

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

Health Insurance Act 1973

Health Insurance (Diagnostic Imaging Accreditation) Instrument 2020

Authority

The instrument to which this explanatory statement relates is made under subsection 23DZZIAA(1) of the *Health Insurance Act 1973* (the Act).

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

The instrument is a legislative instrument for the purposes of section 8 of the *Legislative Instruments Act 2003*.

Purpose

The instrument establishes a scheme under which diagnostic imaging premises and bases for mobile diagnostic imaging equipment ('diagnostic imaging practice') may be accredited for diagnostic imaging procedures. The instrument sets out the requirements for the operation of an accreditation scheme for diagnostic imaging practices seeking to provide Medicare funded diagnostic imaging services.

This instrument repeals and replaces, with amendments, the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010* (2010 Instrument) which was otherwise due to sunset on 1 April 2020 in accordance with sunset provisions in the *Legislation Act 2003*. Repealing and remaking the instrument will ensure the requirements and the standards in the instrument remain fit for purpose. It will also enable the continued operation of the diagnostic imaging accreditation scheme, ensuring that patient access to Medicare funded diagnostic imaging services is not disrupted.

Background

Subsection 23DZZIAA of the Act provides a legislative framework for the introduction and operation of an accreditation scheme for practices providing diagnostic imaging services under Medicare. Subsection 23DZZIAA(1)(a) provides that the Minister may, by one or more legislative instruments, establish one or more schemes for the accreditation of diagnostic imaging practices. Subsection 23DZZIAA(1)(b) allows the Minister to approve, if required, one or more persons (approved accreditors) to accredit diagnostic imaging practices under the scheme.

Pursuant to subsection 16EA(1) of the Act, unless the Minister otherwise directs, a Medicare benefit is not payable for a diagnostic imaging service unless the service is rendered from a diagnostic imaging practice (premises or a mobile base) accredited under a diagnostic imaging accreditation scheme.

The diagnostic imaging accreditation scheme was implemented in stages. The first stage was established under the *Health Insurance (Diagnostic Imaging Accreditation) Determination 2008* (no longer in force). It applied to all diagnostic imaging services in the Diagnostic Imaging Services Table (DIST) regulations made under section 4AA of the Act, except cardiac ultrasound, cardiac angiography, obstetric and gynaecological ultrasound, and nuclear medicine imaging services (known as non-radiology services). The first stage commenced on 1 July 2008 and concluded on 30 June 2010.

The second stage of the scheme was established by the 2010 Instrument. It commenced on 1 July 2010 and was extended to include all diagnostic imaging services in the DIST regulations, including those non-radiology services which had previously been exempted.

Under the scheme, the proprietor of an imaging practice may apply to an approved accreditor for accreditation of the diagnostic imaging practice. Diagnostic imaging practices are assessed against the accreditation standards specified in Schedule 1 of the instrument by an approved accreditor in accordance with the requirements which are also set out in the instrument. First time applicants are assessed against a set of entry level standards, with other imaging practices assessed against all of the standards.

Diagnostic imaging practices approved under the Medical Imaging Accreditation Program (MIAP), which is jointly administered by the Royal Australian and New Zealand College of Radiologists (RANZCR) and the National Association of Testing Authorities (NATA), may be granted accreditation under the instrument on that basis. In acknowledgement of the standards required for MIAP accreditation, diagnostic imaging practices with MIAP approval will be recognised for the purposes of accreditation under this instrument

A separate instrument, the *Health Insurance (Diagnostic Imaging Accreditation – Approved Accreditors) Instrument 2010* names the organisations approved to assess applications and accredit practices in accordance with the requirements in the 2010 Instrument. This separate accreditor related instrument is also due to sunset on 1 April 2020 and is being remade.

Accreditation

Some changes have been made to the instrument to address feedback obtained by the Department of Health as part of consultation undertaken with the Diagnostic Imaging Accreditation Scheme (DIAS) Advisory Committee. The changes include:

- amending the definition of the ‘Medical Imaging Accreditation Program’ (section 6 of the instrument) to refer to the current version of the standards which practices seeking MIAP accreditation must be assessed against
- replacing all ‘Department of Human Services’ references in the instrument to ‘Services Australia’ to reflect a name change in accordance with the most current Administrative Arrangements Order
- strengthening the existing requirement in section 11 in the 2010 instrument to specify who is eligible to lodge an application for accreditation with an approved accreditor, including that an application must specify the type of accreditation being sought (refer to section 12 in the 2020 instrument)
- strengthening the current eligibility requirements in section 8 in the 2010 instrument for practices seeking entry level accreditation against a sub-set of the accreditation standards in Schedule 1 (refer to section 9 in the 2020 instrument). ‘Entry level standards’ is defined by

section 6(1) of the instrument to mean Standard 1.2, Standard 1.3 and Standard 1.4 in Schedule 1.

