Dr Megan Keaney  
A/g Assistant Secretary  
Medical Specialist Services Branch  
Commonwealth Department of Health

Email: diagnosticimagingandaccreditation@health.gov.au

Dear Megan,

Thank you for the opportunity to contribute a response to the **Consultation Regulation Impact Statement: Improving the quality and safety of Medicare funded diagnostic imaging services through enhancement of regulatory and accreditation requirements** (the RIS).

The Australasian Sonographers Association (ASA) would like to thank the Department of Health for the great work in producing the RIS, a vitally important mechanism in driving reform of the existing regulatory and accreditation requirements to improve the quality of Medicare funded diagnostic imaging services.

In our response the ASA recognises the significant progress achieved with development of proposed reforms to the health system that enhance quality, reduce waste and minimise harm caused by inappropriate, unnecessary and sub-optimal diagnostic imaging services.

However we note, as currently presented, the RIS focuses heavily on the role of the radiologist as the single supervising medical practitioner. Where this is appropriate for the majority of the diagnostic imaging modalities, this perspective does not accurately represent the current provision of comprehensive diagnostic ultrasound by other suitably qualified medical practitioners, or their supervision of ultrasound examinations provided by accredited sonographers.

As work on determining the shape of these reforms progresses the ASA strongly recommends that the broader contexts where comprehensive diagnostic ultrasound are provided are fully considered before making any changes to regulatory or accreditation systems.

Thank you for taking the time to consider this information. The ASA looks forward to continuing to work with the Department to progress this crucial work.

If you have any queries on the content or require any additional information please do not hesitate to contact James Brooks-Dowsett, Policy & Advocacy, by phone on (03) 9552 0008 or email at policy@a-s-a.com.au

Yours sincerely

Dr Stephen Duns  
Chief Executive Officer  
Australasian Sonographers Association
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.

Introductory Comments from the Australasian Sonographers Association (ASA)

The ASA would like to take this opportunity to thank the Department of Health for the great work in producing the Consultation Regulation Impact Statement (RIS), a vitally important mechanism in driving reform of the existing regulatory and accreditation requirements to improve the quality of Medicare funded diagnostic imaging services.

The RIS identifies many of the challenges of the current systems and some opportunities for reform, many of which for sonographer provided ultrasound the ASA has vocally supported for some time.

Other suitably qualified medical practitioners
The ASA however would like to note the RIS as currently presented focuses heavily on the role of the radiologist as the single supervising medical practitioner. Where this is appropriate for the majority of the diagnostic imaging modalities, this perspective does not accurately represent the current provision of comprehensive diagnostic ultrasound by other suitably qualified medical practitioners, or their supervision of ultrasound examinations provided by accredited sonographers.

Such practitioners include sports physicians, rheumatologists, orthopedists, cardiologists, obstetricians and gynaecologists, vascular surgeons and some general practitioners (particularly in rural and remote areas) with qualifications as per the Royal Australian and New Zealand College of Radiologists’ (RANZCR) guidelines.

Although these medical professionals are broadly referenced to some degree under “Non-radiologist specialist practice” (p30 of the RIS), the document does not represent an appropriate level of consideration of their undertaking, or supervision of accredited sonographers performing, comprehensive diagnostic ultrasound – many of whom will be operating in clinical settings or practices which will not have or require a radiologist to be on site.
Any changes to supervision statements, determination of minimum qualifications or practice attendance requirements for the provision of Medicare funded ultrasound services must consider the current context of the broader professions who are suitably qualified through their specialisation or additional qualification, so as to not unintentionally create barriers to the provision of quality diagnostic ultrasound services outside of a radiologist led practice setting.

**Supervision: practice level vs modality**

The ASA strongly recommends that differences between supervision requirements are determined on the basis of modality, not of the practice setting. This is a position that echoes those of the Australian Diagnostic Imaging Association (ADIA) which represents private radiology practices across Australia, as presented at the June Diagnostic Imaging Advisory Committee meeting.

Different modalities require varying levels of supervision by a radiologist or other medical practitioner due to the clinical complexity and competency of the supporting medical professional. For example, it is reasonable to expect a comprehensive medical diagnostic ultrasound examination can be provided by a sonographer accredited with the Australian Sonographer Accreditation Registry (ASAR) under limited supervision, due to the investigative and decisional competence achieved by a sonographer to become accredited.

Additionally as the “Non-radiologist specialist practice” setting is not fully explored in the context of the RIS, there is a real risk of embedding practice type requirements in the Medicare regulatory arrangements which will unintentionally impact the provision of quality diagnostic services through non-radiologist attended practices.

