



# STANDARDS FOR PROCEDURAL SEDATION & ANALGESIA (PSA)

STANDARD

Department: Quality Improvement Department

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## STANDARD – Standards for Procedural Sedation & Analgesia

### Introduction

The number of noninvasive and minimally invasive procedures performed outside of the operating room has increased significantly over recent times. Sedation, analgesia, or both may be needed for many of these interventional or diagnostic procedures. Procedural Sedation and Analgesia (PSA) is a technique of administering sedatives or dissociative agents with or without analgesics. By relieving anxiety, reducing pain and providing amnesia, PSA induces a state that allows patients to tolerate uncomfortable procedures while maintaining cardiorespiratory function. PSA may also expedite procedures that require the patient not to move i.e. in children and uncooperative adults. PSA comprise a continuum of depressed level of consciousness ranging from minimal sedation to general anesthesia.

The response of individual patients to the administration of PSA is difficult to predict. The types of drugs used, the dosages administered, the preservative effects of concomitant drugs and the patient's pharmacogenetic profile will all influence the depth of sedation. The drugs and techniques used should provide a margin of safety that is wide enough to render loss of consciousness unlikely. An unexpected progression of the depth of sedation must be anticipated, and practitioners must be able to rescue patients who enter a deeper level of sedation than intended. Healthcare Professionals require special training and experience to provide PSA effectively and safely.

### 1. PURPOSE

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| 1.1 | This Standard defines the minimum requirements including licensing and service specifications to ensure acceptable minimum levels of quality, performance, safety and reliability for the use of Procedural Sedation and Analgesia within Dubai Healthcare City (DHCC). |
| 1.2 | This standard also defines qualified personnel, scope of practice and service limitations for the provision of PSA in DHCC.   |

### 2. SCOPE OF APPLICATION

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| 2.1 | This Standard applies to all Healthcare Operators and Healthcare Professionals providing or intending to provide PSA for diagnostic and interventional medical, surgical and dental procedures within DHCC.   |
| 2.2 | This Standard does not apply to the use of PSA on patients requiring long term management such as those in intensive care units, prescription of sedation for palliative care, sedation for use in the home setting, and sedation for psychiatrically disturbed patients. |



## STANDARD – Standards for Procedural Sedation & Analgesia

- 2.3 This Standard also does not apply to the use of oral medications, nitrous oxide inhalation and non-pharmacological techniques for minimal sedation or anxiolysis.

### 3. STANDARD

3.1	<b>LICENSURE</b>
3.1.1	PSA may be provided by DHCA Licensed Healthcare Operators holding a Clinical Operating Permit for Single and Multi-Specialty Clinics, Radiological and Endoscopic Diagnostic Centers, Outpatient Surgical Clinics, Fertility Centers, Hospitals and other Inpatient Healthcare Facilities in accordance with the requirements of the Standards defined herein.
3.1.2	Each Healthcare Operator may provide PSA appropriate to its approved Licensure, Clinical Operating Permit and approved Clinical Activities.
3.1.3	The Clinical Activities where PSA may be required includes, but are not limited to: <ul style="list-style-type: none"> <li>3.1.3.1 Cardiology</li> <li>3.1.3.2 Dentistry</li> <li>3.1.3.3 Gastroenterology/Endoscopic procedures</li> <li>3.1.3.4 Interventional and Diagnostic Radiology</li> <li>3.1.3.5 Surgery and invasive procedures</li> <li>3.1.3.6 Pain medicine</li> <li>3.1.3.7 Artificial Reproductive Technology</li> <li>3.1.3.8 Emergency Medicine</li> </ul>
3.1.4	Each Licensed Healthcare Operator must obtain approval from the Ministry of Health and Prevention of the United Arab Emirates for the use of narcotic/controlled drugs in accordance with applicable Federal and local regulations.
3.1.5	PSA must be performed in a safe environment where the qualified personnel, facilities, monitoring equipment, and emergency drugs and equipment are immediately available.
3.1.6	Each Licensed Healthcare Operator providing PSA shall provide such services in accordance with all applicable regulations, rules, policies and standards of DHCA.

3.2	<b>QUALIFIED PERSONNEL</b>
3.2.1	Each Healthcare Operator providing PSA shall appoint appropriately qualified Licensed Healthcare Professionals to deliver these services as required by this Standard, the Dubai Outpatient Clinic Quality Standards or equivalent accreditation standards, and other applicable DHCA regulations, standards and policies.



