

# **Health Services (Private Hospitals and Day Procedure Centres) Amendment Regulations 2018**

## **Introduction**

In late 2017, the Department of Health and Human Services (the department) consulted publicly on proposed amendments to the *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013* (the Regulations) through a discussion paper. The department received 34 responses from medical practitioners, professional colleges, associations, private hospital groups, and day procedure centres. The draft *Health Services (Private Hospitals and Day Procedure Centres) Amendment Regulations 2018* (the amending Regulations) have been developed after consideration of all submissions.

This document has been written to accompany the amending Regulations for a final round of targeted consultation with the sector before they are made on 1 July 2018.

## Prescribed Services and other definitions

The Regulations define medical, surgical and speciality health services, and prescribe a list of speciality health services that must be undertaken in private hospitals and registered day procedure centres. These are procedures that, due their complexity and associated risk, may not be undertaken in an unregistered premises.

Currently, the *Health Services Act 1988* (the Act) exempts premises where medical, surgical or speciality health services are not the premises' 'major activity' from registration as a private hospital or day procedure centre. The *Health Legislation Amendment (Quality and Safety) Act 2017* which takes effect on 1 July 2018 repeals this provision.

## Definitions

This section aims to refine the definitions for medical, surgical and speciality health services. With the removal of the 'major activity' provision in the Act, it is necessary to revise the definitions of medical health services, surgical health services, and speciality health services in the Regulations. In considering these changes, it is important that procedures associated with a higher patient safety risk fall within scope of the legislation but that minor surgical procedures routinely and safely carried out by general practitioners, dentists and specialists in consultant rooms remain exempt.

The list of speciality health services has also been revised. Since the list was originally generated, some services included on this list now have new targeted regulatory oversight and for others there is little evidence to justify regulatory oversight. Some procedures currently listed to be undertaken in day procedure centres are not suitable to be carried out in those types of premises. At the same time, new procedures have evolved which are not currently listed. Some of these procedures carry a high patient safety risk and should only be performed at registered premises.

## Medical Services

The definition of medical health services, requires revision to accommodate and support the amendments to the Act to manage patient safety.

The new definition of *medical health services* within the draft Regulations, is as follows:

***Medical Health Services*** means health services provided to a patient by a registered medical practitioner that involve diagnosis and treatment and either require-

(a) require nursing supervision or care; or

(b) require the use of anaesthesia;

or both, but does not include emergency stabilisation treatment.

In the new definition, the term 'non-operative' has been removed from the definition. Section (a) remains the same and section (b) has been added. This section reflects the addition of anaesthesia (including intravenous sedation) as a speciality health service to the Regulations. Also, a phrase following section (c) has been added. By adding anaesthesia to the listed speciality services, it is necessary to ensure there is no unintended consequence for emergency stabilisation treatment. Appropriate emergency stabilisation treatment must be permitted to occur in unregulated premises, such as general practitioners' consulting rooms. This is particularly important for patients in rural

areas where, for example, a patient may present in significant pain with a broken arm and require emergency stabilisation treatment while waiting for an ambulance transfer to hospital that may be an hour or more away. Therefore, it is necessary to define emergency stabilisation treatment.

The draft definition is: “**Emergency Stabilisation Treatment**: is where a patient requires immediate on-site treatment to stabilise and manage a serious or a life threatening condition whilst awaiting transport to an appropriate health service”.

With the removal of ‘major activity’ from the Act, general practitioners, dentists and specialists are no longer exempt from the Regulations when they perform prescribed services of any kind in their consulting rooms. Procedures using safe doses of local anaesthesia will be permitted to continue in unregistered premises. This provision should exempt practitioners undertaking minor procedures safely in their consulting rooms from the Act. The amended Regulations will impact practitioners who occasionally undertook services of a prescribed kind in their consulting rooms, and were exempt from the Act because these infrequent procedures were not considered a ‘major activity’. These health practitioners will now be required to undertake these services in a registered premises.

Practitioners performing medical health services, regardless of the frequency of these services, will have the option to discontinue provision of medical health services in their rooms and be credentialed at a registered premises; or to upgrade their premises to meet current legislative requirements.

## Surgical health services

The definition of surgical health services is redefined for the same reasons outlined above for medical health services.

The definition of *surgical health services* within the draft Regulations is:

**Surgical Health Services** means health services provided by a registered medical practitioner, registered dental practitioner, registered medical radiation practitioner, or a registered podiatrist that involve the use of surgical instruments and an operating theatre, procedure room, or treatment room, and require one or more of—

- a) the use of general anaesthesia;
- b) the attendance of one or more other registered health practitioner or;
- c) post operative observation of the patient by nursing staff;

but does not include emergency stabilisation treatment.

As outlined above, surgical health services that are performed infrequently would no longer be exempt from the Act and will be required to be performed in a registered premises. Only procedures using safe doses of local anaesthesia will be permitted to be performed in unregistered premises. This provision should exempt medical practitioners who safely perform minor procedures within their consulting rooms from the Act, in the same way as ‘major activity’ used to.

Health practitioners performing surgical health services, regardless of the frequency of these services, will have the option to discontinue provision of surgical health services in their rooms and

be credentialed at a registered premises; or to upgrade their premises to meet legislative requirements.

In response to the discussion paper, there was wide support for the proposed definition of surgical health services.

## Speciality health services

This section describes the proposed changes to the list of speciality health services in the Regulations. Services that carry a higher patient safety risk will be added to the list, and some services will be removed.

There are currently 13 speciality health services listed for private hospitals and 11 for day procedure centres. It is acknowledged that with any speciality area, there is a range of complexity and risk depending on the procedure, hence this is an imperfect approach. It is not practical, however, to list each individual high risk sub speciality or procedure.

Speciality health services are a subset of medical and surgical health services that are associated with higher risk. Before the department registers a private hospital or day procedure centre to provide any speciality health service, the department must be satisfied that the premises has the capacity and capability to provide the service in a safe manner. If a premises is already registered with the department and decides to add a new speciality health service to its operations, assessment by the department to ensure safe service provision will still be required.