- broadening the scope of the existing requirement in section 15 in the 2010 instrument to allow an approved accreditor to make a decision to revoke the accreditation of a practice with entry level accreditation which was not eligible for that accreditation (refer to section 16 in the 2020 instrument)
- introducing a new requirement in section 8 in the 2020 instrument to clarify that when an application for reaccreditation is made more than six months before the expiry of the current accreditation, the reaccreditation must commence within six months of the date of the application
- strengthening the existing requirement in section 9 in the 2010 instrument to ensure that at all times an accredited practice maintains compliance with the standards in Schedule 1 (refer to section 10 of the 2020 instrument)
- adding transitional provisions (section 19 of the 2020 instrument) to preserve the status of accreditation granted under the 2010 instrument and enable any accreditation or reconsideration decisions currently being considered under the 2010 Instrument to progress under the standards in that instrument to ensure that practices are not disadvantaged.

Fees

Pursuant to paragraph 23DZZIAA(4)(c) of the Act, the scheme may provide for the charging of fees by approved accreditors in relation to the services they provide to diagnostic imaging practices. The instrument sets out the types of fees that an approved accreditor may charge proprietors of diagnostic imaging practices. It also limits the potential impact of fees on remotely located practices by imposing a condition that when charging fees, an approved accreditor must not discriminate against a diagnostic imaging practice on the basis of its geographic location.

Standards

The accreditation standards specified in Schedule 1 were amended in 2015 and as part of this remake have been reassessed by the DIAS Advisory Committee to ensure their continued relevance. Some minor editorial changes have been made to correct out-of-date references and to ensure the applicability of the radiation safety related standards (Standard 1.3 and Standard 1.5) to practices providing services on Norfolk Island. The DIAS Advisory Committee supports the changes to the standards.

Consultation

The DIAS Advisory Committee was consulted about the remake of this instrument. The DIAS Advisory Committee reviewed and provided advice on the requirements in the instrument, including the requirements for obtaining and maintaining accreditation. The DIAS Advisory Committee comprises individuals with expertise in diagnostic imaging policy, practice, standards development and accreditation; health administration and health consumer advocacy.

The Royal Australian and New Zealand College of Radiologists and the National Association of Testing Authority was also consulted about the change in the instrument relating to the definition of MIAP which they jointly administer.

This instrument commences on 1 April 2020.

Details of this instrument are set out in the Attachment.

Details of the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2020*

1 Name

This section provides that the name of the instrument is the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2020*.

2 Purpose

This section explains that the purpose of the instrument is to set out the arrangements for operating a scheme under which diagnostic imaging practices can obtain and maintain accreditation.

3 Commencement

This section provides that the instrument commences on 1 April 2020.

4 Authority

This section provides that the instrument is made under subsection 23DZZIAA(1) of the *Health Insurance Act 1973*.

5 Repeal of previous instrument

This section provides that the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010* is repealed.

6 Interpretation

This section provides definitions for words and phrases used in the instrument. The effect of the definitions is unchanged from the 2010 instrument other than the definition for the Medical Imaging Accreditation Program (MIAP) which is amended to refer to the correct version of the standards which practices seeking MIAP accreditation must be assessed against. In this instrument the definitions are as follows:

Act means the *Health Insurance Act 1973*.

adverse event has the meaning given in subsection 16(1).

applicant means an applicant for accreditation of a diagnostic imaging practice under section 9, 10 or 11.

desktop audit means a review by an approved accreditor carried out other than in a diagnostic imaging practice to assess whether the diagnostic imaging practice meets the entry level standards or the standards in Schedule 1 or has MIAP approval.

diagnostic imaging modality means a set of diagnostic imaging procedures identified as a modality in Schedule 2.

diagnostic imaging practice means diagnostic imaging premises or a base for mobile diagnostic imaging equipment.

entry level standards means Standard 1.2, Standard 1.3 and Standard 1.4 in Schedule 1.

initial decision has the meaning given in subsection 18(1).

