Consultation Regulation Impact Statement
May 2015

Improving the quality and safety of Medicare funded diagnostic imaging services through the enhancement of regulatory and accreditation requirements
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Purpose

The legislative framework that underpins the provision of diagnostic imaging through the Medicare programme sets out the requirements for radiologists and other imaging specialists in the provision of Medicare rebated services. These requirements include:

- the qualification requirements of those who can provide the various diagnostic imaging modalities;
- specifying which health practitioners can assist radiologists or other suitably qualified specialists providing these services; and
- the level of supervision required to ensure that services are of high quality, safe and appropriate.

The purpose of this regulation impact statement (RIS) is to review the existing requirements for the provision of Medicare eligible diagnostic imaging services and explore options for enhancing quality, reducing waste and minimising harm caused by inappropriate, unnecessary and sub-optimal diagnostic imaging services. The principal focus of this RIS is to clarify the existing supervision requirements, to remove any ambiguity and confusion around the intention of the rules. However, this RIS will also set out other options that seek to strengthen the current regulatory and accreditation framework.

This RIS has been prepared on the basis that it will be publically released to facilitate further stakeholder input on the impacts of the various options detailed in this paper. Following consideration of feedback, further consultation will occur and the options further refined. A list of stakeholders for consultation can be found at Appendix A. Stakeholders will be provided with at least six weeks to consider this RIS. The form of any further consultation will depend on the nature of the feedback received. It is expected that further consultation will involve stakeholder meetings, in either small groups or one on one. A final RIS will be prepared. The intention is for any proposed changes to be implemented with sufficient time for diagnostic imaging practices, requestors of diagnostic imaging services, and consumers of diagnostic imaging services to incorporate the changes into their arrangements.

Background and Context

Diagnostic imaging is a core component of the health care system, allowing appropriate initial diagnosis and ongoing assessment of many medical conditions.

Diagnostic imaging involves a wide range of services, delivered using different modalities and by different clinical groups. The inherent complexity of the clinical and service arrangements is compounded by the way services are funded and regulation applied through a combination of Commonwealth and state and territory laws. Medicare eligible diagnostic imaging services are regulated through three main pieces of Commonwealth legislation. These are:

- the Health Insurance Act 1973 (HI Act);
- the Health Insurance Regulation 1975 (HI Regs); and
- the Health Insurance (Diagnostic Imaging Services Table) Regulation (DIST) which is re-made every year.
A full list of relevant Commonwealth legislation is included in Appendix B.

There are a number of different diagnostic imaging modalities available in Australia, including:

- ultrasound;
- computed tomography (CT);
- diagnostic radiography (DR) (eg. x-ray, mammography);
- magnetic resonance imaging (MRI); and
- nuclear medicine (NM).

The Australian Government provides patient rebates for a range of diagnostic imaging services, for all the modalities mentioned above, through the Medicare Benefits Schedule (MBS).

In 2013-14 there were over 22 million Medicare eligible diagnostic imaging services provided to patients in Australia. The Government, through the Department of Human Services (DHS) Medicare program, paid over $2.9 billion in patient rebates. These services where provided by over 4,000 providers who are registered with DHS.

Table 1: MBS service volumes by modality including expenditure for 2013-14

<table>
<thead>
<tr>
<th>Modality</th>
<th>Group</th>
<th>Item Range</th>
<th>Services</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound</td>
<td>Group I1</td>
<td>55005-55855</td>
<td>8,570,775</td>
<td>$975,834,282</td>
</tr>
<tr>
<td>Computed Tomography</td>
<td>Group I2</td>
<td>56001-57361</td>
<td>2,709,088</td>
<td>$848,178,969</td>
</tr>
<tr>
<td>Diagnostic Radiology</td>
<td>Group I3</td>
<td>57506-61110</td>
<td>10,051,941</td>
<td>$532,438,438</td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>Group I4</td>
<td>61302-61729</td>
<td>643,855</td>
<td>$259,182,398</td>
</tr>
<tr>
<td>Magnetic Resonance Imaging</td>
<td>Group I5</td>
<td>63001-63523</td>
<td>828,719</td>
<td>$323,963,357</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>22,804,378</strong></td>
</tr>
</tbody>
</table>

Table 1 shows that in 2013-14, Diagnostic Radiology (Group I3) is the modality for which there is the highest number of services (just over 10 million services). Ultrasound (Group I1) is the modality with the highest expenditure with over $975 million paid in patient benefits. Additional data on MBS diagnostic imaging is included in Appendix C.

The data captured by DHS are an excellent source of information on service volume, expenditure, provider characteristics and patient demographics. However, the Medicare data are not able to provide information relevant to determining the appropriate use of diagnostic imaging including;

- why the imaging was requested;
- whether the optimal imaging study was requested and performed;
- who performed the imaging;
- the result of the imaging; or
- whether the imaging benefited the patient.

Therefore, other sources of information are vital to understanding the magnitude of the potential harm caused by inappropriate use of Medicare funded diagnostic imaging services including stakeholder input, peer reviewed literature, and case studies.
The Current Framework

Medicare funded diagnostic imaging is governed by the HI Act and its regulations as noted above. More recently, quality service provision has been assured through the Diagnostic Imaging Accreditation Scheme (DIAS).

The HI Act and the DIST set out requirements for eligible diagnostic imaging health professionals but historically created no obligations for diagnostic imaging practices. Diagnostic imaging, and in particular radiology, practices are complex entities that depend on the use of high tech and expensive equipment and employ a range of health professionals, IT and support staff. Commonly these businesses are not owned by radiologists but instead may be private or listed companies, with the principal source of revenue for the entity being Medicare. With the move away from traditional medical models of practice ownership these businesses have become increasingly sophisticated and efficient. Necessarily there is a balance to be achieved between providing efficient services, maintaining revenues and ensuring quality service provision.

In June 2007, legislation was enacted to amend the HI Act to establish an accreditation scheme for diagnostic imaging under which mandatory practice accreditation would be linked to the payment of Medicare benefits for diagnostic imaging services listed in the DIST. Since 1 July 2010, all diagnostic imaging practices intending to render any diagnostic imaging services for the purpose of Medicare benefits must be accredited under the DIAS.

Currently, the DIAS consists of a total of 15 practice standards, including three entry level standards, which include registration and licensing, radiation safety, equipment servicing, infection control and consumer consent and information standards. To demonstrate compliance against either the Entry Level Practice Accreditation Standards or the Full Suite of Practice Accreditation Standards, practices are required to submit an application and evidence to a DIAS approved accreditor.

As the main safety and quality instrument within the current regulatory framework, there is strong support from the sector to expand the DIAS standards and introduce further standards relating to the supervision of diagnostic imaging services, image quality, storage and equipment maintenance, to ensure that the DIAS keeps pace with innovations in clinical science and that potential harms are minimised.

Prior to the implementation of the DIAS, there was no single mechanism that ensured the various elements involved in the delivery of a diagnostic imaging service worked together and that a safe and effective service was provided to patients. The DIAS addresses the need for consistency in the delivery of diagnostic imaging services and at a practice level, seeks to ensure that diagnostic imaging services are safe and cost effective. Through accreditation the Government is assured that services supported by Medicare are provided by practices that are performing in line with industry agreed standards regardless of where and by whom a service is provided.
Both the regulations and DIAS are intrinsically linked but there is a view that there should be more emphasis on accreditation with the opportunity for the diagnostic imaging profession to drive the quality agenda through the progressive enhancement of practice standards. Given that the DIAS is only relatively young and requires practices to meet only minimum standards, any changes to develop or strengthen the standards would need to be implemented gradually and over time.

The Department of Health engages formally with the major stakeholders in the diagnostic imaging sector through the Diagnostic Imaging Advisory Committee (DIAC) and the Diagnostic Imaging Accreditation Scheme Monitoring and Implementation Committee (MIC). The DIAC consist of representatives from a wide range of organisations and bodies, including:

- Royal Australian and New Zealand College of Radiologists (RANZCR);
- Australian Institute of Radiography (AIR);
- Australian Medical Association (AMA);
- Royal Australian College of General Practitioners (RACGP);
- Australian Cardiac Society (ACS);
- Australian Sonographers Association (ASA);
- Australian Diagnostic Imaging Association (ADIA); and
- Australasian Society of Nuclear Medicine Specialists (AANMS).

The DIAC provides the opportunity for the Department to consult with the sector on diagnostic imaging issues and receive the views of members.

The MIC consists of members with technical expertise and/or clinical experience in the diagnostic imaging field (either public or private sector) in one or more of the following:

- delivery of diagnostic imaging services;
- health administration and quality management;
- drafting of technical standards for healthcare services;
- auditing or assessment of standards as a healthcare professional; and
- health consumer advocacy.