***Speciality Health Services*** means health services that are ordinarily undertaken only by, or under the supervision of, a registered medical practitioner, registered dental practitioner, registered medical radiation practitioner, or a registered podiatrist that require either

(a) the use of specialist equipment; or

(b) the area in which the services are provided to be fitted out specifically for those kinds of services;

and are prescribed speciality health service in listed in either regulation 6 or regulation 7 or both (list of speciality health services).

The term *admission* has been removed from the definition of a speciality health services as this does not determine whether a service is a speciality health service. However, before a hospital or a day procedure centre can treat a patient it is necessary to admit the patient, thus *admission* will be defined and new requirements for patient admission will be introduced in the draft Regulations.

To clarify what is intended and to allow for enforcement of the prescribed speciality services listed, the draft Regulations will include a short description of each speciality service.

## Proposed removals

A number of changes are proposed to the listed speciality services of private hospital and day procedure centres.

The department proposes removing the following two listed speciality services for both private hospitals and day procedure centres:

- artificial insemination
- assisted reproductive treatment

The Victorian Assisted Reproductive Treatment Authority (VARTA) regulates providers of artificial insemination and assisted reproductive treatment.

In earlier versions of the Regulations, these two speciality services were listed due to uncertainty over the level of patient risk associated with these procedures. Since then, the sector has matured with advancements in technology and additional specifically targeted legislation.

In other changes, cardiac services, obstetrics, and emergency medicine will be removed from listed prescribed speciality health services in day procedure centres because provision of these services is more safely provided at private hospital premises.

### **Proposed additions**

The following services will be added to the list for prescribed speciality health services for day procedure centres:

anaesthesia, cataract surgery, oocyte retrieval, paediatric services, bariatric procedures and liposuction.

The following services will be added to the list of prescribed speciality health services for private hospitals:

anaesthesia, cataract surgery, paediatric services, oocyte retrieval, bariatric procedures, neurosurgery, alcohol or drug withdrawal (detoxification), cardiac surgery, cardiac catheterisation and liposuction.

### ***Alcohol or other drug withdrawal (detoxification)***

The acute phase of withdrawal from alcohol or other drugs can be dangerous with a risk of death. Safe withdrawal services requires medical practitioner and nursing staff oversight within a suitable environment. Appropriate structures and medical supervision are important components of safe withdrawal services. Therefore, withdrawal services will be required to take place in a private hospital whenever it is provided as a residential care service.

In response to the discussion paper, there was strong support for the regulation of operators providing withdrawal services. Some respondents were concerned with the potential reduction in service provision in remote or low socioeconomic areas due to limited workforce.

Premises that do not register with the department may choose to no longer offer withdrawal services and to simply continue to offer rehabilitation services.

Alcohol and other drug rehabilitation (following completion of withdrawal) is often undertaken using an allied health model of care with limited or no medical supervision. This phase of treatment is considered lower risk. It is not listed as a speciality health service and therefore not required to be undertaken at a registered premises.

## *Anaesthesia*

Anaesthesia and intravenous sedation pose significant patient safety risks. A new definition of anaesthesia will be included to ensure the administration of all anaesthesia and intravenous sedation that carries patient safety risks can be safely managed. Introduction of this definition will mean that the provision of cosmetic surgery, dental surgery, interventional radiology and any other medical or surgical procedure using anything more than a safe dose of local anaesthesia will be required to be carried out in a registered premises.

A definition of intravenous sedation will be included in the draft Regulations, as follows:

**intravenous sedation** means the administration of sedative or pain relieving drugs via a cannula inserted into the vein of a patient

Currently, Victoria is the only state that does not regulate the use of anaesthesia. As office-based surgery has grown over the past two decades, medical practitioners now perform more invasive office-based surgery using general anaesthesia, intravenous sedation and repeated doses of local anaesthetic. This trend has led to increased risks for patient safety.

Practitioners currently performing procedures that use anaesthesia or intravenous sedation may choose to register their premises, be credentialed at a registered premises, employ the services of a mobile health service performing anaesthesia or sedation where appropriate, or cease providing the service.

Feedback from the discussion paper indicated strong support for this regulatory change. It is expected that requiring anaesthesia and intravenous sedation to be undertaken in a registered premises will particularly affect dental practices, interventional radiologists and cosmetic surgeons.

## *Bariatric procedures*

Bariatric procedures are considered high risk because most are surgical procedures and the patient cohort brings certain comorbidities with it. Bariatric patients are inherently obese which can cause complications for surgery, anaesthesia and post-operative recovery. Obesity is also related to a number of other conditions that are risk factors such as sleep apnoea, heart disease, type two diabetes and high blood pressure among others.

As bariatric procedures already take place at registered premises, listing them as a speciality health service would not change practice in the private sector. However, registered premises will now be required to notify the department when bariatric procedures are introduced and apply for a variation of registration. Importantly, it would enable the department to verify that services that are introducing bariatric procedures have the requisite procedures and appropriately trained staff in place before the service commences.

## *Cardiac surgery and cardiac catheterisation*

Previously cardiac services incorporated cardiac surgery and catheterisation. The amended draft Regulations will separate cardiac services into cardiac catheterisation and cardiac surgery for the purpose of identifying appropriate premises for the delivery of these services. These changes are not expected to impact current service provision within the sector.

### *Cataract surgery*

The current Regulations for eye surgery can be interpreted to include lasers as surgical instruments (“laser device that disrupts the integrity of epithelial tissue or stroma”) and therefore, some have interpreted this to include what is commonly called, “laser eye surgery”. Following consultation with the Royal Australian and New Zealand College of Ophthalmologists (the college), the department understands eye surgeries that use laser technology is a broad category and is not accurately described by the term “laser eye surgery”. Furthermore, some eye surgery using laser technology does not breach external epithelial, while others do. The department understands that multiple types of lasers are used within ophthalmology for the treatment of eye disorders.

