INAHTA IMPACT STORY: LEGISLATIVE AND ACCREDITATION REQUIREMENTS FOR OFFICE-BASED SURGERY IN AUSTRALIA

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Background: There is growing trend for some surgical procedures previously performed in hospitals to be done in alternative settings, including office-based facilities. There has been some safety concerns reported in the media, which document serious adverse events following procedures performed in an office-based setting. To understand the current regulatory oversight of surgery in this setting ASERNIP-S conducted a review of the legislative and accreditation process governing these facilities in Australia.

Methods: Using rapid review methodology, internet searches targeted government Web sites for relevant publicly-available documents. Use of consolidated versions of legislative instruments ensured currency of information. Standards were sourced directly from the issuing authorities or those that oversee the accreditation process.

Results: Within Australia, healthcare facilities for surgery and their licensing are defined by each state and territory, which results in significant jurisdictional variation. These variations relate to the need for anesthesia beyond conscious sedation and listing of procedures in legislative instruments. In 2013, Australia adopted National Safety and Quality Health Service standards (NSQHS standards) for the accreditation of hospitals and day surgery centers; however, there is no NSQHS standard for office-based facilities. The main legislative driver for compliance is access to reimbursement schemes for service delivery.

Conclusions: The legislative and accreditation framework creates a situation whereby healthcare facilities that provide services outside the various legal definitions of surgery and those not covered by a reimbursement scheme, can operate without licensing and accreditation oversight. This situation exposes patients to potential increased risk of harm when receiving treatment in such unregulated facilities.

Keywords: Ambulatory surgical services, Legislation, Accreditation, Office surgery

Hugh Bartholomeusz in his 2012 editorial highlighted that office-based surgery has been safely practiced in the United States for many years. However, in Australia, the office-based setting is largely unregulated compared with hospitals and day surgery centers (1). Patients are largely unaware about the unregulated nature of the office-based setting and the associated potential risks when electing to receive significant surgery in such locations. This is illustrated by recent media reports documenting the occurrence of life threatening complications in patients who received cosmetic procedures within an office-based setting (2).

In 2015, the issue of office-based surgical procedures was identified as a major risk to patient safety by the New South Wales (NSW) Department of Health (3). The Department focused on surgical procedures previously performed in hospital or day-surgery units that may be conducted under local anesthetic or conscious sedation in the office-based setting. Dur-

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ing their review, the Department posed the question of whether current regulation of office-based surgical procedures, for example, cosmetic procedures such as liposuction and breast implants, is safe and appropriate. In addition, the review focused on a series of events that resulted in serious harm to patients (3). These events have received significant public attention through media reports (Australian Broadcast Corporation) documenting the lack of patient consent for anesthesia, use of high drug doses, and serious adverse events and deaths following cosmetic surgery conducted in the office-based setting (2).

Drawing on the ASERNIP-S staff skill-base in health technology assessment and rapid review methods, the aim of this project was to determine the legal definition of surgery as well as the legislative and regulatory requirements for accreditation of office-based facilities as defined in the legislative instruments from all Australian state and territory governments. The goal was to map across states and territories the variations in definitions for surgery and office-based facilities. The review's purpose was to provide the necessary background research to assist the Royal Australasian College of Surgeons (RACS) communications and advocacy staff to prepare submissions to state and territory governments regarding proposed changes to legislation to increase the governance of office-based facilities.

METHODS

A Private Hospital Data Collection Review prepared by KPMG Australia for the Australian Department of Health and Ageing summarized the legislation regarding healthcare facilities in Australia (4). However, because of the publication date being 2011, the KPMG report served only as an initial guide to identify relevant legislative instruments with all information verified before inclusion in this review, and updated to 2016.

To confirm and update data we conducted targeted Web searches using the advanced search tool of Google's search engine. Searches were restricted to Web sites of the Australian Commonwealth government as well as each state and territory government and focused to identify legislative instruments relating to both the accreditation and licensing of healthcare facilities, which included statutes and delegate legislations that define healthcare and healthcare facilities. To ensure currency and accuracy of information, only consolidated documentation of legislative instruments, accessed directly from government Web sites (5) were used and appropriate sections extracted verbatim.