The role of the MIC has been to provide advice and feedback on the DIAS including:

- reviewing the first five years of DIAS and its implementation;
- input on future standards development for the DIAS including:
  - the most appropriate method for assessing compliance against standards for practices in the four year maintenance program; and
  - reviewing standards under other healthcare accreditation programs (including the National Safety and Quality Health Service (NSQHS) Standards) to ensure the Scheme standards are comparable.
- reviewing DIAS standards with regard to feedback from stakeholders; and
- providing guidance on the future of DIAS.
ADIA and RANZCR have raised a number of issues affecting the sector and presented a Diagnostic Imaging Quality Framework Proposal which outlines a vision for diagnostic imaging in Australia which provides for quality diagnostic imaging with a primary focus on patient safety\(^1\). Many of the problems identified in the ADIA/RANZCR proposal are addressed in this RIS.

\(^1\) *The DI Reform Package: A Quality Framework to underpin sustainable, quality medical imaging*, developed by the Australian Diagnostic Imaging Association and the Royal Australian and New Zealand College of Radiologists (RANZCR). Available on the [RANZCR website](https://www.ranzzcr.org.au).
Consultation Process

This RIS has been prepared to assist stakeholders in considering options regarding the regulation of diagnostic imaging services. The paper explores the nature of current regulatory systems and includes discussion of the issues and concerns which have been raised by stakeholders. A range of options are outlined, which examine the feasibility of changes to the regulation of diagnostic imaging for input to the consultation.

Over the last 18 months the Department has been involved in a number of discussions with the above mentioned committees, in preparation of the RIS. Members of both the DIAC and MIC have provided feedback to the Department on the areas of the current supervision regulation which are causing confusion and issues within the diagnostic imaging environment. The Department has also undertaken meetings with stakeholders such as ADIA and RANZCR to discuss various options for improvements to the regulations. This advice has been vital in identifying the issues and developing the proposed options in the RIS.

Following the release of this RIS, an extensive full public consultation will be conducted, to ensure all relevant parties are involved and that any resulting changes are developed in a transparent and consulted manner. Stakeholder groups as represented on the DIAC, nominating bodies from the MIC, as well as any interested parties will be invited to provide written submissions addressing the issues raised in the paper. These can be provided on an organisation, group or individual level to allow all interested persons to voice any concerns, suggestions and views on the options. Advice is being sought on:

- appropriateness and workability of the changes;
- whether the proposed changes will address current concerns with the regulations in the diagnostic imaging industry;
- potential cost impacts;
- potential workforce impacts;
- 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; and
- any other comments, questions and concerns that relate to the proposed options.

Following each option presented in the Objectives section of the RIS are a number of questions specific to the proposed changes. This is not an exhaustive list for stakeholders, but rather specific queries the Department is seeking further information on, to allow for progression of the RIS and the proposed options. A guidance document for feedback is published with the RIS to assist with framing responses and will include a consolidated list of the Departments questions. This will assist in focusing stakeholder feedback on the issues presented and ensuring the Department receives the necessary advice to estimate the costs and potential impact of each of the options.
During the initial consultation process, when the RIS is published, all stakeholders listed at Attachment A will be advised. Details for making a written submission are included in the guidance document. Stakeholders are encouraged to provide written feedback on the RIS options, and will also be invited to meet with the Department to discuss their feedback if they wish to do so. The RIS will be published on the Department of the Prime Minister and Cabinet webpage, under the Office of Best Practice Regulation section. A link to the RIS will be provided on the Department of Health webpage. Stakeholders will be given six weeks to provide written feedback for this initial consultation stage. Extensions to this timeframe will be considered on a case by case basis.

The RIS will also be tabled for discussion at any DIAC or MIC meetings held during this consultation process. The next MIC meeting is scheduled for May 2015 and the DIAC meeting is scheduled for June 2015.

Once all feedback has been received and assessed, the RIS options will be revised and further consultation will occur. It is intended that this initial feedback will enable the Department to estimate the potential impact and cost of the options. This information, including costs, will be tested during discussions with stakeholders. Due to the nature of the proposed changes the Department is mindful that there are many factors to consider in implementing any changes, thus it is accepted that significant consultation will continue until a decision is made. A final RIS will be prepared that reflects stakeholder feedback including costs. Once an option is selected appropriate time will be allocated to allow for a successful implementation.

The following table outlines the anticipated timeframe for the consultation process:
<table>
<thead>
<tr>
<th>Action</th>
<th>Mode</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-RIS consultation</td>
<td>ADIA, RANZCR, DIAC, DHS</td>
<td>2014</td>
</tr>
<tr>
<td>Publication of consultation RIS</td>
<td></td>
<td>April 2015</td>
</tr>
<tr>
<td>Public consultation</td>
<td>Initial consultation process (6 weeks) inviting written submissions. Consultation guidance materials will be made available on the Department’s website. See list in Appendix A; also any other stakeholders alerted via Department of Health website</td>
<td>May/June 2015</td>
</tr>
<tr>
<td>Focussed consultation with key stakeholders</td>
<td>MIC meeting</td>
<td>May 2015</td>
</tr>
<tr>
<td>Department’s consideration of submissions.</td>
<td>DIAC meeting</td>
<td>June 2015</td>
</tr>
<tr>
<td>This will include further discussions with stakeholders and consideration of costs and any alternative options including deregulation options</td>
<td>Further details will be included in the consultation guidance materials available on the Department’s website.</td>
<td></td>
</tr>
<tr>
<td>Publication of a revised consultation RIS.</td>
<td>The RIS will be revised based on feedback during the initial stakeholder consultation process, including potential costs based on evaluation of stakeholder advice.</td>
<td></td>
</tr>
<tr>
<td>Public consultation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>This will include further discussions with stakeholders.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focussed consultation with key stakeholders</td>
<td>MIC &amp; DIAC meetings</td>
<td>July 2015 – June 2016</td>
</tr>
<tr>
<td>Final RIS</td>
<td></td>
<td>2016</td>
</tr>
</tbody>
</table>
The Problem

The Government’s objective is to ensure that Medicare benefits are currently claimed and paid for diagnostic imaging services that are provided by appropriately qualified professionals, who have the training, knowledge, and experience required to provide quality outcomes for patients and that patients receive services that are clinically appropriate, safe and provide benefit.

While diagnostic imaging is an important component of patient care, the inappropriate and/or sub-optimal use of diagnostic imaging can increase the risk of patient harm and contributes to unnecessary use of resources and expenditure. For example, it is recognised that there is an incidence of repeat imaging caused, in part, by imaging being of inadequate quality or done for the wrong reason. This not only increases healthcare costs but potentially causes patient harm. There are published studies that consider rates of inappropriate imaging, internationally and in Australia. A US study found that 26% of diagnostic images ordered were inappropriate\(^2\) and led to additional tests or follow-up. Referrals for treatment for lower back pain often resulted in invasive procedures of limited or questionable benefit to the patient\(^3\). Similarly, another study estimates that for every 25 patients who undergo x-rays or MRI scans for lower back pain, only about one is found to have serious issues\(^4\). A recent Australian study has shown that the high rate of imaging for initial presentations for back problems is inconsistent with the established guidelines for the management of back problems with about 30% of all initial GP presentations in Australia for new back problems leading to some form of imaging.\(^5\)

Unnecessary and/or inappropriate diagnostic imaging can lead to a number of harms for patients including unnecessary anxiety, complications from downstream and unnecessary further investigation and treatment and additional cost. Importantly, a 2013 Australian study demonstrated that childhood exposure to radiation increases the lifetime risk of developing cancer. All of this reduces consumer confidence in the diagnostic imaging industry.

\(^2\) Lehnert BE, Bree RL. Analysis of appropriateness of outpatient CT and MRI referred from primary care clinics at an academic medical centre: how critical is the need for improved decision support? J Am Coll Radiol, 2012;7:192-197.


\(^5\) Britt et al. Evaluation of imaging ordering by general practitioners in Australia 2002-03 to 2011-12.
The Diagnostic Imaging Review (2011)\(^6\) and the Australian National Audit Office report (2014)\(^7\) both raised concerns about quality and safety issues for diagnostic imaging services and recommended regulatory action. In accepting the Review’s recommendations and implementing the Diagnostic Imaging Reform Package, the Government reiterated the objective that diagnostic imaging services:

- reflect best clinical practice;
- are performed by qualified practitioners;
- are provided within facilities which meet accreditation standards; and
- minimise exposure to unnecessary radiation.