Medical Imaging Accreditation Program means the diagnostic imaging accreditation program that:

- (a) is jointly administered by NATA and RANZCR;
- (b) relates to the Version 11-2019 RANZCR standards as at 30 June 2019; and

- (c) provides diagnostic imaging practices with accreditation under the program for a period of no more than four years.

MIAP approval means accreditation under the Medical Imaging Accreditation Program.

MIAP expiry date means the date the diagnostic imaging practice's MIAP approval is due to end as most recently evidenced under subsection 11(2).

NATA means the National Association of Testing Authorities Australia, Australian Company Number 004 379 748.

previous instrument means the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010*.

prior accreditation has the meaning given in section 8.

RANZCR means The Royal Australian and New Zealand College of Radiologists, Australian Company Number 000 029 863.

re-accreditation has the meaning given in section 8.

reconsideration decision has the meaning given in subsection 18(4).

responsible accreditor has the meaning given in section 7.

7 Responsible accreditor

Three organisations are approved as accreditors to accredit diagnostic imaging practices under the *Health Insurance (Diagnostic Imaging Accreditation – Approved Accreditors) Instrument 2020*. Section 7 of this instrument provides that there is one responsible accreditor for decisions under the instrument in respect of each diagnostic imaging practice. The effect of section 7 is unchanged from the 2010 Instrument. References to the ‘Department of Human Services’ have been replaced with ‘Services Australia’ following the recent name change.

Subsection 7(1) provides a definition of a 'responsible accreditor' as one of the following:

- (a) the approved accreditor who last granted the diagnostic imaging accreditation to the practice under the instrument, or
- (b) the approved accreditor last notified to Services Australia, by either the proprietor or an approved accreditor, as being the responsible accreditor.

Subsection 7(2) is a transitional provision for diagnostic imaging practices that were accredited under the 2010 Instrument. It provides that the accreditor who granted accreditation under the 2010 Instrument is the responsible accreditor under this instrument.

Subsection 7(3) imposes an obligation on the proprietor of a diagnostic imaging practice to ensure that the practice has a responsible accreditor at all times.

8 When application can be made for re-accreditation

This section provides that accreditation granted under sections 9, 10, or 11 (‘prior accreditation’) of the instrument ceases to have effect on the day when a subsequent accreditation granted under section 10 or 11 (‘re-accreditation’) takes effect. This section ensures that the maximum period of accreditation cannot be exceeded by virtue of an early application for re-accreditation.

Subsection 8(1) provides that applications for re-accreditation may be made before the expiry date of the prior accreditation.

Subsection 8(2) provides that if an application for re-accreditation is made earlier than 6 months before the expiry of that accreditation, the reaccreditation must commence within 6 months after the application date.

Subsection 8(3) provides that if a diagnostic imaging practice is granted re-accreditation before the expiry of the current accreditation, the current accreditation ceases when the re-accreditation takes effect.

9 Accreditation against entry level standards

This section sets out the requirements relating to accreditation against entry level standards and includes new provisions not included in the 2010 Instrument. Section 9 is intended to allow new practices which are unlikely to initially have records demonstrating compliance against all the standards in Schedule 1 of the instrument, to seek accreditation against a subset of the standards. 'Entry level standards' is defined by section 6(1) of the instrument to mean Standard 1.2, Standard 1.3 and Standard 1.4 in Schedule 1.

A proprietor of a diagnostic imaging practice may apply for accreditation against the entry level standards (Standard 1.2, Standard 1.3 and Standard 1.4) in Schedule 1 of the instrument only if the practice is an entry level practice (subsection 9(2)). Subsection 9(1) provides a definition of an 'entry level practice'.

Once an application is received, the approved accreditor must assess an application made under section 9 against the entry level standards, and must grant accreditation if satisfied that the entry level standards have been met by the diagnostic imaging practice (subsections 9(3) and 9(4)).

Subsection 9(5) requires the proprietor to maintain compliance with the entry level standards during the period of accreditation, and to provide evidence in relation to the entry level standards specified in Schedule 1 to the responsible accreditor on request. The proprietor is also required to immediately notify the responsible accreditor on becoming aware of a failure by the practice to meet the entry level standards or satisfy a condition of accreditation (subsection 9(6)).