## STANDARD – Standards for Procedural Sedation & Analgesia

3.2.2	Each Healthcare Operator shall have a documented process for determining appropriate staffing needs, by number and type of staff for the provision of PSA.
3.2.3	A Licensed Anesthesiologist may provide all levels of PSA subject to the Healthcare Operator's Clinical Operating Permit.
3.2.4	The Medical/Dental Director of the Licensed Healthcare Operator is responsible for the formulation and implementation of appropriate standards, policies and procedures for PSA, oversight and delineation of clinical privileges; coordinating the proficiency and update of clinical knowledge and skills; and clinical evaluations.
3.2.5	In the absence of relevant expertise, DHCR may guide Healthcare Operators and facilitate processes to determine clinical privileging of Licensed Healthcare Professionals to provide PSA.
3.2.6	Healthcare Professionals holding DHCA licensure in General Medicine, General Dentistry, a Dental Specialty or a Medical Specialty only may be granted clinical privileges by the Licensed Healthcare Operator to provide PSA.
3.2.7	All such Licensed Healthcare Professionals shall hold current and valid certification in Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) and/or Paediatric Advanced Life Support (PALS) as appropriate. (Please refer to DHCR Life Support policy and guideline- Document Identifier: PP/HCP/005/01)
3.2.8	Each Licensed Healthcare Professional granted clinical privileges by a Licensed Healthcare Operator shall be suitably trained and qualified to provide PSA. They shall be proficient in: <ul style="list-style-type: none"> <li>3.2.8.1 Understanding the continuum of sedation and be able to perform defined methods and levels of sedation for which they have received formal training;</li> <li>3.2.8.2 Understanding the actions and interactions of the sedative and analgesic drugs being administered and their possible synergistic effects; the use of reversal agents; and be able to modify the technique appropriately in patients of different ages;</li> <li>3.2.8.3 Providing simple sedation, advanced sedation as permissible in this Standard, and managing failed sedation as is applicable to their training and granted privileges;</li> <li>3.2.8.4 Effectively monitoring the patient's level of consciousness and cardiorespiratory status;</li> <li>3.2.8.5 Detecting and rescuing patients from sedation-related adverse responses including anaphylaxis and cardiorespiratory failure.</li> </ul>

## STANDARD – Standards for Procedural Sedation & Analgesia

3.2.9	Licensed Physicians and Medical Specialists intending to provide PSA, must successfully obtain certification in a recognized accredited PSA training program. Each training program must include a minimum of 60 hours didactic training; 20 supervised cases of active PSA provision to demonstrate competency; applicable airway management competency; and a written structured assessment.
3.2.10	Sedationists who are qualified and proficient to administer a specific sedation technique may also supervise the administration of that sedation technique.
3.2.11	Licensed Medical Specialists including Anesthesiologists, Emergency Physicians, Neonatologists, and Physicians who completed Critical Care Medicine are qualified to administer PSA by virtue of their specialist training and experience.
3.2.12	Licensed Dentists or Dental Specialists must successfully complete an accredited postgraduate Diploma PSA training program, or equivalent.
3.2.13	In addition to certification in PSA each Licensed Physician and Licensed Dentist trained in PSA shall also participate in a crisis resource management simulation center course.
3.2.14	The training program shall encompass the following learning outcomes in accordance to the UK Academy of Medical Royal College's "Safe Sedation Practice for Healthcare Procedures": <ul style="list-style-type: none"> <li>3.2.14.1 To gain a fundamental understanding of what is meant by conscious sedation and the risks associated with deeper levels of sedation.</li> <li>3.2.14.2 To be able to describe the differences between conscious sedation and deeper levels of sedation, with its attendant potential risks to patient safety.</li> <li>3.2.14.3 To gain a fundamental understanding that loss of verbal responsiveness/deep sedation requires the same level of skills and care as for general anesthesia.</li> <li>3.2.14.4 To recognize the important principle of minimum intervention, where the simplest and safest technique which is likely to be effective is used to achieve the clinical goal.</li> <li>3.2.14.5 To gain a fundamental understanding of the particular dangers associated with the use of multiple sedative drugs, especially in the elderly and young children.</li> <li>3.2.14.6 To be able to safely deliver pharmacological sedation to appropriate patients and recognize the limits of their competency and experience.</li> <li>3.2.14.7 To be able to discuss where and when deeper levels of sedation or anesthesia may be indicated.</li> <li>3.2.14.8 To be able to manage sedation-related side effects in a timely manner, ensuring patient safety is of paramount consideration at all times.</li> </ul>