The Australian Commission on Safety and Quality in Health Care (ACSQHC) was the source of accreditation information and processes for healthcare facilities in Australia. The National Safety and Quality Health Service standards (NSQHS standards) were published in 2011 for public access (6). A review of the implementation and oversight of the NSQHS standards assessed any variation between states and territories.

Citation of legislative instruments was annotated according to the Australian Guide to Legal Citation (7).

Key Definitions

To interpret legislation or regulations it is necessary to define four key concepts: conscious sedation (often referred as simple sedation), licensing, accreditation, and certification. There are multiple definitions for these terms. However, for this review, the definitions used are provided in Table 1.

RESULTS

Based on definitions presented in Table 1, data were extracted from national, state and territory legislative instruments and documented in Table 2. Data have been presented to provide definitions of surgical care and office-based surgical procedures and facilities. Additionally, the accreditation of healthcare facilities and the linkage between accreditation and reimbursement of health care through the Australian Governments Medical Benefits Scheme (MBS) and private health insurers are presented.

Defining Surgical Care

Figure 1 summarizes the key take-home messages regarding the various definitions of surgical care as defined by Australian state and territory legislative instruments. In NSW, Queensland, and Tasmania, the primary classification for surgical care is based on levels of anesthesia. Procedures are classified as surgical if conducted under general anesthesia or with the use of a spinal, epidural, major, or regional nerve block. In addition to anesthesia levels, NSW also classifies cardiac surgeries, cardiac catheterization, and gastrointestinal endoscopy as belonging to a specialty service category (8).

In Queensland, diagnostic, surgical or other procedures are collectively prescribed but only for day surgery centers where levels of anesthesia (general, spinal, epidural anesthesia as well as sedation other than conscious sedation) comprise the major classification criteria (9). Similarly, surgical care is only prescribed in day surgical centers in Tasmania and is based on anesthesia levels involving administration of general, spinal, epidural anesthetics, major regional block anesthetics, and intravenous sedatives other than for "simple sedation" (10).

In contrast, surgical services are prescribed in both private hospital and day surgery centers in Victoria. However, these are not prescribed through anesthesia levels but rather on whether the providers delivering the service are specified as registered medical practitioners, podiatric surgeons, dental specialists or dentists, as well as whether surgical instruments are used and in which facility the procedure is performed (11).

In summary, irrespective of jurisdiction, procedures that can be conducted under local anesthesia or conscious (simple) sedation and/or not listed as a prescribed service (e.g., liposuction) fall outside of the definition of a surgical service. This creates a potential loophole that has been exploited to deliver some surgical services.

Defining "Office-Based Surgical Procedures and Facilities"

No Australian state or territory defines office-based surgical procedures and facilities in legislative instruments. It is also unclear whether these facilities have mandatory licensing processes. However, centers offering certain specialty procedures performed in an office setting may have to comply with requirements for day surgery centers based on existing legislation if the procedure is listed as a prescribed procedure in legislation. This scenario varies across jurisdictions. For example, in Victoria centers offering the specialty service of endoscopy are mandated for licensing as a day surgery center because endoscopy is prescribed in legislation. This may not be the case for other states. Similarly, under Tasmanian legislation, low-risk procedures requiring only conscious sedation (simple sedation) that are performed in an office setting are classified prescribed services and subject to regulation applicable to "day surgery" centers (12).

In summary, nonprescribed surgical procedures performed in office settings are unlikely to be regulated in any state or territory, and these facilities may not require a license or accreditation for operation.