The college advises that refractive corneal laser surgery (Laser-Assisted In-Situ Keratomileusis) presents a low patient safety risk and any unsatisfactory outcomes can be corrected with further treatment. The risk of infections is also low. There is limited international data available but the available reports support the view of the college. Consultation with a medical indemnity insurer and the Health Complaints Commissioner confirmed this view. Safer Care Victoria has also advised that regulatory oversight of refractive corneal laser surgery premises is not a priority. No other state or territory requires premises providing refractive corneal laser surgery to be registered.

The department has never registered health premises providing only refractive corneal laser surgery. Premises that provide cataract surgery, however, have been registered with the department. This is largely due to the fact that cataract procedures attract Medical Benefits Scheme funding, which can only be accessed by registered premises. However the requirement for regulation should be based on clinical processes and patient safety risk rather than accessing health insurance funding. The college agrees that cataract surgery should be undertaken only at registered premises due to the greater risk to patient safety associated with this more invasive procedure.

### *Neurosurgery*

Listing neurosurgery as a speciality health service would not change practice in the private sector. Through the variation of registration requirement, the department would have oversight of the provision of neurosurgery across Victoria. Importantly, it would ensure that premises providing neurosurgical services meet legislative requirements related to patient safety and service provision before such services are commenced.

### *Oocyte retrieval*

Currently oocyte (egg) retrieval must be undertaken in a registered premises because it is a procedure that falls under the speciality health services of artificial insemination and assisted reproductive treatment. Unlike artificial insemination and assisted reproductive treatment, patient safety risks are associated with oocyte retrieval.

In consultation with the sector, including VARTA and the Royal Australian and New Zealand College of Gynaecologists and Obstetricians, the department noted significant support for the continued regulation of oocyte retrieval once artificial insemination and assisted reproductive treatment are removed from the listed speciality health services.

In follow up consultation with expert groups, the department understands that 95 per cent of oocyte retrieval procedures are performed through transvaginal oocyte retrieval. It is possible, though not

common practice, to undertake this procedure safely using only local anaesthesia. It is also unclear if this procedure would meet the definition for surgery. To avoid any possible ambiguity as to whether this procedure should be performed in a registered premises, the department will add oocyte retrieval to the list of speciality services.

### *Paediatric services*

Currently, paediatric services are not speciality health services in Victoria. Paediatric services require a specific speciality skill set and escalation procedures. Furthermore, it may be important to identify premises providing paediatric services due to the introduction of the Child Safe Standards and the Reportable Conduct Scheme requirements arising out of the Betrayal of Trust report.

As medical and surgical paediatric services are already required to be undertaken in a registered premises, including paediatric services on the speciality health service would not change practice in the private sector. With this change, the department would simply receive notification of where paediatric services are performed when premises apply for a variation of registration. Importantly, it would enable the department to ensure that premises providing paediatric services have the requisite procedures in place and appropriately trained staff before the service commences.

### *Liposuction*

Currently liposuction is not a regulated procedure in Victoria. In recent years, both New South Wales and Queensland have passed legislation that requires any procedure during which more than 2.5 litres of lipoaspirate is removed or transferred be undertaken in a registered premises. Clinical advice received during the consultation period was that 2.5 litres as a threshold is not low enough to capture risk associated with this procedure. A lower threshold of 200 ml was suggested.

Responses to the discussion paper showed strong support for the regulation. There was some difference in opinion about the appropriate threshold volume of lipoaspirate that must be carried out in a registered premises. Most agreed with the volume of 200 ml. It should be noted that some of the larger procedures would be required to be undertaken in a registered premises due to the use of anaesthesia or intravenous sedation.

Several cosmetic surgeons commented on the fact that there are many factors that contribute to the safety of liposuction procedures. These are all important factors, however, they cannot be regulated if they occur in an unregistered premises. Requiring procedures removing more than 200mls of lipoaspirate to be conducted at registered premises would allow the department to regulatory oversight to ensure patient safety

Additionally, the Australian Society of Plastic Surgeons recently surveyed their members with a range of threshold levels at which liposuction should be carried out in a registered premises. The overwhelming response was that the threshold level should be set at 200ml.

### **Definitions of Speciality Health Services**

The definitions to be included in the draft Regulations are listed below in alphabetical order:

- **alcohol or other drug withdrawal (detoxification)** – treatment and care of patients undergoing the acute phase of withdrawal from alcohol and/or other drugs on which they are physically dependent, involving medical supervision where the patient is admitted overnight

- **anaesthesia** – the treatment involving the administration of general anaesthesia, major regional anaesthetic blocks, intravenous sedation or high doses of local anaesthetic that have the potential to create systemic toxicity excluding dental nerve blocks.
- **bariatric procedures** – treatment that promotes weight loss by changing the digestive system's anatomy or inserting a device that, limits the amount of food that can be eaten or regulates appetite
- **cardiac catheterisation** – procedures involving the passing of a catheter, or other instrument, through a major blood vessel and into the heart for a diagnostic or therapeutic purpose
- **cardiac surgery** – surgery within or on the heart
- **cataract surgery** – a procedure to replace the lens of the eye
- **emergency medicine** – the treatment of patients injured in accidents, or those suffering from medical emergencies, through the provision of resuscitation, medical and surgical treatment and use of life support systems
- **endoscopy** – treatment using a flexible, hollow endoscope that can accommodate the passage of an instrument to examine the upper or lower gastrointestinal tract
- **intensive care** – the observation, care and treatment of patients with life threatening or potentially life threatening illnesses, injuries or complications, from which recovery is possible, in a premises that is specifically staffed and equipped for that purpose
- **liposuction** – any procedure involving the transfer or removal of fat of more than 200 ml of lipoaspirate
- **mental health services** – treatment of mental or emotional illness symptoms, conditions or disorders
- **neonatal services** – the care and treatment of a baby under the age of 28 days
- **neurosurgery** – surgical treatment of any portion of the nervous system including the brain, spinal cord, peripheral nerves, and extra-cranial cerebrovascular system
- **obstetrics** – antenatal care related to child birth, assistance and care associated with child birth, surgical intervention in achieving childbirth and care and assistance of a mother admitted to the premises immediately after childbirth
- **oncology (chemotherapy)** – treatments using parenteral administration of one or more cytotoxic agents
- **oncology (radiation therapy)** – the use of high-energy radiation to kill cancer cells and diminish tumors
- **oocyte retrieval** – the removal of oocytes from an ovary
- **paediatric services** – the care and treatment of patients between the ages of 28 days and 18 years
- **renal dialysis** – (haemodialysis) treatment that uses a dialyzer machine to remove waste and excess water from the blood
- **specialist rehabilitation services** – rehabilitation and specialised physical rehabilitation

### **Additional Definitions**

It is necessary to define a number of other terms to provide clarity in the Regulations. As the new regulations to set out minimum requirements for admission of patients it is necessary to define admission.