## STANDARD – Standards for Procedural Sedation & Analgesia

	<p>3.2.1.4.9 To gain a fundamental understanding that for all but brief and simple procedures, undertaken on fit patients, serious consideration must be given to the use of a trained dedicated sedationist, whose sole responsibility is to administer sedation, monitor the patient and address any sedation-related issues and that if a dedicated sedationist is not used the operator-sedationist must be prepared to justify the decision.</p>
3.2.15	<p>Non-anesthesiologist Sedationists shall be restricted to the planned provision of minimal and/or moderate sedation subject to the clinical privileges granted and the Healthcare Operator's Clinical Operating Permit.</p>
3.2.16	<p>Such Non-anesthesiologist Sedationists shall be limited to the provision of PSA techniques that includes: Topical Anesthesia, Local Anesthesia, Parenteral Sedation, and Regional Anesthesia. This excludes Epidural and Spinal Anesthesia and the administration of Propofol and inhalation anesthetic agents which shall only be provided by a Licensed Anesthesiologist.</p>
3.2.17	<p>Sedationists providing pediatric sedation shall undergo directed pediatric training and education. They must be certified and proficient in PALS and be able to manage any related adverse event that might occur.</p>
3.2.18	<p>A Sedationist shall either be a Dedicated Sedationist (responsible only for the provision of PSA sedation and monitoring of the patient), or a Proceduralist- Sedationist.</p>
3.2.19	<p>A Sedation Assistant shall be a Licensed Registered Nurse, Licensed Anesthesiology Technician, Licensed Physician or Licensed Dentist.</p>
3.2.20	<p>Each Sedation Assistant responsible for monitoring patients under PSA shall be skilled in airway management and cardiopulmonary resuscitation relevant to the patient's age and condition and shall be currently certified and proficient in BLS, ACLS and/or PALS as applicable.</p>
3.2.21	<p>Each Sedationist that actively provides PSA shall demonstrate and document sustained competency and update of knowledge and skills by attending training programs and/or courses at least every two years in the area for which PSA services they provide. They shall possess evidence of obtaining a minimum of 10 continued professional development (CPD) credits in related PSA techniques for every two (2) years of practice. Evidence of all CPD trainings must be maintained in the each professional's staff file.</p>
3.2.22	<p>Each Sedationist must keep a comprehensive logbook of cases performed under sedation, as well as the technique used and provide audit records of the safe administration of sedation and analgesic drugs.</p>



## STANDARD – Standards for Procedural Sedation & Analgesia

3.2.23	Each Licensed Healthcare Operator shall make provisions for regular in-house training and ongoing professional development to ensure Sedationist's scope of practice remains valid. This shall include participation in periodic medical emergency preparedness drills. All records of the drills conducted must be maintained in the staff files.
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3.3	<b>PATIENT MANAGEMENT</b>
3.3.1	Each Licensed Healthcare Operator providing PSA shall manage patients and treatment processes in accordance with this Standard, the CPQ Outpatient Clinic Quality Standards, the standards in use from the approved accreditation agency and all other relevant DHCA regulations, standards and policies.
3.3.2	PSA administration shall be standardized throughout each Licensed Healthcare Operator, and supported by policies and procedures.
3.3.3	<p><b>Patient Assessment:</b></p> <p>3.3.3.1 Each patient shall undertake a relevant age appropriate physical assessment by a qualified Licensed Physician to assess the fitness and appropriateness of the patient for PSA.</p> <p>3.3.3.2 An up-to-date patient history must be taken and carefully reviewed to identify any aspects of the patient's medical history that might affect the patient's response to PSA.</p> <p>3.3.3.3 Based on the pre-procedure/operation assessment, the patient shall be assigned a standardized physical status class in accordance with the American Society of Anesthesiologists (ASA) Physical Status.</p> <p>3.3.3.4 The pre-sedation assessment shall identify and classify those patients at increased risk of cardiovascular, respiratory or airway compromise.</p> <p>3.3.3.5 High risk patients for PSA (ASA class III, IV, V or E) shall be managed accordingly by a Licensed Specialist Anesthesiologist with a fully equipped operating theatre, a full range of emergency drugs and resuscitation equipment available. Patients in ASA class IV, V or E shall only be managed in a hospital environment.</p> <p>3.3.3.6 Appropriate Licensed Medical Specialists must be consulted before administration of PSA to high risk patients with significant underlying conditions. These consultations shall be recorded in the medical record.</p> <p>3.3.3.7 Pre-procedure laboratory and diagnostic testing shall be guided by the patient's underlying medical condition and the likelihood that the results will affect the</p>

## STANDARD – Standards for Procedural Sedation & Analgesia

	<p>management of PSA. These results must be confirmed and documented before PSA is initiated.</p> <p>3.3.3.8 An appropriate PSA plan shall be formulated and documented by the Sedationist. Choice of agents, techniques and personnel for PSA must be based on the specific needs of patients.</p>
<p>3.3.4</p>	<p><b>Pre-sedation Preparation:</b></p> <p>3.3.4.1 Each Sedationist providing PSA shall maintain effective communication and clear explanation at every stage of patient management to reassure the patient.</p> <p>3.3.4.2 The Sedationist must ensure that all necessary equipment (including monitoring equipment) is present and in working order before the initiation of PSA.</p> <p>3.3.4.3 The Sedationist shall ensure the suitability of establishing intra-venous access on a case-by-case basis.</p> <p>3.3.4.4 Venous access must be secured prior to sedation if the administration of intravenous sedatives is planned, and must remain in situ until the patient has fully recovered from the effects of the sedation.</p> <p>3.3.4.5 A minimum of three appropriately trained Licensed Healthcare Professionals shall be present at each procedure in either scenario:</p> <p>3.3.4.5.1 the Proceduralist-Sedationist, the Sedation Assistant to monitor the patient, and an assistant to the proceduralist;</p> <p>3.3.4.5.2 the Proceduralist, the Sedationist, and an assistant to the proceduralist.</p> <p>3.3.4.6 Prior to initiation of PSA, either the Sedationist or the assigned Sedation Assistant shall be responsible for patient monitoring during the administration of PSA and throughout the procedure, and be in attendance at the patient's side throughout the procedure.</p> <p>3.3.4.7 All staff shall partake in the 'time out' process prior to the procedure to assure correct patient, side, site, and correct procedure and document it in the medical record.</p> <p>3.3.4.8 Each Sedationist shall review the patient's condition and vital signs prior to a procedure to assess any change in the condition of the patient that may affect the administration of PSA.</p> <p>3.3.4.9 The Sedationist must ensure that sufficient stock of reversal agents are available for the drugs being administered during the procedure.</p>