The ASA does not consider this would detract from the radiologist’s ability to make decisions on the level of supervision required of radiologist attended practices, a role central to the radiologist’s role as the decision maker and gatekeeper in mixed/multimodality diagnostic imaging services.

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 ASA does not support Option 1.

The ASA welcomes the publication of the RIS and is enthusiastic about working with the Department of Health and other Australian diagnostic imaging stakeholders to achieve important reforms to the health system that enhance/ensure quality, reduce waste and minimise harm caused by inappropriate, unnecessary and sub-optimal diagnostic imaging services.
Access to, and the provision of, quality diagnostic imaging is critical in supporting clinical decision making across the breadth of the healthcare system. However, as described in the RIS, there are a range of inconsistencies and issues under the current funding and regulatory arrangements that need to be addressed for diagnostic imaging.

The ASA strongly believes this opportunity for reform must be fully realised in the interest of patient care and safety. Furthermore any failure to achieve the potential system changes seriously jeopardises the future quality and appropriateness of diagnostic imaging services and their sustainability under Medicare.

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

Comment

Although some aspects of option 2 respond to the identified issues, the ASA does not favor option 2.

Supervision Requirement

As identified in the RIS there is a need to amend the current supervision requirements statement on the circumstances under which a radiologist or other suitably qualified medical practitioner must provide supervision, and how the supervision must be provided.

The ASA agrees with RANZCR and ADIA’s position that the definition proposed in the RIS (page 24) remains a loosely defined criterion which does not address the ambiguity of the current definition.

Also, in agreement with ADIA’s response, the ASA warns of the danger of attempting to generate a ‘one-size fits all’ supervision requirement for all the diagnostic imaging modalities.

Different modalities require varying levels of supervision by a radiologist or other medical practitioner due to the clinical complexity and competency of the supporting medical professional. For example, it is reasonable to expect a comprehensive medical diagnostic ultrasound examination can be provided by a sonographer accredited with the Australian Sonographer Accreditation Registry under limited supervision, due to the investigative and decisional competence achieved by a sonographer to become accredited.

Furthermore in considering a supervision requirement the ASA encourages the department to consider the role of technology, both now and into the future, in the provision of comprehensive medical diagnostic ultrasound (and other modalities).

Telehealth solutions are already recognised under the Medicare regulations as appropriate and cost effective solutions to addressing access barriers to health services for communities in both rural and metropolitan areas. With the growing digitisation of diagnostic ultrasound, increased portability of the technology and efficacy of telecommunications, telehealth is a reasonable approach to supervision, should the supervising medical professional not be able to be physically present in the examination room.

For ultrasound, the ASA recommends a revision to the supervision requirement that requires the radiologist or other suitably qualified medical practitioner to be available provide consultative supervision while the service is being performed, either:

- on-site; or
- off-site, through the use of technology
**Personal attendance for MSK ultrasound**
In agreement with RANZCR and ADIA’s positions, the ASA strongly agrees with the proposal to amend the personal attendance requirement of musculoskeletal ultrasound to align with the other ultrasound items.

**The current substitution rules in the Health Insurance Act 1973 remain**
The ASA is aware that the substitution rules in their current form can be an impediment to the provision of appropriate imaging and maintain that radiologists have specialist expertise in determining are the most appropriate clinical test across modalities. The ASA is supportive of RANZCR and ADIA’s position that in certain circumstances it may be appropriate to substitute the requested service for a more expensive alternative without first discussing it with the referring clinician, and that a radiologist should have the ability to do this.

**Rural and remote exemptions.**
As noted in the RIS the current 30km rules are a crude method to grant patients in rural and remote areas access to quality diagnostic imaging services and we are aware that they have proven very difficult to enforce. However, varied arrangements for rural and remote areas of Australia are crucial to ensure the community has access to these essential services.

As with RANZCR, the ASA would like to engage with the Department and other diagnostic imaging stakeholders to determine the best model for rural and remote service provision further with the Department when we have a clear understanding of how the complete package of reforms is taking form. Only as the other reforms are being determined can the impact on rural and remote areas be clearly understood. At this time the ASA requests to engage with the Department to explore more appropriate criteria for any rural and remote exemptions, which might include the ASGC-RA classification, the Modified Monash Model and/or other requirements.

**Qualification requirements for ultrasound providers & Definition of diagnostic ultrasound**
The ASA acknowledges there is already a qualification/accreditation requirement for professionals (i.e. sonographers) practicing under the supervision of a radiologist or other suitably qualified medical practitioner under DIAS. The ASA supports retention of this requirement.

