The Royal
Australian &
New Zealand
College of
Psychiatrists

1.0   Descriptive summary of station:

In this station the candidate is expected to take a brief history from a patient Jack Flynn, a 36-year-old man with bipolar disorder, who wants to stop his current psychotropic medication. He is insisting on switching to medicinal cannabis. The candidate must demonstrate their level of knowledge regarding the evidence for medicinal cannabis and that they are able to negotiate with the patient to continue current treatment.

1.1   The main assessment aims are:

- To demonstrate the ability to take a brief history to confirm that the patient's mood symptoms are stable and that there is no reason to change medication.
- To demonstrate an awareness of the indications for medicinal cannabis and its role in the current clinical environment.
- To demonstrate the ability to provide advice and negotiate reconsideration of medicinal cannabis.

1.2   The candidate MUST demonstrate the following to achieve the required standard:

- Identify that the patient's bipolar disorder is stable.
- Elicit weight gain as the major driver for desire to change treatment.
- Clearly advise the patient that medicinal cannabis is not indicated for mood disorders.
- Recommend options for management of weight gain.
- Explain the most evidence-based indications for medicinal cannabis that are likely to meet legislative requirements.
- Identify that it is still illegal for the patient to grow cannabis.

1.3   Station covers the:

- **RANZCP OSCE Curriculum Blueprint Primary Descriptor Category:** Mood Disorders
- **Area of Practice:** Adult Psychiatry
- **CanMEDS Domains:** Medical Expert, Collaborator, Professional
- **RANZCP 2012 Fellowship Program Learning Outcomes:** Medical Expert (Assessment – Data Gathering Content; Management – Treatment Contract), Collaborator (Relationships), Professional (Compliance & Integrity)

References:

- Adler JN, Colbert JA. Clinical decisions: medicinal use of marijuana — polling results. *N Engl J Med* 2013; 368: e30.
- Belendiuk KA, Baldini LL, Bonn-Miller MO, Narrative review of the safety and efficacy of marijuana for the treatment of commonly state-approved medical and psychiatric disorders, *Addiction Science & Clinical Practice,* 10/10 (2015), para. 14, http://www.ascpjournal.org/content/10/1/10.
- Carter GT, Flanagan AM, Earleywine M, et al. Cannabis in palliative medicine: improving care and reducing opioid-related morbidity. *Am J Hosp Palliat Care* 2011; 28: 297-303.
- Compton M,T. Marijuana and Mental Health. 18 May 2016. American Psychiatric Association Publishing; 1000 Wilson Boulevard, Suite 1825, Arlington, VA, 22209.
- Joy JE, Watson SJ Jr, Benson JA Jr, editors. *Marijuana and medicine: assessing the science base.* Washington, DC: National Academy of Sciences, 1999. http://www.nap.edu/readingroom/books/marimed
- Kleijnen Systematic Reviews Ltd, *Systematic review of cannabis for medical use* (York: Kleijnen Systematic Reviews Ltd, September 2014).
- Martin JH, Bonomo YA. Medicinal cannabis in Australia: the missing links. Med J Aust 2016; 205 (9): 425.
- Mather, LE, Rauwendaal, ER, Moxham-Hall, VL, Wodak, AD. (Re)introducing medicinal cannabis. *Med J Aust 2013; 199 (11): 759-761.*

Committee for Examinations
Objective Structured Clinical Examination

Station 4
Perth April 2017

The Royal
Australian &
New Zealand
College of
Psychiatrists

- Penington,DG. Medical cannabis: time for clear thinking. *Med J Aust 2015; 202 (2) Pages:74 – 76.*
- Porter BE, Jacobson C Report of a parent survey of cannabidiol-enriched cannabis in pediatric treatment resistant epilepsy. *Epilepsy Behav* 2013; 29: 574-577.
- Victorian Law Reform Commission, Medicinal Cannabis Report, August 2015.
- Whiting, Penny et al. Cannabinoids for medical use: a systematic review and meta-analysis. *JAMA 2015; (vol 313) June23/30: no.24.*
- Wilsey B, Marcotte T, Deutsch R, et al. Low-dose vaporized cannabis significantly improves neuropathic pain. *J Pain* 2013; 14: 136-148.
- Therapeutic Uses of Cannabis: Report and Evidence (House of Lords Papers) Select Committee on Science and Technology Second Report March 2001. http://www.publications.parliament.uk/pa/ld200001/ldselect/ldsctech/50/5002.htm
- Information for Health Care Providers – Health Canada http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf
- Barnes M, Barnes J, Cannabis: The Evidence for Medical Use, May 2016 http://www.drugsandalcohol.ie/26086/1/Cannabis_medical_use_evidence.pdf
- The Health Effects of Cannabis and Cannabinoids: The current state of evidence and recommendations for research - A report of the National Academies of Sciences Engineering Medicine in the https://www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state

1.4   Station requirements:

- Standard consulting room; no physical examination facilities required.
- Four chairs (examiner x 1, role player x 1, candidate x 1, observer x 1).
- Laminated copy of 'Instructions to Candidate'.
- Role player: male (must be slightly overweight), late 30s, dressed casually.
- Pen for candidate.
- Timer and batteries for examiner.

2.0   Instructions to Candidate

You have **eight (8) minutes** to complete this station after **two (2) minutes** of reading time.

You are working as a junior consultant in a community psychiatry clinic.

One of your patients, 38-year-old Jack Flynn, has come to see you for a regular check-up of his bipolar disorder which was diagnosed 12 years ago, and has been well controlled over the last 2 years. Jack would like you to prescribe medicinal cannabis.

Your tasks are to:

- Discuss with Jack his request to get access to medicinal cannabis for treatment of his bipolar disorder.

- Negotiate a treatment plan with Jack.

You will not receive any time prompts.

Station 4 - Operation Summary

Prior to examination:

- Check the arrangement of the room, including seating and other specifics to your scenario.
- On the desk, in clear view of the candidate, place:
  - A copy of 'Instructions to Candidate' and any other candidate material specific to the station.
  - Pens.
  - Water and tissues are available for candidate use.
- Do a final rehearsal with your simulated patient.