The draft definition is:

**admission** means where a patient is formally admitted to a registered health service on the orders of a registered medical practitioner, registered dental practitioner, registered medical radiation practitioner, or a registered podiatrist and requires an admission procedure with completion of registration documents and a formal acceptance of the patient by the health service.

The definition of *Registered Nurse* will be amended and a definition of *Registered Midwife* included to align with the National Law and AHPRA.

## Governance

Good governance is essential to ensuring patient safety and quality health care. The current Regulations have very few requirements for the governance of private health premises. The Targeting Zero report recommended that the department should strengthen governance requirements in the private sector to align it more closely with that of the public sector and improve the quality and safety of patient care provided in Victoria.<sup>1</sup> The amendments to the Regulations aim to strengthen these requirements.

## Objectives

The objectives of this section are divided into areas covering premises governance and clinical governance.

The first objective of this section is to strengthen governance in the private health sector by assigning responsibility to the highest level of governance of a premises to ensure patient safety and quality of care through improved governance processes. These will include oversight of the delivery of safe care through documentation of processes including escalation and review processes. Amendments to premises governance will also focus on written rules (by-laws) governing the credentialing process for registered medical practitioners, and determining their scope of practice. **Note:** that the Regulations will refer to by-laws as “rules” as the term by-laws is already used in legislation for another purpose.

The second objective of this section is to improve clinical governance in the private health sector through the introduction of key amendments to the Regulations. These amendments have been designed to ensure safety for patients at critical points during their journey through the private health system.

## Premises Governance

Private hospitals and day procedure centres generally have their own self-regulatory processes set out in their by-laws, policies and procedures. By-laws, the published internal rules of a registered private hospital or day procedure centre, set out the requirements for every medical practitioner working at that premises. For example, private hospitals and day procedure centres undertake credentialing and delineation of scope of practice for all clinical staff, including visiting medical practitioners under their by-laws.

### *Highest level of governance*

The amended Regulations will require the highest level of governance at each premises to be responsible for the safety and quality of patient care at the premises including determining the scope of practice of the premises and key systems and practices required to deliver safe, effective, patient-centred care.

---

<sup>1</sup> Department of Health and Human Services 2016, *Targeting zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care. Report of the Review of Hospital Safety and Quality Assurance in Victoria*, State of Victoria, Melbourne.

Examples of matters the highest level of governance at each premises will be expected to take responsibility for are:

- premises oversight of clinical governance
- documented policy that determines the scope of practice of the premises
- oversight of medical practitioners' ongoing credentialing and scope of practice processes
- ensuring patient quality and safety is a standing agenda item at each meeting of the highest level of governance
- oversight of the quality and safety culture across the premises, including documented patient experience and staff safety culture reporting.

Responses from the discussion paper showed overall support for the concept of a highest level of governance to achieve transparency, and oversight of medical practitioners.

### *Independent member: Highest level of governance*

To ensure robust, ongoing safety and quality of care throughout the private sector, the Regulations will require that each premises' highest level of governance include a clinician (registered medical practitioner) who is independent of the premises. Inclusion of the Director of Nursing, while important to represent nursing activities of the premises, will be at the discretion of proprietors.

The key role of the independent clinician is to provide neutral oversight of quality and safety matters considered by the highest level of governance such as clinical reviews, formal credentialing processes for the purpose of ensuring competence, performance, and professional suitability to provide safe, high quality health care services. It is not necessary for the independent clinician to be involved in financial matters of the premises.

In response to the discussion paper, many supported a premises-based highest level of governance and proposals to include an independent medical practitioner on the premises' highest level of governance. Safer Care Victoria agrees that an independent medical practitioner is required at the highest level of governance to ensure robust review of quality and safety and to ensure consistency with similar requirements being imposed on the boards of public health services.

To comply with this amendment, a hospital or day procedure centre group could use independent practitioners from other sites within the group. This mirrors processes within the public health services. Stand-alone premises would have the options of partnering with other premises (public or private) or engaging a medical practitioner for the express purpose of participating at the highest level of governance for an agreed fee. Where a premises is run by a sole operator medical practitioner, an additional independent registered medical practitioner will be required to be part of the highest level of governance.

### *Scope of practice and credentialing*

All registered premises are understood to have credentialing processes in place. The Regulations will require all registered health services implement a three-year credentialing cycle for all registered medical practitioners, a registered dental practitioners, registered medical radiation practitioners, or a registered podiatrists (employed or visiting) to align with the public sector requirements.

Amendments to the Regulations will require the highest level of governance to have oversight of the credentialing processes and defining the scope of practice of every registered medical practitioner operating at the premises. Proprietors will be responsible for ensuring that all registered medical practitioners working at that premises are credentialed and have their scope of practice defined. This forms part of a wider organisational quality and risk-management system designed to protect patients.

To ensure safety of patients, it is important that they only be admitted to premises where the treating clinician has an appropriate scope of practice. The department however, is aware of variation in processes in communicating the scope of practice of a credentialed medical practitioner to admissions and theatre staff. Therefore, the amended Regulations will require that the proprietor ensure all premises admissions are for treatment that is within the treating medical practitioner's scope of practice.