## STANDARD – Standards for Procedural Sedation & Analgesia

3.3.5

### Peri-sedation and procedure:

- 3.3.5.1 All drugs shall be carefully titrated to the patient's individual needs and administered in small, incremental doses. Care should be taken that patients are not over sedated and that drug dosages should not exceed what is required. The sum of the incremental doses must not exceed the recommended maximum dose.
- 3.3.5.2 Sedationists must carefully consider the use of combined drugs for the possibility of progression to deeper levels of sedation.
- 3.3.5.3 Sufficient time should be given for drugs that are administered by non-intravenous routes (e.g. oral, rectal, transmucosal), to absorb effectively before additional dosages are considered.
- 3.3.5.4 Intravenous anesthetic agents such as propofol shall only be provided by a Licensed Anesthesiologists. These agents must not be administered by the Proceduralist.
- 3.3.5.5 For painful procedures, analgesics should be administered first to prevent pain, before using sedation. A signalling system for pain or discomfort should be established prior to the initiation of sedation. The Sedationist shall be physically present throughout PSA and remain immediately available until the patient is medically discharged from the post procedure recovery area.
- 3.3.5.6 Patients shall be monitored at 5 minute intervals after administration of PSA and throughout the procedure.
- 3.3.5.7 Clinical signs must be monitored and documented continually in a PSA monitoring chart prior to commencement of sedation, during the procedure and recovery period, until discharge from the recovery area. This will include monitoring of the patient's level of consciousness, ventilatory and oxygenation status, hemodynamic variables, temperature, pain and anxiety levels.
- 3.3.5.8 During PSA, patient responsiveness to an appropriate stimulus (e.g. verbal command or light touch) should be sought, unless contraindicated, to ensure that the patient has not drifted into a deeper state of sedation. Patients may either respond verbally or give a physical sign like a tap or thumbs up sign.
- 3.3.5.9 For prolonged procedures/operations, capnography may be used to monitor gas exchange, adequacy of ventilation and pulmonary perfusion.
- 3.3.5.10 Prior to being transferred to the recovery area, a comprehensive PSA record must be included in the patient's chart in accordance with DHCR Medical Record Policy.



## STANDARD – Standards for Procedural Sedation & Analgesia

3.3.6

### Post procedure Recovery:

- 3.3.6.1 Patients requiring to be relocated for recovery purposes, shall be transported safely (with care and monitoring as indicated) to a specifically designated recovery area with suitable equipment and qualified staff.
- 3.3.6.2 Patients that may recover in the same bed/chair/area, shall receive care in a safe environment.
- 3.3.6.3 After the procedure, the Sedationist must formally hand over the care of a patient to an appropriately trained and Licensed Healthcare Professional who shall either be a Licensed Physician or Licensed Registered Nurse.
- 3.3.6.4 A designated area for recovery of children must be in place that is appropriately equipped and staffed.
- 3.3.6.5 A Licensed Physician shall assume overall responsibility for patients during recovery, and may not leave the premises until patient discharge criteria to a ward or home (as applicable) are met.
- 3.3.6.6 All patients must be assessed for post procedure pain and shall be managed accordingly.
- 3.3.6.7 During recovery the vital signs shall be monitored and recorded at least every 10 minutes until full recovery has occurred, and will include the recovery period start and end time.
- 3.3.6.8 Adequate staffing and facilities must be available in the recovery area for managing patients who have become unconscious or who have suffered complications during the procedure.
- 3.3.6.9 No fewer than two qualified staff should be present in the recovery area when there is a patient who does not fulfil the medical criteria for discharge to the ward or home.

