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| Registering a Health Service Establishment |
| Regulatory Compliance: Self-assessment template |
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| Clinical Governance & Quality & Safety | | |
| **REGULATION**  (refer to Health Services (Health Service Establishment) Regulations 2024 | **EVIDENCE – PLEASE COMPLETE THIS SECTION AND SUBMIT DOCUMENTS LISTED IN BLUE** (Delete as appropriate and indicate N/A as required) | **Department of Health Use only** |
| **6 and 7 Prescribed Services:** | Complete and return bed numbers form:  Surgical services – please list specialties to be provided  Plastic surgery – does this include cosmetic surgery and liposuction?  Mental Health – Does this include ECT or TMS?  Paediatric services – age and specialties? |  |
| **8 Health service establishment protocols for quality and safety**   1. For the purpose of ensuring the quality and safety of health services provided, the proprietor must prepare health service establishment protocols in accordance with this regulation.   (2) The health service establishment protocols must be—  (a) documented in writing; and  (b) made available to the public -   1. published on the health service establishment's website; or 2. in the manner and form determined by the Secretary; and   (c) made available to the Secretary on request.   1. **The health service establishment protocols must include the following—**   (a) processes for assessing every 3 years the credentials of each health professional practising at the health service establishment;  (b) processes for setting the scope of practice for each health professional practising at the health service establishment;  (c) processes for continually assessing the competence and performance of each health professional practising at the health service establishment;  (d) processes for continually assessing and reviewing health services provided by each health professional practising at the health service establishment;  (e) processes for continually assessing the capacity of the health service establishment to provide safe, patient centred and appropriate health services to patients at each of its premises;  (f) setting the frequency of, and procedures for, meetings of committees of the health service establishment with responsibility for the quality and safety of health services provided at, or from, the health service establishment;  NOTE: Relevant committees may include, but not limited to a medical advisory committee, a quality and safety committee and the board of the health service establishment.  (g) processes for ensuring that appropriate arrangements have been made for evaluating, monitoring -and improving the quality and safety of health services provided at each premises of the health service establishment.   1. On and from 31 August 2025, the description and allocation of quality and safety roles in relation to the health service establishment 2. On and from 31 August 2025, having regard to the kind or kinds of health services being provided at, or from, the health service establishment, processes and procedures for the following –    1. The availability of appropriate adjunct diagnostic services.    2. Review of adverse patient safety events, including participation of all relevant personnel in the review (whether employees or not).    3. Addressing the specific needs of Aboriginal persons;    4. Recognising and responding to deteriorations in the condition of patients.   (4) The proprietor of a health service establishment must ensure that the health service establishment's quality and safety protocols are implemented and complied with.  In this regulation – **health professional** means a registered medical practitioner, a registered dental practitioner, a registered medical radiation practitioner or a registered podiatrist. | Documentation should clearly articulate **ALL** processes in Regulation 8  **Provide links to facility website where these protocols are housed.**  **Please give a brief summary of each process (2a-g) and identify in which policy/protocol these protocols can be found.**  **Please summarise how this will be managed at the facility.