The responsible accreditor must revoke an accreditation granted to a diagnostic imaging practice under section 9 after a period of two years (subsection 9(7)). This means that within those two years, the diagnostic imaging practice will need to obtain accreditation under sections 10 or 11 of the instrument for the services to remain eligible for Medicare benefits. A decision by the responsible accreditor to revoke accreditation under subsection 9(7) will not take effect until the proprietor's review rights have expired or have been exhausted in accordance with section 17 of the instrument.

10 Accreditation against standards

This section sets out requirements relating to accreditation against standards. The effect of this section is unchanged from the 2010 Instrument other than to strengthen the requirement in subsection 10(4) to require proprietors to comply with accreditation standards at all times.

Subsection 10(1) provides that a proprietor of a diagnostic imaging practice may apply to an approved accreditor for accreditation against the standards in Schedule 1 of the instrument.

Accreditation will be granted under section 10 if the approved accreditor has assessed the proprietor's application against the standards in Schedule 1, and is satisfied the diagnostic imaging practice meets those standards (subsections 10(2) and 10(3)).

Subsection 10(4) requires the proprietor to maintain compliance with the standards in Schedule 1 during the period of accreditation, and to provide evidence specified in Schedule 1 to the

responsible accreditor on request. The proprietor is also required to immediately notify the responsible accreditor on becoming aware of a failure by the practice to meet the standards or satisfy a condition of accreditation (subsection 10(5)).

The responsible accreditor must revoke an accreditation granted under section 10 to a diagnostic imaging practice after a period of four years (subsection 10(6)). This means that within those four years, the diagnostic imaging practice will need to obtain accreditation under sections 10 or 11 for the services to remain eligible for Medicare benefits. A decision by the responsible accreditor to revoke accreditation under subsection 10(6) will not take effect until the proprietor's review rights have expired or have been exhausted in accordance with section 17 of the instrument.

11 Accreditation based on the Medical Imaging Accreditation Program

This section sets out requirements for accreditation based on the MIAP. The MIAP is diagnostic imaging accreditation program jointly administered by NATA and RANZCR. In acknowledgement of the standards required for MIAP accreditation, diagnostic imaging practices with MIAP approval will be recognised for the purposes of accreditation under this instrument. The effect of section 11 is unchanged from the 2010 Instrument.

Subsection 11(1) provides that the proprietor of a diagnostic imaging practice which has MIAP approval may apply for accreditation under section 11.

Pursuant to subsection 11(2), the approved accreditor must grant accreditation if the proprietor provides documented evidence that the diagnostic imaging practice has MIAP approval, and the date that the MIAP approval is to end.

Subsection 11(3) requires the proprietor of a diagnostic imaging practice accredited under section 10 to maintain compliance with the MIAP standards and requirements. MIAP compliance will continue to be regulated by NATA and RANZCR.

The proprietor is also required to notify the responsible accreditor of any changes to the diagnostic imaging practice's MIAP approval, and upon becoming aware of a failure to satisfy a condition of accreditation under subsections 11(4) and 11(5).

Subsections 11(6), 11(7) and 11(8) set out requirements where changes are made to a diagnostic imaging practice's MIAP approval. These subsections are intended to ensure that the form of accreditation under section 11 is consistent with the form of MIAP approval, specifically:

- where a diagnostic imaging practice's MIAP approval lapses or is revoked, the practice's accreditation under section 11 must also be revoked by the responsible accreditor.
- where a diagnostic imaging practice's MIAP approval is varied or suspended under MIAP, the practice's accreditation under section 11 must also be varied or suspended (as relevant).
- where a diagnostic imaging practice's MIAP approval expires, the practice's accreditation under section 11 must also be revoked..

A decision to revoke, vary or suspend a diagnostic imaging practice's accreditation under section 11 will not take effect until the proprietor's review rights have expired or have been exhausted in accordance with section 17 of the instrument.

12 Applications for accreditation

This section sets out requirements for lodging an application for accreditation under sections 9, 10 or 11 of the instrument, and for making and giving notice of a decision in relation to such an

application. This effect of this section is largely unchanged from the 2010 Instrument but has been updated to include new requirements intended to strengthen the requirements relating to who is permitted to lodge an application and how an application must be assessed.