3.3.7

### Discharge from Recovery:

- 3.3.7.1 Discharge of the patient from the recovery area to a ward or home, shall be authorized by the Sedationist or another appropriately qualified Licensed Physician in accordance with established criteria and documented in the medical record.
- 3.3.7.2 Criteria for discharge must include:
- 3.3.7.2.1 that the patient returned to their baseline level of consciousness;
- 3.3.7.2.2 vital signs are stable within acceptable limits;

## STANDARD – Standards for Procedural Sedation & Analgesia

	<p>3.3.7.2.3 sufficient time has elapsed following administration of reversal agents (if applicable) to ensure that patients do not become re-sedated;</p> <p>3.3.7.2.4 and outpatients are discharged in the presence of a responsible adult who will accompany them home.</p> <p>3.3.7.3 The patient or carer must be supplied with written and verbal information with regard to post discharge activities and be advised to seek immediate help in case of vomiting, strange and unusual behavior, or any other symptom or sign that does not seem normal for the patient.</p>
3.3.8	<p><b>Emergency:</b></p> <p>3.3.8.1 During patient loss of consciousness, all staff must devote their entire attention to monitoring and treating the patient until recovery, or until such time as another Licensed Physician becomes available to take responsibility for the patient's care.</p> <p>3.3.8.2 If an emergency requires the brief temporary absence of the Sedationist, a clear written 'handover protocol' shall be in place when responsibility for care is transferred from one Sedationist practitioner to another. All relevant information about the patient's history, medical condition, sedation status, and plan must be communicated.</p> <p>3.3.8.3 The Licensed Physician to whom responsibility is delegated to shall be both suitably qualified and conversant with all relevant information regarding the PSA and the patient.</p> <p>3.3.8.4 Each Healthcare Operator providing PSA services shall have a written transfer agreement in effect with a Paramedic service and a nearby hospital(s) preferably within DHCC for the immediate and safe transfer of patients that need emergency medical care.</p> <p>3.3.8.5 During such emergency cases, the attending Licensed Physician shall be notified and responsible for arranging the patient's transfer to the appropriate hospital. A qualified and licensed Physician must accompany the patient during transfer to the hospital. All patient assessments and monitoring done during transfer must be documented in the medical record.</p>

3.4	<b>HEALTH INFORMATION MANAGEMENT</b>
3.4.1	Each Healthcare Operator providing PSA services shall comply with DHCA regulations, policies and standards for the management of patient health information and medical records.



## STANDARD – Standards for Procedural Sedation & Analgesia

3.4.2	Each Healthcare Operator providing PSA services shall ensure the confidentiality of patient health information as per the provisions of the DHCA Health Data Protection Regulation Numb (7) of 2013.
3.4.3	When necessary only standardized diagnosis codes, procedure codes, symbols, abbreviations, and definitions must be used.
3.4.4	All Sedation Practitioners and Licensed Healthcare Professionals involved in the care of patients undergoing PSA should have access as necessary to patients' health information to plan, provide and document the care delivered.
3.4.5	All written documentation of the informed consent process must be available in the medical record prior to a procedure.
3.4.6	The patient medical record shall contain the name(s) of staff providing PSA, with documentation of the related history, examination and investigation findings.
3.4.7	Details of each PSA administration must be entered into the patient's medical record with outcome/complications, if any. This should include details of the pre-operative assessment and the post-operative course.
3.4.8	Each Healthcare Operator providing PSA shall report applicable clinical and managerial performance measures to DHCR Clinical Affairs Department to monitor and improve patient care and outcomes as defined in DHCA Performance Measures Policy.

3.5	<b>PATIENTS RIGHTS AND RESPONSIBILITIES</b>
3.5.1	Each Healthcare Operator licensed to provide PSA shall provide patients and families with information regarding the DHCA Patients' Rights and Responsibilities in accordance to the DHCA Governing Regulation Number (1) of 2013. This information shall also be displayed in English and Arabic throughout the facility for patients and visitors to review.
3.5.2	Each Healthcare Operator providing PSA is responsible for providing processes that support patients' and families' rights during care.
3.5.3	Informed Consent shall be obtained through a process defined by each Healthcare Operator providing PSA and carried out by trained staff in a manner and language the patient can understand in accordance to the DHCA Informed Consent Policy. The patient or legal guardian shall be informed of and agree to the administration of PSA, including its risks, benefits, limitations and possible alternatives.
3.5.4	Written and oral informed consent must be obtained at an appropriate time (not at the last moment) prior to the procedure, to afford the patient/carer a chance to ask questions and



