Health Insurance (Diagnostic Imaging Accreditation) Amendment Instrument 2015

made under subsection 23DZZIAA(1) of the

Health Insurance Act 1973

Compilation No. 1

Compilation date:	24 June 2015
Includes amendments up to:	Health Insurance (Diagnostic Imaging Accreditation) Amendment Instrument (No. 2) 2015

Includes uncommenced provisions

Prepared by Department of Health, Canberra

About this compilation

This compilation

This is a compilation of the *Health Insurance (Diagnostic Imaging Accreditation) Amendment Instrument 2015* that shows the text of the law as amended and in force on 24 June 2015 (the ***compilation date***).

This compilation was prepared on 3 September 2015.

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on ComLaw (www.comlaw.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on ComLaw for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on ComLaw for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

1. Name of Instrument

This legislative instrument is the *Health Insurance (Diagnostic Imaging Accreditation) Amendment Instrument 2015.*

2. Commencement

This Instrument commences on 1 January 2016.

3. Authority

This Instrument is made under the *Health Insurance Act 1973*.

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 Amendments

Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010

1 Subsection 4(1), definition of *relevant time*

Repeal the definition.

2 Paragraph 5(1)(b)

Omit "Medicare Australia" (wherever appearing), substitute "the Department of Human Services".

3 Section 6

Omit "7,".

4 Section 7

Repeal the section.

5 Paragraph 15(1)(a)

Omit "7 or".

6 Paragraph 15(1)(c)

Omit "7,".

7 Schedule 1

Repeal the Schedule, substitute*:*

Schedule 1

Diagnostic Imaging Accreditation Scheme – Standards
(sections 8 and 9)

PART 1 ORGANISATIONAL STANDARDS

Standard 1.1 Safety and Quality Manual Standard

The diagnostic imaging practice must prepare a comprehensive safety and quality manual that includes all diagnostic imaging accreditation scheme (DIAS) related policies and addresses DIAS standards, including the title and /or names of the persons at the diagnostic imaging practice who develop, approve, implement, maintain, and review these policies.

Required Evidence

A documented safety and quality manual for the diagnostic imaging practice which addresses the practice's:

- governance, policies and procedures regarding DIAS (Standard 1.1);
- registration and licensing of personnel (Standard 1.2);
- radiation safety and optimised radiation technique charts (Standards 1.3 and 3.2);
- diagnostic imaging equipment and servicing (Standards 1.4 and 1.5);
- healthcare associated infection policies and procedures (Standard 1.6);
- provision of diagnostic imaging services and reporting and recording image findings policies (Standards 2.1, 4.1 and 4.2);
- consumer consent and information policies (Standard 2.2);
- patient identification and procedure matching policies (Standard 2.3);
- medication management policies (Standard 2.4);
- diagnostic imaging protocols (Standard 3.1); and
- consumer and stakeholder feedback and complaints policies (Standard 4.3).

Evidence which demonstrates that mechanisms are in place to evaluate, audit, review and monitor each one of the Standards and their specific requirements.

Standard 1.2 Registration and Licensing Standard (Entry Level Standard)

Staff, students, contractors or locums and any other practitioner eligible to provide or assist in the provision of diagnostic imaging services to the practice must provide evidence of and maintain all appropriate and current registration and/or licences to undertake diagnostic imaging procedures.

Required Evidence

Copies of each registered health practitioner's Australian Health Practitioner Regulation Agency (AHPRA) registration documentation, or an AHPRA registration number which can be verified on the public register. These practitioners include:

- medical practitioners;
- dentists;
- medical radiation practitioners;
- nurses; and
- allied health practitioners (including podiatrists, osteopaths, chiropractors and physiotherapists).

Copies of the AHPRA registration documentation of each student who is registered on the AHPRA student register.

Where the practice provides imaging modalities that involve ionising radiation, copies of each registered health practitioner's State or Territory radiation user licence, or a registration number which can be verified on the public register, if required in the State or Territory.

Copies of each non-registered health practitioner's State or Territory radiation use licence, or a licence number which can be verified, if required in the State or Territory.

Where the practice provides ultrasound services, copies of each sonographer's statement of accreditation on the Australian Sonographer Accreditation Register (ASAR) or a registration number which can be verified on the ASAR register for the purpose of determining registration on the Department of Human Services Register of Sonographers.

Evidence that the registration status of practitioners is reviewed annually, in line with AHPRA's annual registration process.

Standard 1.3 Radiation Safety Standard (Entry Level Standard)

Where a diagnostic imaging practice uses ionising radiation, the practice must comply with the requirements of the relevant State or Territory radiation safety legislation.

Required Evidence

Copies of relevant State or Territory Radiation Safety Regulator equipment licences and registrations or registration numbers which can be verified.