There are five main problems in current MBS arrangements that will be addressed in this RIS. These are:

- The existing regulations do not consistently specify who can assist in the performance of a Medicare eligible diagnostic imaging procedure.
- The existing regulations do not clearly state the level of supervision that is required, or tailor the level of supervision to the quality and safety risks of the modality.
- Current funding and regulatory requirements do not support appropriate requesting of imaging.
- The current rural exemption lacks an adequate rationale and is difficult to administer.
- Ultrasound services are provided by a range of imaging specialists, where qualifications are not mandatory and hence are variable. There is no assurance that Medicare funded ultrasound services are always provided for diagnostic purposes.

Without changes to the current regulations, it is likely that Medicare will continue to operate inefficiently, funding inappropriate and unnecessary imaging. Patients will have little assurance and confidence in the services they require and will continue to receive lower quality and potentially unsafe services due to inadequate supervision. Supervision requirements will continue to be applied inconsistently throughout the sector, with industry already suggesting that an unequal playing field exists, with some practices doing less than the current supervision regulations require, hence are able to operate practices that have a much lower cost base. DHS will continue to face difficulties in relation to their compliance role because of the lack of clarity in the regulations.

**The existing regulations do not consistently specify who can assist in the performance of a diagnostic imaging procedure.**

Diagnostic imaging specialists work with other health professionals who have undergone specific training in the acquisition of images (generally radiographers) but who are not generally qualified to interpret imaging and hence are not themselves Medicare eligible. They work in employed practice and are supervised by diagnostic imaging specialists’. Under the current regulations there are inconsistencies across the different modalities, in clearly identifying who can assist in the performance of the imaging service.

\(^6\) \textit{Review of funding for diagnostic imaging services: Final report, Medical Benefits Reviews Task Group, Diagnostic Imaging Review Team, Department of Health and Ageing, November 2011. Available on the RANZCR website}

\(^7\) \textit{The Auditor-General, ANAO Report No.12 2014–15, Performance Audit, Diagnostic Imaging Reforms, Department of Health. Available on the ANAO website.}
Subordinate legislation does not align with the HI Act

The primary supervision rule is provided in the HI Act.

Under section 3(1) of the HI Act, Medicare eligible diagnostic imaging services are to be rendered by or on behalf of a medical practitioner. A medical practitioner means ‘a person registered or licensed as a medical practitioner under a law of a State or Territory that provides for the registration or licensing of medical practitioners’.

The HI Act defines when a diagnostic imaging service is provided on behalf of a medical practitioner, it must be provided under the supervision of the medical practitioner (section 3(17)(a)).

However, the DIST, which is subordinate to the HI Act, provides a general supervision rule in Schedule 1, part 1, Division 1.2, Section 1.2.7 allowing a medical practitioner, or a person employed by a medical practitioner, or a person who provides the service under the supervision of a medical practitioner in accordance with accepted medical practice, to provide Medicare eligible diagnostic imaging services, unless the contrary intention appears elsewhere in the DIST. As the DIST adds a category of persons (i.e. an employee of a medical practitioner) to the group of persons who can perform a diagnostic imaging service, it is not aligned with the head legislation and should be amended.

It is proposed that the DIST be amended to remove ‘or a person employed by a medical practitioner’ to ensure consistency throughout the legislation.

The Department has no mechanism for determining if employees of a medical practitioner are being supervised, so the regulatory impact of any supervision requirements is unknown. It is assumed, however that most employers supervise their staff as a matter of course, so it is possible that the impact of this change would be very low.

The existing regulations do not clearly state the level of supervision that is required

Supervision is a key component of safe and effective diagnostic imaging services. The policy intention behind the current legislative requirements for CT, MRI and mammography services is that a radiologist should always be available and in close proximity to supervise and influence the conduct of the service, and if necessary to attend the patient personally during the imaging process.

However, stakeholders have reported that they estimate that as many as 80 diagnostic imaging providers in metropolitan areas do not have a radiologist on-site when providing CT services. This problem may be more pronounced in rural Australia. It has been argued that some providers are exploiting a loophole in the current regulations to gain a competitive advantage by not employing an on-site radiologist whilst continuing to provide CT and ultrasound services.

The Diagnostic Imaging Services Review identified concerns about the interpretation of the professional supervision requirements:
‘Professional supervision is a crucial component of quality diagnostic imaging services. Further work needs to be undertaken to better understand the role of the radiologist in contemporary quality practice and to consider options for supporting diagnostic imaging specialists to ensure patients receive appropriate high quality imaging.’

The view of the Department of Human Services (DHS), which has responsibility for Medicare compliance activities, is there is unnecessary complexity and ambiguity in the wording of the supervision requirements in the current regulation, and until this is resolved it is challenging to undertake appropriate compliance activities. Tables 2 and 3 below show the personal performance and supervision requirements of MBS diagnostic imaging modalities and the qualifications required to provide MBS diagnostic imaging services.

**Table 2: Summary of personal performance and supervision requirements for MBS diagnostic imaging modalities**

<table>
<thead>
<tr>
<th>Modality</th>
<th>Personal performance required</th>
<th>Supervision</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 11: Ultrasound</td>
<td>No</td>
<td>Yes</td>
<td>Exception: Musculoskeletal Ultrasound (items 55800 to 55854) must be personally attended by a medical practitioner</td>
</tr>
<tr>
<td>Group 12: Computed Tomography</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Group 13: Diagnostic Radiology</td>
<td>No</td>
<td>No</td>
<td>Exception to supervision: - where a person registered as a medical radiation practitioner provides the service under the supervision of a medical practitioner, and - mammography items (items 59300 to 59319) must be performed under the professional supervision of a radiographer.</td>
</tr>
<tr>
<td>Group 14: Nuclear Medicine</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Group 15: Magnetic Resonance Imaging</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3: Summary of qualifications required to provide particular MBS diagnostic imaging services**

<table>
<thead>
<tr>
<th>Modality</th>
<th>Qualification</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 11: Ultrasound</td>
<td>• Medical Practitioner; • Sonographer; or • Specialist or consultant physician</td>
<td></td>
</tr>
<tr>
<td>Group 12: Computed Tomography</td>
<td>• Specialist in the specialty of diagnostic radiology</td>
<td></td>
</tr>
<tr>
<td>Group 13: Diagnostic Radiology</td>
<td>• Medical Practitioner; or • Registered medical radiation practitioner</td>
<td>Some services can also be performed by a dental practitioner.</td>
</tr>
<tr>
<td>Group 14: Nuclear Medicine</td>
<td>• Specialist or consultant physician</td>
<td>Name is on the register of participants in the Joint Nuclear Medicine Specialist Credentialing Program of the JNMCAC</td>
</tr>
<tr>
<td>Group 15: Magnetic Resonance Imaging</td>
<td>• Specialist in diagnostic radiology</td>
<td>Participant in the Royal Australian and New Zealand College of Radiologists’ Quality and Accreditation Program</td>
</tr>
</tbody>
</table>
Ultrasound

The current wording for the supervision of most ultrasound services is ambiguous. Under the current requirements a registered sonographer can perform the service on behalf of the practitioner however this does not specify the level of supervision required. R-type services must be performed under the supervision of a specialist or consultant physician, where a specialist may be a radiologist or specialist in the particular area being scanned, such as a cardiologist. Under the supervision requirements a specialist must be available to monitor and influence the scan, and if necessary attend on the patient personally. In practice, this creates some confusion over the level of supervision required (e.g. whether the specialist needs to be in the room, on the premises, or be available by phone).

While ultrasound services do not have the same safety concerns as with other modalities (e.g. radiation exposure for CT services), supervision-related issues have been raised by stakeholders. Without appropriate supervision there is no assurance that services will be performed correctly and capture the necessary images to allow for an appropriate diagnosis and therefore treatment options for the patient. This will result in repeat imaging for the patient and potential patient harms with delaying or missing a diagnosis along with additional costs to Medicare.

In addition, stakeholders have argued that musculoskeletal (MSK) ultrasounds do not require the personal attendance of a medical practitioner to be of diagnostic quality and should be aligned with the requirements of other ultrasound services which can be provided under the supervision of a specialist or consultant physician.

Computed Tomography

The current requirements for supervision of CT services (DIST, Division 2.2, section 2.2.1) are that they must be performed under the supervision of a specialist in the specialty of diagnostic radiology (with the exception of items 57360 and 57361), who must be available to monitor and influence the service, and if necessary to attend on the patient personally. Again, the ambiguity arises around the qualifications of those able to perform the service and the level of supervision that is required. For items 57360 and 57361, CT of the coronary arteries, the service must be performed under the supervision of a specialist or consultant physician who is recognised by the Conjoint Committee for the Recognition of Training in CT Coronary Angiography, who must be available to monitor and influence the service, and if necessary to attend on the patient personally. In practice this will be a radiologist or cardiologist.