Subsection 12(2) provides that an application for accreditation under sections 9, 10 or 11 of the instrument must be made in writing to an approved accreditor, and specify the diagnostic imaging practice and the diagnostic imaging modalities in respect of which accreditation is to be granted. Paragraph (b) requires that an application for accreditation must either be lodged by the proprietor or by an employee of the proprietor. This is to ensure that an application is lodged by a person directly involved in the operation of the practice and not by a person engaged on a fee for service basis to assist with the preparation of documentation to include in an application for accreditation. Paragraph (c) requires that an application must specify the type of accreditation being sought, either entry level accreditation (section 9), accreditation against standards (section 10) or accreditation based on the MIAP (section 11).

An applicant must provide information that the approved accreditor reasonably requires in support of the application (subsection 12(3)). An application must also authorise the approved accreditor to check the accuracy of the information by whatever means the approved accreditor sees fit, and to store and use the information for the purposes of Division 5 of Part IIB of the Act and for the purposes of the instrument (subsection 12(4)).

Without limiting any other powers provided under the instrument, subsection 12(5) provides that an approved accreditor must make a decision in respect of an application made under sections 9, 10 or 11. by:

- granting accreditation to the diagnostic imaging practice for all of the diagnostic imaging modalities for which accreditation was sought, with or without conditions
- granting accreditation to the diagnostic imaging practice for only some of the diagnostic imaging modalities for which accreditation was sought, with or without conditions, or
- refusing to grant accreditation.

Subsection 12(6) requires an approved accreditor to assess an application in accordance with the section of the instrument under which the proprietor has sought accreditation (paragraph 12(2)(c)). This is to ensure that an application for accreditation is only assessed under one section of the instrument.

Subsection 12(7) states that a condition of accreditation may include (but is not limited to) requiring the proprietor of the diagnostic imaging practice to notify the responsible accreditor of any changes relating to the certifications or approvals affecting the diagnostic imaging practice, staff or equipment. The types of conditions which an approved accreditor may impose are not listed exhaustively. Mandatory conditions of accreditation under the instrument are set out in subsection 13(1) and subsection 14(2).

Subsection 12(8) sets out notification requirements in relation to decisions. An approved accreditor must notify the applicant in writing of a decision as soon as practicable after making the decision. The notice must set out:

- (a) the decision and any conditions imposed;
- (b) reasons for the decision;
- (c) a statement of the applicant's reconsideration rights under section 18;
- (d) if the diagnostic imaging practice is granted accreditation for some or all of the diagnostic imaging modalities referred to in the application:

- (i) the date from which the diagnostic imaging practice is accredited; and
- (ii) the diagnostic imaging modalities for which accreditation is granted.

13 Diagnostic imaging modalities

This section provides that it is a condition of all accreditations granted under the instrument (sections 9, 10 and 11) that the proprietor of the diagnostic imaging practice notifies the responsible accreditor of any change in the diagnostic imaging modalities carried out by the practice. The effect of this section is unchanged from the 2010 Instrument.

Subsection 13(2) enables the responsible accreditor to vary a diagnostic imaging practice's accreditation so that the practice is accredited for additional or fewer diagnostic imaging modalities. The responsible accreditor is required to give written notice of the decision to vary accreditation which sets out:

- (a) the diagnostic imaging modalities for which the diagnostic imaging practice is accredited (as varied);
- (b) reasons for the variation; and
- (c) a statement of the proprietor's reconsideration rights under section 18.

A decision to vary accreditation so that a diagnostic imaging practice is accredited for fewer diagnostic imaging modalities does not take effect until the proprietor's review rights have been exhausted or expired in accordance with section 17.

14 Conditions of accreditation

This section contains further provisions in relation to the mandatory and discretionary conditions of accreditation. The effect of this section is unchanged from the 2010 Instrument.

Subsection 14(1) allows the responsible accreditor to impose conditions of accreditation after accreditation has been granted by written notice to the proprietor of the diagnostic imaging practice. The notice must set out the terms of the conditions, the reasons for imposing the conditions, and a statement of the proprietor's reconsideration rights under section 18 of the instrument.

Subsection 14(2) imposes mandatory conditions that apply to all accreditations granted under the instrument to enable a responsible accreditor to determine whether the diagnostic imaging practice meets, or continues to meet, any requirements for accreditation under the instrument. These conditions relate to access and inspection of diagnostic imaging premises and documents, and the provision of information to the responsible accreditor.