Copies of radiation safety plans and all other relevant radiation safety documents required by State or Territory radiation safety legislation, with evidence that they are reviewed a minimum of once per accreditation cycle.

Standard 1.4 Equipment Inventory Standard (Entry Level Standard)

The diagnostic imaging practice must maintain a current diagnostic imaging equipment inventory demonstrating that relevant equipment used to provide diagnostic imaging services is registered with Department of Human Services (DHS) and complies with specifications in the *Health Insurance Act 1973* and the *Health Insurance Regulations 1975*.

Required Evidence

A current, documented equipment inventory which includes:
- the name of item;
- manufacturer; and
- serial number (or other identifier).

A copy of the most recent DHS Location Specific Practice Number (LSPN) register equipment record.

Standard 1.5 Equipment Servicing Standard

The diagnostic imaging practice must demonstrate that equipment used to acquire, manipulate, print or report images for diagnostic imaging procedures is safe and appropriate for its intended use.

Required Evidence

Records and service reports, demonstrating the equipment used to provide images is serviced according to manufacturer's guidelines by qualified persons and the requirements of applicable radiation safety legislation, including the:
- date of service, details and results of the service and the date of the next service; and
- actions taken at the practice in response to the results of the service.

A record of the service provider's qualifications are to be provided to the approved accreditor, however they do not need to appear on every service report. The service provider shall:
- hold a radiation use licence for service and repair (if servicing ionising radiation equipment) issued by the State or Territory where the service is performed; and
- provide evidence of successful completion of a recognised service training course appropriate to the equipment being serviced.

NOTE:
A "service" in this context refers to "maintenance carried out at predetermined intervals, or according to prescribed criteria, and intended to reduce the probability of failure or the degradation of the functioning of an item" (AS/NZS 3551:2012 §1.4.36). A breakdown repair is not a service. The

service frequency would normally be as defined by the medical equipment manufacturer however a variation can exist "supported by a documented rationale for the deviation" (AS/NZS 3551:2012 §6.4.2).

Standard 1.6 Healthcare Associated Infection Standard

The diagnostic imaging practice must mitigate the risk of the transmission of infectious agents to patients, carers, healthcare workers, support staff and other visitors, by:

a) identifying, assessing and managing and reporting the risk of the transmission of infectious agents;

b) meeting the requirements specified in infection control guidelines/policies produced by Commonwealth, State and Territory government authorities;

c) reporting, investigating, and responding to incidents at the diagnostic imaging practice arising from the transmission of infectious agents; and

d) ensuring consumer-specific information on the management and reduction of healthcare associated infections is available at the point of care.

Required Evidence

A documented policy and procedure for preventing the transmission of infectious agents to patients and carers, healthcare workers, support staff and other visitors which includes the process for identifying, assessing and managing risks and reporting, investigating and responding to the transmission of infectious agents when they occur. (Standard 1.1)

Where relevant, documented quality improvement activities, which describe the actions taken in response to the transmission of an infectious agent(s).

Where ultrasound services are being provided, a documented policy that meets the requirements of the *Therapeutic Goods Order No. 54 — Standard for Disinfectants and Sterilants* or equivalent.

Copies of consumer-specific information on the management and reduction of healthcare associated infections.

PART 2 PRE-PROCEDURE STANDARDS

Standard 2.1 Provision of Service Standard

The diagnostic imaging practice must demonstrate that diagnostic imaging services are only undertaken where there is an identified clinical need and:

a) upon receipt of an appropriate request from a medical practitioner or a practitioner who is able under the *Health Insurance Act 1973* to request services of that kind as a service for which a medicare benefit is payable; or

b) where the providing and reporting practitioner self-determines the service in accordance with requirements of the *Health Insurance Act 1973*.

Required Evidence

For practitioners providing requested services:

- the practice must have a documented policy and procedure in response to inappropriate requests for diagnostic imaging procedures. (Standard 1.1)
- a sample of de-identified requests documenting the clinical need for the diagnostic imaging procedures rendered at the diagnostic imaging practice.

For practitioners providing self-determined services:

- a sample of de-identified records documenting clinical need.

Standard 2.2 Consumer Consent and Information Standard

Prior to a diagnostic imaging procedure being rendered, except in cases of emergency, the diagnostic imaging practice must ensure that:

a) patients have access to information about the diagnostic imaging procedure;

b) risks are advised to the patient or substitute decision maker;

c) practice staff obtain and record relevant information about the patient's health status and individual patient risk factors;

d) consent for each diagnostic imaging procedure is obtained from the patient or the substitute decision maker; and

e) patient consent requirements reflect the risk attached to the diagnostic imaging procedure.

Required Evidence

A documented policy and procedure for obtaining patient consent prior to a diagnostic imaging procedure being provided, ensuring that the consent requirements reflect the level of risk attached to each procedure. It is expected that practices obtain written patient consent prior to invasive or high risk procedures. (Standard 1.1)

A sample of de-identified records of consent obtained from the patient in respect of the diagnostic imaging procedure.