The recent Mathews research\(^8\) has provided valuable insight into the risks associated with radiation exposure in the Australian setting and reinforced the critical importance of reducing imaging frequency and dosage, particularly for CT services for children and adolescents. The study found ‘overall cancer incidence was 24% greater for exposed than for unexposed people, after accounting for age, sex, and year of birth (incidence rate ratio (IRR) 1.24 (95% confidence interval 1.20 to 1.29); P<0.001)’. The study also noted a dose-response relation, and found the IRR increased by 0.16 (0.13 to 0.19) for each additional CT scan.

Stakeholders have argued that the unsupervised delivery of CT services puts patient safety at risk. The potential risks associated with inappropriate supervision involve incorrect radiation exposure, capturing of incorrect images, poor diagnosis, delayed treatment and additional imaging. A specialist is also appropriately trained to deal with any contraindications resulting from the administration of contrast.

Stakeholders submit that CT examinations should only be provided in a comprehensive practice where radiologists play a gate-keeper role to ensure that unnecessary and inappropriate services are not provided. The radiologist has a key role in ensuring that the patient receives the lowest possible radiation dose and should provide clinical oversight of the administration of contrast agents. Radiologists are trained to respond to emergencies in cases where the patient has an adverse reaction to contrast and can also intervene when there is a finding in the examination which necessitates urgent action. Arguably, none of these aspects of providing a safe and high quality service can be provided unless the radiologist is very closely involved with the provision of the service. There has been no suggestion that CT services should be provided or supervised by other than radiologists (or recognised specialists in the case of CTCA). Indeed, concerns about the possible injudicious use of some CT services in dental practices have been addressed, in part, by restricting MBS payments for Cone Beam CT from 1 November 2014.

The Diagnostic Imaging Services Review identified concerns for patient safety associated with unnecessary exposure to radiation:

‘Unnecessary exposure to radiation is of concern, especially when attributed to inappropriate imaging. This is because CT relies on significantly larger radiation doses than most modalities. Compared to the US, Australia has a lower rate of CT scans per capita.

Children and pregnant women are two vulnerable populations at risk from radiation exposure due to over-utilisation of services. Children are particularly at risk because they are more sensitive to radiation and have more years of life remaining in which to develop radiation-induced cancer.’

The ANAO report reiterated stakeholder concerns about appropriate supervision of CT services:

‘Stakeholders have estimated that around 80 diagnostic imaging providers in metropolitan areas do not have a radiologist on site when performing CT services, arguing that some providers are putting patient safety at risk by exploiting a loophole in the current legislation to gain a competitive advantage by not employing an on-site radiologist and continuing to provide CT and ultrasound services.’

**Magnetic Resonance Imaging**

The supervision requirements for MRI (DIST Division 2.5, section 2.5.3) are similarly unclear and the regulations do not stipulate the qualifications required for health practitioners who can provide these services under the supervision of a radiologist.

Although it is believed that MRI is a safe modality, as it does not use ionised radiation, requiring specified qualifications for health providers who provide MRI services under the supervision of radiologists would align MRI with all other modalities and support the provision of high quality services.
Research has shown that poor MRI services can lead to significant levels of false positive and false negative findings that may lead to unnecessarily invasive medical interventions.  

**Mammography**

Under the current requirements (DIST, Division 2.3, section 2.3.2) mammography services can only be performed under the supervision of a specialist in the specialty of diagnostic radiology. The requirements of supervision are the same for CT services in that the specialist must be available to monitor and influence the service and if necessary attend on the patient personally.

Stakeholders have argued for the need to increase the supervision requirements for mammography services to address safety and quality issues which will reduce the likelihood of false positives and false negatives results. The recent South Australia Health Breast Screening Program experience highlights that major causes of the errors can be the result of sub-optimal handling protocols, poor soft copy reading practices, and image quality issues related to the picture archiving and communication system (PACS).

**Diagnostic Radiology**

The current requirements for diagnostic radiology procedures, excluding mammography (DIST, Division 2.3, section 2.3.1) are that the procedure must be performed by a medical practitioner or a person either employed or under the supervision of a medical practitioner, in accordance with accepted medical practice. The qualifications of the person performing the service are specified as a person registered as a medical radiation practitioner.

A select number of services can also be performed by a dental practitioner.

Stakeholders have not raised any particular concerns about the clarity around the supervision for diagnostic radiology. No changes to current diagnostic radiology (excluding mammography) arrangements are proposed.

**Nuclear Medicine Services**

The requirements for who can perform and supervise nuclear medicine and PET service are clearly outlined (DIST, Division 2.4, sections 2.4.1 and 2.2.3). For nuclear medicine services (excluding PET), it requires the service to be performed by a specialist or consultant physician who participates in the Joint Nuclear Medicine Specialist Credentialing Program or a person acting on behalf of the specialist or consultant physician, but the final report must be compiled by the specialist or consultant physician who originally examined the patient. For PET services, it requires the service to be performed by or under the personal supervision of, a credentialed specialist. No changes to current nuclear medicine arrangements are proposed.

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Current funding and regulatory requirements do not support appropriate requesting of imaging

Diagnostic imaging specialists are not only experts in the acquisition and reporting of imaging but have the expertise to best determine the most appropriate imaging study for a particular clinical presentation. The HI Act, section 16B (10A) currently prescribes the circumstances under which radiologist can substitute services where they have formed the opinion that it would be more appropriate in the diagnosis of the person’s condition to render an alternative service.

Currently, the substituted service must be accepted by the imaging specialist, and the practitioner must consult the person who made the request or take all reasonable steps to consult the person. Stakeholders have commented that this substitution rule does not give radiologists appropriate scope to alter services based on their expertise, and that some patients are receiving inappropriate services as a result.

The Diagnostic Imaging Services Review raised some concerns regarding the role of radiologists with respect to substitution:

‘The role of radiologists and other imaging specialists needs to be reviewed with respect to substitution and improved communication with the requesting practitioner. The role of the radiologist could be better utilised and defined to ensure patients are receiving only appropriate imaging and that the requesting practitioners receive sufficient information from the imaging service to appropriately treat the patient.’

The ANAO made appropriation requesting a key recommendation:

‘The ANAO recommends that the Department of Health develop, as part of its implementation planning, targeted plans which identify proposed strategies and actions to progress key initiatives not yet implemented, including ‘appropriate requesting’ of diagnostic imaging services and the review of MBS fees for diagnostic imaging.’

The current rural exemption lacks a good rationale and is difficult to administer

The purpose of rural exemptions is to ensure patient access to services in areas of workforce shortage without unduly compromising quality. However, necessarily there is a trade-off between quality and access. Rural exemptions apply to the supervision requirements and also to equipment standards, through the capital sensitivity rules. Consideration needs to be given to ensure that the method for determining rural exemptions is meeting this purpose.

The current rural/remote exemption can be difficult to administer. It can also difficult for diagnostic imaging providers to adhere to the requirements. For example, the current ultrasound and CT 30 kilometre rule used to determine exemptions for rural and remote areas is difficult to administer. The Department of Health and the Department of Human Services must be aware of all existing practice locations and changes to their locations, to properly administer the 30km rule. Diagnostic imaging providers must also maintain an awareness of such changes to locations.
It is also a fairly blunt approach to determining whether rural/regional services should be treated differently to urban services. For instance, there are many large rural centres in Australia that support a broad range of local specialist services from a base hospital. Such centres offer CT and in many instances MRI and nuclear medicine services. Local diagnostic imaging specialists are highly valued and enhance the overall capacity of the local health service to manage more complicated cases locally. It seems reasonable that centres that support other specialist medical and surgical services should have available locally based imaging specialists rather than rely on tele-radiology services. Although it seems likely that some regional exemptions should remain in place and align with the Regional Area Geographical Classification system, a more nuanced approach that recognises the growth in regional centres and the increased sophistication of health services delivered in rural/regional Australia should be considered. The current approach to remote exemptions being used for capital sensitivity is based on the Australian Standard Geographical Classification (ASGC) system.

**Ultrasound services are provided by a range of imaging specialists, where qualifications are not mandatory and hence are variable. There is no assurance that ultrasound services are always provided for diagnostic purposes.**

The Diagnostic Imaging Services Review identified concerns some ultrasound services are provided by practitioners that lack appropriate qualifications:

‘Many ultrasound services are provided by non-diagnostic imaging specialists as an inherent part of their examination of a patient; for example, obstetricians monitoring a pregnancy. These ultrasound services might be more appropriately remunerated as part of consultation or other MBS items for relevant specialty groups, rather than through the Diagnostic Imaging Services Table. This could potentially reduce complexity for diagnostic imaging and allow those services to be remunerated more appropriately.

As there is no requirement for non-diagnostic imaging specialists to meet minimum training requirements in order to perform MBS-eligible ultrasound services, some services are presently being provided by practitioners without formal training. This gap could be addressed through the expansion of the diagnostic imaging accreditation scheme and/or the introduction of credentialing requirements.