15 Fees

This section sets out the types of services for which an approved accreditor may and may not charge fees. Subsection 15(1) provides that fees may be charged for work in receiving and processing applications, undertaking desktop audits, re-issuing accreditation certificates and for membership.

Subsection 15(2) provides an approved accreditor must not charge a separate fee for work performed in considering taking action, or taking action under section 16 of the instrument (variation, suspension or revocation of accreditation), or work performed in receiving and processing an application for reconsideration under section 18 of the instrument. The effect of this section is unchanged from the 2010 Instrument.

Subsection 15(3) prohibits an approved provider from charging fees in a manner that discriminates against a diagnostic imaging practice on the basis of its geographic location. This is intended to ensure that diagnostic imaging practices in regional or remote areas are not unfairly financially disadvantaged.

16 Variation, suspension or revocation of accreditation

This section sets out requirements in relation to the making of decisions to vary, suspend or revoke accreditation. This section includes new requirements to allow an approved accreditor to make a decision to revoke the accreditation of a practice with entry level accreditation which was not eligible for that accreditation and require the proprietor to make a new application for accreditation against the full accreditation standards. The requirements in section 16 are set out in three parts as follows:

- subsections 16(1)-(4) set out a process in relation to the making of variation, suspension and revocation decisions in specific circumstances (i.e. where a specified ‘adverse event’ occurs).
- subsection 16(5) provides that a responsible accreditor may also immediately vary, suspend or revoke accreditation if the accreditor considers there is a potential danger to public health or safety.
- subsection 16(6) sets out notice requirements in relation to all revocation decisions made under the instrument, as well as decisions to vary or suspend accreditation under subsections 16(4) and 16(5) and subsection 11(7).

Variation, suspension or revocation where an “adverse event” has occurred

An adverse event is described under subsection 16(1) as arising in the following circumstances:

- (a) in relation to a diagnostic imaging practice that has accreditation under section 9 – the responsible accreditor considers that the practice may no longer meet the entry level standards;
- (b) in relation to a diagnostic imaging practice that has accreditation under section 10 – the responsible accreditor considers that the practice may no longer meet the standards in Schedule 1;
- (c) in relation to a diagnostic imaging practice that has accreditation under section 9, 10 or 11 – the responsible accreditor considers that the proprietor may have breached or not fulfilled a condition of accreditation; and
- (d) in relation to a diagnostic imaging practice which has accreditation under section 9 (entry level accreditation) and was not eligible.

Where an approved accreditor believes an adverse event has occurred in relation to a diagnostic imaging practice, the approved accreditor must give the proprietor notice in writing explaining the situation as it appears to the accreditor, with reference to any material the approved accreditor has taken into consideration, and giving the proprietor 28 days in which to make written submissions in response (subsection 16(2)).

Subsection 16(3) provides that if the responsible accreditor is satisfied that a diagnostic imaging practice has not met the accreditation standards, or a condition of accreditation has been breached or not fulfilled, or the practice was not an entry level practice, the responsible accreditor must require the proprietor to rectify the breach of the standards or the failure to comply with the condition or make a new application for accreditation under section 10 or 11, within a nominated period. Such a requirement must be imposed within 28 days after the end of the 28 day period

referred to in subsection 16(2) (i.e. the period for submission by the proprietor), and only after the responsible accreditor has considered any submissions made by the proprietor in respect of the alleged breach or failure to comply with conditions.

If the responsible accreditor is satisfied that the proprietor has failed to rectify the breach of the accreditation standards, or breach or non-fulfilment of a condition, or make a new application for accreditation within the nominated period specified in the notice given under subsection 16(3), the responsible accreditor must vary, suspend or revoke the accreditation of the diagnostic imaging practice (subsection 16(4)).

Variation, suspension or revocation – danger to public health or safety

In addition to action that may be taken in relation to adverse events, a responsible accreditor may also immediately vary, suspend or revoke an accreditation where the accreditor considers there is a potential danger to public health or safety (subsection 16(5)).

Notice requirements in relation to certain variation, suspension and revocation decisions

The notice requirements specified under subsection 16(6) apply in respect of:

- a decision to vary or suspend accreditation under subsection 16(4) on the basis that the proprietor has failed to rectify a breach of the standards, or a breach or non-fulfilment of a condition, within the nominated period;
- a decision to immediately vary or suspend accreditation under subsection 16(5) on the basis that there is a potential danger to public health or safety;
- a decision to vary or suspend accreditation under subsection 11(7) on the basis that the diagnostic imaging practice's MIAP approval has been varied or suspended; and
- any decision to revoke accreditation under the instrument, including (but not limited to) the circumstances mentioned above.