**  **Please provide the following documents:**  Clinical Governance Framework  By-laws  Organisational Structure  Committee Structure  Medical Credentialing Policy (department recommends SCV Policy https://www.safercare.vic.gov.au/best-practice-improvement/publications/credentialing-and-scope-of-clinical-practice-for-senior-medical-practitioners-policy)  Terms of Reference for Key Committees for Quality & Safety  Standing Agenda for Key Committees for Quality & Safety  Quality Manual or equivalent  Risk Management System  Clinical Incident Management System  Audit Schedule  Policy Manual and protocols (provide index and at a minimum copy of):   * Admission policy * Admission criteria/Exclusion Criteria * Pre-admission health questionnaire * Admission pack including all relevant forms and documents * Discharge policy * Medication safety * Clinical deterioration policy and protocols (includes members of MET team and medical cover)   Deterioration in mental state  Patient/family escalation of care concerns  BLS, ALS, APLS, Anaphylaxis management  Malignant hyperthermia  Sepsis protocol   * Communicating for safety   Clinical handover  Consent   * Staff Orientation manual * Theatre protocols   **Prescribed Services**: Policies relating to prescribed services including but not limited to:   * Paediatric policies * Mental Health * Endoscopy |  |
| Health Services Act  107A Proprietor to comply with approved accreditation scheme | Letter of engagement from accrediting agency |  |
| **Statistical returns and Quality and safety Review Data:**  **60 Returns and reports to be given to the Secretary**  -VAED  -HAI  -ECT  -VEMD | Facility to acknowledge requirement for data reporting and has systems in place to report. |  |
| **63 Review of quality and safety of health services provided –**   1. at least every 3 months in writing 2. information in relation to the decisions and actions taken for the purposes of improving quality and safety of health services 3. if applicable, information in relation to - 4. all adverse events 5. all sentinel events 6. mortality and morbidity 7. all transfers to another health service for escalation of patient care 8. compliance with health service protocols 9. results from staff and patient surveys. | * Where is this data captured and which committees are responsible for the review of the data? * How will the data be used for quality improvement?   What other data will the facility report?  How will the facility benchmark?  Does the facility report to clinical registries? |  |
| **64 Patient experience survey data**  The proprietor of a health service establishment must ensure that at each premises of the health service establishment—  (a) patient experience survey data is collected  (b) patient experience survey data is reviewed  (c) the data is made available to the Secretary on request. | Provide information on how this will be captured and reviewed.  Copy of survey |  |
| **65 Staff safety culture survey data**  (a) staff survey data is collected  (b) staff survey data is reviewed  (c) data is made available to the Secretary on request. | Copy of survey |  |
| **Complaints**  38 Nomination of complaints officer  39 Dealing with a complaint  40 Record of complaint  41 Person making the complaint must not be adversely affected | Nomination form  Complaints management policy |  |
| **61 Reporting of compliance with the duty of candour**  <https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events/adverse-event-review-and-response/duty-of-candour> | Please outline how this requirement is communicated to staff e.g. as part of open disclosure policy/incident management system?  Requirement to report quarterly |  |
| **62 Open disclosure policy**   1. Documented in writing   to be published on facility website and aligns with national framework. <https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework> | Open disclosure policy |  |
| **66 Reporting of sentinel events**  <https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events> | Onboard to SCV portal.  Please outline how this requirement is communicated to staff e.g. as part of policy/incident management system? |  |
| **67 Review of sentinel events**   1. Proprietor must ensure review is conducted of each sentinel event 2. Must be conducted within timeframe as determined by Secretary 3. Must record outcome in writing & submit to Secretary within timeframe and form as determined by Secretary. | Please outline how this requirement is communicated to staff e.g. as part of open disclosure policy/incident management system?  Requirement to report quarterly |  |
| Workforce | | |
| **REGULATION** | **EVIDENCE** | **Department of Health Use only** |
| **21 Chief Executive Officer and Medical Director** | Nomination form |  |
| **18 Director of Nursing must be appointed**  (must comply with reg 18 i.e.RN with 5 years post reg and 1-year managerial experience)  NOTE: not applicable to mobile anaesthesia services | Nomination form (must comply with reg 14 i.e., 5 years post reg with 1-year managerial experience) |  |
| **32 Nurses must be registered and competent**  (a) is an enrolled nurse or a registered nurse;  (b) is professionally competent through education or experience to provide nursing care at the health service establishment having regard to the kind or kinds of health services being provided.  **Staff education and training** | Please provide details of staffing arrangements.  How will staff competency be assessed?  Position descriptions  Skills Matrix  Orientation package  Staff training register  Is there an educator? EFT?  Who is responsible for staff education and oversight? |  |