Reaching a consensus on what these minimum standards might be and including these in requirements for Medicare-eligible services could improve the quality of services.’

The ANAO report reiterated concerns about a lack of appropriate credentialing:

‘Appropriate credentialing is important because it impacts on the quality of the images obtained, and therefore the diagnostic potential of the images.'
The reform package stated that Health would work with professional bodies to ensure that appropriate credentialing schemes or essential educational requirements for each diagnostic imaging modality were implemented and that ultrasound would be the first modality reviewed.

To date, Health has not yet introduced more stringent credentialing requirements for providers of ultrasound services, although work has commenced to progress this initiative.

With the enhancement of ultrasound technology and reduction of equipment cost, the use of ultrasound in clinical practice has broadened beyond a truly diagnostic purpose. Point of care ultrasound is used by many clinicians to assist in procedures or as an adjunct to clinical examination. Currently many of these ultrasound services are funded though the DIST even though they are not truly diagnostic services.

The DIAC have discussed the value of introducing a number of changes to the ultrasound regulations, including the introduction of credentialing requirements for ultrasound providers, the introduction of minimum ultrasound equipment standards, and also the introduction of a definition of diagnostic ultrasound. It has been proposed that these measures would ensure that only high quality diagnostic ultrasounds attract Medicare funding which would result in high quality services for patients and cost efficiencies for Government.

Under the current arrangements there are some modalities, such as ultrasound, that can be provided by radiologists and other medical practitioners who practice in particular specialities and can perform and supervise the provision of some ultrasound items in the MBS (eg. cardiology, urology, obstetrics and gynaecology, and sports medicine). Ultrasound is generally viewed as a safe imaging modality, with lower risk than those which utilise ionizing radiation (eg. CT, X-Ray and Nuclear Medicine). However, it is the diagnostic imaging modality with the highest expenditure ($975 million paid in patient benefits in the 2013-14 financial year).

Many ultrasound items can be performed by a medical practitioner or a sonographer on behalf of a medical practitioner. Other ultrasounds (R-type services) must be performed under the professional supervision of a specialist or consultant physician in the practice of their speciality who must be available to influence and monitor the service, and where necessary attend on the patient personally.

A range of studies and reviews\(^{11}\) have indicated that there are concerns about the low barriers to entry for ultrasound provision, and the potential for ultrasound services to be provided by practitioners without the requisite skills or qualification. While the modality is generally considered safe, the dynamic nature of capturing the images requires a certain level of expertise; otherwise there are a high safety and quality risks resulting from poor image acquisition and interpretation which can adversely impact on consequential patient management.

Objectives

The objectives of this RIS include a review of the existing requirements for the provision of diagnostic imaging and to explore options for enhancing quality, minimising waste and reducing harm caused by inappropriate, unnecessary and sub-optimal diagnostic imaging services. This will ensure that risks to public health are addressed and Medicare funded imaging services represent a value for money investment by Government. Once feedback from stakeholders is received a preferred option will be selected. The selected option will be based on feedback and identified/estimated costs and benefits to all stakeholders, including providers and consumers. It may be that a combination of elements from a number of options will be preferred.

It is anticipated that should any changes be made to the regulatory requirements as a result of this RIS, the changes will be reflected in the HI Regs and/or the DIST and/or the DIAS. It is not anticipated that any change will be required to the HI Act. With any changes sufficient consultation and time will be given to stakeholders.

To meet these objectives, the Department is considering a range of options to reduce inappropriate imaging and to ensure that radiologists and other imaging specialists continue to play a key role in the provision of safe and high quality imaging services. Any ambiguity about supervision and other requirements would be addressed so that DHS is better able to undertake any necessary action in the event of non-compliance. In addition the role of accreditation through the DIAS will be enhanced, recognising that quality assurance is best achieved through industry self-regulation with appropriate links to regulation rather than a top down compliance approach. The following options are to be considered, with details of the options included in the table below:

- Option 1 – No regulatory changes or deregulation
- Option 2 – Minor changes including clarification of current requirements
- Option 3 – Practice based approach

It is anticipated that the options presented will have a range of costs associated with the proposed changes. It is not feasible to predict these costs without a better understanding of the current practice arrangements. Stakeholder feedback on the impact and costs associated with each of the options is sought to allow for a realistic estimation of costs. These indicative costs will be tested during the further consultation rounds with stakeholders.
**Option 1 – No regulatory changes or deregulation**

The government is responsible for providing Medicare benefits for a range of diagnostic imaging services. In doing so, it is vital the government regulates the conditions under which these services are provided, to ensure safe, effective and appropriate services are provided to patients.

If no regulatory changes occur, it is likely that Medicare will continue to operate inefficiently by funding inappropriate and unnecessary imaging which has no benefit to the patient. The sustainability of Medicare is reliant on minimising waste and inappropriate usage of services. Some patients will continue to receive lower quality and potentially unsafe services as there will be inadequate supervision of these services by diagnostic imaging specialists. DHS will continue to face difficulties in undertaking appropriate compliance activities.

Without any changes to the definition of the supervision requirements, the current requirements will continue to be applied inconsistently throughout the sector, offering patients little assurance and confidence in the services they require. Industry suggests that an unequal playing field will continue with some practices doing less that the current supervision regulations require and hence able to operate practices that have a much lower cost base. DHS will argue that they are hamstrung in relation to their compliance role because of the lack of clarity in the regulations.

A communication/education program has not worked previously and is not expected to address the misinterpretation of the regulations. Despite the intention of the regulations some practices think that the radiologist does not need to be onsite or in the close proximity for imaging services. The issues being addressed in this RIS are long standing problems and to date there have not been any shifts in the behaviour of providers. Even with a communication program the regulations are too ambiguous and will prevent DHS from performing any compliance activities.

Possibilities for deregulation have been considered, however a shift to the deregulation of imaging services is not expected to be a valid option. Option two includes deregulation of MSK ultrasound supervision, to bring the supervision requirements in line with the remainder of the modality.

The consensus from a diverse range of stakeholders is the current regulatory requirements require at least clarification and perhaps strengthening. In relation to quality service provision, there has been no suggestion by the sector that regulation should be abandoned. The regulatory changes should address the policy intent that diagnostic imaging specialists should provide appropriate oversight of diagnostic imaging service being performed.

Therefore, it is unlikely this option, or deregulation, would be feasible. Industry will be dissatisfied if the status quo continues.

**Potential Impact**

Under this option there will be no changes to the regulatory impact on providers.

**Questions:**
- Are there any deregulation opportunities within the scope of this RIS?
- What would be the changes in costs associated with any deregulation options?
Option 2 – Minor changes including clarification of current requirements

The policy intention of the current regulations is that a radiologist should be readily available and in close proximity to supervise and where necessary personally perform many imaging services and specifically CT, MRI, and mammography. This is because supervision by diagnostic imaging specialists is a key component in the provision of high quality, safe, and effective diagnostic imaging services. For example, for CT services a radiologist is responsible for ensuring that the practice has appropriate protocols in place; that the general and specific quality of image acquisition by radiographers is high; that the patient receives the lowest possible radiation dose; that the imaging study is directed to the correct site and any detected abnormality; and for contrast agents, responding to any adverse reaction from patients. In addition, the radiologist is responsible for interpreting the study and communicating the result to the requesting practitioner.

The regulations could be amended to clarify the circumstances under which a radiologist and/or specialist and/or consultant physician must provide supervision, and the manner in which this supervision must be provided, in a way that does not amend, but instead clarifies, the original intention of the regulations.

Who may provide a diagnostic imaging service?

It is proposed that the regulations will be based on the following principles. The precise wording in the regulations will reflect these principles and will be revised to remove any ambiguity.

A diagnostic imaging service may be provided by:
- a medical practitioner (a person registered or licensed as a medical practitioner under a law of a state or Territory that provides for the registration or licensing of medical practitioners); or
- a person, other than a medical practitioner, who provides the service under the supervision of a medical practitioner in the practice of his or her speciality in accordance with accepted medical practice.

For supervision:
- the medical specialist or consultant physician must be available to:
  - observe and guide the conduct and diagnostic quality and safety of the imaging; and
  - if necessary and in accordance with accepted medical practice, to attend on the patient personally, within a reasonable period of time.

This would make it clear a diagnostic imaging specialist (including radiologists and other specialists) could not meet the supervision requirements by being located off-site from the practice such that it would be impractical for them to physically attend to the patient personally if necessary. For example, a specialist could not be located in the Sydney CBD and provide supervision for a practice in regional NSW.