The ASA, together with RANZCR and other stakeholders, believe that two clearly distinct models of delivery of ultrasound care have emerged: ‘comprehensive diagnostic ultrasound’ and ‘focused ultrasound’ (also known as point-of-care ultrasound).

Given that all ultrasound services are arguably diagnostic in some capacity (i.e. a ‘point-of-care’ test is intended to answer a rudimentary clinical question) the ASA supports the use of the RANZCR favoured terms ‘comprehensive diagnostic ultrasound’ and ‘focused diagnostic ultrasound’.

A comprehensive diagnostic ultrasound should include the following six components as a minimum:
- the service should be initiated following a referral or request, and involve interpretation of a full range of anatomy relevant to the patient’s symptoms
- the service is provided by a sonologist (i.e. radiologist or other medical specialist with subspecialty ultrasound training) or an accredited sonographer
- standard protocols are in place for the range of ultrasound services provided
- the sonologist and sonographer act as a team
- the sonologist provides a written comprehensive report. If the ultrasound is performed by a sonographer, the sonographer contributes to the sonologist the anatomical, physiological and technical data as a preliminary report to assist in the interpretation of the images and aid in the preparation of the Final report
- the captured images are stored and available to the referring clinician, if appropriate other clinicians involved in the patient’s care and the patient if appropriate/relevant.
The ASA provisionally supports the proposal to describe the minimum qualifications for medical professionals providing ultrasound, noting it is important that any description respond to the many settings comprehensive diagnostic ultrasound is provided (not just diagnostic imaging practices) and includes the various suitably qualified medical practitioners which competently provide and/or supervise comprehensive diagnostic ultrasound, including sports physicians, rheumatologists, orthopedists, obstetricians and gynaecologists, cardiologists and some general practitioners (particularly in rural and remote areas) with qualifications as per RANZCR guidelines.

The introduction of a clear definition of comprehensive diagnostic ultrasound would respond to the issues identified in the RIS and ensure:

- patients having Medicare funded examinations would benefit from minimum qualifications and consistent standards of care
- minimum qualifications are broadly defined which would allow suitably skilled medical specialists to continue to access training and Medicare rebates
- reports would be consistently provided which benefit the original referring doctors and inform patients about the care they receive
- images would be consistently captured and stored for use by subsequent clinicians.

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

**Comment**

**Are the principles as outlined satisfactory to clarify the requirements?**
Yes. ASA supports the removal of the personal attendance requirement for MSK ultrasound as this is not required for every MSK ultrasound. Sonographers and the supervising radiologist or other suitably qualified medical practitioner provide diagnostic ultrasound as a team. As with other areas of ultrasound examination it is appropriate to provide the supervising medical professional the responsibility to determine whether or not their personal attendance is required. This is consistent with current RANZCR Standards and reflects contemporary practice.

**What reasons, if any, are there for the personal attendance requirements for MSK ultrasound to remain?**
The ASA does not believe there are reasons for this requirement to remain, noting the sonographer would continue to have access to the supervising radiologist or other suitably qualified medical practitioner while the service is being performed under the supervision requirements for sonographer performed diagnostic ultrasound recommended above.

**Would a minimum set of guidelines for ‘accepted medical practice’ per modality be appropriate?**
In 2014, in consultation with other diagnostic imaging stakeholder, the ASA produced a Standards of Practice for sonographers, complementing the ASA competency standards for the entry level sonographer (2010), used to accredit sonographers. The ASA would happily support the development of a national guideline for ‘accepted medical practice’ for ultrasound.

**What savings are anticipated to be realised from removing the personal attendance requirements for MSK ultrasound services?**
Any savings would be minimal. It is likely this would not significant changes to the current provision of MSK ultrasound, as supervising medical practitioner would continue to be involved in the service. The minimal savings may be achieved in more appropriate use of a radiologist’s time (self-determined) and any efficiencies achieved for the provision on MSK ultrasound.
Option 3 – Practice based approach (refer to page 27-34 of the RIS)

Comment
The ASA supports option 3 generally, with the following comments.

Amendment to the current supervision requirement statement
The ASA is supportive of amending the current supervision requirement statement noting the definition in the RIS (page 24) remains a loosely defined criterion which does not address the ambiguity of the current definition.

As previously stated, for the supervision of comprehensive diagnostic ultrasound by an accredited sonographer, the ASA notes any definition should be: clear and transparent; flexible to accommodate all supervision arrangements (i.e. non-radiologist); and should reflect current practice.