| **33 Post-operative care of surgery patients**  If DON not present must be RN with at least 3 years post reg and **relevant** clinical experience to supervise surgical list & post-op care of patient. |  |  |
| **35 Sufficient nursing staff must be on duty**  **Regs;** 1 RN to 10 patients day/evening shift. 1 RN to 15 patients’ night shift  If a day procedure centre, 1 RN to 10 patients.  If 3 or more nurses on duty 2 RN:1EN noting that still require 1RN to 10 patients.  This is minimum regulatory requirement. For quality and safety and to ensure patient centred care ratios may vary based on acuity and other standards eg. ACORN standards, anaesthetics, ICU/HDU |  |  |
| **34 Care of maternity, obstetric and neonatal patients**  Midwife with at least 3 years **relevant** clinical experience to provide clinical oversight. |  |  |
| **46 Staff Register**  (a) Is documented in writing and  (b) the prescribed period is 2 years  (c) the prescribed particulars are—  (i) the full name of every member of the nursing staff and other registered health practitioners;  (ii) the date of birth of every member;  (iii) the designation of every member;  (iv) the qualifications of every member;  (v) if applicable, the registration number or code of every member. |  |  |
| Admission of Patients | | |
| **REGULATION** | **EVIDENCE** | **Department of Health Use only** |
| **23 Unit record to be allocated** |  |  |
| **Information to be given to patients**  **24 Information about services and fees**   1. Info about facility health services to be provided, fees and any likely third-party fees and out of pocket expenses. 2. **Statement to contain:**   Quality/standard of health care and services  Courteous treatment  Cultural, gender, religious considerations  Dietary needs  Privacy  That patient may request names & role of key workers  Patient’s entitlement to ask for referral if seeking another medical opinion  Confidentiality  Consent to treatment  Patient may refuse presence of workers not involved with care  Right to self-discharge  Right to make a complaint   * Information about fees * Clear explanation of treatment and services to be provided   This is all included in the Australian Charter of Healthcare Rights. Most private providers adopt this, noting it is mandated in public facilities. <https://nrch.com.au/wp-content/uploads/2017/01/Australian-Charter-of-Healthcare-Rights-in-Victoria.pdf> |  |  |
| **25 Pre-admission assessment**  The proprietor of a health service establishment must ensure that for a non-emergency patient admitted to the health service establishment—  (a) a pre-admission clinical risk assessment is carried out by a registered health practitioner for that patient before admission; and  (b) the following matters are recorded in writing, not less than 24 hours before admission—   1. the matters considered and assessed by the registered health practitioner as part of the pre-admission clinical risk assessment; 2. the results of the pre-admission clinical risk assessment; 3. the name and signature of the registered health practitioner carrying out the pre-admission clinical risk assessment; and   (c) the health service for which the patient is admitted is assessed in relation to the scope of practice of the registered health practitioner who will provide the health service to that patient. | Admission policy  Admission criteria/Exclusion Criteria  Pre-admission health questionnaire  Patient admission pack from pre-admission to discharge (ie templates and forms)  Skills and qualifications of person responsible for pre-admission assessment?  Escalation process and documentation if risk identified?  Admission/exclusion criteria - consider:   * Complexity and level of care required:   Comorbidities  BMI and weight  Likelihood of deterioration and resources to manage  Age limit  ASA score  Mental status  Infection risks  Availability of equipment  Activities of daily living  Staff with appropriate skills  Discharge destination |  |
| **26 Pre-presentation assessment**  **(applicable to mobile health services)**  The proprietor must ensure that for each non-emergency patient provided with a health service by the facility but is not admitted—  (a) a pre-presentation clinical risk assessment is carried out by a registered health practitioner; and  (b) the following matters are recorded in writing, not less than 24 hours before the health service is provided—   1. the matters considered and assessed by the registered health practitioner as part of the pre-presentation clinical risk assessment; 2. the results of the pre-presentation clinical risk assessment; 3. the name and signature of the registered health practitioner carrying out the pre-presentation clinical risk assessment; and   (c) the health service for which the patient presents is assessed in relation to the scope of practice of the registered health practitioner who will provide the health service to that patient. |  |  |