It would allow for a medical specialist or consultant physician to provide supervision for a number of practices in a similar geographical location.
For example, a specialist could potentially be located on the Sunshine Coast and provide supervision for a number of different practices operating in the Sunshine Coast region. The specialist could provide remote supervision for some services, such as telephone and on-line where the appropriately qualified person providing the service seeks guidance, but the onus would be on specialists to be capable of making themselves available to attend to the patient personally during a reasonable period of time, where this is necessary.

For additional clarity, a ‘reasonable period of time’ could be defined as either ‘within the same day’ or ‘within the examination’. That is, the medical practitioner would need to be located close enough to attend to the person during their scheduled appointment.

This would help clarify the personal attendance requirements to ensure that where personal attendance is required, the medical practitioner responsible for the report attends the imaging, and attends the patient, in person.

It is important to note that where currently the qualifications of the specialist are described in the DIST these will remain, for example:
- CT, MRI and Mammography will continue to specify “under the supervision of a specialist in the specialty of diagnostic radiology.”

No changes will be made to the nuclear medicine and PET supervision requirements.

**MSK – Ultrasound**

Under the current arrangements MSK ultrasound services are subject to personal attendance requirements, where a medical practitioner responsible for the conduct and report of the examination personally attends during the imaging, and personally examines the patient. Stakeholder advice has indicated that in many instances the involvement of the medical practitioner is minimal and while available during the scan, they are in a supervisory role. It is suggested that the requirements for MSK ultrasound be deregulated and amended to align with all other ultrasound items whereby supervision, but not personal attendance, is required.

**Potential Impacts**

Under this option the proposed changes would result in minimal regulatory impact on the providers of diagnostic imaging services. The changes would improve clarity to providers and would only impact those who are not currently complying with the regulations. Clearer regulations should also reduce to some degree the level of regulatory burden on stakeholders.

Changes to the MSK ultrasound requirements are considered a deregulation option and would reduce the regulatory burden for providers of MSK ultrasound services. Medicare may see an increase in services and consumers may see an increase in availability of services, however with appropriate requesting of services this should not be significant.

**Questions:**
- Are the principles as outlined satisfactory to clarify the requirements?
- What reasons, if any, are there for the personal attendance requirements for MSK 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 MSK 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) associated with the proposed changes?

What are the potential consequences of the proposed changes?
Option 3 – Practice based approach
Under this option the approach to supervision would be tailored to the type of practice in which diagnostic imaging occurs. Currently, diagnostic imaging services are typically provided in the following types of practices:

- comprehensive practice;
- non-comprehensive practice; or
- non-radiologist practice.

A practice based approach to supervision recognises that radiologists operate in a diverse range of imaging environments, each with their own risks, which should be appropriately managed. The radiologist would have the flexibility to implement efficient and effective processes, consistent with industry accepted standards, with a view to maximising the quality and safety of diagnostic imaging services.

Definition of a Comprehensive Practice
A comprehensive practice is currently defined as a medical practice or a radiology department of a hospital that provides the following services (Dictionary, Part 3 of the DIST):

- X-ray;
- Ultrasound; and
- Computed tomography services (whether or not it provides other services).

Medicare eligible MRI equipment must be located at the premises of a comprehensive practice, so where a practice has a Medicare eligible MRI, a comprehensive practice may also provide MRI services (DIST, Sections 2.5.5 and 2.5.6).

There is currently no supervision requirement attached to comprehensive practices. Fundamentally, this proposal is that the supervision requirements be linked to the notion of ‘comprehensive practice’.

The proposed arrangements are based on four possible structures for practices:

1. A comprehensive practice
2. A non-comprehensive practice – radiologist attended practice
3. A non-comprehensive practice without a radiologist in attendance
4. A non-radiologist practice – specialist only practice

If a practice meets the definition of a comprehensive practice it will be required that a radiologist be physically present in the practice for a specified minimum number of hours on ordinary working days. As a comprehensive practice includes CT, a radiologist will be the required attending specialist.
CT – Comprehensive Practice Only

Due to concerns regarding safety and appropriate usage of CT services, CTs must be provided as part of a comprehensive practice. Non-comprehensive practices will not be able to provide Medicare eligible CT services. A possible exception could be provided for the two coronary artery CT services (items 57360 and 57361) which currently do not have to be provided under the supervision of a radiologist, although it is understood that such services are currently provided within comprehensive practices.

The potential impact of having CT services only provided in a comprehensive practice will significantly impact those CT providers who do not meet the definition of a comprehensive practice. Based on accreditation data there are around 100 practices that are either CT only or a combination of CT and up to two other modalities (but not the combination of modalities required to be a comprehensive practice). The financial impact on these facilities will depend on several factors including the business arrangements, staffing levels and location (i.e. whether rural exemptions are applicable). For some facilities it may be viable for them to add additional modalities to meet the comprehensive requirements which can involve significant costs and regulatory impact on the provider. For other facilities this may not be an option which will significantly impact the provider and potentially impact patient access to services.

1. A comprehensive practice

A comprehensive practice meets the conditions of the current definition and also has a radiologist in attendance during minimum agreed hours.

The radiologist provides the supervision of the services within the practice and determines the appropriate level of supervision required.

The radiologist is responsible for ensuring quality services and establishing protocols and appropriate procedures for the practice. The radiologist would have flexibility to implement and supervise efficient and effective processes, by determining the particular level of supervision required for particular services, including when it was necessary to personally attend a patient.

The person who is under the supervision of the radiologist would continue to have the appropriate qualifications, credentials, or training to provide the service (eg. radiation license).

There would be no change to the personal performance requirements for nuclear medicine and PET services.

Practices would be required to maintain records to indicate the name of the radiologist who provided the supervision in addition to the name of the radiologist who compiles the report. This will ensure accountability for practices making it clear who the supervising and reporting radiologists are. The supervising and reporting radiologists need not be the same person. The reporting radiologist would not have to be located on-site, but could be located anywhere in Australia, providing the practice had an appropriate mechanism for transmitting and storing images of satisfactory quality.
The radiologist will be permitted to substitute a more appropriate imaging service in place of the requested imaging service, without the need for consultation with the requester, if the substituted service is more clinically appropriate and has a lower MBS fee than the requested service. This rule will be in addition to the current substitution rule located in Section 10A of the HI Act.

There would be no exemptions for regional areas as, under this arrangement it would not necessary.

Practices providing the services within a comprehensive practice are likely to face increased costs to ensure that a radiologist is present for the minimum agreed hours. It is not possible to speculate how many practices this would affect. Practices will also be subject to additional regulatory impact in order to establish the new policies and procedures in line with the proposed comprehensive practice model. In the longer term however the impact on comprehensive practices would be a reduction in regulatory burden as radiologist would be responsible for setting and managing the supervision requirements for their practice.

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 radiologists 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) associated with the proposed changes?
- What are the potential consequences of the proposed changes?

Existing Models – Practice Arrangements

2. A non-comprehensive practice – Radiologist attended practice

Under these arrangements a radiologist attended practice is one with a radiologist in attendance during minimum agreed hours. The difference between this structure and the comprehensive practice is the modalities provided. With this structure all modalities provided under the definition of a comprehensive practice are not available but it is likely a number of different modalities would be offered. There will not be a minimum range of services that need to be provided.

All other requirements are the same as for a comprehensive practice where the radiologist is responsible for the supervision of the services within the practice and determining the appropriate level of supervision required.
3. A non-comprehensive practice without a radiologist in attendance.

For many practices, a radiologist may not be available on the premises for the entire day, and may share their time between several practices located in a similar geographical location. The radiologist could provide remote supervision for some services, such as telephone and on-line where the appropriately qualified person seeks guidance, but the onus would be on the radiologist to be capable of making themselves available to attend to the patient personally, within the examination, where it is necessary (i.e. where the supervision regulations require it).

In this instance, the supervision requirements as they currently exist, along with the amended clarifications in option 2 to ensure the policy intent of the legislation is clear, would apply.

Under the current supervision requirements, when the following services are being provided, the radiologist must be available in close proximity to supervise and influence the conduct of the service:

- mammography;
- the administration of contrast; and
- image guided intervention procedures / surgical interventions.

A radiologist is required to supervise the above services due to the potential safety risks associated with the administration of contrasts and other therapeutic substances and the consequences associated with incorrect imaging and misdiagnosis of mammography services.

Aligning the supervision requirements to the original policy intent of the current legislation will close the loop-hole for providers who have interpreted the current wording of the DIST that a radiologist only needs to be on-site when ‘necessary’ and thus gain a commercial competitive advantage over diagnostic imaging providers who have an on-site radiologist.

Only services that do not require the supervision of a radiologist will be able to be performed when the radiologist is not on site.

The person who is under the supervision of the radiologist would continue to require the appropriate qualifications, credentials, or training to provide the service (e.g. radiation license).