During examination:

- Please ensure mark sheets and other station information, are out of candidate's view.
- At the **first bell**, take your places.
- At the **second bell**, start your timer, check candidate ID number on entry.
- TAKE NOTE that there are no cues / scripted prompts for you to give.
- DO NOT redirect or prompt the candidate unless scripted – the simulated patient has prompts to use to keep to the aims.
- If the candidate asks you for information or clarification say:

  'Your information is in front of you – you are to do the best you can.'

- At **eight (8) minutes**, as indicated by the timer, the final bell will ring. Finish the examination immediately.

At conclusion of examination:

- Retrieve all station material from the candidate.
- Complete marking, and place your mark sheet in an envelope by / under the door for collection (**do not seal envelope**).
- Ensure room is set up again for next candidate. (See 'Prior to examination' above.)

If a candidate elects to finish early after the <u>final task</u>:

- You are to state the following:

  'Are you satisfied you have completed the task(s)?
  If so, you <u>must</u> remain in the room and <u>NOT</u> proceed to the next station until the bell rings.'

- If the candidate asks if you think they should finish or have done enough etc., refer them back to their instructions and ask them to decide whether they believe they have completed the task(s).

3.0 Instructions to Examiner

3.1 In this station, your role is to:

Observe the activity undertaken in the station and judge it according to the station assessment aims and defined tasks as outlined in 1.1 and 1.2.

When the candidate enters the room briefly check ID number.

The role player opens with the following statement:

'Doc, I am keen to change my medication.'

3.2 Background information for examiners

This station aims to assess the candidates' ability to take a brief history from a stable bipolar patient who wants to stop his current psychotropic medication. They are expected to be able to demostrate their level of knowledge regarding the evidence for medicinal cannabis and use this knowledge to negotiate with the patient to continue current treatment based on lack of evidence for medicinal cannabis in bipolar disorder.

To ensure that the patient is stable and that the request is not part of a relapse, the candidate would be expected to briefly assess the patient's mental state.

Risk assessment may be undertaken by the candidate and could include important aspects of the history, for instance:
- Pattern of illness: highs and lows, hospitalisations, treatments
- Problems or losses from either mania or depression e.g. job, relationship

In attempting to better understand the patient's request the candidate should consider issues like:
- Duration of current treatment regime
- Rationale for wanting to cease treatment
- Knowledge of and reason for considering medical cannabis.

When discussing treatment options, the pros and cons of stopping medication for any reason should be considered.

It is critical that the candidates work in a non-judgemental collaborative manner and allow the patient to explore his options for treatment.

With respect to medicinal cannabis, candidates are expected to demonstrate knowledge of the common indications for medicinal cannabis in countries where it is allowed and understand the level of availability in Australia / New Zealand.

There is no robust evidence to support the use of medicinal cannabis in bipolar disorder and the candidate must manoeuvre their way through a negotiation to end the station with some degree of acceptance by the patient.

In order to 'Achieve' this station the candidate **must**:
- Identify that the patient's bipolar disorder is stable.
- Elicit weight gain as the major driver for desire to change treatment.
- Clearly advise the patient that medicinal cannabis is not indicated for mood disorders.
- Recommend options for management of weight gain.
- Explain the most evidence-based indications for medicinal cannabis that are likely to meet legislative requirements.
- Identify that it is still illegal for the patient to grow cannabis.

A surpassing candidate may:

- Be able to incorporate the variances in legislation or the controversies related to production, monitoring and distribution as part of their discussion with the patient.
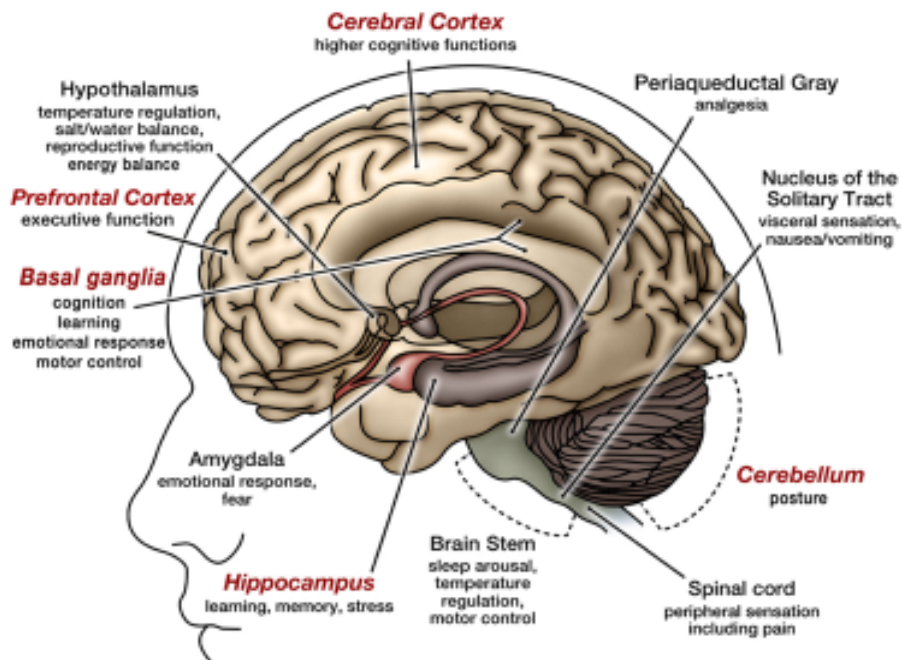
Cannabinoids

Cannabinoids are classified here as:

- Phytocannabinoids – plant leaves, flowers, stems, and seeds collected from the *Cannabis sativa* plant and ingested in some form (cigarettes, vapour).

- Endogenous – cannabinoids including *N*-arachidonoylethanolamine or anandamide (AE) or 2-arachidonoylglycerol (2-AG). AE and 2-AG activity can be manipulated by inhibiting their corresponding hydrolases FAAH or MAGL, preventing their degradation.

- Purified naturally occurring cannabinoids purified from plant sources: including cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC).

