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MEDICATION SAMPLES

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NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

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OBJECTIVES

- To establish a safe, consistent, and transparent approach to the management of **medication samples** (including **natural health products** and medication **payment assistance cards** [also known as smart cards or discount cards]) within **Alberta Health Services (AHS) settings**.
- To ensure medication product quality, integrity, efficacy, safety, security, and storage in accordance with legislative and accreditation requirements.

PRINCIPLES

AHS' drug formularies ensure medically appropriate and cost-effective medications are available to meet the needs of the **patient** populations being served within AHS settings.

Medications shall be procured, **ordered**, distributed, and administered using systems and standards that ensure patient safety.

The receipt, storage, and distribution of medication samples should be limited, whenever possible, to ensure safe and consistent methods of medication management within AHS settings.

Distribution of medication samples or payment assistance cards to outpatients shall be at the discretion of an **authorized prescriber**, in consideration of the benefits and safety risks to the patient's care, and in accordance with the professional standards and ethics of the authorized prescriber's regulatory college.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Exceptions to this Policy

- 1.1 This policy does not apply to medication samples in the following AHS settings:
- a) Continuing Care contracted service providers;
 - b) Home Care;
 - c) Supportive Living;
 - d) Respite Care;
 - e) Restorative Care; and
 - f) Corrections.

2. Professional Responsibilities

- 2.1 **Health care professionals** distributing medication samples shall have the knowledge, competence, and authorization to provide these services, and ensure they are acting within their scope of practice.
- 2.2 Health care professionals shall comply with the *AHS Conflict of Interest Bylaw* and the *AHS Code of Conduct* when accepting or distributing medication samples and medication payment assistance cards.

3. Distributing and Administering Medication Samples

- 3.1 Inpatient Settings and Emergency Departments
- a) Medication samples shall not be distributed to:
 - (i) **inpatients** within AHS settings or upon discharge from inpatient settings; or
 - (ii) patients visiting Emergency Departments.
 - b) When patients require non-formulary medications, refer to the AHS non-formulary processes (e.g., Low Cost Non-Formulary Process, Short-Term Exceptional Drug Therapy [STEDT]).

- c) Medication samples shall not be administered to inpatients within AHS settings or patients visiting Emergency Departments, unless the medication sample is:
- (i) the property of the patient and either brought in at presentation or admission to a health care facility, program, or service or brought in from an external source at a later time;
 - (ii) ordered by an authorized prescriber; and
 - (iii) received, stored, and documented in accordance with the AHS *Management of Patient's Own Medications Policy and Procedure*, and AHS *Management of Patient's Own Medications Procedure (Continuing Care)*.

3.2 Outpatient and Community-based Clinics and Urgent Care Centres

- a) Medication samples shall only be distributed to **outpatients** visiting an outpatient or community-based clinic or urgent care centre when there is an order from an authorized prescriber.
- (i) Medication samples shall not be distributed in Cancer Care outpatient and community-based clinics.
- b) All distribution, labelling, patient education, and documentation of medication samples to outpatients shall follow the AHS *Distributing Medication Samples to Outpatients Procedure*.

4. Receipt of Medication Samples from Manufacturers or Vendors

- 4.1 Only authorized prescribers who are registered and entitled to practice in Alberta are authorized to request or accept medication samples from manufacturers or vendors. Refer to the *Food and Drugs Act and Regulations (Canada)*.
- 4.2 Authorized prescribers shall only request or accept medication samples from a manufacturer or vendor that are intended for use by AHS outpatients.
- a) Medication samples must be in compliance with applicable legislative requirements. All medications may be requested or accepted by authorized prescribers as samples, except for **controlled substances** (including **narcotics, controlled drugs, and targeted substances**) and prescription and non-prescription medications that contain cannabis.
- 4.3 The requesting authorized prescriber shall only accept medication samples from manufacturers and vendors who have distributed the medication samples by mail or direct delivery. Upon delivery, an authorized prescriber is responsible for ensuring safe and secure storage of the medication samples in outpatient care areas in accordance with Section 5 of this Policy.

- 4.4 Vendors shall be referred to the *Vendor Guide to Doing Business with Alberta Health Services*.

5. Storage and Disposal of Medication Samples

- 5.1 High-alert medication samples shall comply with the storage and labelling requirements in the AHS *Management of High-Alert Medications* Policy and Procedure, and the AHS *High-Alert Medications* Guidelines.
- 5.2 Medication samples that are not the property of a patient shall be stored separate from any wardstock medications and in a secure location such as a locked cabinet or drawer, or a secure medication room.
- 5.3 Medication samples that are the property of the patient, brought in at presentation or admission to a health care facility, program, or service, or brought in from an external source at a later time, shall be received, stored, and documented in accordance with the AHS *Management of Patient's Own Medications* Policy and Procedure, and AHS *Management of Patient's Own Medications* Procedure (Continuing Care).
- a) For visits to outpatient or community-based clinics or urgent care centres, the patient shall take their own medication samples home after the visit or completion of treatment.
- 5.4 Unusable medication samples (e.g., expired, damaged, or deteriorating medications) shall be disposed of as per Zone/program/site processes.