A sample of de-identified records documenting the patient's health status, relevant to the diagnostic imaging procedure being undertaken, with regard to:

- asthma;
- previous exposure to intravenous contrast;
- allergies;
- medical conditions such as diabetes, kidney disease or heart disease;
- pregnancy status;
- medications such as metformin hydrochloride;
- breastfeeding; and
- medical devices and implanted devices such as intra- cranial aneurysm clips, cardiac pacemaker, coronary stents, intra ocular foreign bodies and cochlear implants.

Examples of service specific information for the diagnostic imaging services available at the practice.

A sample of de-identified records must be provided which demonstrate that risks have been advised to the patient.

Standard 2.3 Patient Identification & Procedure Matching Standard

The diagnostic imaging practice must ensure that all patients are correctly identified and matched to their intended procedure or treatment by:

a) using at least three (3) approved patient identifiers to match a patient to their request or medical record from the time the patient presents and through all stages of the diagnostic imaging service and when transferring responsibility of care;

b) correctly matching patients with their intended diagnostic imaging service and the anatomical site and side (if applicable) of the diagnostic imaging procedure;

c) utilising the 'time-out' technique for high risk procedures, including confirming the patient's allergy status; and

d) reporting, investigating, and responding to patient care mismatching events when they occur and implementing changes, where relevant, to reduce the risk of future incidents.

Required Evidence

A documented policy and procedure for matching patients to their intended diagnostic imaging procedure including the report for that procedure, through all stages of the service and when transferring responsibility of care. (Standard 1.1)

A sample of appropriately de-identified records documenting the use of three patient identifiers.

A documented policy and procedure which sets out the process for reporting, investigating and responding to patient care mismatching events when they occur.

Where relevant, documented quality improvement activities, which describe the actions taken in response to patient care mismatching events.

Standard 2.4 Medication Management Standard

The diagnostic imaging practice must ensure that medication risks are managed by:

a) correctly and safely storing, preparing and disposing of medications in accordance with manufacturer's guidelines and relevant Commonwealth, State or Territory requirements;

b) identifying patients at risk from adverse reactions;

c) administering medication safely, actively monitoring the effects of medication, and all relevant details recorded in the patient's records;

d) personnel capable of providing timely and appropriate care in the event of an adverse reaction to medication; and

e) reporting, investigating and responding to incidents arising from adverse reactions or medication mismanagement.

Required Evidence

A documented policy and procedure describing the procedures for:
- storing, preparing and disposing of medications;
- identifying at risk patients;
- administering medications safely;
- monitoring and recording the effects of medication; and
- reporting, investigating, and responding to adverse reactions or medication mismanagement incidents when they occur.

A documented management plan which identifies the procedures for managing adverse reactions at the time they occur;
- the type and location of resuscitation equipment and associated drugs at the practice; and
- the personnel certified in basic life support and qualified to use resuscitation equipment and drugs. (Standard 1.1)

Where a practice performs examinations using contrast, a documented protocol which ensures the appropriate use and administration of contrast.

A sample of de-identified records for relevant diagnostic imaging procedures documenting the information collected about the patient's medication use and/or history regarding previous reactions to medications.

Example of records demonstrating managing adverse reactions at the time they occur.

Where relevant, documented quality improvement activities, which describe the actions taken in response to incidents related to medication management.

NOTE:
A 'medication' in this context refers to anything administered to a patient:
- to create or enhance a diagnostic quality image; and/or
- where imaging is used as part of an interventional procedure.

PART 3 PROCEDURE STANDARDS

Standard 3.1 Diagnostic Imaging Protocol Standard

The diagnostic imaging practice must have documented protocols which describe the required projections, list of anatomy to be visualised, contrast injection requirements and/or positioning required for the acquisition of optimised quality images.

Required Evidence

Documented protocols for routine diagnostic imaging procedures or groups of diagnostic imaging procedures rendered at the diagnostic imaging practice, with evidence that they have been reviewed a minimum of once per accreditation cycle, which include all necessary information for the proper conduct of the examination taking into account any specifications for the required qualifications, experience and specialisation of the personnel. Where specific tasks are delegated to members of the imaging team, the protocols shall indicate any specific circumstances under which personnel shall seek further guidance and/or input from the supervising medical practitioner.

Standard 3.2 Optimised Radiation Technique Charts Standard

A diagnostic imaging practice which uses ionising radiation must ensure that patient radiation exposure is kept as low as reasonably achievable (ALARA) by selecting

equipment and techniques for diagnostic imaging procedures sufficient to provide the required clinical information.

Required Evidence

A technique chart, consistent with the ALARA principle, for each unit of ionising radiation equipment located at the diagnostic imaging practice.