## STANDARD – Standards for Procedural Sedation & Analgesia

	understand the choices and risks before making a decision to sedate. Risks and benefits must be clearly explained and alternatives shall be clearly explained.
3.5.5	Legal guardians, in the case of minors or legally incompetent adult, shall be informed of and agree to the administration of PSA, including its benefits, risks, and limitations, including possible alternative management. Psychological preparation of patients, especially children and their carers is an important part of preparation for sedation.
3.6	<b>MINIMUM FACILITY REQUIREMENTS</b>
3.6.1	PSA shall be administered in procedure rooms and relevant treatment areas of adequate size to allow for the presence of necessary procedure equipment, patient and staff. They must also allow for the presence of emergency personnel and equipment and the safe care and transfer of the patient in case of a medical emergency.
3.6.2	Corridors in all possible areas used to transport patients on gurneys shall have a minimum width of 2.44 meters as per FGI guidelines.
3.6.3	PSA may only be provided by Licensed Healthcare Operators located in buildings which provide for the safe transport of patients in a medical emergency. When the Healthcare Operator is located in upper floors of a building then elevators must be able to accommodate the accompanied patient on a medical gurney.
3.6.4	Installation and maintenance of any piped gas system must comply with FGI guidelines. Servicing of such piped gases must occur on a regular basis and at least annually.
3.6.5	Each Licensed Healthcare Operator providing PSA services must provide appropriate equipment and a safe environment for the administration of inhalation sedation/anesthetic gases and vapors, including a scavenging system to vent waste gases.
3.6.6	Air supply of scavenging systems shall be at or near the ceiling and return/exhaust air inlets shall be near the floor level. Gases shall be exhausted directly to the outside and should not be part of a recirculation system.
3.6.7	If Nitrous Oxide (N <sub>2</sub> O) is utilized, Healthcare Operators shall make provisions for calibrated flow meters, a functional oxygen analyzer, a delivery system that covers the nose and mouth of the patient, and the ability to deliver no less than a minimum of 30% oxygen and a capability to deliver 100% oxygen on demand.
3.6.8	Each Licensed Healthcare Operator providing PSA shall ensure suitable and secure storage space for consumables, equipment, pharmaceutical drugs/products required for PSA.



## STANDARD – Standards for Procedural Sedation & Analgesia

3.6.9	Appropriate equipment and drugs required for cardiopulmonary resuscitation and airway support should be readily available in the area where PSA is provided. This shall include adequate and age appropriate: suctioning facilities, airway control devices such as endotracheal tubes, tracheostomy kits and laryngoscopes, defibrillators, pulse oximeters, sphygmomanometer, and immediate access to an electrocardiograph, capnography and reversal agents as and when applicable.
3.6.10	Available audible signals and audible alarms (with appropriately set limit values) should be activated at all times and loud enough to be heard throughout the operating or procedure room.
3.6.11	Age appropriately sized equipment for establishing a patent airway and providing positive pressure ventilation with supplemental oxygen must be available whenever sedation and/analgesia is administered.
3.6.12	Each Licensed Healthcare Operator providing PSA shall have appropriate call systems with call points located in patient treatment, assessment areas and toilets. Systems must be regularly performance tested and test results retained.
3.6.13	A Safety Management Program must be established to manage risks in the environment and reduce the risk of injury to patients and staff.

3.7	<b>QUALITY OVERSIGHT AND ACCREDITATION</b>
3.7.1	Each Healthcare Operator licensed to provide PSA services shall be subject to this Standard, the Dubai Outpatient Clinic Quality Standards or equivalent, the DHCR Quality Oversight Policies, and other applicable DHCA regulations, standards and policies.
3.7.2	Prior to commencing PSA services each Licensed Healthcare Operator shall have in place written policies and procedures required for safe and effective practices in compliance with the accreditation standards of the approved accreditation agency and all other applicable regulations, policies and standards. Written PSA documents, including policies, procedures, and programs shall be managed in a consistent and uniform manner.
3.7.3	Policies and procedures shall address all aspects of PSA management, including the appropriate documentation of the provision of PSA, patient management and monitoring.
3.7.4	A policy for Pediatric PSA shall include the difference in drugs used, NPO time, and discharge criteria, and the requirement of the qualified Licensed Physician or Dentist, skilled in PALS.
3.7.5	The policies and procedures shall include provision for regular review as well as making provision for training of all appropriate staff on the content of the policies and procedures.



## STANDARD – Standards for Procedural Sedation & Analgesia

3.7.6	Quality Assurance Committees of each Healthcare Operators providing PSA shall monitor and review the quality and safety of PSA services provided in accordance with the requirements of the DHCA Healthcare Operators Regulation number (4) of 2013.
3.7.7	All staff members involved in PSA activities shall continuously participate in risk management and quality improvement activities.
3.7.8	Each Healthcare Operator licensed to provide PSA shall report all related sentinel events to Clinical Affairs Department as per the applicable DHCA Sentinel Event policy.
3.7.9	Sedation practitioners shall regularly seek to audit their practice in PSA.
3.7.10	Each Licensed Healthcare Operator shall audit procedures performed by each Sedationist as part of the periodic review of clinical privileges.
3.7.11	Each Healthcare Operator licensed to provide PSA shall ensure the review of guidelines; review of pharmacovigilance of sedative and analgesic drugs, review of reported clinical incidents where sedation is a factor; annual audit of sedation cases and the incidence of complications; and overview of staff training and continuing professional development in sedation practice. Results shall be reported to the quality assurance committee.
3.7.12	Audit results shall inform ongoing training, education and support of all team members involved in the care of patients who receive sedation.

