

# Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)

## SUBMISSION FEEDBACK

Please provide comments on all or any of the following, particularly in relation to each Option outlined in the Consultation Regulation Impact Statement:

- The appropriateness and feasibility of the proposals.
- Whether the proposed changes will address current concerns with the regulations in the diagnostic imaging sector.
- Potential costs associated with each option.
- Potential benefits associated with each option.
- Potential workforce impacts.
- Impacts on patient access to appropriate imaging.
- Rural and remote access for patients.
- Time required to implement the potential changes.
- Impact on both smaller diagnostic imaging practices and larger practices.
- Any other comments, questions and concerns that relate to the proposed options.

In addition, you may wish to respond to questions listed against specific Options.

Submissions should include substantiating evidence, where possible.

### **Option 1 – No regulatory changes or deregulation (refer to page 23 of the RIS)**

#### **Features:**

- The current supervision requirements remain unchanged.
- The person under the professional supervision of the radiologist would require the appropriate qualifications, credentials, or training to provide the service.
- The current substitution rules in the *Health Insurance Act 1973* remain.
- Rural and remote exemptions.

#### **Comment**

The ACPSEM does not support this option.

### **Option 2 – Minor changes including clarification of current requirements (refer to page 24-26 of the RIS)**

#### **Features**

- Amendments to the current supervision requirements to clarify the circumstances under which a radiologist and/or specialist or consultant physician must provide supervision and how the supervision must be provided.
  - Professional supervision would require: the medical practitioner be available to observe and guide the conduct and diagnostic quality and safety of the examination and if necessary in

accordance with accepted medical practice, attend the patient personally, within a reasonable period of time.

- The personal attendance requirement of musculoskeletal ultrasound would be amended to align with all other ultrasound items.
- The person under the professional supervision of the radiologist would require the appropriate qualifications, credentials, or training to provide the service.
- The current substitution rules in the *Health Insurance Act 1973* remain.
- Rural and remote exemptions.
- Specified qualification requirements for ultrasound providers.
- Definition of diagnostic ultrasound.

#### **Comment**

The ACPSEM does not support this option.

### **Musculoskeletal Ultrasound (refer to page 25-26 of the RIS)**

#### **Questions:**

- Are the principles as outlined satisfactory to clarify the requirements?
- What reasons, if any, are there for the personal attendance requirements for musculoskeletal ultrasound to remain?
- Would a minimum set of guidelines for 'accepted medical practice' per modality be appropriate?
- What savings are anticipated to be realised from removing the personal attendance requirements for musculoskeletal ultrasound services?
- What additional costs are anticipated to be incurred by requiring a medical practitioner (e.g. radiologist) to be in close proximity to attend on a patient personally within a reasonable period of time in circumstances where this is not currently the situation?
- What other costs (if any) might be associated with the proposed changes?
- What are the potential consequences of the proposed changes?

#### **Comment**

The ACPSEM has no comment on this matter.

### **Option 3 – Practice based approach (refer to page 27-34 of the RIS)**

#### **Features**

- Amendments to the current supervision requirements to clarify the circumstances under which a radiologist and/or specialist or consultant physician must provide supervision and how the supervision must be provided.
  - Professional supervision would require: the medical practitioner be available to observe and guide the conduct and diagnostic quality and safety of the examination and if necessary in accordance with accepted medical practice, attend the patient personally, within a reasonable period of time.
- The personal attendance requirement of musculoskeletal ultrasound would be amended to align with all other ultrasound items.

- The person under the professional supervision of the radiologist would require the appropriate qualifications, credentials, or training to provide the service.
- Computed Tomography services would only be able to be provided in a comprehensive practice, with the exception of CT of the coronary arteries (items 57360 and 57361).
- Supervision would be tailored to the type of diagnostic imaging practice.
- A comprehensive practice would require a radiologist to be available during agreed operating hours.
- Where a radiologist is on site during ordinary operating hours, the radiologist would be allowed to determine the supervision requirements for the practice and have the flexibility to implement and supervise efficient and effective processes.
- Where a radiologist is on site during ordinary operating hours, the radiologist would be allowed to substitute a requested service for a more appropriate service, without the need for consultation with the requester, if the substituted service has a lower MBS fee than the requested service.
- The current substitution rules in the *Health Insurance Act 1973* remain.
- Where a radiologist is NOT on site during ordinary operating hours, a radiologist must be on site for the performance of the following services:
  - Mammography;
  - The administration of contrast; and
  - Image guided intervention procedures/surgical interventions.
- The reporting and supervising radiologist would not have to be the same person, but practices would be required to maintain records which indicate the name of all the radiologists involved in the service.
- Rural and remote exemptions.
- Specified qualification requirements for ultrasound providers.
- Definition of diagnostic ultrasound.