This could be described as ‘supervision by either a radiologist or other suitably qualified medical practitioner, who is available provide consultative supervision while the service is being performed, either:

• on-site; or
• off-site, through the use of technology.

The personal attendance requirement of musculoskeletal ultrasound would be amended to align with all other ultrasound items
As described above, the ASA strongly supports removal of the personal attendance requirement of musculoskeletal ultrasound for sonographer performed examinations, in alignment with the 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 ASA acknowledges this is already the case for sonographer performed ultrasound and supports retention of this requirement.
Supervision would be tailored to the type of diagnostic imaging practice
The ASA does not support this. It would be more appropriate to tailor supervision requirements to the diagnostic imaging modality.

Different modalities of diagnostic imaging require different levels of supervision. Consistent with ADIA and RAZCR’s positions it is reasonable to expect a lower level of direct supervision by a radiologist or other suitably qualified medical practitioner for a comprehensive diagnostic ultrasound provided by an accredited sonographer than a mammography, for example.

Additionally, there are many clinical settings where sonographer performed ultrasound are appropriately supervised by suitably qualified medical practitioners other than radiologists. Whereas it is reasonable to expect that services such as mammography will require all times access to a radiologist.

Finally, for comprehensive diagnostic ultrasound provided by an accredited sonographer the supervising requirements should be consistent across the four practice settings of the RIS. Additionally, the supervision requirements need to be flexible to supervision by either a radiologist or other suitably qualified medical practitioner. It is recommended that these supervising medical specialists be available to provide consultative supervision while the service is being performed, either:

- on-site; or
- off-site, through the use of technology.

A comprehensive practice would require a radiologist to be available during agreed operating hours
The ASA is generally supportive of this noting there are many ‘no-radiologist specialist practices’ which support the healthcare system, and that any change to achieve this requirement must not restrict their ability to provide services or create increased financial burden for them (e.g. if they had to employ a radiologist in addition to the other suitably qualified medical practitioner(s) relevant to the practice).

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.
The ASA is supportive of this noting it does not represent a change to the current arrangements for radiologist supervised ultrasound.

Changes to the current substitution rules and the Health Insurance Act 1973
As previously stated, the ASA is supportive of RANZCR’s request to expand the substitution rules to include substituting the requested service for a more expensive alternative without first discussing it with the referring clinician, should it be determined as more appropriate.

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 ASA is supportive of an on-site Radiologist or other medical practitioner requirement for Interventional and Surgical procedures as defined in “Tier A” and “Tier B” in the credentialing guidelines published by the Interventional Radiology Society of Australasia, and referenced in the RANZCR Standards (Section 11 plus appendices “B” and “C”).

Further the ASA recommends the removal of any impediment to the future possibility of enhanced scope of practice for sonographers who are suitably trained and qualified. Sonographers with advanced higher education qualifications who have demonstrated competency should be able to work with delegated authority from a radiologist or other medical practitioner to perform agreed specified procedures on behalf of that medical practitioner.
Ultimately this could include the possibility of a small number of advanced sonographer practitioners having their own provider number and taking full clinical responsibility.

**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**

The ASA is supportive of this, as most practices will already be recording this information in some form, and it would be a useful mechanism for any audit process and workforce determination.

**Rural and remote exemptions** (Please see below)

**Specified qualification requirements for ultrasound providers**

The ASA provisionally supports this, noting it is important that any description respond to the many settings and includes all professions which competently provide and/or supervise comprehensive diagnostic ultrasound, (e.g. Sports Physicians, Rheumatologists, Orthopedists, Cardiologists, etc…)

**Definition of diagnostic ultrasound**

As described above the ASA strongly supports the establishment and implementation of a definition of comprehensive diagnostic ultrasound as a fundamental mechanism to ensuring quality, reducing waste and minimising harm caused by inappropriate, unnecessary and sub-optimal diagnostic ultrasound services.

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**

As described in the introduction there are a multitude of other services where ultrasound is either provided by a non-radiology specialist, or provided by an accredited sonographer under the supervision of a non-radiology specialist. Such suitably qualified practitioners include sports physicians, rheumatologists, orthopedists, cardiologists, obstetricians and gynaecologists, vascular surgeons and some general practitioners (particularly in rural and remote areas).

For the purpose of the RIS the ASA has interpreted that all of these different practice settings fall under the category of ‘Non-radiologist specialist practice’.