### 4 DEFINITIONS

4.1	<p><b>Advanced sedation technique:</b> involves the combination of drugs and should be administered only by the dedicated Sedationist. Any of the following sedation techniques would be classified as an advanced technique:</p> <p>Infusion technique: i.e. target controlled infusions or total intravenous anesthesia; Sedation by intravenous route with any of Propofol, ketamine, dexmedetomidine, etomidate and the opiates; an inhalation anesthetic agent: i.e. sevoflurane; and any combination of drugs, administered by any route.</p>
4.2	<p><b>American Society of Anesthesiologists (ASA) Patient Physical Status Classification:</b></p> <p><b>ASA I</b> – A normal healthy patient.</p> <p><b>ASA II</b> – A patient with mild systemic disease.</p> <p><b>ASA III</b> – A patient with severe systemic disease.</p> <p><b>ASA IV</b> – A patient with severe systemic disease that is a constant threat to life.</p>



## STANDARD – Standards for Procedural Sedation & Analgesia

	<p><b>ASA V</b> – A moribund (declining) patient who is not expected to survive without the operation.</p> <p><b>ASA VI</b> – A declared brain-dead patient whose organs are being removed for donor purposes.</p> <p><b>E</b> – Emergency operation of any variety (used to modify one of the above classifications, i.e. ASA III-E).</p>
4.3	<p><b>Analgesia:</b> means the reduction or elimination of pain. It is usually induced by drugs that act locally (by interfering with nerve conduction) or generally (by depressing pain perception in the central nervous system).</p>
4.4	<p><b>Anesthesia:</b> involves the administration of a medication to produce a blunting or loss of pain perception (analgesia); voluntary and involuntary movements; autonomic function; and memory and/or consciousness, depending on where along the central neuraxial (brain and spinal cord) the medication is delivered. Anesthesia exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications.</p>
4.5	<p><b>Anesthesiologist:</b> means a DHCC Licensed Physician holding a Specialty Medical License in Anesthesiology.</p>
4.6	<p><b>Clinical privileges:</b> It is an entitlement that the health organization grants to a physician to permit them to perform at the facility. Clinical privileges represent the scope of clinical responsibility that a medical practitioner may exercise in a facility. Clinical privileges are specific to an individual, and are according to their education, training, experience and competence, to manage and treat patients with a level of proficiency which minimizes the risk of causing harm. Clinical privileges also relate to the role delineation resources, equipment and staff available in the healthcare facility.</p>
4.7	<p><b>Continuum of Depth of Sedation:</b> ASA Definition of General Anesthesia and Levels of Sedation/Analgesia. Sedation and/or analgesia comprise a continuum of states ranging from minimal sedation through general anesthesia. The response of individual patients to the administration of sedation and/or analgesia is difficult to predict. Therefore, Licensed Healthcare Professionals intending to produce a certain level of sedation and/or sedation should always expect a sudden progression of the depth of sedation, and must be able to rescue patients who enter a deeper level of sedation than intended and effectively manage any adverse events that might occur. Built into the concept of a sedation continuum is the fundamental concept of titration.</p>



## STANDARD – Standards for Procedural Sedation & Analgesia

4.8	<b>Deep Sedation/Analgesia:</b> is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
4.9	<b>DHCA:</b> the Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body.
4.10	<b>DHCC:</b> Dubai Healthcare City.
4.11	<b>DHCR:</b> Dubai Healthcare City Regulatory is the regulatory arm of Dubai Healthcare City Authority. An independent licensing and regulatory authority for all healthcare providers, medical, educational and other business operating within DHCC.
4.12	<b>Dissociative Drugs:</b> alter perceptions of pain and sight and elicit feelings of detachment/dissociation from the environment and self.
4.13	<b>Dissociative Sedation:</b> produced with ketamine, cause a trance-like cataleptic state characterized by intense analgesia, amnesia, sedation, retention of protective reflexes, spontaneous breathing and cardiovascular stability. When ketamine is administered in doses used for PSA, it does not operate on the sedation continuum and should not lead to loss of consciousness.
4.14	<b>Epidural Anesthesia:</b> is a fine plastic tube (an epidural catheter) that is threaded through a needle and the tube is left in the epidural space in the back. Local anesthetic is injected down the tube to cause numbness, which varies in extent according to the amount of local anesthetic injected.
4.15	<b>FGI:</b> the Facility Guidelines Institute, USA. A not-for-profit entity responsible to manage related guidelines development process, protect the intellectual property of the guidelines, and manage funding of research supporting guidelines development.
4.16	<b>General Anesthesia:</b> is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
4.17	<b>Immediately Available:</b> means physically located in the facility and ready for immediate response or utilization.