Premises will be required to have a documented policy covering processes of credentialing and defining the scope of practice of medical practitioners providing care at the premises, including practitioners who are temporarily credentialed. This is also part of the National Safety and Quality Health Service Standards.

Feedback on the discussion paper recommended partnership models to assist smaller premises to meet credentialing requirements. The department will also produce model by-laws to support all operators in meeting credentialing requirements.

### *Director of Nursing*

It is imperative that the highest level of nursing and midwifery governance must rest with the person appointed to the position of Director of Nursing (DON), in partnership with the Medical Director (where appointed). The current Regulations require that each registered premises appoint a DON and nominate a suitably qualified and experienced delegate to act in that capacity during periods of absence, incapacity or vacancy of the DON.

The Regulations will extend this requirement of the proprietor to ensure that a DON has at least five years' clinical practice experience as a nurse including at least 12 months' experience in nursing management.

Respondents to the discussion paper generally agreed to strengthening experience requirements for the DON position. It was generally agreed that registered nurses and/or midwives should consolidate their clinical skills before developing their management skills or being promoted to executive positions, such as the DON or lead midwife.

### *Senior nurse on site*

The amendments to the Regulations will require that a designated senior registered nurse must be on site at a registered premises when a surgical list is underway and while the initial stage (Stage 1) post-operative patient care is being provided when the DON is not present. The senior clinical nurse is required to have suitable training and competence in the procedures being undertaken at a premises.

NB: a surgical list is the list of patient cases booked in for surgery that day at a particular registered hospital or day procedure centre. Stage 1 post-operative care is the period where the patient has been moved out of the operating theatre and is regaining consciousness under the supervision of surgeon and nursing staff.

### *Senior midwife oversight of on-site obstetric services*

In circumstances where the DON is not a registered midwife, appointment of a Director of Midwifery was suggested to the department through the public consultation process. However, Safer Care Victoria and the sector advised that the option of mandating a Director of Midwifery to be employed in obstetric hospitals was onerous and not necessary.

The amendments to the Regulations will therefore require premises providing obstetric services to appoint a senior midwife who will be responsible for clinical nursing oversight of maternity and neonatal patients. A senior midwife will have a minimum of three years' clinical and leadership experience. Whenever the senior midwife is not on site and there are maternity or neonatal patients at the premises, the hospital proprietor is required to ensure there is a midwife with suitable training and competence designated as responsible for clinical oversight of those patients.

### *Open Disclosure*

Open disclosure is a response to incidents of patient harm. It is distinct from the statutory duty of candour, recommended in the Targeting Zero report, which is a subset of open disclosure.

Open disclosure operates at both an individual level and a health service level. It is a process in which health care providers communicate with, and support, patients who have been harmed as a result of health care. Open and honest discussion between healthcare providers, patients and families affected by error is considered to be a central feature of high quality and safe patient care. This is evidenced by the implementation of open disclosure policies and guidance internationally.

Most premises will already undertake open disclosure as it is considered best practice. It is also an accreditation requirement for registered health services under the NSQHS Standards which is supported by the Australian Open Disclosure Framework.<sup>2</sup> The amended Regulations will require premises to implement and document their policy for open disclosure. The policy should cover how to have an open discussion with a patient, and the patient's family and carers, of any adverse event that results in harm to the patient. It is expected the policy will reflect the Australian Open Disclosure Framework.

### **Clinical Governance**

The Targeting Zero report found that the health service at the centre of the review (Djerriwarrh health service) had inadequate clinical governance, and was not monitoring and responding to adverse clinical outcomes in a timely manner. This finding triggered a review of clinical governance practices throughout the sector, which generated a number of recommendations.

---

<sup>2</sup> <https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework/>

In response to these recommendations, the amending Regulations will be strengthened with additional requirements intended to ensure the provision a safer environment for patients and health professionals.

### *Drug registers*

Not all registered day procedure centres currently have a health services permit to store and use scheduled poisons (drugs) at the premises. In these cases, they rely on registered medical practitioners to supply the required scheduled drugs directly. Where registered medical practitioners supply the scheduled drugs, these premises generally do not maintain a drug register in the operating theatre or procedure room.

While the drugs given to a patient should be recorded on the patient's record, regulatory inspections by the department have shown that records are not always as complete as they should be and are not always legible. A patient's record may note what he or she was given, but not the discarded drug quantity and not the identification of the drug vial or source container or whether a new vial or container was used for each patient. Should a patient have an adverse reaction as a result of his or her procedure, these gaps in information can make it difficult to identify the cause of the reaction when the matter is investigated.

The amended Regulations will require registered premises to maintain a drugs register in operating theatres and procedure rooms to record what drugs are used in what quantities on which patients, and what drugs are discarded. The registers will also identify all vials or source containers used.

### *Patient Admission*

Documented pre-admission clinical assessments are integral to ensuring that patient risk factors and pre-existing conditions are identified, and planned for, prior to admission. The documented admission process should begin well in advance of the scheduled admission (for elective procedures) with sufficient time for the patient, together with clinical staff, to prepare for the associated risks or consider referral to a more suitable premises. Failure to identify patient risk factors prior to admission can lead to situations in which patients, premises and practitioners are not adequately prepared, and safety and quality may be compromised.

The amended Regulations will require that proprietors of a premises ensure that patients have been evaluated through a formal clinical assessment in advance of their planned admission, to preclude patients at high risk from being treated in a health service unable to support their acuity safely.

The amended Regulations will require that all admissions are treated within the premises' scope of practice and within each registered medical practitioner's scope of practice. Additionally, the amended Regulations will require the proprietor of a registered premises ensure and document that every patient admission for a procedure is cross checked against the treating medical practitioner's defined scope of practice to ensure that the medical practitioner is not undertaking procedures outside the defined scope and to ensure the hospital can safely support the medical practitioner in his or her work.

Responses to the discussion paper were in agreement with the principle of risk reduction through improved admission processes.