- Synthetic cannabinoids synthesised in a laboratory: examples include CB1 agonists (CPP-55, ACPA), CB2 agonists (JWH-133, NMP7, AM1241), CB1/CB2 nonselective agonist (CP55940), ajulemic acid (AJA), nabilone, and dronabinol.
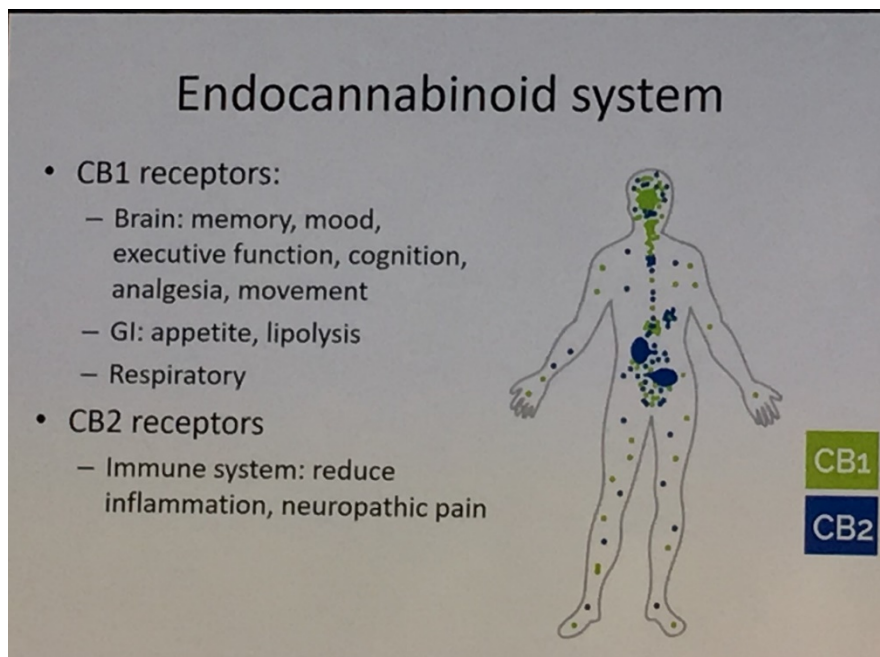
As well as THC and CBD, the marijuana plant contains more than 100 other cannabinoids, most of which are non-psychoactive, as well as terpenes. CB_1 receptors are among the most abundant G protein–coupled receptors in the brain, present in almost every brain region and on many different types of neurons. CB_1 receptors are particularly abundant in brain regions such as the hippocampus, cortex, cerebellum, and basal ganglia.

Brain regions that express the CB₁ cannabinoid receptor

Red = abundant CB₁ receptor expression   Black = moderately abundant CB₁ receptor expression

Cerebral Cortex
higher cognitive functions

Hypothalamus
temperature regulation,
salt/water balance,
reproductive function
energy balance

Periaqueductal Gray
analgesia

Prefrontal Cortex
executive function

Nucleus of the
Solitary Tract
visceral sensation,
nausea/vomiting

Basal ganglia
cognition
learning
emotional response
motor control

Amygdala
emotional response,
fear

Cerebellum
posture

Hippocampus
learning, memory, stress

Brain Stem
sleep arousal,
temperature
regulation,
motor control

Spinal cord
peripheral sensation
including pain

In Australia and New Zealand there is widespread use of illicit cannabis as a medicine which suggests that there is significant demand even though this use is neither supervised nor regulated. Concerns have been raised that there are no current legally available products of medicinal cannabis and therefore no oversight by appropriate health professionals. The risks are that illegal products may contain unknown ingredients that can put people at risk; that it is difficult to monitor appropriate dosages; and there are risks of interactions and reactions with other medications.

There is disagreement as to whether medicinal cannabis should be made legal despite several states legislating towards this. People argue from both sides; that it is too fast and too soon based on insufficient clinical evidence versus those who claim that enabling legal access has not come soon enough for people suffering specific disorders.

According to Whiting, Penny et al, the term Medicinal Cannabis has been defined as cannabis used 'as a medical therapy to treat disease or alleviate symptoms'. The Victorian Law Reform Commission noted that the use of cannabis to attempt to cure or reduce severity of symptoms due to illness distinguishes it from recreational cannabis.

Pennington would argue that 'cannabis can never be a pharmaceutical agent in the usual sense for medical prescription, as it contains a variety of components of variable potency and actions, depending on its origin, preparation and route of administration'.

Evidence

Mather et al refer to a German medical review that found 'a preponderance of favourable controlled trials for treatment of a range of conditions including spasticity resulting from disseminated sclerosis (nine favourable, three unfavourable), chemotherapy-induced nausea and vomiting (40 favourable, one unfavourable), HIV / AIDS-related cachexia (seven favourable, none unfavourable), cancer-related cachexia (three favourable, one unfavourable), chronic neuropathic pain (12 favourable, two unfavourable) and other chronic (cancer, rheumatism, fibromyalgia) pain (11 favourable, two unfavourable)'.

Medicinal cannabis is not curative for the indicated disorders, but it can relieve the symptoms associated with them. It may also enable other medication to be given at a lower dosage, especially morphine, and reduce their side effects. Side effects of marijuana that usually do not last long can include dizziness, drowsiness, short-term memory loss and euphoria. More serious side effects include severe anxiety and psychosis.

The FDA requires clinical trials to determine the benefits and risks and so far, researchers have not conducted enough large-scale clinical trials that show that the benefits of the marijuana plant (as opposed to its cannabinoid ingredients). The American Medical Association reviewed the evidence in 2009 and recommended rescheduling cannabinoid-based medicines to allow their legal prescription in the United States. Research into cannabinoids has led to two FDA-approved medications that contain cannabinoid chemical. At least 23 US states have legalised use of cannabis for medical conditions, as has Canada, followed by countries who are also legalising medicinal use of cannabis.

In July 2015 the NSW government announced Australia's first clinical trial of medicinal cannabis in terminally ill cancer patients using pharmaceutical grade cannabis sourced from commercial suppliers overseas.

Diagnostic Indications for Medicinal Cannabis:

Preclinical and a range of small clinical trials with marijuana and its extracts have been undertaken in the treatment of numerous diseases and conditions. The evidence continues to be mainly anecdotal, limited to small trials or hampered by poor design.

- The use in epilepsy is among its historically oldest indications of cannabis. Animal experiments provide evidence of the antiepileptic effects of some cannabinoids. There are case reports of its use in otherwise unmanageable seizure disorder and there is feedback from parents that cannabis reduces seizures in Dravet syndrome (a rare genetic myoclonic epileptic encephalopathy beginning in infancy). The anticonvulsant activity of phenytoin and diazepam have been potentiated by THC. Cannabis use, however, may occasionally precipitate convulsions.