## STANDARD – Standards for Procedural Sedation & Analgesia

4.18	<p><b>Informed Consent:</b> a process of communication between a person and a physician or other healthcare professional that results in the person's authorization or agreement to undergo a specific medical intervention. It includes the principle that a physician has a duty to inform his or her patients about the nature of a proposed or alternative treatment, procedure, test, or research, including the risks and benefits of each alternative and of not receiving it. An informed patient can then make a choice which procedure, if any, to undergo.</p>
4.19	<p><b>Local Anesthesia:</b> It is the application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed.</p>
4.20	<p><b>Minimal Sedation/Anxiolysis:</b> is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected. Examples of minimal sedation include peripheral nerve blocks, local or topical anesthesia, and either (1) less than 50% nitrous oxide (N<sub>2</sub>O) in oxygen with no other sedative or analgesic medications by any route, or (2) a single, oral sedative or analgesic medication administered in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.</p>
4.21	<p><b>Moderate Sedation/Analgesia (Conscious Sedation):</b> is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation (reflex withdrawal from a painful stimulus in not considered a purposeful response). No interventions are required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. All moderate sedation techniques should provide a margin of safety that is wide enough to render loss of consciousness unlikely.</p>
4.22	<p><b>Non-dissociative Sedation:</b> sedative drugs (including opioids, benzodiazepines, barbiturates, etomidate and Propofol) operate on the sedation dose-response continuum. Higher doses provide progressively deeper levels of sedation with possible respiratory and cardiovascular compromise, loss of protective reflexes and general anesthesia. With the use on non-dissociative drugs, the key to minimizing adverse events/complications is the careful titration of drugs to the desired effect.<sup>10.6</sup></p>
4.23	<p><b>Non-anesthesiologist Sedationist:</b> A licensed physician or dentist who has not completed postgraduate training in anesthesiology but is specifically trained to personally administer or supervise the administration of moderate sedation.</p>



## STANDARD – Standards for Procedural Sedation & Analgesia

4.24	<b>Proceduralist Sedationist:</b> is responsible for both the administration of PSA and performance of the procedure.
4.25	<b>Procedure Room:</b> is a room for the performance of procedures that do not require an aseptic field but may require use of sterile instruments or supplies. Procedure rooms are considered unrestricted areas. Local anesthesia and minimal and moderate sedation may be administered in a procedure room, but anesthetic agents used in procedure rooms must not require special ventilation or scavenging equipment.
4.26	<b>Recovery Area:</b> means a room/area dedicated to providing medical services to patients recovering from surgery and/or sedation and anesthesia.
4.27	<p><b>Routes of Administration:</b></p> <p><b>Enteral</b> – any technique of administration in which the agent is absorbed through the gastro (GI) tract or oral mucosa (i.e., oral, rectal, sublingual).</p> <p><b>Parenteral</b> – a technique of administration in which the drug bypasses the GI tract (i.e., intramuscular, intravenous (IV), intranasal, submucosal, subcutaneous, intraosseous).</p> <p><b>Transdermal</b> – a technique of administration in which the drug is administered by patch or iontophoresis through skin.</p> <p><b>Transmucosal</b> – a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.</p> <p><b>Inhalation</b> – a technique of administration in which the drug is administered across mucosa such as iontophoresis through skin.</p>
4.28	<b>Scavenging:</b> means the collection and removal of vented Anesthetic gases from the operating room. Since the amount of anesthetic gas supplied usually far exceeds the amount necessary for the Patient, operating room pollution is decreased by scavenging.
4.29	<b>Sedation:</b> the administration of a sedative agent or drug to induce a state of calm, restfulness, or drowsiness. The sedative agent or drug depresses activity of the central nervous system and reduces anxiety and induces sleep.
4.30	<b>Sedationist:</b> a qualified and licensed healthcare professional who administers the sedative and analgesic drugs, and monitors the clinical effects of these drugs.
4.31	<b>Sedation Assistant:</b> a dedicated licensed Healthcare Professional required for monitoring the patient's level of consciousness and cardiorespiratory status.
4.32	<b>Simple sedation technique:</b> is the administration of a single drug and not a combination of drugs. Some of the drugs applicable to simple/basic sedation are: Oral or transmucosal drugs



## STANDARD – Standards for Procedural Sedation & Analgesia

	i.e., benzodiazepines like midazolam; Inhaled combinations of nitrous oxide (N <sub>2</sub> O) and oxygen with the concentration of N <sub>2</sub> O not exceeding 50%; Titrated intravenous midazolam.
4.33	<b>Spinal Anesthesia:</b> is a single injection with a thin needle that puts the local anesthetic close to the nerves, within the fluid that surrounds the spinal cord.
4.34	<b>Titration:</b> administration of incremental doses of a drug until a desired effect is reached. Knowledge of each drug's time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.
4.35	<b>Topical Anesthesia:</b> means the application of an anesthetic agent directly or by spray to the skin or mucous membranes that is, intended to produce a transient and reversible loss of sensation to a circumscribed area.

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5.28

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