## *Discharge*

The information patients receive upon discharge and their experience of follow-up from medical practitioners and hospitals or day procedure centres is variable. Patients are advised to contact their medical practitioner if they have any concerns about their recovery, however this requires patients to self-assess their condition without the benefit of medical training. It does not take into account that patients may not be fully mentally alert or be feeling assertive enough to advocate for their own care. Discharging patients from hospitals and day procedure centres without essential basic information about their procedure, instructions about after care and what to do if they have concerns, puts patients at risk unnecessarily.

To address this risk, the amended Regulations will require that the proprietor of a registered premises ensure that, at discharge, patients are provided with written discharge documentation. A copy of the discharge documentation will also be required to be provided promptly to the patient's nominated general practitioner.

Feedback on the discussion paper strongly supported requiring that patients be given written information upon discharge.

## *Clinical handover for patient transport*

Patient transport between hospitals is part of the patient continuum of care and should be treated in the same way that in-hospital patient care is treated. Within private healthcare premises, patient handover occurs at the end of each shift and when a patient is moved to a new ward or clinical area. The same level of care should apply when a patient is being transported out of a hospital to another premises.

During the development of the *Non-Emergency Patient Transport Regulations 2016*, the department received significant feedback from transport providers that private hospitals did not always provide adequate clinical handovers for patients who were to be transported to another hospital even though it was hospital policy. Breakdown in the transfer of information has been identified as one of the most important contributing factors in serious adverse events and is a major preventable cause of patient harm. As a result, the *Non-Emergency Patient Transport Regulations 2016* now require non-emergency patient transport vehicle crews to request a clinical handover for each patient.

To complete the circle and embed appropriate patient-centred care throughout the health system, the amended Regulations will require a written patient clinical handover to be provided to the patient transport vehicle crew every time a patient is transferred out of a hospital using patient transport.

In response to the discussion paper, there was support for written clinical handover to transport crews as an essential part of the patient's journey. It was pointed out that verbal handover risks non-clinically trained 'non-emergency patient crews' misinterpreting instructions.

## *Rules*

Private hospitals and day procedure centres generally have their own self-regulatory processes set out in their rules, (by-laws)<sup>3</sup> policies and procedures. Rules set out the requirements for every registered medical practitioner treating patients at a premises. They are an integral part of a premises' quality and risk-management systems to facilitate safe, high quality health services. Rules typically contain policies that document the principles of credentialing, define scope of practice of credentialed medical practitioners, govern the premises' relationship with credentialed medical practitioners and include rules for the conduct and obligations of credentialed medical practitioners. The department is aware that smaller operators may not have internal rules in place.

Furthermore, during routine inspections, the department has encountered situations where the rules (by-laws) of a premises are not uniformly enforced. Specifically, some proprietors of private hospitals and day procedure centres claim to have limited or no control over the medical practitioners who are credentialed at their premises as visiting medical practitioners. The department considers this approach to be inconsistent with safe patient care. As a result, the amended Regulations will require that all premises have rules and that the proprietors of health service establishments be responsible for ensuring registered medical practitioners who work at their premises comply with the premises' rules.

In response to the public consultation, there was overall support for the requirement of rules that govern medical practitioners.

## *Evacuation planning*

Hospitals and day procedure centres routinely have patients on site who may be unconscious, non-ambulant and/or cannot walk unassisted. Proprietors of premises have a duty of care to maintain the safety of these patients and comply with WorkSafe Victoria requirements.

In the event of a fire, flood, or other disaster, it is the responsibility of the proprietor to ensure that all patients and staff can be evacuated safely if required. While most premises have evacuation plans, it is not currently a regulatory requirement.

The amended Regulations will require that the proprietor of each registered premises have a current written evacuation plan that applies to all patients and staff of the premises, and that staff are trained in the plan and in its use. Where these premises operate paediatric services, the department will expect that there is the provision of specific speciality skill sets, plans and specialist equipment needed to support the safe evacuation of paediatric patients from the premises.

In consultation with stakeholders, this requirement is recognised as a basic safety measure requiring compliance by all premises. Stakeholders recognise the importance that staff are trained in, and familiar with, the use of the plan.

---

<sup>3</sup> Please note, that the Regulations will refer to by-laws as "rules" as the term by-laws is already used in legislation for another purpose.

## Data

Currently, the department's oversight of the health system is not adequate to detect or anticipate catastrophic failures. The information the department receives and analyses is piecemeal and does not convey a clear picture of the Victorian health system. For this reason, the Targeting Zero report recommends that the private sector reporting requirements are brought in line with that of the public sector so that the whole health system can be monitored for potential risks.<sup>4</sup>

Across the Victorian hospital system, private sector data reporting is comparatively limited when compared to public sector data that is routinely reported to the department. To adequately identify and monitor potential risk situations across Victoria<sup>5</sup> the department relies on analysis of high-quality clinical data provided from both the public and private health sectors. Many tools and data sources necessary for accurate monitoring of patient safety are already in existence but are not currently utilised to their full potential.

The department is cognisant of the burden that data collection places on smaller premises and seeks to collect the minimum data necessary to monitor quality and safety of health care services in Victoria. In consultation with the private health sector, the department has learned that approximately one third of day procedure centres collect and report data to a private benchmarking service that in turn generates benchmark reports on performance. This highlights the willingness of private health services to report data to the department *if* benchmarked feedback is provided. This is an important component of the ideal system proposed in the Targeting Zero report.<sup>6</sup>

Creating a more comprehensive quality and safety monitoring framework for the private sector has its technical and conceptual challenges. Variations in the range and methods of data collected, reporting demands, and reluctance to share commercially sensitive data are all important factors to the framework. Further the premises size, types of services provided, and governance structures all pose challenges that must be addressed.

The purpose of requiring more data reporting from the private health sector is to enable the department to have a better overview of Victorian health care system as a whole so that it can better detect potential risk situations. Not only will the amended Regulations require that additional, necessary data sets be reported, the department will also need to make use of the data it already receives. These two changes would provide the department with a starting point for better identifying potential risks in the private sector of the Victorian health system.

### Data currently reported by premises to the department

The department currently receives data for private hospitals and day procedure centres from the Victorian Admitted Episode Data (VAED) and Victorian Perinatal Data Collection (VPDC) from hospitals that provide obstetric services.