It is disappointing the RIS focuses heavily on the role of the radiologist as the single supervising medical practitioner for the bulk of the practice settings. The ASA perceives that one of the flow-on results of this is the recommendation to determine supervision based on practice type (Option 3); which we do not support.

However it does highlight the need to separate comprehensive diagnostic ultrasound out from the other diagnostic imaging modalities, which in majority must operate under the guidance or provision of a radiologist.

The ASA strongly recommends that any changes to supervision statements, determination of minimum qualifications or practice attendance requirements for the provision of Medicare funded ultrasound services must consider the current context of the broader professions who are suitably qualified through their specialisation or additional qualification, so as to not unintentionally create barriers to the provision of quality diagnostic ultrasound services outside of a radiologist led practice setting.
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.

Comment

**Does the current rule meet its goal of increasing access for patients without comprising on quality?**
The ASA agrees with RANZCR’s position that the current rule is crude, and whilst the current rule may in part achieve the goal, it is a poor fit for purpose and, as mentioned above and in the RIS, has been difficult to administer and can be hard to adhere to adhere to.

**Should exemptions be geographically/distance based rather than looking at population base and local availability of specialist services?**
ASA agrees with RANZCR that ideally there would be a tailored approach to exemptions for each rural and remote location based on: criteria such as population base and local availability of specialist services; and striking a balance between access to services and quality for those locations.

As noted above the ASA caution making any decision on changes to the rural and remote exemptions until such time as determination on any of the other elements of the reform are being made. Only at this time will any potential impact on rural and remote areas be understood, and the ASA and other diagnostic imaging stakeholders will be able to work with the Department to explore more appropriate criteria for any rural and remote exemptions. Prior to this the ASA recommends retaining the 30km rules.

**What is the role of teleradiology? Should it be the only service, or an adjunct to the local service provision?**
As described in RANZCR’s response diagnostic imaging services represents a continuum that begins before the image acquisition and extends beyond the rendering of the report and that radiologists should be engaged at all points in the continuum. Teleradiology is now embedded into the workflow of many radiology practices, driven largely by technology and an expanding model of networked practices. It can offer a number of benefits to patients and their healthcare providers regardless of location, including access to second or sub-specialty opinions and cost effective after-hours reporting, but it also has some limitations. We believe that the role of teleradiology needs to be set into the context of the radiologist’s broader responsibilities so that radiologist input to patient care is not compromised.

This model has much potential, however as with all developing medical processes careful implementation must to applied to ensure it is achieved supporting the best patient care and safety. Although not currently available for ultrasound services the ASA is supportive of teleradiology services.

**Should the exemption not be available for certain types of services?**
The ASA supports RANZCR’s assertion that there should not be any rural or remote exemptions for MRI, nuclear medicine and PET.
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.

Comment

Would changes to supervision be better placed in the DIAS or remain in the regulations?
The ASA, in agreement with RANZCR and ADIA’s positions, believes that an effective process for assessing and enforcing compliance with all regulations and practice requirements is an essential aspect of the proposed reform package.

The current arrangements for assessing and enforcing compliance with professional supervision regulations have had mixed success and a more robust approach is required. This should be achieved through clearer regulations in the DIST and a more robust DIAS.

How would a practice based supervision approach be incorporated into regulation?
The ASA does not agree with a system of supervision requirements based on practice types.

Is it necessary to have a modality based approach in the regulations (as a minimum) and a practice based approach in accreditation?
As discussed extensively above the ASA supports the application of a modality based approach to setting the requirements in the regulations (as a minimum). Additional requirements can be captured in the DIAS (assuming a tightening of the requirements).

Furthermore the ASA considers this to be a better approach as for directing requirements across different settings and geographic locations and builds a modicum of flexibility for the ongoing quality assurance and sustainability of diagnostic imaging services across Australia.

The ASA would be happy to work with the Department and other stakeholders on any drafting of the regulations and/or standards.

3. Any additional proposals, suggestions or comments?

Comment

Timeframes
Regarding the timeframes, we support the timeframes outlined on page 11 of the RIS and will work with the Department to progress them.

Other suitably quality medical practitioners
The ASA does not perceive the RIS to appropriately consider other suitably quality medical practitioners (i.e. non-radiologist) who either perform or supervise accredited sonographer provided ultrasound.

The ASA strongly recommends that any changes to supervision statements, determination of minimum qualifications or practice attendance requirements for the provision of Medicare funded ultrasound services must consider the current context of the broader professions who are suitably qualified through their specialisation, so as to not unintentionally create barriers to the provision of quality diagnostic ultrasound services outside of a radiologist led practice setting.