



Disease State Monitoring, Screening, Testing or Risk Assessment Activities Policy Statement

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

Advances in technology have resulted in the public being able to purchase self-testing products or access devices outside of conventional settings for screening, diagnosing, and monitoring diseases and medical conditions and for monitoring drug therapies. These products and services are becoming components of disease education and management programs, preventive care and primary care activities provided by pharmacists. Many are sold or available in pharmacies or are part of activities such as client education, screening or disease state risk assessment clinics held in pharmacies.

Members, other health professionals, the public and authorities question whether this is an appropriate role for the pharmacist and pharmacy technician, and whether current practices achieve quality. When quality is sub-optimal, there is concern with public confusion over the role of the member and the validity of the results, while others are concerned that this generates unjustifiable referrals and utilization of other health care resources.

Conversely, limited access to these services in the conventional system and their availability from alternate sources, such as pharmacies, combined with increasing interest in wellness and personal responsibility for health, have stimulated considerable public demand. Proponents argue that the public should have access to these services as they are safe even though they may not be entirely effective. The public is capable of understanding the limitations. Therefore, this document examines the role of the pharmacist and pharmacy technician and provides members with guidance in providing these products and services to:

- achieve healthy outcomes
- foster collaboration with other members of the health care team
- contribute to the prudent use of health care resources
- minimize public confusion

Council policy is that the scope of practice of the member is based on the concept of pharmaceutical care. It is defined as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life” (Hepler, D. and Strand, L: Am J Hosp Pharm 1990; 47:533-43). The goals of pharmaceutical care are for the member to establish a relationship with the patient to identify, solve and prevent the patient's drug-related problems. Therefore, monitoring, diagnostic screening, risk assessment or educational products and activities offered in the pharmacy as services must both be within the scope of practice of the member and must support pharmaceutical care. This means that:

1. The member must establish or maintain a relationship with the patient;
2. The activity is intended to prevent, identify or resolve an actual or potential drug related problem;

3. The personnel operating the equipment or device, interpreting the results and educating the patient are competent to do so. This may mean engaging other health professionals who are competent in these areas;
4. Any test that is conducted must be scientifically valid. Sufficient evidence must exist to support the reliability of the test;
5. The activity is conducted in a manner that protects the privacy of the patient;
6. Members must cooperate with the patient's physician. This includes disclosing relevant information to the physician with the patient's consent, and providing the physician with an appropriate recommendation;
7. Members must comply with the Saskatchewan College of Pharmacy Professionals statement "Distribution of Diagnostic Products and Laboratory and Diagnostic Testing";
8. Members must comply with relevant legislation including *The Radiation Health and Safety Act* and the *Medical Laboratory Licensing Act*. Members should seek advice from the Radiation Safety Unit of the Occupational Health and Safety Division of Saskatchewan Labour on radiation-emitting devices. Members should also seek the advice of the Laboratory Quality Assurance Program to determine whether testing products or services meet acceptable standards for competency of personnel, and instrument, equipment and testing proficiency;
9. Where an activity has limitations in quality, such as limitations in the reliability of test results, members must disclose these limitations in writing to the patient; and,
10. Disease state screening programs may only be promoted to the public in a professional manner that is consistent with this statement and, without limiting the generality of the foregoing:
 - Uses pharmacy resources appropriately enabling member to follow up properly with the patient;
 - Referring patients to other health services providers when appropriate;
 - Taking reasonable steps to ensure that those who need the service receive it; and
 - Avoiding conflicts of interest that arise when such activities result in the purchase of goods and services that limit the patient's right of choice, or that may not be needed.