- Trials in 1980s indicated the antiemetic effects of cannabis in nausea from multiple causes, including control of nausea and vomiting associated with chemotherapy for cancer. THC in low doses appears to improve the efficacy of other antiemetic drugs if given together.

- AIDS / HIV - cannabis can control the nausea and vomiting caused by medications used in treatment.

- Studies have shown mild to moderate analgesic properties of THC cannabis products, particularly CB1 receptor agonists. Possible indications are neuropathic pain due to multiple sclerosis, damage of the brachial plexus and HIV infection, pain in rheumatoid arthritis, cancer pain, headache, menstrual pain, chronic bowel inflammation and neuralgias. Combination with opioids is possible.

- A 2015 systematic review of efficacy in chronic pain in nine studies demonstrated a 30% or more reduction in pain when compared to placebo (Whiting et al).

- Cannabis has been shown to decrease intraocular pressure and could prevent blindness in people with glaucoma.

- There are some positive anecdotal reports of therapeutic response to cannabis in Tourette's syndrome, dystonia and tardive dyskinesia.

- Small trials of THC, nabilone and cannabis have shown a beneficial effect, particularly subjective, on spasticity caused by multiple sclerosis or spinal cord injury. This is likely to be related to the high density of cannabinoid receptors in the brain areas controlling movement. Among other positively influenced symptoms were pain, paraesthesia, and modest dose related improvements in dystonia, tremor and ataxia. In some studies improved bladder control was observed.

- Animal studies have shown that marijuana extracts may help kill certain cancer cells and reduce the size of others. Research in mice showed that treatment with purified extracts of THC and CBD, when used with radiation, increased the cancer-killing effects of the radiation (Scott, 2014).

- Anti-inflammatory and relaxant effects of cannabis may be responsible for anecdotal improvements in patients with difficulty taking in food / nourishment (appetite or nausea and vomiting problems), inadequate absorption of nutrients, elimination problems (constipation, diarrhoea, irritable bowel) and / or cancer developing anywhere along the GI tract (Crohn's disease, Ulcerative Colitis, Irritable Bowel Syndrome). Cannabis does appear to be ineffective in anorexia nervosa.

- Dronabinol treatment in 11 patients with Alzheimer's disease resulted in substantial weight gains and declines in disturbed behaviour with no serious side effects observed.

- Cell culture and animal studies have established cannabinoids as immunomodulators and is likely to be multi-faceted.

- According to historical and modern case reports cannabis can combat withdrawal in dependency on benzodiazepines, opiates and alcohol. Both the reduction of physical withdrawal symptoms and stress connected with discontinuance of drug abuse may play a role in perceived benefits.
- There are case reports that claim improvement of mood in depression, which has the greatest self-reported benefit, as well as case reports claiming benefit of cannabinoids in sleep disorders, anxiety disorders, bipolar disorders, and dysthymia. This evidence, however, is not robust.

The Dutch Health authorities developed a list of indications based on the outcome of an extensive review of the scientific literature. Currently, there is sufficient reason to assume that medicinal cannabis can help in cases of:

- pain and muscle spasms or cramps associated with multiple sclerosis or spinal cord damage;
- chronic neuropathic pain (mainly pain associated with the nervous system, e.g. caused by a damaged nerve, phantom pain, facial neuralgia or chronic pain which remains after the recovery from shingles);
- nausea, loss of appetite, weight loss, and debilitation due to cancer or AIDS;
- nausea and vomiting associated with chemotherapy or radiotherapy used in the treatment of cancer, hepatitis C or HIV infection and AIDS;
- Gilles de la Tourette syndrome;
- therapy-resistant glaucoma.

In Australia, the Victorian Law Reform Commission, Medicinal Cannabis Issues Paper (March 2015) identified the following list based on evidence:

- Muscle spasticity and other symptoms of multiple sclerosis
- Chemotherapy-induced nausea and vomiting
- Epilepsy and severe seizures
- HIV and AIDS-related symptoms
- Chronic pain
- Arthritis.

Condition	Number of Studies	Strength of Evidence	Conclusion
Nausea & vomiting	3 RCTs	Low	THC or THC/CBD > placebo
Weight gain in HIV & AIDS	1 RCT	Low	THC > placebo
Spasticity in MS / paraplegia	14 RCTs	Moderate	THC/CBD > placebo
Depression	3 RCTs	Low	Placebo > THC/CBD
Anxiety	1 RCT	Low	CBD > placebo
Sleep	12 RCTs	Low	THC or THC/CBD > placebo
Psychosis	1 RCT	Low	CBD = amisulpiride
Tourette's syndrome	1 RCT	Low	THC > placebo
Glaucoma	1 RCT	Low	THC = CBD = placebo
Epilepsy	Not completed	N/A	CBD

Taken from Systematic Review of Cannabinoids – Whiting et al. JAMA June 2015

The reason for this limited list of indications is that the efficacy of medicinal cannabis use for other medical conditions has not yet been properly studied in convincing clinical trials and is subject to change based on new studies.

According to Cochrane, Whiting 2015 and the 2017 US National Academy of Science:

- there is moderate efficacy evidence for nausea and vomiting and analgesia (especially neuropathic pain in MS).
- there is weak efficacy evidence for the treatment of wasting.
- there is limited published evidence for epilepsy.
- there is limited OBJECTIVE evidence for spasticity in MS, but evidence as better than placebo on SUBJECTIVE measures
- there is limited / insufficient evidence in irritable bowel syndrome, Parkinsons disease, Huntington's chorea, anxiety, PTSD and depression.
- there is some weak evidence for CBD-based preparations in schizophrenia.

The evidence differs across the various products; for instance, Dronabinol (nausea & vomiting / appetite); Nabilone (appetite stimulation); nabiximols (Sativex) for spasticity in MS. The last group in the cannabidiol-based preparations (Epidiolex).

However, there are no specific limitations on the conditions for which medicinal cannabis can be prescribed for. Each application from a prescribing doctor will be considered on its merits.

Proponents argue that controlled trials of medicinal cannabis indicate that frequencies of both side effects and dependence are low. Those who oppose the use of medicinal cannabis focus on the lack of evidence, the lack of provenance, inconsistency of dosage, and concern about side effects, including psychosis.

