M4 Healthcare Pty Limited

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 following comments are focused on the Ultrasound modality only.

- The government has a clear policy around 'Cutting the Red Tape'. While there may need to be some change to the regulation in this area it should be consistent with this policy framework and increased regulation should not be the default option.
- Any change in regulation should also be carefully considered to ensure that it does not have unintended consequences in ways such as restricting supply of services, increasing provider costs or limiting patient access, such as at point of care.

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 following comments are focused on the Ultrasound modality only.

General Comment

- Ultrasound is a safe and effectively modality that has a broad diagnostic benefit across a range of specialties. It does not have the safety issues surrounding ionizing radiation devices such as x-ray and CT.
- Technology advancements in Ultrasound in recent years have dramatically improved the ease of use and image quality for the user. In addition, technology has seen appropriate and high quality diagnostic application of Ultrasound in clinical practice that has a positive impact of quality of patient care. (see http://www.dovepress.com/impact-of-point-of-care-ultrasound-on-quality-of-care-in-clinical-prac-peer-reviewed-article-RMI)
- A restrictive definition of a diagnostic imaging specialist is no longer appropriate and in Ultrasound in particular, should appropriately include skilled medical specialists.
- It is already well accepted that specialist ultrasound services provided by specialist medical practitioners is a clinically more appropriate model to provide patients with better access and quality of care (eg Cardiac Ultrasound)
- Traditional/centralised models of care where patients need to attend a centralised general imaging service to receive ultrasound services is outdated and may forego the access, clinical and economic benefits of services provided closer to the point of care.
- Restricting skilled medical specialists to providing ultrasound by placing artificial
 barriers to restrict supply of services through unnecessary credentialing or restrictive
 definitions that reinforce traditional models and providers would potentially forego
 improved access and pricing reform delivered by more efficient and effective clinical
 models.
- No change should be made to Ultrasound services without a full review of the
 positive impacts of new technology on the clinical and economic models for
 providing these services.

Selected Qualification Requirements for Ultrasound Providers

- The assessment 'requisite skills and qualification' of the practitioner providing ultrasound services should not be unnecessarily narrow or restrictive. It should take into consideration the advancements in technology and the broader clinical skills of the practitioner conducting the ultrasound.
- Restricting access to Medicare funding on the basis or specific or narrow qualifications is over regulating and would reduce the supply of specialists capable of safely and effectively providing ultrasound services.
- Restricting supply of available specialists will reinforce traditional clinical models and potentially forego pricing reform in this area through more efficient delivery models.
- A more appropriate response may be to limit Medicare funding for Ultrasound to anatomy that is within the specialty grouping.
- In any case, if a minimum specific qualification was to be introduced, while anticipated not to impact a significant number of providers, there should be sufficient time before this has affect for existing providers to obtain the qualification.

Definition of Diagnostic Imaging

- The definition of diagnostic imaging should not be so restrictive as to reduce the access to clinically beneficial and efficient imaging.
- Early provision of diagnostic ultrasound at the point of care, has the ability to prevent further unnecessary investigation and/or hospitalization.
- In addition, if a more restrictive definition of Diagnostic Imaging was implemented, it does not necessarily detract from the clinical relevance and benefit of ultrasound that does not fit the new criteria.
- To avoid unintended implications of this proposed change, this definition should not be altered to effect existing services provided without adding or adjusting existing specialist item numbers to address the appropriate use of Ultrasound during the examination. To do otherwise would have unintended and detrimental impacts on patient access to services and financially penalise one group of specialist over others.

Introduce equipment standards for Ultrasound

- Any equipment standard around ultrasound should not be as restrictive or rigid as to not keep pace with changing technology.
- Two different items of equipment with the same technical specifications could produce clinically different image outcomes (eg one poor quality and one high quality). The technical specifications of the equipment do not necessarily dictate the quality of the image produced.
- Any attempt to arrive at a standard could potentially be overly bureaucratic or cumbersome to administer. In addition, it is likely to over specify the equipment adding unnecessary cost, placing greater pressure on the Medicare benefit required to achieve an appropriate financial return for providers.
- Further, in specialist ultrasound, the equipment needs to be 'fit for purpose' to be clinically relevant and efficient. Using what is considered high quality ultrasound in one discipline could produce clinically inappropriate images in another. A standard to cover all specialties would need to be applied which would be complex and time consuming to produce as well as cumbersome and costly to administer.
- A degree of self-regulation is more appropriate, where the quality of the ultrasound required to produce a diagnostic quality image should be at the discretion of the provider.

• Low quality, non-diagnostic quality equipment will not be accepted by all but a very few providers and is not seen currently as an issue with many providers. Applying additional regulation in this space could result in unintended 'red tape', inefficiency and over regulation.

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

- 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 (eg 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

No comments are made.

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:
 - o Mammography;
 - o The administration of contrast; and
 - o 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

The following comments are focused on the Ultrasound modality only.

General Comment

- Refer to General Comments under Option 2.
- Any amendments to the current supervision requirements should not create artificial barriers to restrict supply of services or limit the access, clinical and economic benefits of services provided closer to the point of care.

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?

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No comments are made.

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 following comments are focused on the Ultrasound modality only.

General Comment

- Refer to General Comments under Option 2.
- We support the intention not to reduce the scope of these services or change the requirements for non-radiologist specialists performing services.

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 the local service provision?
- Should the exemption not be available for certain types of services?

Comment

The following comments are focused on the Ultrasound modality only.

General Comment

 The current rural exemption is appropriate and an effective means of increasing access for patients.

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?

Comment	
No comment	
3. Any additional proposals, suggestions or comments?	
Comment	
No further comment	

Is it necessary to have a modality based approach in the regulations (as a minimum) and a practice based approach in accreditation?