Ionising radiation equipment where settings are entered manually:

- evidence must be supplied that demonstrates the settings have been reviewed and authorised by a qualified person, annually for each episode.

Ionising radiation equipment where settings are embedded in the software and operators select a protocol:

- evidence must be supplied that demonstrates the underlying settings have been reviewed and authorised by a qualified person annually.

For each item of screening fluoroscopy equipment:

- a copy of a log of screening times, and evidence that the log has been reviewed by a qualified person annually.

For each item of interventional angiography equipment:

- evidence that system generated dose metrics have been logged and reviewed by a qualified person annually. If the interventional angiography equipment is not capable of generating dose metrics alternatively a copy of a log of screening times, and evidence that the log has been reviewed by a qualified person annually should be provided.

The practice must establish a program to ensure that radiation doses administered to a patient for diagnostic purposes are:

a) annually compared with diagnostic reference levels (DRLs) for diagnostic procedures for which DRLs have been established in Australia; and
b) if DRLs are consistently exceeded, reviewed to determine whether radiation protection has been optimised.

PART 4 POST PROCEDURE STANDARDS

Standard 4.1 Communicating Results and Reports Standard

The diagnostic imaging practice effectively communicates the results of a requested diagnostic imaging procedure by:

a) providing timely, clear and concise written reports which address the information:
   - requested by the requesting practitioner;
   - required by the diagnostic imaging service; and
   - that is necessary for the interpretation of the images;

b) taking all reasonable steps to personally advise the requesting practitioner (or another practitioner where necessary) about urgent and unexpected findings; and

c) responding to feedback and requests from requesting practitioners about the content or provision of reports and/or advice provided.

Required Evidence

A documented policy for the provision of reports to requesting practitioners and patients. (Standard 1.1)

A sample of de-identified imaging reports, consistent with the practice's documented policy for reporting.

Where relevant, documented quality improvement activities, which describe the actions taken in response to feedback from requesting practitioners.

Standard 4.2 Findings of Self-Determined Services Standard

When the service is a self-determined service, information about the findings of the diagnostic imaging procedure must be documented in a report* and retained in the patient record.

*as required by 1.2.8 of the diagnostic imaging services table

Required Evidence

A sample of de-identified records documenting the image findings and that show that it has been retained in the patient records.

Standard 4.3 Consumer and Stakeholder Feedback and Complaints Management Standard

The diagnostic imaging practice must provide opportunities for, and respond to, feedback and complaints from consumers, requestors and all other stakeholders about the provision of a diagnostic imaging service.

Required Evidence

A documented policy for inviting, recording, managing and responding to feedback and complaints which is consistent with the principles of open disclosure and fairness, accessibility, responsiveness, efficiency and integration. (Standard 1.1)

Evidence of publically accessible information for inviting, managing and responding to feedback and complaints which is consistent with the principles of open disclosure and fairness, accessibility, responsiveness, efficiency and integration.

Evidence of training practice staff in managing and responding to feedback and complaints.

A sample of de-identified feedback and complaints received and records of the actions taken.

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Endnotes about misdescribed amendments and other matters are included in a compilation only as necessary.

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the amendment is set out in the endnotes.

Endnote 2—Abbreviation key

A = Act
ad = added or inserted
am = amended
amdt = amendment
c = clause(s)
C[x] = Compilation No. x
Ch = Chapter(s)
def = definition(s)
Dict = Dictionary
disallowed = disallowed by Parliament
Div = Division(s)
exp = expires/expired or ceases/ceased to have effect
F = Federal Register of Legislative Instruments
gaz = gazette
LI = Legislative Instrument
LIA = *Legislative Instruments Act 2003*
(md) = misdescribed amendment
mod = modified/modification
No. = Number(s)
o = order(s)
Ord = Ordinance
orig = original
par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
pres = present
prev = previous
(prev…) = previously
Pt = Part(s)
r = regulation(s)/rule(s)
Reg = Regulation/Regulations
reloc = relocated
renum = renumbered
rep = repealed
rs = repealed and substituted
s = section(s)/subsection(s)
Sch = Schedule(s)
Sdiv = Subdivision(s)
SLI = Select Legislative Instrument
SR = Statutory Rules
Sub-Ch = Sub-Chapter(s)
SubPt = Subpart(s)
underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	FRLI registration	Commencement	Application, saving and transitional provisions
Health Insurance (Diagnostic Imaging Accreditation) Amendment Instrument 2015	29 April 2015 (F2015L00606)	1 January 2016	s 2 and s 7 (am by F2015L00894, Sch 1, items 1, 2)
Health Insurance (Diagnostic Imaging Accreditation) Amendment Instrument (No. 2) 2015	23 June 2015 (F2015L00894)	24 June 2015	—

Endnote 4—Amendment history

Provision affected	How affected
s 2	am F2015L00894
Sch 1	am F2015L00894