Table 1. Defining Conscious Sedation, Licensing, Accreditation and Certification as Applied to the Australian Context

Conscious sedation as defined by the Australia and New Zealand College of Angesthetists (ANZCA)^a

Licensing

Accreditation

Certification

- "A drug-induced depression of consciousness during which patients are able to respond purposefully to verbal commands or light tactile stimulation. Interventions to maintain a patent airway, spontaneous ventilation, or cardiovascular function may, in exceptional situations, be required. Conscious sedation may be achieved by a wide variety of drugs including propofol, and may accompany local anaesthesia. All conscious sedation techniques should provide a margin of safety that is wide enough to render loss of consciousness unlikely" (14).
- "Licensure is a process by which a governmental authority grants permission to an individual practitioner or health care organisation to operate or to engage in an occupation or profession. Licensure regulations are generally established to ensure that an organisation or individual meets minimum standards to protect public health and safety. Licensure to individuals is usually granted after some form of examination or proof of education, and may be renewed periodically through payment of a fee and/or proof of continuing education or professional competence. Organisational licensure is granted following an on-site inspection to determine if minimum health and safety standards have been met. Maintenance of licensure is an ongoing requirement for the health care organisation to continue to operate and care for patients" (15).
- "Accreditation is independent recognition that an organisation, program or activity meets the requirements of defined criteria or standards. Accreditation is an internationally recognised evaluation process used to assess the quality of care and services provided in a range of areas including health care" (16).
- "Accreditation standards are usually regarded as optimal and achievable, and are designed to encourage continuous improvement efforts within accredited organisations."
- "Certification is a process by which an authorized body, either a governmental or non-governmental organisation, evaluates and recognizes either an individual or an organisation as meeting pre-determined requirements or criteria. Although the terms accreditation and certification are often used interchangeably, accreditation usually applies only to organisations, while certification may apply to individuals, as well as to organisations. When applied to individual practitioners, certification usually implies that the individual has received additional education and training, and demonstrated competence in a specialty area beyond the minimum requirements set for licensure. An example of such a certification process is a physician who receives certification by a professional specialty board in the practice of obstetrics. When applied to an organisation, or part of an organisation, such as the laboratory, certification usually implies that the organisation has additional services, technology, or capacity beyond those found in similar organisations" (15).

Accreditation Process

Accreditation ensures that all public health services maintain the highest standards of quality and safety, and delivery of continuous service improvements. The ACSQHC in collaboration with the Australian government along with state and territory health departments, health services and other stakeholders developed the National Standards (6). Health Ministers endorsed the two sets of NSQHS standards in 2011, one specific to hospitals (13), and one specific to day procedure centers (14). Since January 2013, all Australian hospitals and day surgery centers offering health services that attract a MBS reimbursement have been required to be accredited to the NSQHS standards. However, there are no NSQHS standards covering office-based facilities.

State legislation governs which facilities are included in the definition of hospital and/or day surgery, and accordingly, which facilities in their jurisdiction are required to be accredited. Other standards specified by state governments may apply in addition to the NSQHS standards for private health facilities.

In summary, at the time of writing, neither the NSQHS nor state legislation requires accreditation for office-based facilities.

Commonwealth Legislation and Reimbursement for Service

Central to the delivery of private health care in Australia is the reimbursement of service fees and the linkage between accreditation of facilities, listing of services on the MBS and payment from private health funds. The Australian Commonwealth government enacts the Private Health Insurance Act (2007) (15) which prohibits MBS reimbursement for private health services and private health insurance payments for treatment in a nonaccredited facility. The Act mandates accreditation by an appropriate accreditation body, as defined in the Private Health Insurance (Accreditation) Rules (2011) which is a body approved by the ACSQHC to accredit healthcare providers against the NSQHS standards (16). This ensures that surgical services that are included on the MBS and covered by private health insurance are performed in facilities accredited to the NSQHS standards regardless of State or Territory legislation. In addition, nonmedically necessary elective plastic/cosmetic surgeries that alter appearance or body cannot be listed on the MBS. The Act also prohibits private health insurers reimbursing patients/healthcare providers for such surgeries.

In summary, nonmedically necessary surgical procedures do not attract a MBS or private health reimbursement. This

^aWhen referencing legislation or regulations in this document, the term "simple sedation" will be directly quoted in the text to maintain congruency with source documentation.