The acute side effects of cannabis include vomiting, impaired coordination and performance, anxiety, suicidal ideation and psychotic symptoms, as well as impaired ability to drive.

Chronic cannabis use is associated with a number of negative health and social effects including increased risk of respiratory diseases associated with smoking, cancer, mood disorders, exacerbation of psychotic disorders in vulnerable people, decreased memory and learning abilities and decreased motivation in areas such as study, work and concentration. The side effects of cannabis when used for medicinal purposes are not well understood.

There is growing evidence that occasional cannabis use by adolescents is associated with greater risk of amotivation, reduced academic performance, lower educational attainment and potentially school dropout. Some adolescents go on to develop addiction. Evidence strongly suggests that heavy cannabis use in adolescence is an independent risk factor for schizophrenia and other psychotic disorders.

Access and Administration:

Prior to medicinal cannabis becoming readily available there are several issues that need to be resolved. The production and supply of medicinal cannabis should not differ from other botanical medicines. Governance for regulation / registration, and good manufacturing practice (GMP) needs to be in place.

In other countries a range of pharmaceutical-grade products have been made by extracting compounds from cannabis plants. These manufactured products better fit the usual definition of medicines. This is because they are produced so that their composition of active ingredients and purity is standardised, and they can be taken in measured doses, so their likely effects are known.

Questions that still need to be answered include whether in Australia and New Zealand the plant will be grown for the base or will it be synthetic? If it is to be grown, where will this be to ensure consistency and stability?

Other issues include whether scripts should be written or should patients be able to self-titrate; which drug / chemical / combination will be available; and what route(s) of administration, dose and frequency will be available.

As medicinal cannabis will not be listed on the Pharmaceutical Benefits Scheme (PBS), the cost of obtaining medicinal cannabis could amount to thousands of dollars per month. There are difficulties in importing medicinal cannabis products from overseas because of limited supply and legal constraints in those countries.

The product can be imported from a legal supply source overseas according to the *Customs (Prohibited Imports) Regulations 1956*, or in the future produced lawfully under an amended *Narcotics Drug Act 1967*. Despite changes to legislation in 2016, supplies of medicinal cannabis are not expected to be available until early 2017 at the earliest.

In February 2014, Tasman Health Cannabinoids proposed trials of cultivation and processing of medicinal cannabis in Tasmania in conjunction with the University of Tasmania; approved in principle by the Labor Health Minister but subsequently rejected by the incoming Liberal Health Minister. The company then was granted a licence by the Norfolk Island Government to produce medical cannabis, but that licence was overturned by the island's Administrator.

The most common modes of administering botanical cannabis is by transpulmonary, peri-oral, or oral transmucosal routes. Smoking does not deliver an accurate dosage and is not acceptable to many patients, nor is it medically acceptable; however it may be of benefit to certain patients with a short life expectancy or as an expedient self-medication treatment. Vaporisation in an electrically heated vaporiser produces comparable results and is preferable.

Vaporising cannabis:

- Similar to 'e-cigarettes' - vaporising heats cannabis at lower temperature than 'smoking'.
- Higher bioavailability
- No side stream smoke (fewer concerns re: passive smoking)
- Peak THC effects: typically 15-90 min after dose, psychoactive effects for 2-3 hours

Factors that affect drug toxicity / benefit that need to be adjusted for:

- Target symptoms
- Route of administration
- t1/2, clearance
- Age, gender, presence of other diseases
- Obesity
- Known / unknown drug AND food interactions
- Patient side effects - tolerability
- Surrogates of efficacy or toxicity
- Drug supply / chemistry

Potential and relative contraindications include:

- Hypersensitivity
- Severe unstable cardiopulmonary disease (CB1 increases the risk of myocardial infarction, especially in the first hour post dose)
- Personal or family history of schizophrenia
- <25 years (due to relative neuroplasticy)
- Severe liver and renal dysfunction
- Heavy drug dependence or prescription of other psychoactive medications.

LEGISLATION

Australia:

According to the *Therapeutic Goods Act 1989 (Cwlth),* the *Narcotic Drugs Act 1967 (Cwlth)* cannabis is a prohibited substance. However, in February 2016 the *Narcotic Drugs Act* was amended to establish a national licensing and permit scheme for lawful use. In August 2016, the Poisons and Therapeutic Goods Amendment (Designated Non-ARTG Products) Regulation (under the Poisons and Therapeutic Goods Act 1966) took effect. The TGA rescheduled all botanical cannabis products and all botanically-derived extracts, when prepared and packed for therapeutic use as Schedule 8. This came into force on 1 November 2016. This now allows for doctors to apply to the health authority for approval to prescribe cannabis-based products that are not on the Australian Register of Therapeutic Goods, in appropriate circumstances.

The Therapeutic Goods Administration (TGA) has approved three cannabis products classified as Schedule 8 (controlled drugs). With restrictions, these drugs can be used in states / territories: nabiximols (e.g. Sativex) for multiple sclerosis; dronabinol and nabilone for therapeutic purposes.

There are three TGA pathways to access medicinal cannabis:
1. Special Access Scheme (A or B)
2. Authirised Prescriber
3. Clinical Trial under CTN / CTX

State government approval to prescribe Schedule 8 drug.

The use of cannabis is not a first line therapy and all other options must have to have been trialled. The 'prescribing' process, as in other states / territories, is a dual step process requiring both TGA and state approval. TGA requires demographic data as well as diagnosis and target symptom, with a clinical justification for a specific product, the administration monitoring details. Information about the dose, form, active ingredients, shelf-life and storage conditions as well as manufacturer-supplier details.

The NSW Government introduced clinical trials in 2014 in patients with drug-resistant and uncontrollable epilepsy: CBD in paediatric epilepsy (NSW, QLD, Victoria) and adult focal epilepsy (Victoria, NSW, QLD).

Other trials include THC (vaporised and oral) in palliative care in NSW; oral THC:CBD in NSW for chemotherapy-induced nausea and vomiting (CINV); cannabis dependence with nabiximols as substitution treatment (NSW) and safety in driving (NSW).

A national working party is to decide the initial list of specialists; however areas are likely to be paediatric neurology, oncology and palliative care medicine. Approved hospital and dispensing pharmacies may also be specified.