### **Comment**

1. As a general principle, the ACPSEM fully supports the practice based approach as a method of improving quality and safety in the provision of diagnostic imaging, particularly the requirements for radiologist supervision of CT through a comprehensive practice model.
2. The ACPSEM believes it is possible for CT of the coronary arteries (CTCA - items 57360 and 57361) to be safely and effectively performed outside of a comprehensive practice. Due to the potential for high radiation doses associated with these procedures we are, however, concerned to ensure these practices have in place processes to ensure outcomes of these procedures are closely monitored. The ACPSEM stresses the need for this requirement to cover the radiation related components of procedures, specifically in the form of auditing and benchmarking of procedural radiation risk. We also believe that minimization of population radiation burden is achieved through the continuous evaluation of disease detection rates and clinical outcomes (ensuring that case by case justification for undergoing the procedure is continually monitored).

3. While the ACPSEM agrees that for safety and quality reasons a comprehensive practice should require a radiologist to be available during agreed operating hours, we also recommend that both of these objectives can best be achieved by ensuring that comprehensive practices have access to and make use of the services of a qualified medical physicist as an integral part of their imaging team. Through their unique knowledge and skill set, qualified medical physicists can make a unique and valuable contribution to the establishment and ongoing support of programs aimed at driving clinical quality through optimization of the process of imaging. This is particularly applicable to the areas of imaging technology management and compliance with the requirements of radiation based regulations and guidelines.
4. The ACPSEM supports the view that where a radiologist is NOT generally required on site during ordinary operating hours, they must be present for mammography, contrast administration and when image guided intervention procedures/surgical interventions are performed. We do not believe that this requirement should apply in circumstances where the procedures are performed by clinicians specifically trained in the use of contrast such as dedicated cardiovascular imaging services operated either as part of general radiology practices or as standalone cardiovascular imaging services. However, due to the level of radiation risk associated with the procedures performed in these services we believe that benefit would be derived from instituting the same level of auditing and benchmarking described for CTCA procedures (in 2 above). In both instances the quality and safety should be enhanced through involvement of a qualified medical physicist as part of the team. To facilitate the quality and safety agenda, we recommend that practices undertaking cardiovascular imaging be required to participate in the cardiac (CSANZ – ACOR registry) and vascular clinical quality registries (aligned with the RACS guidelines on clinical audit) with a further recommendation that these registries be extended to include radiation metrics as a key outcome measure for procedures involving ionizing radiation based imaging equipment against which individual clinicians and services are audited.
5. With regards to the matter of substitution, the ACPSEM believes that optimized use of radiation is achieved if the patient undergoes a procedure that has the best proven record of achieving the required clinical outcome at the lowest procedural and radiation risk (especially where a non-ionizing radiation based imaging technology can achieve the same outcome as one employing ionizing radiation). In general circumstances, radiologists, due to their training, are best placed to make these decisions. This capacity is particularly pertinent where the radiologist is acting to minimize radiation exposure, particularly for vulnerable patient populations such as children and women of child bearing age. To support this outcome, however, the decision making process must be supported by the development and implementation of robust mechanisms to educate and inform radiologists of the radiation risks posed by the imaging modalities and clinical procedures with which they are actually dealing. This requires specific knowledge of the radiation doses involved in their own practices using their technique on their equipment. Due to the wide variation in technology, clinical practice and competence it is not sufficient to just rely on published literature as this can reflect the outcomes achieved in clinical practices and populations remote from the point of care. This requirement underscores the role for routine audit with the scope of audit expanded to include benchmarking (of radiation doses and clinical outcomes) with achievable (best practice) outcomes. Where substitution does take place, the function of audit should specifically review the outcomes of this practice to confirm the impact of the substitution both clinically and financially.