 Table 2. Definitions and Processes of Prescribed Services, Surgery, and Office-Based Facilities across Australian States and Territories

Australian Capital Territory	Northern Territory	New South Wales	Queensland	South Australia	Tasmania	Victoria	Western Australia
Prescribed services Five categories are defined for health care facilities that provide overnight accommodations, prescribed health care services: -anesthesia/ nerve blocks, -endoscopy, -dialysis, -prolonged IV for cytotoxic agent(s) and -cardiac catheterization ⁱ Surgery	Information is not provided regarding to prescribed services or classes.	Prescribed services are categorized by 18 classes that can be performed or delivered on the premises ⁱⁱ for eligible private facilities.	No specific prescribed services listed for the purpose of defining private hospitals or day procedure centers. The Clinical Service Capability Framework (CSCF) outlines the six level of service with 27 service module Specialty services are categorized into 44 typesiii.	No information is provided regarding to prescribed services or classes.	Three types of procedures are defined based on whether overnight stay and professional attendance is required ^{iv} ;	Prescribed services are defined for both day centers and private hospitals, including medical, surgical and specialty services; categories where the healthcare provision for specialty health services are different for private hospital and day procedure centers.	The definition is specified at a high level ^{vi} Licensing of private and day facilities are governed by a set of standards where day hospitals were categorized into four types from A to D relating to level of anesthesia, sedation and renal dialysis services.
Not clear.	Not clear.	Defined by level of anesthesia where patients administered general, epidural or major regional anesthetic or sedation resulting in more than conscious sedation ^{vii} . Dental surgery is excluded.	Surgical services are collectively defined with medial and diagnostic services where the involvement is based on the level of anesthesia viii including administration of general, spinal, epidural anesthetics or sedation other than simple sedation (conscious sedation).	Not clear.	In the context of day-procedure centers, surgical services are defined through level of anesthesia, nerve block and sedation ^{ix} .	Surgical health services are defined consistently in both private hospital and day procedure centers by a registered medial practitioner, registered podiatric surgeons, dental specialist or a dentist ^x	Not clear.

Requirements for office-based surgery in Australia

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Australian Capital Northern Territory New South Wales Queensland South Australia Tasmania Victoria Western Australia Territory Office-based centers Not Clear. Not Clear. Not Clear Not Clear Not Clear. Not Clear Not Clear. Not Clear. Some procedures may Some procedures may Low risk surgeries when Some procedures maybe partially covered by partially covered by simple sedation is partially covered by safe are included in some classes**. the standard (see activities prescribed in above, "simple the scope of surgical, medical or sedation"). day-procedure speciality health centers^{xi}. However. services. definition of simple sedation is not provided. Accreditation oversight The NSW Department of The Qld government The Department of Both registered private The Department of Unclear. Unclear. Unclear. ACT Health is an uses the 'Clinical The SA government Health and Human Health of WA oversees Health oversees the facilities and public accredited accreditation process Services Capability published the Services of Tas hospitals are required the accreditation organization by the and acknowledges Framework (CSCF)' Accreditation Policy oversees the to be accredited. process, requiring Australian Council of accreditation the terminology to oversight and The oversight and public, private and Directives that makes consistency between maintain the clinical the accreditation according to the governance regarding day hospitals that Healthcare Standard (ACHS). mandatory. It is national standard, provide general 'the standard' and all capacity where it is accreditation The fee structure is current relevant concurrent with the unclear how the requiring both private processes is provided anesthesia (Class A) to be accredited. different for legislations. current national oversight can be and day hospitals to in The Victorian **Health Services** Accreditation is based accredited or accreditation process. undertaken. be accredited. non-accredited Governance on the national Handbook. licensing for new standard. hospitals.

Table 2. Continued

Commonwealth level

A hospital is defined by declaration of the Minister of Health. The criteria needed to be reviewed by the Minister including:

- (a) the nature of the facility; and
- (b) the range and scope of the services provided, or proposed to be provided, under the management or control of the facility and at or on behalf of the facility; and
- (c) whether the necessary approvals by a State or Territory, or by an authority of a State or Territory, have been obtained in relation to the facility; and
- (d) whether the accreditation requirements of an appropriate accrediting body have been met; and
- (e) whether undertakings have been made, or have been complied with, relating to providing private health insurers information, of the kind specified in the Private Health Insurance (Health Insurance Business)

 Rules, relating to treatment of persons insured under *complying health insurance products that are *referable to *health benefits funds; and
- (ea) if the Minister is deciding whether to revoke such a declaration—any contravention of conditions to which the declaration is subject; and
- (f) any other matters specified in the Private Health Insurance (Health Insurance Business) Rules.