Single-patient and patient-class prescriber pathways are available under the legislation. The patient-class pathway may state a class of specialist doctors that have as-of-right authority to prescribe specific medicinal cannabis products for patients suffering a specific range of conditions, without any need for additional approval.

A range of new offences will be covered in the provisions of any monitoring, investigation and enforcement framework; for instance it is an offence to perform a regulated activity (e.g. prescribing, possessing, obtaining or manufacturing medicinal cannabis) without authorisation.

Victoria

The Victorian Parliament became the first Australian state to legalise medicinal cannabis when it passed the *Access to Medicinal Cannabis Act 2016* on 12 April 2016. This now enables access to locally manufactured medicinal cannabis products for a defined group of patients in exceptional circumstances. Children with severe epilepsy will be able to access legal medicinal cannabis products from early 2017.

It is expected that the Office of Medicinal Cannabis will be established within the Department of Health and Human Services which will be responsible for all clinical and manufacturing aspects of the medicinal cannabis framework. An Independent Medical Advisory Committee will provide advice to the Victorian Government on the types of medicinal cannabis products that should be available to Victorian patients, and the expansion of eligibility to include other patient groups.

New South Wales

In May 2013, a New South Wales parliamentary committee comprising members of five political parties unanimously recommended making medicinal cannabis available for selected conditions. New South Wales (NSW) started a Terminal Illness Cannabis Scheme in late 2014. The scheme allows NSW residents aged 18 years and over who have a terminal illness to register to use natural cannabis. The scheme, now called the Medicinal Cannabis Compassionate Use Scheme, provides guidelines for NSW police officers so as not to charge people on the scheme using cannabis or cannabis products to help their symptoms, or carers who help them.

In July 2016, the New South Wales Government secured a licence from the Federal Government to grow cannabis for medical use in Australia. This is the first licence approved by the Federal Government since legislation changed earlier in 2016.
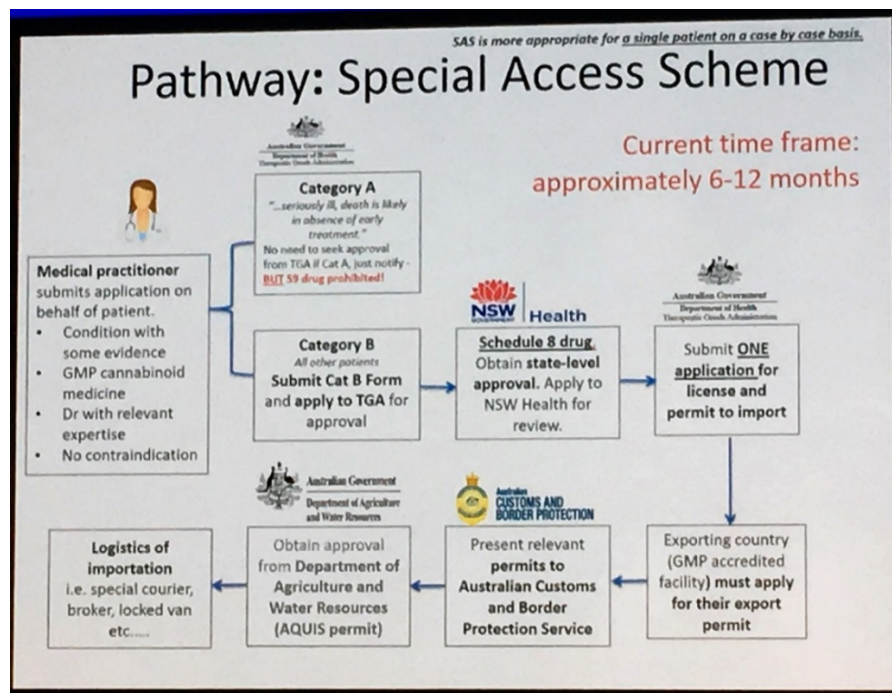
(source: International Medicine in Addictions 2017: Nlintzeris)

<u>Western Australia</u>

Cannabis remains a prohibited Schedule 9 substance in WA, making it illegal to cultivate, possess, use, sell or supply cannabis. The *Misuse of Drugs Act 1981* is in place to prevent the misuse of certain drugs and plants such as cannabis.

WA Health will set up an 'expert advisory council', to which doctors must apply, as well as the Federal Therapeutic Goods Administration, before prescribing new cannabis drugs from early next year.

<u>Queensland</u>

Cannabis was a prohibited substance under the *Health (Drugs and Poisons) Regulation* 1996 and it is an offence to produce, possess and supply cannabis without authorisation, justification or lawful excuse under the *Drugs Misuse Act 1986*. In December 2015, the Queensland Government amended the Regulation to allow the use of cannabis for clinical trials and where the TGA has approved an individual accessing these products, under special authority.

The Public Health (Medicinal Cannabis) Act 2016 was passed in October 2016. Under this legislation medicinal cannabis will only be approved:

- if the patient has already tried the conventional treatments available and these have failed; AND

- the doctor provides evidence that medicinal cannabis is effective for the particular condition or symptoms.

<u>South Australia</u>

South Australia adopted the national scheduling changes from 1 November 2016, when medicinal cannabis products became in the same class as medicines such as morphine. Medicinal cannabis products will be prescription only medicines, with only authorised medical practitioners able to prescribe medicinal cannabis. All other types of cannabis remain prohibited.

The *Controlled Substances Act 1984 (SA)* and the *Controlled Substances (Poisons) Regulations 2011 (SA)* regulate the sale, supply, administration and possession of prescription drugs.

New Zealand

The Minister or Ministry of Health has the power to authorise the medicinal use of cannabis products, as long as the application is put forward by a medical specialist on behalf of the patient. There have been few applications and ministerial approval has been granted for only a small number of patients. The cannabis-based drug *Sativex®* oromucosal spray was gazetted for use in 2011 in New Zealand.

Medsafe (the government's medicines regulatory agency) approved *Sativex®* for use as an add-on treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

Using cannabis or cannabis-based products as medicine without the proper approval of the Minister or Ministry of Health is illegal in New Zealand. As part of an election promise in New Zealand Labour have promised to legalise the prescription of medicinal cannabis for people with chronic pain or terminal conditions.