| **27 Clinical** **record must be created and updated**   1. as soon as practicable after patient admission 2. the clinical record is updated whenever a patient receives a health service |  |  |
| **28 Information to be included in clinical record**  Must include –   1. Patients UR number 2. Name, address, date of birth, gender 3. nominated person contact details 4. relevant clinical details    1. clinical history on admission    2. progress notes    3. meds    4. allergies or drug sensitivities    5. current medication    6. pre-procedure assessment in accordance with reg. 25    7. results of diagnostic tests. 5. If procedure carried out the following info 6. Consent for procedure and anaesthesia 7. date of procedure 8. names and signatures of practitioners carrying out procedure 9. type of procedure 10. pre-procedure checklist 11. drug administered & dosage 12. record of monitoring 13. IV fluids 14. procedure room report including any findings 15. final diagnosis on discharge. |  |  |
| **45 Patient Admission and Discharge Records**  (a) the prescribed manner is in writing; and  (b) the prescribed period is 7 years; and  (c) the prescribed particulars are—  (i) the unit record number of the patient;  (ii) the full name of the patient;  (iii) the sex of the patient;  (iv) the address and telephone number of the patient;  (v) the patient's date of birth;  (vi) the date of the patient's admission and discharge;  (vii) a description of care received and the status of the patient at discharge;  (viii) if the patient is transferred to another health service establishment or health care agency, the name of that establishment or agency and the reason for the transfer. |  |  |
| **29 Means of identifying patient**  ID band or photo attached to clinical record |  |  |
| **30 Identification of infants**  2 ID bands – surname of infant, full name of mother, UR number of mother |  |  |
| **47 Surgical Procedure Register**   1. Date and time of procedure 2. UR number, 3. Name, sex, date of birth 4. Nature of procedure 5. name of practitioner and assistant 6. anaesthetist and assistant 7. attending clinical staff 8. remarks about outcome 9. any complications |  |  |
| **37 Reversal agents must be available**  If providing anaesthesia or sedation |  |  |
| **48 Birth Register**  Record must contain:   1. Date and time of birth 2. name of mother 3. UR number of mother 4. sex of infant 5. all staff in attendance at birth.   Required to keep for 25 years |  |  |
| **31 Respect, dignity and privacy**  (a) is treated with dignity and respect, and with due regard to gender identity, religious beliefs and ethnic and cultural practices; and  (b) is given privacy; and  (c) is not subjected to unusual routines, particularly with respect to the timing of meals and hygiene procedures, unless the routines are for the benefit of the patient |  |  |
| **36 Needs of patient must be met**  The proprietor of a health service establishment must take reasonable steps to ensure that the needs of patients are met promptly and effectively by nursing staff and other professionally competent registered health practitioners. |  |  |
| **43 Information provided to patient transport**  Patient transport provided with written handover and copy of advance care directive if applicable |  |  |
| **44 Discharge information to be given to patients**  Provide to patient:   1. Name and contact details in writing of whom to contact for post procedural advice 2. Copy of discharge summary and summary to GP (or patient to give to GP)   Discharge summary to include –   1. name of patient 2. Date of birth 3. description of treatment patient received 4. post-discharge instruction for patient care 5. itemised list of new meds & changes to regular prescribed meds,   if patient admitted overnight, a list, summary or statement re: unchanged, regular prescribed meds |  |  |
| Infection Control | | |
| **REGULATION** | **EVIDENCE** | **Department of Health Use only** |
| **56 Infection Control Management Plan**  Must provide for surveillance, prevention and control of infection at HSE  (a) state its objectives;  (b) identify and assess all the infection risks specific to the health service establishment which the proprietor knows, or can reasonably be expected to know, exists or may exist, and state how these risks are to be minimised;  (c) provide for an ongoing infection control education program for the staff of the health service establishment;  (d) state the particulars of training for persons who provide services at the health service establishment that involve infection control risks;  (e) set out how the proprietor will monitor and review the implementation and effectiveness of the plan. | Infection Control Management Plan  Audit Schedule  Staff training |  |