6. Medication Payment Assistance Cards

- 6.1 **Health care providers** may distribute medication payment assistance cards to patients within AHS settings when there is an order from an authorized prescriber for a medication that is partially or entirely supplemented by a payment assistance card.
- 6.2 Medication payment assistance cards may be received from a manufacturer or vendor by any health care provider.
- 6.3 Medication payment assistance cards that are received from a manufacturer or vendor shall be stored in a secure location such as a locked cabinet or drawer or a secure medication room.
- 6.4 Void or expired medication payment assistance cards that have not been distributed to patients shall be disposed of in accordance with the AHS *Waste Management* Policy and Zone/program/site processes for handling confidential waste.

DEFINITIONS

Alberta Health Services setting means any environment where treatment/procedures and other health services are delivered by, on behalf of, or in conjunction with, Alberta Health Services.

Authorized prescriber means a health care professional who is permitted by federal and provincial legislation, their regulatory college, Alberta Health Services, and practice setting (where applicable) to prescribe medications.

Controlled substance means any type of drug that the federal government has categorized as having a potential for abuse or addiction and is included in Schedule I, II, III, IV or V of the *Controlled Drugs and Substances Act*.

Controlled drug means a drug or preparation set out in the Schedule to Part G of the *Food and Drug Regulations* (FDR). A drug categorized federally as having higher than average potential for abuse or addiction.

Narcotic means any substance set out in the Schedule to the *Narcotic Control Regulations* (NCR) or anything that contains any substance set out in that Schedule. A substance that has a high potential to become physically and psychologically addictive or liable for abuse.

Targeted substance means a controlled substance that is included in Schedule 1 of the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR) or a product or compound that contains a controlled substance.

Health care professional means an individual who is a member of a regulated health discipline as defined by the *Health Disciplines Act* (Alberta) or the *Health Professions Act* (Alberta), and who practises within scope and role.

Health care provider means any person who provides goods or services to a patient, inclusive of health care professionals, staff, students, volunteers and other persons acting on behalf of or in conjunction with Alberta Health Services.

Inpatient means a patient admitted to and staying in an Alberta designated hospital, or other approved facility, where goods or services are delivered by, on behalf of, or in conjunction with Alberta Health Services.

Medication means any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings, and restoring, correcting or modifying organic functions in human beings.

Natural health products mean medicinal products containing herbs, vitamins, minerals, and nutritional supplements (also known as traditional, natural, holistic or homeopathic medicines).

Order means a direction given by a regulated health care professional to carry out specific activity(-ies) as part of the diagnostic and/or therapeutic care and treatment to the benefit of a patient. An order may be written (including handwritten and/or electronic), verbal, by telephone or facsimile.

Outpatient means a patient staying at home or in another facility that is not a designated hospital in Alberta, or who is accepted as a registered patient for goods or services offered or delivered by, on behalf of or in conjunction with Alberta Health Services, but who returns to their normal abode after the good or service is rendered or delivered.

Patient means an adult or child who receives or has requested health care or services from Alberta Health Services and its health care providers or individuals authorized to act on behalf of Alberta Health Services. This term is inclusive of residents, clients and outpatients.

Payment assistance card means some or all out of pocket expenses for a medication are paid for by the manufacturer in the form of a physical card or digital printout that can be redeemed at a community pharmacy. Also known as a smart card.

Sample(s) means a trial package of medication distributed by the manufacturer without cost. Also known as a clinical evaluation package.

Vendor means an individual or company that supplies, or seeks to provide, goods and/or services to AHS and includes contractors and suppliers and excludes AHS representatives.

REFERENCES

- Alberta Health Services Governance Documents:
 - *Code of Conduct*
 - *Conflict of Interest Bylaw*
 - *Distributing Medication Samples to Outpatients Procedure (#HCS-233-01)*
 - *Management of High-Alert Medications Policy (#PS-46)*
 - *Management of High-Alert Medications Procedure (#PS-46-01)*
 - *Management of Patient's Own Medications Policy (#PS-98)*
 - *Management of Patient's Own Medications Procedure (#PS-98-01)*
 - *Management of Patient's Own Medications Procedure (Continuing Care) (#PS-98-02)*
 - *Waste Management Policy (#ESM-01)*
- Alberta Health Services Resources:
 - *Vendor Guide to Doing Business with Alberta Health Services*
- Non-Alberta Health Services Documents:
 - *Food and Drugs Act and Regulations (Canada)*
 - *Health Professions Act (Alberta)*
 - *Medication Guidelines, 2015 (College and Association of Registered Nurses of Alberta)*
 - *Medication Management Standards (Accreditation Canada)*

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