Drug	Suggested medical use
Sativex® (GW Pharmaceuticals) A mouth spray made from natural extracts of the cannabis plant. Contains THC and CBD (cannabidiol)	Treating neuropathic pain and muscle stiffness from MS; analgesia for adults with advanced cancer
Dronabinol / <u>Marinol</u>® (Unimed Pharmaceuticals) Contains artificial THC	Treating nausea and vomiting from cancer treatment; appetite stimulant for AIDS patients; painkiller for nerve pain from MS
Nabilone / Cesamet® (Valeant Pharmaceuticals International) Contains an artificial drug like THC	Treating nausea and vomiting from cancer treatment
Canasol (Medi-Grace Pharmaceuticals Ltd.) (only approved in Jamaica) A cannabis plant-based solution	Glaucoma treatment
Bedrocan® (Bedrocan BV) Medicinal grade natural full-bud cannabis plant material	All the above conditions and to treat Tourette syndrome
Epidiolex (new cannabis-based medicine)	Showing some promising results for difficult to treat childhood epilepsy conditions Dravet syndrome and Lennox-Gastaut syndrome

(adapted from NZ Drug Foundation)

3.3 The Standard Required

Surpasses the Standard – the candidate demonstrates competence above the level of a junior consultant psychiatrist in several of the domains described below.

Achieves the Standard – the candidate demonstrates competence expected of a junior consultant psychiatrist. That is the candidate is able to demonstrate, *taking their performance in the examination overall*, that

i.   they have competence as a ***medical expert*** who can apply psychiatric knowledge including medicolegal expertise, clinical skills and professional attitudes in the care of patients (such attitudes may include an ability to tolerate uncertainty, balance, open-mindedness, curiosity, 'common sense' and a scientific approach).

ii. they can act as a ***communicator*** who effectively facilitates the doctor patient relationship.

iii. they can ***collaborate*** effectively within a healthcare team to optimise patient care.

iv. they can act as ***managers*** in healthcare organisations who contribute to the effectiveness of the healthcare system, organise sustainable practices and make decisions about allocating resources.

v.   they can act as ***health advocates*** to advance the health and well-being of individual patients, communities and populations.

vi. they can act as ***scholars*** who demonstrate a life-long commitment to learning as well as the creation, dissemination, application and translation of medical knowledge.

vii. they can act as ***professionals*** who are committed to ethical practice and high personal standards of behaviour.

Below the Standard – the candidate demonstrates significant defects in several of the domains listed above.

Does Not Achieve the Standard – the candidate demonstrates significant defects in most of the domains listed above or the candidate demonstrates significant defects in the first domain of being a medical expert.

4.0   Instructions to the Role Player

4.1   This is the information you need to memorise for your role:

You are Jack Flynn, a 36-year-old man with bipolar mood disorder. You have been married to Grace for 8 years and do not have any children. You work as a carpenter in your own business which has been going well over the last few years. Grace works part-time as a secretary at a local real estate agent.

The main purpose of your visit is to persuade the psychiatrist that you want to change medication to medicinal cannabis. You have been following all the media hype and have been reading bits and pieces on the subject. On the internet, you have seen that medicinal cannabis has been used in people with mood disorders and you want to try it.

If you are asked: you started smoking cigarettes when you were 17 years old, and you regularly smoked cannabis in your early 20's. You very occasionally smoke cannabis now. You do not believe cannabis has any negative impact on your mental illness, and have not been aware of any link between smoking and worsening of symptoms.

Your friends think it is a great idea to switch, especially as you have kind of tested cannabis already by smoking weed. Your wife's boss told you about his mother who lives in California: she is having chemotherapy and feels really terrible, and she has been prescribed medicinal cannabis to help her feel better. If asked, in what way she feels better: it helps reduce severe nausea and pain.

About your mental illness:
If you are asked about the history of your illness: you were diagnosed with bipolar mood disorder when you were 22 years old after you were admitted to an acute inpatient unit because you were '*out of control'*. Over a number of weeks you had become more and more irritable and elevated in mood, and started to believe you had a special mission for God. At the time, you had been setting up our own business which was very stressful. You had so much energy, had found you didn't need to sleep and felt really great within yourself. Since then you have had two further admissions in 2010 and 2013 – both for recurrence of these kind of manic symptoms.

Each admission was for more than three weeks long, and it took at least another 6-8 weeks to get the business back on track. There was a cost: to your business reputation as you were picked up by the police on worksites on the last two admissions; and to your family financial stability.

Your bipolar disorder has been stable for about 2 years, and you have not needed an admission for three years.

Reasons for stopping medication:
Your current medication is quetiapine and lithium (see doses in section 4.7 below). You have taken them for many years and have become worried about 12kg of weight gain, and you have also read that lithium can '*wreck your kidneys*'.

If asked what would a relapse of your illness cost you at this stage of your life: your business is stable and you have a regular contract with a large house & land package firm, and without it your finances would be much more unstable. Your wife has said that she is scared about you getting ill again after what happened last time when you spent a lot of money on multiple credit cards, and it took the last three years to get sorted out.

If asked about your daily schedule / any routine of eating & exercise: you get up at 6am most days and take breakfast with you to the work site, coffee and a snack; lunch is whatever the local café has, and you get home around 5pm; you do not do much regular exercise since you stopped playing football and cricket after your last admission.

4.2   How to play the role:

You are a casually dressed man, usually with an easy-going manner. You are keen to talk with the doctor about stopping your current medications. You want to do this for several reasons; you have been well for a few years, but you have put on at least 12 kg since you have been on these medications.

You have heard increasing media about medicinal cannabis being legal for use, and want it prescribed for your own use. You used to smoke cannabis regularly when you were younger, and liked the way it made you feel. So you do not see why you shouldn't be able to get the legal cannabis now as you do not think that is will be dangerous for you.

You are adamant you want to change, and will not be talked out of this easily. You expect the candidate to explain all the legal and clinical aspects related to access to medicinal cannabis.

4.3 Opening statement:

'Doc, I am keen to change to my medication.'

4.4 What to expect from the candidate:

The candidate should try to engage you in a discussion to better understand why you want to stop your medications and switch to medicinal cannabis. They are expected to provide you with the current evidence that is available that does not support the use of cannabis in bipolar disorder, and explain the conditions under which medicinal cannabis has good evidence to be prescribed.