| Premises and Equipment | | |
| **REGULATION** | **EVIDENCE** | **Department of Health Use only** |
| **50 Identification of rooms**  Each room in which beds or recovery chairs are provided for the accommodation of patients is clearly identified at the entrance to that room by a sign stating—  (a) the letter or number of that room; and  (b) the number of beds and recovery chairs ordinarily in that room. |  |  |
| **51 Communications**  (1) The proprietor of a health service establishment (other than a health service establishment which provides health services solely at premises other than the premises for which it is registered) must ensure that an effective electronic communication system is provided and kept operational at the health service establishment.  (2) For the purposes of subregulation (1), an electronic communication system must—  (a) enable patients and staff to summon assistance; and  (b) enable calls to be made from—  (i) each bed;  (ii) any recovery chair in a recovery room;  (iii) each toilet, shower or bath or other facility used for the bathing of patients;  (iv) any common room, recreational or rest area or other place where patient care is provided. |  |  |
| **52 Repair and cleanliness of premises**  Must ensure that the premises are kept—  (a) in a clean and hygienic condition; and  (b) in a proper state of repair; and  (c) free of hazards or the accumulation of materials which may become offensive, injurious to health or likely to facilitate the outbreak of fire |  |  |
| **53 Suitability and cleanliness of facilities, equipment, furnishings and fittings**  (1) Must ensure that facilities, equipment, furnishings and fittings at the health service establishment are suitable for the kind or kinds of health services being provided by the health service establishment.  (2) Must ensure that facilities, equipment, furnishings and fittings at the health service establishment are—  (a) kept in a proper state of repair and maintained in good working order; and  (b) kept in a clean and hygienic condition. | Please advise how equipment requirements have been assessed eg. against ANZCA guidelines, ACORN standards, visits to other facilities. |  |
| **54 Premises, staff and equipment outside health service establishment**  For the purpose of ensuring the quality and safety of health services provided by a health service establishment at premises other than the premises for which it is registered, the proprietor of the health service establishment must ensure that—  (a) those other premises are suitable for the provision of safe patient care; and  (b) persons with appropriate training and experience provide those health services; and  (c) the equipment used to provide those health services is suitable for the type of health services provided. |  |  |
| **55 Evacuation plan**  (a) an evacuation plan for all patients and members of staff at the health service establishment is prepared; and  (b) the evacuation plan is displayed in a prominent position at the entrance foyer or reception area of the health service establishment and in each common room, recreational or rest area or other place where patient care is provided; and  (c) all staff are trained in its implementation. |  |  |
| **57 Information to be prominently displayed**  At foyer/main reception:   1. Certificate of registration 2. Certificate of accreditation 3. Name of DON, CEO, MD   Name and contact number of complaints officer |  |  |
| **49 Drugs and Poisons permit**   1. The proprietor of the health service establishment is required to hold a permit issued under section 19 of the **Drugs, Poisons and Controlled Substances Act 1981** by which the proprietor is authorised under section 20(3) of that Act to purchase or otherwise obtain certain poisons or controlled substances for the provision of health services. 2. Sub regulation does not apply to –    1. Proprietor not required to purchase or otherwise obtain of any poisons or controlled substances, other than a patient's own medicine, for the provision of those health services e.g. AOD withdrawal and dialysis.    2. Proprietor of a health service -       1. Provided solely at an unregistered premises e.g. mobile anaesthetic service at dental clinic       2. Where at those premises only 1 medical practitioner provides the health services. | Advise application status |  |

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