---

<sup>4</sup> *ibid*

<sup>5</sup> Department of Health and Human Services 2016, *Targeting zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care. Report of the Review of Hospital Safety and Quality Assurance in Victoria*, State of Victoria, Melbourne.

<sup>6</sup> *ibid*, page 85.

VAED is a rich dataset that reports demographics, diagnostic and treatment information for every episode of care in public and private hospital, and day procedure centres. VAED data can be used to calculate important safety and quality information including hospital acquired complications (HACS), number of deaths in low mortality diagnostic related groups (DRGs), and readmissions.

The department also receives Victorian Perinatal Data Collection (VPDC). This collection is a requirement under the *Public Health and Wellbeing Act* and is used to analyse comprehensive information on the health of mothers and babies, in order to contribute to improvements in their health. It includes all live births and still births after 20 weeks of gestation as well as information on obstetric conditions, procedures and outcomes, neonatal morbidity and congenital anomalies.

The department is working with the Victorian Agency for Health Information (VAHI) on a process for analysing these datasets for the private sector.

### **Proposed data collection**

There are a number data sets that are currently reported to the department by public health services but not private health premises. Of these, six data sets considered to add the most value to the department's oversight of the Victorian health system were put forward for potential inclusion in an extensive consultation with the sector and Safer Care Victoria.

The data sets that will be required to be reported to the department are: Sentinel Events, Victorian Healthcare Associated Infection Surveillance System (VICNISS), Victorian Emergency Management Data (VEMD), and Electroconvulsive Therapy Data.

Patient experience and staff safety culture data will be required to be collected by registered health services, however not reported to the department. The data will be required to be considered by the highest level of premises governance and made available for the department to review during inspections.

### **Sentinel Events**

Sentinel events reflect some of the most serious adverse events in patient care and result in death or serious harm to the patient. These are events that should never happen.

The sentinel events program in the public sector was designed to monitor and investigate sentinel events with the goal of identifying and addressing potential deficiencies in the health care system and to prevent such deficiencies in other services by sharing lessons learned.<sup>7</sup> Reporting sentinel events is mandatory for all public hospitals in Victoria but has not been required of the private health sector.

---

<sup>7</sup> Holmstrom, AR, Airaksinen, M, Weiss, M, Wuliji T, Chan XH & Laaksonen R 2012, 'National and local medication error reporting systems: a survey of practices in 16 countries.' *Journal of Patient Safety*, vol 8 [4], pp. 165-76.

Registered private health premises will be required to report sentinel events to the department as per the Victorian Sentinel Events Program.<sup>8</sup> This program aligns with the criteria for reporting sentinel events set out by the Australian Commission on Safety and Quality in Health Care.<sup>9</sup>

Responses to the discussion paper showed wide support for sentinel event reporting.

#### ***Victorian Hospital-acquired Infection Surveillance System (VICNISS) data***

The Victorian Hospital-acquired Infection Surveillance System (VICNISS) collates and analyses data on healthcare associated infections in the public sector and reports data back to participants and to the department. The purpose of this data collection is to monitor hospital acquired infection.

Currently 18 private hospitals voluntarily contribute to the VICNISS dataset. Consultation with the private hospital sector showed great support for reporting infection surveillance data to the department. Hospitals who participated and others who supported the inclusion of this data set, did so because they felt that regulatory oversight was important and useful. Many of the respondents said they would be motivated by benchmarking reports to be provided by the department. Safer Care Victoria has also advised the department that the collection of VICNISS data is imperative in ensuring quality of care and safety for patients in the Victorian private health sector.

VICNISS reporting would not only allow the department to have an oversight of infection control in the private health sector in Victoria and identify areas of risk, it would also make it possible to share learnings across the sector.

Day procedure centres would not be required to report VICNISS data. A large portion of the VICNISS data set measures post-operative infections or infections related to intensive care. Day procedure centres would not be able to contribute meaningfully as they have no ability to monitor post-operative infections because the patients are discharged on the day of surgery.

#### ***Victorian Emergency Minimum Data (VEMD)***

The Victorian Emergency Minimum Dataset (VEMD) comprises de-identified demographic, administrative and clinical data on presentations at Victorian public hospitals with designated emergency departments. The data is used to help plan health services, undertake clinical research and improve quality of care. The department intends to collect this dataset from all private hospitals with emergency departments to provide a comprehensive overview of the emergency medical service system in Victoria.

Currently no private hospitals report VEMD to the department. A data vacuum of private emergency departments presents a potential risk to patient safety because the department does not have adequate oversight. Furthermore, the department lacks knowledge of the capacity of the private emergency departments necessary to develop state-wide emergency planning, such as for thunderstorm asthma.

---

<sup>8</sup> <https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/sentinel-event-program>

<sup>9</sup> <https://www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list/>

The proposed Regulations would require the ten private hospitals that currently operate an all-hours emergency department to report VEMD to the department. These premises would be required to report only selected VEMD data variables (approximately 22 items) as several data points are used for public health sector research purposes and are therefore not relevant.

Feedback from the discussion paper demonstrated moderate agreement to require private hospital emergency departments to report VEMD, aligned with public emergency departments. Resourcing and competition issues were identified as potential barriers to compliance with this data collection.

### *Electroconvulsive therapy*

Electroconvulsive therapy (ECT) is an effective treatment for some mental illnesses, particularly severe depression and other mood disorders.

When the *Mental Health Act 2014* was reviewed, the requirement for the Chief Psychiatrist to collect ECT data from private hospitals was removed and as a result private hospitals discontinued the supply of data. It is proposed to realign with the public hospital reporting requirements to provide the department with more comprehensive oversight of ECT treatment undertaken in Victoria. Private health premises providing ECT will be required to report a minimal dataset consisting of approximately 19 items.