## **A Comprehensive practice (refer to page 28-29 of the RIS)**

### ***Questions:***

- Are there any other types of practices which have not been identified?
- Are there comprehensive practices that do not currently have a radiologist onsite?
- What are the costs of employing a radiologist onsite during ordinary operating hours?
- What are the costs of non-comprehensive practices expanding to become comprehensive practices?
- Are there enough radiologist for this to occur? What are the barriers?
- Is there any role for standalone CT and, if so, how would current safety and quality concerns be addressed? What will be the impact of this change on providers and patients?
- What other costs (if any) might be associated with the proposed changes?
- What are the potential consequences of the proposed changes?

### **Comment**

As indicated in the previous broad response to option 3 (point 2) we have general concerns regarding the radiation protection of the patient for standalone CT practices when these are operated in the absence of the governance framework normally associated with larger medical imaging services. Involvement of a qualified medical physicist for expert dosimetry advice and management and optimization of radiation dose would address some of the concerns regarding safety and quality. When coupled with an over-arching program linking radiation use with clinical outcomes monitoring (involving disease detection, referral for treatment and adverse events), this would have a positive impact on patients in terms of ensuring their safety and lowering their radiation dose. For providers there would be an up front cost in utilizing the services of a qualified medical physicist and establishment of a registry but the return on this would be via an overall reduction in population radiation burden (and reduction in overall cancer incidence) coupled with a potential improvement in miss-diagnosis (and the consequent over treatment of those not requiring care or the under treatment of those in clinical need).

## **Non-radiologist specialist practice (refer to page 30-31 of the RIS)**

### ***Question***

- Are there any other services currently performed by non-radiology specialists?

### **Comment**

The RIS document states that the services performed in non-radiologist specialist practices are generally ultrasound services and two CT items (57360 and 57361 related to CT coronary angiography). It is suggested that these procedures do not need to be performed under the supervision of a radiologist.

One major category of imaging practice not covered by these statements is standalone cardiovascular imaging services. It is not uncommon, particularly in private hospitals, for these services to be run independently of any radiology practice (which is usually provided by a 3rd party service contracted to undertake this work). This is quite distinct from the CT issue and as stated in this class of practice, this is presently allowed for under this option

As for cardiovascular angiography imaging suites, at least 30-40% (~20 of ~50 imaging platforms) of these systems operating in Queensland are run by private hospitals in standalone services. In the overall context of medical imaging workload, while not accounting for a large number of facilities or cases, the types of procedures performed in these services are amongst the most complex imaging procedures with the highest radiation doses and potential for detrimental skin effects.

As these labs are generally operated independently of large radiology services, they are not covered by the same radiation hygiene governance processes (mainly discharged by a qualified medical physicist) which large radiology services may have in place. As the radiation related risks (to both patients and staff) are quite high, these services would benefit from the input of appropriately qualified medical physicists to ensure the technical specification of equipment is appropriate, training of staff in radiation protection is appropriate, that the equipment is maintained and operated in a manner that ensures the outcome for all concerned (primarily the patient) is optimized, that all steps are taken to minimize doses (appropriate PPE is provided, facilities are designed and tested) and that high skin doses are followed up with both the patient and referrer as suggested in the Safety Guide issued by ARPANSA (Australian Radiation Protection and Nuclear Safety Agency, RPS No. 14.1). This expertise is not necessarily provided by the cardiologists or vascular surgeons (who in most cases are visiting medical officers) or radiographers (although these tend to be some of the more clinically competent people involved in imaging).

Quality and safety in this environment can be enhanced through involvement of a qualified medical physicist as part of the team. To facilitate the quality and safety agenda, we recommend that practices undertaking cardiovascular imaging be required to participate in the cardiac (CSANZ – ACOR registry) and vascular clinical quality registries (aligned with the RACS guidelines on clinical audit). We further recommend that these registries be extended to include radiation metrics as a key outcome measure for procedures involving ionizing radiation based imaging equipment against which individual clinicians and services are audited. Finally, state legislation should be amended to make it a requirement of licenses for these faculties to comply with the requirements of RPS 14, in particular, with regards to benchmarking against published Diagnostic Reference Levels and participation in the ARPANSA national DRL program.

## **ADDITIONAL ISSUES FOR CONSULTATION**

### **1. Rural and remote exemptions (refer to page 31-32 of the RIS)**

The intention of having rural exemptions is to ensure patients have access to services without compromising on quality. However, current arrangements for rural exemptions vary for each of the modalities, creating confusion due to an inconsistent approach. The current approach is also difficult to administer.