4. Non-radiologist specialist practice

This structure describes the current practice where non-radiologist specialists are appropriately performing services, as outlined in the DIST. There is no intention to reduce the scope of these services or change the requirements. This structure captures where select services are performed and/or supervised by specialists, including cardiologists, obstetricians and gynaecologists and vascular surgeons.
These services are generally ultrasound services, and two CT items (57360 and 57361) that do not need to be performed under the supervision of a radiologist. The supervision requirements for these services would remain with all ultrasound R-type eligible services and the two CT items being subject to modality specific supervision requirements. The current qualifications would remain for the two CT items as outlined in the DIST; where they can be performed under the supervision of a specialist or consultant physician who is recognised by the Conjoint Committee for the Recognition of Training in CT Coronary Angiography.

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

**Rural and Remote exemptions**

Under the proposed new arrangements rural/remote exemptions will not be possible or necessary for a comprehensive practice.

For non-comprehensive practices, without a radiologist in attendance a rural/remote exemption for the supervision requirements may still remain. Where remote/rural exemptions are required remote reporting rules could be expanded to require real time access to supervising radiologists in order to recognise the workforce constraints in these areas.

The intention of having rural exemptions is to ensure patients have access to services without compromising on quality. The aim is to encourage local radiologist attendance, even if it is not full time. Exemptions should not commercially disadvantage practices that provide local services.

The current arrangements for rural exemptions vary for each of the modalities, creating confusion due to an inconsistent approach. If a modality warrants a rural exemption, ideally the requirements for meeting this should be consistent across all modalities.

**Table 4: Current rural exemptions as outlined in the DIST**

<table>
<thead>
<tr>
<th>Modality</th>
<th>Rural Exemption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound</td>
<td>2.1.2 (d)(ii) in a location that is not less than 30km by the most direct road route from another practice where services that comply with paragraph (a) or (b) are available</td>
</tr>
<tr>
<td>MSK Ultrasound</td>
<td>2.1.7 (b) the service is performed, because of medical necessity, in a location that is more than 30km by the most direct road route from another practice where services that comply with paragraph (a) are available</td>
</tr>
<tr>
<td>CT</td>
<td>2.2.1 (3)(b) because of medical necessity, in a remote location*</td>
</tr>
<tr>
<td>Diagnostic radiography</td>
<td>2.3.1 (3) Subclauses (1) and (2) do not apply if the procedure is performed: (a) in RA2, RA3 or RA4; or (b) in: (i) RA1 ; and (ii) RRMA4 or RRMA5</td>
</tr>
<tr>
<td>Mammography</td>
<td>2.3.2 (b)(ii) because of a medical necessity, in a remote location*</td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>No exemption</td>
</tr>
<tr>
<td>MRI</td>
<td>2.5.3 (b)(ii) performed because of medical necessity, in a remote location*</td>
</tr>
</tbody>
</table>
*remote location is defined as a place within Australia that is more than 30km by road from: (a) a hospital that provides a radiology or computed tomography service under the direction of a specialist in the specialty of diagnostic radiology; or (b) a free-standing radiology or computed tomography facility under the direction of a specialist in the specialty of diagnostic radiology.

The current rural/remote exemption can be difficult to administer. For example the Department of Health and the Department of Human Services must be aware of all existing practice locations and changes to their locations, to properly administer the 30km rule. It has been suggested that a different approach to managing rural/remote exemptions be considered.

The current approach to remote exemptions being used for capital sensitivity is based on the Australian Standard Geographical Classification (ASGC) system.

If any changes are made to the classification of areas for exemption a grandfathering mechanism would be used as a temporary measure, during the transition period, to prevent any practice being disadvantaged by moving to this system. Initial analysis suggests that few practices will be affected.

Questions:
- Does the current rule meet its goal of increasing access for patients without compromising 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 incentive for local service provision in rural Australia?
- What is the role of tele-radiology? Should it be the only a service or an adjunct to local service provision?
- Should the exemption not be available for certain types of services?

Changes to Ultrasound requirements

It is proposed that there be changes to ultrasound requirements in both option 2 and 3.

A diagnostic ultrasound would be a clinically necessary service, which investigates, provides imaging and reports on the relevant anatomy with sufficient detail for a treating practitioner to make an informed diagnosis or assessment of the patient’s current condition and appropriate treatment options. It would be provided by suitably qualified professionals using equipment that is appropriate to the service and meets quality and safety standards. There will be a requirement that a written report is provided to the requesting practitioner and in the case of self-determined ultrasound to the referring practitioner.

Practices need to be able to demonstrate that providers of ultrasound services possess appropriate credentials for safe and effective ultrasound provision.

The introduction of credentialing arrangements for ultrasound would ensure that diagnostic ultrasounds will be provided by practitioners with the requisite skills and qualification.
Specialists providing Medicare funded ultrasound services would have to demonstrate that they have obtained an appropriate qualification (as specified in the DIAS standards or DIST) which at a minimum would be a Diploma of Diagnostic Ultrasound (DDU). It is not expected that this will impact a significant number of ultrasound providers.

**Definition of Diagnostic Ultrasound**

The introduction of a definition of diagnostic ultrasound would ensure that only ultrasound services that met the requirements of the definition would attract a Medicare rebate and would ensure standards remain high and that opportunistic ultrasound services that are provided as part of a specialist consultation would not attract Medicare funding unless they met these requirements.

**Introduce equipment standards for Ultrasound**

Currently, there are no requirements for the equipment specifications that must be used in order to perform diagnostic ultrasound, apart from the transducer frequency for two types of ultrasound services. With the emergence of new technologies members of the DIAC have raised concerns, on a number of occasions, of the poor quality of some of the new ultrasound equipment that is now available.

Providers of diagnostic ultrasound could be required to meet the RANZCR recommended standards for diagnostic ultrasound equipment and have equipment with the required capability (RANZCR Standards of Practice for Diagnostic and Interventional Radiology (2014: version 10) pages 83 – 84).

**Potential Impacts**

The potential impact of these changes will involve additional training and purchasing of appropriate equipment for some ultrasound providers. It is not anticipated that this will affect a significant number of stakeholders.

**Implementing any changes and the relative role of regulation and the DIAS.**

Based on feedback on the options proposed in this RIS there may be changes that will need to be made to the HI Act, the DIST and the DIAS. 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. It seems likely that if supervision requirements were linked to a comprehensive practice model, there would still be need for modality specific regulation particularly with respect to diagnostic ultrasound, which is performed commonly in stand-alone settings. Nevertheless, it is anticipated that into the future some enhancement to quality standards will be advanced through changes to DIAS, with an increasing role for practice accreditation, rather than relying on DHS compliance activity as the vehicle for assuring Australian consumers and government that diagnostic imaging services are safe and of high quality.

**Questions:**

- Would changes to supervision be better placed in the diagnostic imaging accreditation scheme 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?
### Table 5: A comparison / summary of the features of Options 1, 2 and 3

| Option 1: No regulatory change or deregulation | 1 |
| Option 2: Minor changes, including clarification of current requirements | 2 |
| Option 3: Practice based approach | 3 |

**FEATURES**

- The current supervision requirements remain unchanged.  
  - X

- Amendments to the current supervision requirements, to clarify the circumstances under which a radiologist and/or specialist or consultant physicians must provide supervision and the how the supervision must be provided.  
  - X X

  i) 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.  
  - X

- The personal attendance requirement of musculoskeletal ultrasound would be amended to align with all other ultrasound items.  
  - X X

- The person under the professional supervision of the radiologist would require the appropriate qualifications, credentials, or training to provide the service.  
  - X X X

- 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).  
  - X

- Supervision would be tailored to the type of diagnostic imaging practice.  
  - X

- A comprehensive practice would require a radiologist to be available during agreed operating hours.  
  - X

- Where a radiologist is NOT on site during ordinary operating hours, a radiologist must be onsite for the performance of the following service:  
  - mammography  
  - the administration of contrast; and  
  - image guided intervention procedures / surgical interventions  
  - X

- 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.  
  - X

- Where a radiologist is on site during ordinary operating hour the radiologist would be allowed to substitute a requested service for a more appropriate service, without the need for consultation with the requestor, if the substituted service has a lower MBS fee than the requested service.  
  - X

- The current substitution rules in the *Health Insurance Act 1973* remain.  
  - X X X

- Where a radiologist is NOT on site during ordinary operating hours, a radiologist must be onsite for the performance of the following service:  
  - mammography  
  - the administration of contrast; and  
  - image guided intervention procedures / surgical interventions  
  - X

- 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.  
  - X

- Rural and remote exemptions.  
  - X X X

- Specified qualification requirements for ultrasound providers.  
  - X X

- Definition of diagnostic ultrasound.  
  - X X
CONSULTATION WITH Stakeholders - There are a number of key stakeholders whom have involvement in the diagnostic imaging sector.

