

South Australian Medicines Advisory Committee
Guidance Document

Management and Use of Pharmaceutical Company Sponsored Home Infusion Services

Public hospitals and health services currently provide home or alternate site (e.g., specialist clinic) infusion services to patients.

As the number and type of infused medicines increases (e.g. biologics, antimicrobials) some pharmaceutical companies are sponsoring home infusion services for the administration of some of their products to public health patients. These sponsored services are **not** supported by the South Australian Medicines Advisory Committee.

Existing services including SA health home infusion services (i.e. Hospital in the Home, Priority Care Centres, Wellbeing SA, My Home Hospital, Virtual Care) and community nursing services and GP practices are to be considered. If a sponsored home infusion service is to be considered by a public hospital or health service there are potential risks regarding governance and operational management of the service that require consideration and risk management strategies to ensure safe, quality and equitable patient care, and to promote optimal patient outcomes.

Purpose

This guidance document provides the SAMAC position, risks and factors for consideration by Local Health Networks (LHNs) and state-wide services if considering a sponsored home infusion service for their patients.

Definition

Pharmaceutical company sponsored home infusion service (sponsored home infusion service) refers to a parenteral infusion service provided by a pharmaceutical company to administer one of their parenteral medicinal products (examples include antimicrobials and biologics). The service is provided to public patients under an agreement with the treating public hospital or health service. The sponsored infusion service is provided in the home or alternate site, e.g., off-site infusion suite.

Background

Parenteral medicine administration is more complex than other routes of administration because aseptic technique must be used to prepare and administer the medicine. Parenteral administration may also require the use of a rate-controlled administration system such as a syringe driver or an infusion pump. Parenteral medicines often have specific storage and handling arrangements to ensure their stability and efficacy is maintained.

Position

SAMAC supports SA Health programs for provision of home or alternate site infusion services. If LHNs and state-wide health services choose to consider sponsored home infusion service, to ensure optimal treatment outcomes and reduce the risk to patient safety, LHNs and state-wide health services should have a formal written agreement and/or memorandum with the pharmaceutical company sponsoring the home infusion service that includes the:

- Scope of the service
 - The use of pharmaceutical company sponsored home infusion service does not replace formal contractual SA Health arrangements.
- Governance arrangements
 - Evaluation of the factors for consideration and approval of sponsored home infusion services should include approval from the LHN Drug and Therapeutics Committee (DTC) (or equivalent committee) and the LHN Chief Executive Officer (or delegate).
 - LHNs and state-wide service should ensure the sponsored home infusion service meets all relevant regulatory requirements and professional standards, and adhere to SA Health, LHN and state-wide services policies, guidelines, and procedures.
- Communication arrangements.
 - Communication is key to ensuring delivery of a safe and effective service. There should be a process in place to ensure effective communication between the patient, public hospital/health service and a dedicated contact for the sponsored home infusion service to provide adequate oversight of the patient's care, including appropriate monitoring and evaluation of therapy and any complications that arise.

Risks and Factors for consideration

- > Regulatory requirements and professional standards

The sponsored home infusion service must meet the appropriate regulations and professional standards for the scope of the agreed service provision.
For example:

 - Appropriately trained and credentialed nurses providing the specialist services, e.g., certified infusion skills, oncology/chemotherapy accreditation.
 - Service provider staff with satisfactory background checks including police and criminal history, vaccine checks (e.g., COVID-19 vaccination) and relevant Department of Communities and Social Inclusion (DCSI) checks.
- > Service operational arrangements

The sponsored home infusion service must comply with professional standards and regulatory requirements for the storage, transportation, dispensing, preparation and administration of medicines to ensure the safety and stability of the medicines.

 - The nursing services should be provided by the sponsor's own employees. If the service is through a separate third-party health provider, the provider must comply with the same requirements as the sponsor's employees.
 - The sponsor is responsible for ensuring their staff have the required training and education to undertake the scope of their duties.
- > Service operating hours and location
 - The service operates on weekends and/or public holidays with after-hours support to meet the patient's needs
 - The sponsored service is equitable and extends across all SA Health sites
- > Referral process and treatment delivery
 - Consider the referral criteria and referral processes established to guide appropriate patient referrals
 - Consider the turnaround times from point of referral to delivery of the home infusion service and the first home visit
 - Patient status e.g., ambulatory outpatient

- > Access to the medicine
 - Access to medicines is in accordance with the usual SA Health processes, policies and guidelines.
 - The SA Medicines Formulary listed medicines and restrictions, and brands on the SA Health Pharmaceuticals and Large Volume Fluids Contract must be utilised.
 - Provision of medicines should be through SA Pharmacy responsible for providing professional pharmacy service to South Australian public hospitals.
- > Patient factors
 - Informed patient consent must be sought before referring the patient to the sponsored home infusion service. Other arrangements may need to be considered for patients who do not wish to use sponsored home infusion services.
 - Patients should be supplied with information on the service and the way it will be provided.
 - Consider whether patient and carer education and training and patient support services is provided by the sponsor
 - The provider must have privacy and confidentiality policies in place and adhere to the SA Health confidentiality policy.
- > Evaluating service quality and effectiveness
 - Consider agreeing to key performance indicators or clinical outcome measures to demonstrate the service is successful.
 - To support quality improvement activities there should be processes in place to allow patients and health professionals to provide feedback on the sponsored home infusion service and the public hospital/health service.
- > Communication

Consider:

 - Defining communication pathways and responsibility for co-ordinating the medical, pharmacy and nursing services to ensure continuity of patient care.
 - Establishing a patient liaison service to meet with patients before the first home visit, if this is a representative of the sponsoring pharmaceutical company.
- > Adverse events and medication incidents reporting
 - To support safe patient care, there should be processes for the reporting, evaluation and management of any adverse events or medication incidents. Patients and health professionals must be aware of the procedure for reporting incidents and adverse events.
- > Contingencies

LHNs and state-wide health services should consider developing a contingency plan to ensure continuity of patient care if the sponsored home infusion service is withdrawn or is temporarily unavailable. Consideration should be given to the additional resources that may be required, e.g., additional nursing staff, clinic time and medicine supply arrangements. Maintaining good communication links with patients and health professionals will be essential to help ensure continuity of care.

For more information

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