Additionally, the Minister must include either a statement that the hospital is a public hospital or a statement that the hospital is a private hospital.

- i. ACT Health Care Facilities Code of Practice 2001 (ACT) Dictionary (definition of prescribed medical and dental procedures).
- ii. Private Health Facilities Regulation 2010 (NSW) reg 5.
- ii. Private Health Facilities Act 1999 Standard (Qld).
- iv. Health Service Establishments Act 2006 (No. 17 of 2006) (Tas) s 3.
- v. Health Services (Private Hospitals and Day Procedures Centres) Regulations 2013 (No 113) (Vic) regs 6, 7.
- vi. Hospitals and Health Services Act 1927 (WA) s 2.
- vii. Private Health Facilities Regulation 2010 (NSW) reg 5(r).
- viii. Private Health Facilities Act 1999 (Qld) ss 10(3)(a)(b).
- ix. Health Service Establishments Regulations 2011 (S.R. 2011, No. 97) (Tas) reg 5(2)(c).
- x. Health Services (Private Hospitals and Day Procedures Centres) Regulations 2013 (No 113) (Vic) reg 5 (definition of surgical health services).
- xi. Health Service Establishments Regulations 2011 (S.R. 2011, No. 97) (Tas) reg 5(2).

- Surgical care is primarily defined through *levels of anaesthesia* of the procedure where general, spinal, epidural, major and regional nerve blocks are included.
- Alternatively, surgical care is define by listing of prescribe procedures with legislative instruments.
- Procedures performed under local anaesthesia or conscious sedation are excluded from surgical care unless specified as a prescribed procedure.
- Office-based facilities are not defined in any state or territory legislation.
- Some centres offering specialty services in office settings may be defined as day surgery centres, depending on the prescribed services for day procedure centres.
- Centres offering surgical procedures that are not prescribed by legislation and/or performed under conscious sedation or local anaesthesia are unlikely to be mandated for licensing by state or territory governments.

Summary of key information presented in Table 2

Figure 1. Key take-home messages.

removes the necessity for facility accreditation to perform cosmetic surgical procedures if the surgery falls outside the legal definition of surgery.

DISCUSSION

The application of HTA methods provided a structured approach to generate an accurate and rapid mapping of the current governance processes, licensing and accreditation requirements for office-based facilities. This novel application of HTA methods facilitated the identification of key legislative documents, the extraction of all necessary data and crosschecking for accuracy. It documented the significant diversity among the states and territories of Australia in defining surgery and the lack of any legislative oversight over surgery conducted in the office-based setting.

This diversity meant there were multiple legislative instruments that had to be negotiated when assessing whether a healthcare facility is required to be licensed and / or accredited. This was compounded by different definitions of surgery used in the legislative instruments of the various Australian jurisdictions. The review provided clarity regarding how surgery is defined through the use and depth of anesthesia or listing as prescribed procedures within legislative instruments. This information was used to prepare a submission to the NSW government commenting on their proposed changes to their Acts and Regulations governing health care. The proposed change was to create a new class of facilities for cosmetic surgery that perform surgeries such as breast augmentation, abdominoplasties, and high-volume liposuction. Such premises will be subject to the same standards as hospitals and daysurgery centers. These changes are deemed necessary to protect patients from harm and will stop complex surgical interventions from being conducted in an unregulated office-based setting.

Critical to determining whether a facility requires licensing and accreditation for surgery is the definition of surgery as documented in State and Territory legislative instruments. As stated earlier, the definition of surgery varies across the States and Territories. This raises significant concerns given the ongoing improvements in surgical techniques and anesthetics which allow increasingly complex surgery under lighter anesthesia or even with appropriate local anesthetic (1). At present, in most Australian jurisdictions, procedures performed under conscious (simple) sedation or the use of local anesthetics are not defined as surgery.