Key diagnostic imaging stakeholders

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Description</th>
<th>Email contact</th>
<th>Internet Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Diagnostic Imaging Association (ADIA)</td>
<td>Peak body for private specialist radiology practices</td>
<td><a href="mailto:pbeerens@adia.asn.au">pbeerens@adia.asn.au</a></td>
<td>ADIA website</td>
</tr>
<tr>
<td>The Royal Australian and New Zealand College of Radiologists (RANZCR)</td>
<td>Professional organisation for medical specialities of radiology, medical imaging, and radiation oncology</td>
<td><a href="mailto:ranzcr@ranzcr.edu.au">ranzcr@ranzcr.edu.au</a></td>
<td>RANZCR website</td>
</tr>
<tr>
<td>The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)</td>
<td>Professional organisation for obstetrics and gynaecology and women's health</td>
<td><a href="mailto:ranzcog@ranzcog.edu.au">ranzcog@ranzcog.edu.au</a></td>
<td>RANZCOG website</td>
</tr>
<tr>
<td>The Royal Australian College of General Practitioners (RACGP)</td>
<td>Professional organisation for general practitioners</td>
<td><a href="mailto:racgp@racgp.org.au">racgp@racgp.org.au</a></td>
<td>RACGP website</td>
</tr>
<tr>
<td>Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM)</td>
<td>Professional organisation for medical physicists, physical scientists, and biomedical engineers</td>
<td><a href="mailto:Geoff.Barbaro@acpsem.org.au">Geoff.Barbaro@acpsem.org.au</a></td>
<td>ACPSEM website</td>
</tr>
<tr>
<td>Diagnostic Imaging and Monitoring Association</td>
<td>Professional organisation providing collective representation to governments and other bodies regarding diagnostic imaging issues</td>
<td><a href="mailto:dima@theassociationspecialists.com.au">dima@theassociationspecialists.com.au</a></td>
<td></td>
</tr>
<tr>
<td>Cardiac Society of Australia and New Zealand (CSANZ)</td>
<td>Professional society for cardiologists and those working in the area of</td>
<td><a href="mailto:info@csanz.edu.au">info@csanz.edu.au</a></td>
<td>CSANZ website</td>
</tr>
<tr>
<td>Organization</td>
<td>Description</td>
<td>Email</td>
<td>Website</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
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<td>----------------------------------------------</td>
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<tr>
<td>Australasian Association of Nuclear Medicine Specialists (AANMS)</td>
<td>Peak body for nuclear medicine and molecular imaging</td>
<td><a href="mailto:aanms@aanms.org.au">aanms@aanms.org.au</a></td>
<td><a href="http://www.anzapnm.org.au/">http://www.anzapnm.org.au/</a></td>
</tr>
<tr>
<td>Australian Institute of Radiography (AIR)</td>
<td>Peak body for radiographers, radiation therapists, and sonographers</td>
<td><a href="mailto:info@air.asn.au">info@air.asn.au</a></td>
<td><a href="http://www.air.asn.au/">http://www.air.asn.au/</a></td>
</tr>
<tr>
<td>Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)</td>
<td>Federal Government agency focused on ionising and non-ionising radiation</td>
<td><a href="mailto:info@arpansa.gov.au">info@arpansa.gov.au</a></td>
<td><a href="http://www.arpansa.gov.au/">http://www.arpansa.gov.au/</a></td>
</tr>
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</table>
Legislation

The legislation and sub-ordinate legislation with key relevance to diagnostic imaging are:

- **Legislation**

  *Health Insurance Act 1973*

- **Regulations**

  *Health Insurance Regulations 1975*

  *Health Insurance (Diagnostic Imaging Services Table) Regulations 2012*

  *Health Insurance (General Medical Services) Table Regulations 2012*

- **Determinations**

  *Health Insurance (Diagnostic Imaging Capital Sensitivity) Determination 2011*

  *Health Insurance (Bone Densitometry) Determination 2012*

  *Health Insurance (Diagnostic Imaging Capital Sensitivity) Facilities Determination 2011*

  *Health Insurance (Cone Beam Computed Tomography) Determination 2011*

  *Health Insurance (Gippsland and South Eastern New South Wales Mobile MRI service and Rockhampton, Bundaberg and Gladstone Mobile MRI service) Determination 2013*

  *Health Insurance (MRI for patients 16 years and over) Determination 2013*
Legislative Instruments

Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010
Health Insurance (Diagnostic Imaging Accreditation-Approved Accreditors) Instrument 2010
Health Insurance (Diagnostic Imaging Accreditation-Designated Persons) Instrument 2010

In addition to the Commonwealth health insurance legislation, there is additional Commonwealth and state and territory legislation regulating the use of radiation. Practices must comply with and be licenced under the radiation laws in their own jurisdictions in order to provide Medicare-eligible services.
## Medicare Data – Services by Subgroup - 2013/14 Financial Year

<table>
<thead>
<tr>
<th>Modality</th>
<th>Group</th>
<th>Subgroup</th>
<th>Number</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound</td>
<td>I1</td>
<td>1. General</td>
<td>3,443,999</td>
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<tr>
<td></td>
<td></td>
<td>2. Cardiac</td>
<td>1,094,636</td>
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<tr>
<td></td>
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<td>3. Vascular</td>
<td>942,538</td>
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<tr>
<td></td>
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<td>4. Urological</td>
<td>26,547</td>
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<td></td>
<td></td>
<td>5. Obstetric and Gynaecological</td>
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<td></td>
<td></td>
<td>6. Musculoskeletal</td>
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<tr>
<td>Computed Tomography</td>
<td>I2</td>
<td></td>
<td>2,709,088</td>
<td>12%</td>
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<tr>
<td>Diagnostic Radiology</td>
<td>I3</td>
<td></td>
<td>10,051,941</td>
<td>44%</td>
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</table>

1. Extremities
2. Shoulder or Pelvis
3. Head
4. Spine
5. Skeletal Surveys etc
6. Thoracic
7. Urinary Tract
8. Alimentary Tract etc
9. Foreign Bodies
10. Breasts
11. Pregnancy related
12. Opaque/Contrast Media
13. Angiography
14. Tomography
<table>
<thead>
<tr>
<th>Modality</th>
<th>Group</th>
<th>Subgroup</th>
<th>Number</th>
<th>Proportion</th>
</tr>
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<tbody>
<tr>
<td>15. Fluoroscopic exam</td>
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<td>145,956</td>
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<td>16. Radiological Procedure</td>
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<td>76</td>
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<td>17. Interventional Techniques</td>
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<tr>
<td><strong>Nuclear Medicine</strong></td>
<td><strong>I4</strong></td>
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<td>643,855</td>
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<tr>
<td><strong>Magnetic Resonance Imaging</strong></td>
<td><strong>I5</strong></td>
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<td>828,719</td>
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<tr>
<td>1. scan of head</td>
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<tr>
<td>2. scan of head</td>
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<tr>
<td>3. scan of head and neck vessels</td>
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<td>8,456</td>
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<td>4. scan of head and cervical spine</td>
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<td>5. scan of head and cervical spine</td>
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<td>5,404</td>
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<tr>
<td>6. scan of spine - one region or two contiguous regions</td>
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<td>7. scan of spine - one or two contiguous regions</td>
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<td>10. scan of cervical spine and brachial plexus - specified conditions</td>
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<td>11. scan of musculoskeletal system</td>
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<td>21,103</td>
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<td>12. scan of musculoskeletal system</td>
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<td>13. scan of musculoskeletal system</td>
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<td>14. scan of cardiovascular system</td>
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<td>15. magnetic resonance angiography - scan of cardiovascular system</td>
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<td>16. magnetic resonance angiography - under 16 yrs</td>
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<tr>
<td>17. magnetic resonance imaging - person under 16 yrs</td>
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<tr>
<td>18. magnetic resonance imaging - for specified conditions - person under 16 yrs</td>
<td></td>
<td></td>
<td>555</td>
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<td>Modality</td>
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<td>Proportion</td>
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<tr>
<td>19.</td>
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<td>scan of body - for specified conditions</td>
<td>4,380</td>
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<td>20.</td>
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<td>scan of pelvis and upper abdomen</td>
<td>2,714</td>
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<td>21.</td>
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<td>Scan of body for specified conditions</td>
<td>15,890</td>
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<td>22.</td>
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<td>modifying items</td>
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<tr>
<td>32.</td>
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<td>PIP Prostheses</td>
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<td>33.</td>
<td></td>
<td>for specified conditions - person under the age of 16 yrs</td>
<td>21,842</td>
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<tr>
<td>TOTAL</td>
<td></td>
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<td>22,804,378</td>
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