Feedback from the discussion paper was mixed. Some were in favour of re-aligning the private reporting with the public sector. Other respondents questioned the value of the data, perhaps due to lack of understanding as the specific data items were not published in the discussion paper and those who do not work in the area of ECT would not be familiar with them. A large majority of hospitals providing ECT treatment supported the reporting of ECT data to the department for purposes of oversight. The Chief Psychiatrist's Office supports the reporting of ECT data.

### *Patient Experience*

It is a widely accepted fact that reported patient experience is an integral component of the assessment of any health system.<sup>10</sup> In Victoria, private premises should all collect patient experience data as it is part of the National Safety and Quality in Health Service Standards 2.<sup>11</sup>

Most premises already collect patient experience data. The Regulations will require all private hospitals and day procedure centres collect responses to questions on patient safety. After collecting the data, the premises will be required to analyse the data and review it at their highest level of governance. Actions taken in response to issues raised by the data will be documented. Both the data and the documented decisions will be required to be made available to the department upon inspection.

### *Staff Safety Culture*

As we know from the international literature, staff safety culture is recognised as vital factor in ensuring patient safety.<sup>12 13 14</sup> Staff safety culture refers to a shared priority of patient safety among

---

<sup>10</sup> Griffiths, A & Leaver, MP 2017, 'Wisdom of patients: predicting the quality of care using aggregated patient feedback' *British Medical Journal of Quality and Safety*, pp. 1-9.

<sup>11</sup> <https://www.safetyandquality.gov.au/publications/nsqhs-standards-fact-sheet-standard-2-partnering-with-consumers/>

staff, which underpins a set of attitudes and norms. These drive the behaviours that lead to better patient safety outcomes. A principal component of staff safety culture is support for reporting errors and near misses and a willingness to learn from mistakes and solve safety problems.<sup>15</sup> The question that must be addressed is: Does the health premises have a culture in which staff feel supported when reporting problems?

The Regulations will require all private hospitals and day procedure centres analyse the results of the survey, review the analysis at the highest level of governance and document any resulting actions arising from the review. As most premises already collect staff satisfaction surveys on an annual basis, staff safety culture questions could simply be added to the existing questionnaire.

In response to the discussion paper, there was overall support from the sector to collect and review staff safety culture within the hospital as it informs quality improvement and necessitates an organisational response to address any deficiencies. Most people who responded supported collecting the same data to be able to compare like with like across the state health system. Most people who responded did not support reporting the information to the department. Perceived barriers include concerns about workplace or employment repercussions, perceived lack of value, administrative burden, and concerns about competition and the risks of public reporting.

---

<sup>12</sup> Lorenzini, E, Oelke, ND, Marck, PB & Dall'Agnol, MD 2017 'Researching safety culture: deliberative dialogue with a restorative lens', *International Journal for Quality in Health Care*, pp. 1-5.

<sup>13</sup> Agency for Healthcare Research and Quality. 'Patient Safety Primer: Safety Culture', <https://psnet.ahrq.gov/primers/primer/5/safety-culture>

<sup>14</sup> Singer, S, Lin, S, Falwell, A, Gaba, D & Baker, L 2009, 'Relationship of safety climate and safety performance in hospitals', *Health Services Research*, vol 44, pp. 399-421.

<sup>15</sup> Lorenzini, E, Oelke, ND, Marck, PB & Dall'Agnol, MD 2017 'Researching safety culture: deliberative dialogue with a restorative lens', *International Journal for Quality in Health Care*, pp. 1-5.

## Registration Fees

Government policy is that regulatory services should be provided on a full cost recovery basis. Historically, this has not been the case for private hospital regulation and so this opportunity is being taken to rectify the situation and apply government policy. The department will move to a full cost recovery model to align with government policy. Currently, the Regulations require a day procedure centre and private hospital to pay:

- an application fee for an approval in principle
- a fee to vary the approval in principle
- an application fee to register or renew the registration of a premises
- an annual fee
- a fee to vary the registration (including transfer the registration).

The registration and registration renewal fees are to be combined with the annual fee so that a single fee is paid on initial registration and then every subsequent two years. These fees will be set at full cost recovery.

### Application for Approval in Principle fees

The new fees to be charged by the department to assess applications for approval in principle will vary according to whether it is a private hospital or a day procedure centre and whether it is a new build or a renovation of an existing premises. Previously, one fee was charged irrespective of the type of premises or whether it was a new build or a renovation. The new fees reflect the actual cost for each option.

The categories and fees will be:

- Building a new private hospital – fee is \$4,622.57
- Renovating an existing private hospital – fee is \$4,129.23
- Building a new day procedure centre – fee is \$4,050.78
- Renovating an existing day procedure centre – fee is \$3,929.57

### Application for Registration and Renewal of Registration

As stated above, the registration fees and the registration renewal fees will be increased to reflect full cost recovery principles and to incorporate the current annual fee.

These registration fee and renewal of registration fee will be set according to how many beds the premises is operating. The new fees are set out in the table below.

### Registration, and Renewal of registration Fees

Number of Beds	Total fee over 2 years	Fee Units
0-26	5,204.52	366
27-50	5,759.10	405
51-75	6,327.90	445
76-100	6,882.48	484
101-150	7,721.46	543
151-200	8,859.06	623
201-300	9,968.22	701
301-400	11,660.40	820
401-500	13,907.16	978
500 or more	16,708.50	1,175

### Hospital Beds distribution

Number of Beds	Distribution	% Distribution
0-26	101	58.38
27-50	19	10.98
51-75	11	6.36
76-100	9	5.20
101-150	13	7.51
151-200	8	4.62
201-300	9	5.20
301-400	1	0.56
401-500	1	0.56
500 or more	1	0.56

The cost of department staff to regulate private hospital sector is \$801,000.

Income in 2016/17 from fees levied on registered premises was \$336,000 which is 42 per cent of the cost to provide the service. This income includes fees from Approval in Principle (AIP), new registrations and variations which need to be excluded from the renewal fees calculations.

For the department to achieve full cost recovery, after allowing for the increase in AIP fees, overall fees (registration renewal and annual fees combined) must be therefore be doubled (increased by 2.02 times or 202 per cent).