If the candidate flatly refuses to even consider this as an option or is unable to provide you with any information about its approved use then you can respond in an irritated manner, and threaten to grow your own and smoke it anyway.

4.5 Responses you MUST make:

'I want you to prescribe medicinal cannabis for me instead of my current meds.'

'I know that doctors can prescribe medicinal cannabis – so why won't you?'

'So what kind of patients can get cannabis legally?'

'Maybe I can now just grow my own cannabis or someone can grow it for me.'

4.6 Responses you MIGHT make:

'I know that cannabis can be prescribed legally now.'

4.7 Medication and dosage that you need to remember:

Lithium carbonate 500 milligrams twice a day (your last blood level done on 29 March was the same as before – 0.6)

Quetiapine-XR 400 milligrams at night (KWET-I-APEEN)

STATION 4 – MARKING DOMAINS

The main assessment aims are:

- To demonstrate the ability to take a brief history to confirm that the patient's mood symptoms are stable and that there is no reason to change medication.
- To demonstrate an awareness of the indications for medicinal cannabis and its role in the current clinical environment.
- To demonstrate the ability to provide advice and negotiate reconsideration of medicinal cannabis.

Level of Observed Competence:

1.0   MEDICAL EXPERT

1.2   Did the candidate take appropriately detailed and focussed history? (Proportionate value - 25%)

Surpasses the Standard (scores 5) if:
clearly achieves the overall standard with a superior performance in a range of areas; demonstrates prioritisation and sophistication.

Achieves the Standard by:
conducting a detailed but targeted assessment; obtaining a history relevant to the patient's circumstances with appropriate depth and breadth; history taking is hypothesis-driven; demonstrating ability to prioritise; eliciting the key issues; completing a risk assessment relevant to the individual case; clarifying important positive and negative features.

To achieve the standard *(scores 3)* the candidate **MUST**:
a.   Identify that the patient's bipolar disorder is stable
b.   Elicit weight gain as the major driver for desire to change treatment.

A score of 4 may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

Below the Standard (scores 2 or 1):
scores 2 if the candidate does not meet (a) or (b) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

Does Not Achieve the Standard (scores 0) if:
omissions adversely impact on the obtained content; significant deficiencies such as substantial omissions in history.

1.2. Category: ASSESSMENT – Data Gathering Content	Surpasses Standard	Achieves Standard		Below the Standard		Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY	**5** ☐	**4** ☐	**3** ☐	**2** ☐	**1** ☐	**0** ☐

3.0   COLLABORATOR

3.4   Did the candidate demonstrate an appropriately skilled approach to patient? (Proportionate value - 25%)

Surpasses the Standard (scores 5) if:
recognises complexity of liaison; competently manages the interview; actively seeks to evaluate the influence of any local and regional advocacy groups who may be recommending use in bipolar disorder.

Achieves the Standard by:
demonstrating respect; listening to differing views, identifying appropriate techniques to enhance engagement; maintaining an effective working alliance.

To achieve the standard *(scores 3)* the candidate **MUST**:
a.   Clearly advise the patient that medicinal cannabis is not indicated for bipolar mood disorder.

A score of 4 may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

Below the Standard (scores 2 or 1):
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

Does Not Achieve the Standard (scores 0) if:
any errors or omissions adversely impact on a collaborative relationship; being insensitive to the patient; using aggressive or interrogative style; having a disorganised approach.

3.4. Category: PATIENT RELATIONSHIPS	Surpasses Standard	Achieves Standard		Below the Standard		Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY	**5** ☐	**4** ☐	**3** ☐	**2** ☐	**1** ☐	**0** ☐

1.0 MEDICAL EXPERT

1.15 Did the candidate adequately engage, inform and discuss the treatment plan with the patient including suitably incorporating patient goals / preferences? (Proportionate value - 25%)

Surpasses the Standard (scores 5) if:
clearly achieves the overall standard with presentation of a plan that is comprehensive and sophisticated; easily collaborates with the patient to develop an understanding about the pros and cons of biological and psychological treatment options.

Achieves the Standard by:
demonstrating ability to: communicate a more appropriate treatment plan; advise the risk of relapse with change of medication; clearly outline options and recommendations; work around patient treatment goals, and negotiate targeted outcomes; reasonably establish that the patient understands and agrees with a treatment approach.

To achieve the standard *(scores 3)* the candidate **MUST**:
a. Recommend options for management of weight gain.

A score of 4 may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

Below the Standard (scores 2 or 1):
scores 2 if the candidate does not meet (a) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

Does Not Achieve the Standard (scores 0) if:
description of the management plan lacks structure; difficulty tailoring treatment to the patient's specific circumstances.

1.15. Category: MANAGEMENT - Treatment Contract	Surpasses Standard	Achieves Standard		Below the Standard		Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

7.0 PROFESSIONAL

7.2 Did the candidate demonstrate an adequate knowledge of legislation / regulatory requirements? (Proportionate value - 25%)

Surpasses the Standard (scores 5) if:
readily articulates any gaps in their knowledge, offers to follow up on questions they cannot answer; addresses role and reliability of media / Internet.

Achieves the Standard by:
demonstrating the capacity to: apply relevant legislation / regulation; show integrity, honesty and compassion; distinguish between legal and illegal behaviours.

To achieve the standard *(scores 3)* the candidate **MUST:**
a. Explain the most evidence-based indications for medicinal cannabis that are likely to meet legislative requirements
b. Identify that it is still illegal for the patient to grow cannabis in Australia.

A score of 4 may be awarded depending on the depth and breadth of additional factors covered; if the candidate includes most or all correct elements.

Below the Standard (scores 2 or 1):
scores 2 if the candidate does not meet (a) or (b) above, or has omissions that would detract from the overall quality response; significant omissions affecting quality scores 1.

Does Not Achieve the Standard (scores 0) if:
does not demonstrate adequate knowledge of the legislation; does not sufficiently warn the patient of legal risks.

7.2. Category: COMPLIANCE & INTEGRITY	Surpasses Standard	Achieves Standard		Below the Standard		Standard Not Achieved
ENTER GRADE (X) IN ONE BOX ONLY	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐	0 ☐

GLOBAL PROFICIENCY RATING

Did the candidate demonstrate adequate overall knowledge and performance at the defined tasks?

Circle One Grade to Score	Definite Pass	Marginal Performance	Definite Fail