Irrespective of the level anesthesia, listing a surgery as a prescribed procedure can overcome this gap. However, this approach is reactive to developments in surgical techniques meaning lists of prescribed procedures would require constant review and updating of legislative instruments. The problem with this approach is that a list of prescribed procedures considered comprehensive today might not be so in the future. This could mean legislative instruments become obsolete as the prescribed procedures evolve, leading to challenges to the appropriate oversight of surgery and unintentionally placing future patients at harm.

Within Australia, there is presently no direct national legislative instrument requiring a health facility be accredited. However, there is a provision for oversight within the Commonwealth's Private Health Insurance Act (2007) (15) that governs reimbursement for health services within the private sector. For reimbursement of a service under the MBS, that service must be delivered in a facility accredited to the NSQHS standards or to an equivalent standard. This effectively makes accreditation mandatory for any health facility providing a surgical service funded through the MBS. This extends to private health fund reimbursement for surgical services. However, the Private Health Insurance Act (2007) (15) and the MBS do not cover all surgical procedures, such as nonmedically necessary cosmetic surgery.

This is an area for concern because complex nonmedically necessary cosmetic procedures are excluded from the Private Health Insurance Act (2007). In addition, if performed under conscious (simple) sedition or local anesthesia or not listed as a prescribed procedure, they fall outside of the legislative definition of surgery across Australian jurisdictions. This scenario allows procedures to be performed in the office-based environment that are not licensed or accredited; thereby, placing patients at an increased risk of harm.

The situation is changing, and Australian jurisdictions are reviewing or considering reviewing legislation to close this gap in oversight of health facilities. For example, the New South Wales government, in response to adverse incidents of cosmetic surgeries in office-based settings, has reviewed the Private Health Facilities Act (2007) (17) to incorporate facilities carrying out cosmetic surgery. The review resulted in the NSW government approving an amendment to the Private Health

Facilities Act (2007) to cover cosmetic surgery (18). This amendment defines the levels of anesthesia and lists prescribed procedures that qualify the need for licensing of a health-care facility for cosmetic surgery. This is a positive step forward and one that should be replicated across other Australian jurisdictions.

Ideally, such changes to legislation will move complex surgery out of the office-based environment to the day surgery setting. Australia has clear NSQHS standards for day-surgery units, and moving procedures to this setting removes the immediate need to establish standards for the office-based environment. This does not negate the need for standards; and in 2004, RACS in association with the Australian Day Surgery Council, established a guideline for the minimum standards need to ensure safe practice in the office-based setting (19). Furthermore, standards for office-based facilities are available internationally; for example, New Zealand has two Standards these being NZS 8164:2005 and NZS 8165:2005. In the absence of Australian based NSQHS standards for office-based facilities such international standards may be used as alternative resources to guide safe practices in this setting.

The key issue remains that all facilities that provide surgical services should be subject to some form of oversight to maintain a minimum level of safe practice. Further to this, medical practitioners should apply appropriate ethical standards in advising patients considering cosmetic surgery, as exemplified by the recent Medical Board of Australia guidelines on cosmetic medical and surgical procedures (20). These guidelines emphasize the need for medical practitioners to apply a patient "cooling off" period before performing a cosmetic procedure and that for patients under 18 seeking major cosmetic procedures a psychological evaluation is mandatory. In addition, the medical practitioner is to be explicitly responsible for postoperative care, and the facility must have emergency facilities available when using sedation, anesthesia, or analgesia. Patients are also to be given detailed written information about costs.

Conclusions

This project highlights the application of HTA methods to research questions not normally considered within the remit of HTA. The rigor associated with evidence identification and data extraction created a high level of certainty that all appropriate legislative instruments, regulations and policies that govern the licensing and accreditation of healthcare facilities were identified. For RACS communications and advocacy staff, the resulting report provided the necessary background information to draft a consultation response that was submitted to the NSW Department of Health during the review of the NSW Private Health Facilities Act (2007). Other Australian jurisdictions are reviewing legislation to increase regulation of office-based fa-

cilities to reduce the risk to patients given the increasing complexity of surgery undertaken at these facilities.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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