Distribution of Diagnostic Products and Laboratory and Diagnostic Testing

In this document, unless the context indicates otherwise, "member(s)" includes licensed pharmacist(s) and pharmacy technician(s).

INTRODUCTION

The Saskatchewan College of Pharmacy Professionals (SCPP) acknowledges the potential benefits of diagnostic products. Used properly, these products permit earlier detection of health problems and closer monitoring of existing conditions while also encouraging increased patient involvement in personal health. Used improperly, diagnostic products are of limited value and may even be detrimental to the patient's health. Therefore, SCPP recognizes the role of the member in distributing diagnostic products and assisting the patient to understand the proper use of such products.

SCPP also recognizes the diagnostic role of the physician, and the role of other health-care personnel in conducting laboratory and diagnostic tests. The role of the member should complement, and not interfere with or infringe upon the statutory role of other health-care personnel.

Increasing interest in pharmacy sponsored disease state screening and risk assessment programs requires clear understanding of the role of the member in both the distribution of diagnostic products, and in laboratory and diagnostic testing. Therefore, the role of the member should be consistent with the member's knowledge and training and be subject to statutory limitations.

OBJECTIVES

To describe the role of the member in the distribution of diagnostic products intended for patient use outside of conventional laboratory and health care facilities recognizing the traditional and contemporary role of the member, the legal and liability position of the member and the public interest.

DEFINITION

Diagnostic Products - Products which may or may not be associated with a medical device that contain agents, drugs or chemicals designed for patient use outside of conventional laboratory and health care facilities for the purpose of testing, identifying, self-diagnosing, screening or monitoring a human condition or disease.

GUIDELINES

1. The member may sell diagnostic products where such products contain adequate written instructions for the patient and where the product has been approved for sale in Canada.

2. The member should be familiar with the contents of the diagnostic product and the test procedures and protocol established by the manufacturer.

3. The pharmacist should be available to counsel the patient on the proper use of the diagnostic product. This includes advising the patient on the proper procedures for conducting the test and how to properly interpret the test results.

4. Where the nature of the diagnostic product demands, the member should be sufficiently trained to, in turn, train the patient on the proper use of the product.

5. The pharmacist, or another qualified health care professional, may conduct, administer or interpret a diagnostic test in the pharmacy for demonstration purposes only*. This means that the pharmacist, or other health care professional, may collect a personal specimen or specimen from the patient, apply the specimen to the testing device and/or express an opinion on the meaning of the result to demonstrate to the patient on how to use the device properly. For example, the pharmacist may take a sample of blood from the patient to show the patient how to use a home blood glucose monitoring device.

6. The pharmacist may supervise the performance and interpretation by the patient of a diagnostic test performed in the pharmacy.

7. The pharmacist should advise the patient to consult a physician where a self-diagnosis or absence thereof, requires confirmation.

8. The examination or analysis of a specimen taken or collected from a human body for the purposes of screening or assessment of risk for any health-related purpose is considered to be a "test" within the meaning of *The Medical Laboratory Licensing Act*. Any site where such tests are performed must be licensed and meet personnel, instrumentation and testing proficiency criteria. Therefore, the pharmacist responsible for a screening program as described above should ensure that the site where the program is to be conducted is licensed by the Laboratory Quality Assurance Program, College of Physicians and Surgeons of Saskatchewan. The contact information is below.

9. The Saskatchewan Health Authority is responsible for the delivery of most medical laboratory services. The Laboratory Quality Assurance Program (LQAP) is responsible for establishing the requirements and standards of medical laboratories in the province of Saskatchewan and to ensure their compliance with the Medical Laboratory Licensing Act and Regulations. The College of Physicians and Surgeons of Saskatchewan (CPSS) is contracted by the Province of Saskatchewan's Ministry of Health to operate the LQAP Program.

*Subject to change upon full implementation of section 23(3)(c) of *The Pharmacy and Pharmacy Disciplines Act* and section 1(d) of Part M of the regulatory bylaws of SCPP.

For further information contact:

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Questions?
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