#### ***Questions***

- Does the current rule meet its goal of increasing access for patients without comprising on quality?
- Should exemptions be geographically/distance based rather than looking at population base and local availability of specialist services?

- Are there any other mechanisms that provide incentives for local services provision in rural Australia?
- What is the role of tele-radiology? Should it be the only service, or an adjunct to the local service provision?
- Should the exemption not be available for certain types of services?

**Comment**

The ACPSEM has no comment on this matter.

**2. Implementing any changes and the relative role of regulation and the Diagnostic Imaging Accreditation Scheme (DIAS) (refer to page 33-34 of the RIS)**

The relative role of regulation and accreditation in enhancing the quality framework for MBS funded diagnostic imaging services will be determined following feedback received from stakeholders under this consultation process.

**Questions**

- Would changes to supervision be better placed in the DIAS or remain in the regulations?
- How would a practice based supervision approach be incorporated into regulation?
- Is it necessary to have a modality based approach in the regulations (as a minimum) and a practice based approach in accreditation?

**Comment**

The ACPSEM has no comment on this matter.

**Any additional proposals, suggestions or comments?**

**Comment**

The ACPSEM thank the Department for the opportunity to comment on the Regulation Impact Statement (RIS). The main aim of the RIS is to clarify supervision requirements, while also exploring options to improve quality, reduce waste and minimize harm caused by inappropriate, unnecessary and suboptimal diagnostic imaging services. ACPSEM believes that some of the proposed changes in the practice based approach (Option 3), as well as further recommendations that we have made regarding the *radiation protection of the patient* can strengthen the provision of quality, safe and effective diagnostic imaging services in Australia.

In summary, our main recommendations are:

1. Clearer requirements on supervision by radiologists in comprehensive practices are supported. However, radiation protection requires a collaborative approach and we recommend access to the services of a qualified medical physicist to manage the radiation and equipment quality aspects of operation. The qualified medical physicist has specialized expertise in radiation dosimetry and safety that otherwise may not be available. Furthermore, the qualified medical physicist can focus on ensuring radiation protection as their core business.

2. When coronary CT is performed outside of a comprehensive practice, as already occurs, requirements are necessary to ensure the radiation protection of the patient in these practices and that steps are taken to monitor and optimize radiation use.
  - a. These requirements may be addressed through the Diagnostic Imaging Accreditation Scheme (DIAS), although these specific types of practices should be considered in future iterations of the DIAS standards. Measures relating to outcomes (for example rate of disease identification with recommended levels of sensitivity and specificity) may be an option for inclusion.
  - b. Oversight of radiation protection in these practices should be undertaken by a qualified medical physicist. This may not necessarily require someone on-site, but instead access to medical physics expertise to supervise a radiation protection program and be available for specialist advice, as required.
3. We want to ensure that standalone cardiovascular imaging services are considered in the non-radiologist specialist practices. The types of services provided in these practices, such as coronary angiography, are amongst the most complex imaging procedures with the highest radiation doses. Radiation induced deterministic effects of the skin following interventional procedures continue to be reported in the literature, even with modern sophisticated equipment. In these practices, we recommend a mandatory requirement that for interventional fluoroscopy equipment capable of angiographic and other high dose interventions, a qualified radiographer (medical imaging technologist) be in attendance. We also recognize that best practice radiation protection of the patient and staff is accomplished with a teamwork approach to radiation safety responsibilities between the interventionist and radiographer. A multi-disciplinary approach also involves the expert services of a qualified medical physicist to ensure an appropriate radiation protection program is implemented.
4. There are no proposed changes to the nuclear medicine supervision requirements in the RIS. However, if these are to be included then we also recommend measures that ensure the quality and safety of the administered radiopharmaceuticals. The majority of scans use radiopharmaceuticals that are prepared or manufactured on the same day as the patient scan. Radiopharmaceuticals of inferior quality or safety can lead to patient adverse events, or changed patient management decisions based on incorrect information, or repeat scanning increasing the radiation exposure to the patient. Radiopharmaceutical scientists are a 'small but critical workforce' emerging as a profession as a result of work to improve patient outcomes through implementation of professional standards and competencies, which as for the physicists, are managed through ACPSEM. There has also been the development of a pathway of education.