access to health care no matter who the provider is so long as the services are delivered in a safe and qualified manner.

Conclusion

In considering all the relevant public interest principles: protection from harm, accountability and access, HPRAC has concluded that the public interest would be best protected if a regulation respecting "prescribed diseases" was framed specifically, rather than generally, in form and content.

5.0 Analysis Conclusion

Considering the protection of the public interest, the statutory language within the Optometry Act, 1991, the historical context and current professional practice respecting the diseases that optometrists now diagnose, treat, and prevent, the Advisory Council has concluded that the regulation's form should be specific, not general, and the content of the regulation has yet to be identified.

IV. RECOMMENDATIONS

1. HPRAC recommends, with respect to form:

A regulation concerning "prescribed diseases" should be specific rather than general and must be able to identify which *diseases optometrists are capable of communicating to a patient as a diagnosis*.

2. HPRAC recommends, with respect to content:

In providing maximum protection of the public interest, at this time there be no diseases specified for purposes of defining "prescribed diseases."

3. HPRAC recommends that:

The College of Optometrists be invited to propose a specific regulation. In justifying the regulation the College:

1. Name the disease
2. Identify the cause of the disease
3. Identify how the cause is determined
4. Identify the training, education and clinical experience that allow the above to be answered

In preparing the specific regulation, the College should adhere to the following parameters: the regulation must exclude systemic diseases and any other diseases for which testing is required that is beyond optometry's scope of practice.

V. APPENDICES

APPENDIX A
Referral Letter

APPENDIX B
List of Participants

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Ministry of Health

1. The College of Optometrists (COO1) (March 14, 1994)
2. The College of Physicians and Surgeons of Ontario (CPSO1) (May 19, 1994)
3. The School of Optometry, University of Waterloo (SoO) (April 15, 1994)
4. The Opticians Association of Canada (OAC) (May 12, 1994)
5. The Ontario College of Family Physicians (OCFP) (June 6, 1994)
6. The Ontario Association of Optometrists (OAO1) (May 13, 1994)
7. The Vision Council of Canada (VCC) (May 13, 1994)
8. The Vision Institute of Canada (VIC1) (May 13, 1994)
9. The Ontario Medical Association, Ophthalmology Section (OMA1) (May 1994)
10. Dr. Bruce Hawkins (Hawkins) (May 12, 1994)
11. The Chinese Medicine and Acupuncture Association of Canada (CMAAC1) (April 14, 1994)
12. The Union of Ontario Indians (UOI) (June 6, 1994)
13. The College of Optometrists (COO2) (April 18, 1994)
14. Transcript of Public Meeting: Optometry: prescribed diseases (June 28, 1994)

Second round

1. The College of Optometrists (COO3) (July 20,1994)
2. The College of Physicians and Surgeons of Ontario (CPSO2) (June 29, 1994)
3. The Ontario Medical Association—Section on Ophthalmology (OMA2) (July 1994)
4. The Ontario Association of Optometrists (OAO2) (August 1994)
5. The Vision Institute of Canada (VIC2) (July 26, 1994)
6. Ministry of Health (MOH) (September 14, 1994)

Third round

1. The College of Optometrists (COO4) (October 14,1994)
2. The Ontario Association of Optometrists (OAO3) (October 31, 1994)
3. The Vision Institute of Canada (VIC3) (October 26, 1994)
4. The Ontario Medical Association-Section on Ophthalmology (OMA3) (October 1994)
5. The Chinese Medicine and Acupuncture Association of Canada (CMAAC) (October 12, 1994)

APPENDIX D
Legal Opinion

Wang, Fang, Ford, Daniel, Tielsch, James M., Quigley, Harry A., Whelton, Paul K. Undetected eye disease in a primary care clinic population. *Archives of Internal Medicine.* 1994; 154: 1821-1828. August 22, 1994.

Newcomb, R.D., Potter, J.W. Diagnostic outcomes of optometric Referrals in a VA medical center. *Journal of the American Optometric Association*. 50(8): 1979 Aug.

Recommendations of the Health Professions Legislation Review. *Striking a New Balance: a blueprint for the regulation of Ontario's health professions.* Ministry of Health. January 1989.