The responsible accreditor must give notice in writing of a decision of the kind mentioned above, which sets out the decision, the reasons for the decision, and a statement of the proprietor's reconsideration rights under section 18 of the instrument.

17 Date of effect of decisions

This section sets out the requirements for determining the date of effect of decisions made under the instrument. The effect of this section is unchanged from the 2010 Instrument.

Subsection 17(1) imposes a general rule that all decisions made under the instrument (other than those decisions listed in subsection 17(2)) take effect on the day specified in the notice of decision or, if a day is not specified, on the day on which the decision is made.

Subsection 17(2) sets out a range of decisions that do not take effect until the time when a proprietor's potential avenues for internal reconsideration and Ministerial reconsideration expire or are exhausted (subsections 17(2)(a) to 17(2)(f)).

The decisions at subsections 17(2)(a) to 17(2)(f) are adverse decisions where a new decision places a proprietor in a weaker position than the proprietor previously occupied. The status quo and entitlements to Medicare benefits are preserved until reconsideration rights expire or are exhausted.

Subsection 17(2) does not apply to a decision to revoke accreditation, on the grounds that there is a potential danger to public health or safety which may take effect on a day specified in the

notice of decision or on the day on which the decision is made (i.e. the decision may have immediate effect) (see subsection 17(2)(a) and (f)).

18 Reconsideration of decisions

This section sets out the arrangements for seeking a reconsideration of decisions made under the instrument. The effect of this section is unchanged from the 2010 Instrument.

Subsection 18(1) sets out how a proprietor of a diagnostic imaging practice can apply for first reconsideration of a decision made under the instrument. The proprietor may apply in writing to the approved accreditor who made the initial decision for a review within 28 days of the date of the decision. An extension of time may be granted by the approved accreditor where special circumstances exist (subsection 18(2)). The proprietor must set out the reasons for seeking the reconsideration, and can provide new material for the approved accreditor to consider (subsection 18(3)).

Subsection 18(4) allows the approved accreditor 28 days in which to make a new decision (reconsideration decision) where a proprietor has made an application for reconsideration. The approved accreditor may also review the initial decision and make a reconsideration decision on its own motion, regardless of whether the proprietor has applied for reconsideration. The approved accreditor has power to affirm, vary, or set aside the initial decision and make such other decision as the approved accreditor thinks appropriate.

Subsection 18(5) requires the approved accreditor to give the proprietor notice in writing of a reconsideration decision setting out the decision, the reasons for the decision, and the proprietor's right to apply for a reconsideration by the Minister under section 23DZZIAD of the Act.

19 Transitional provisions

This section provides transitional arrangements to ensure continuity in the operation of the accreditation scheme so that practices are not negatively impacted by the repeal and remake of the 2010 Instrument. The transitional provisions relate to:

- accreditation granted under section 8, 9 or 10 of the 2010 Instrument.
- applications for accreditation commenced under the 2010 Instrument but not finalised before the instrument was revoked.
- reconsiderations commenced under the 2010 Instrument but not finalised before the instrument was revoked.

Subsection 19(1) provides that a diagnostic imaging practice accredited pursuant to section 8, 9 or 10 of the 2010 Instrument, is taken to be accredited under the corresponding sections in this instrument from 1 April 2020. Any conditions that were imposed on the diagnostic imaging practice's accreditation will become conditions of accreditation under this instrument. Additionally, any suspensions in force prior to 1 April 2020 will continue under this instrument.

Subsection 19(2) provides that applications for accreditation made under the 2010 Instrument which are not decided before 1 April 2020 must be decided under the 2010 Instrument. An approved accreditor must assess an application in accordance with the standards in force in the 2010 Instrument at the time of the revocation.

Subsection 19(3) provides that reconsiderations applied for but not yet decided under the 2010 Instrument must be reconsidered in accordance with the standards in force in the 2010 Instrument immediately before commencement of this instrument.

Schedule 1

Schedule 1 sets out the standards which apply in respect of accreditations under sections 9 and 10 of the instrument. The entry level standards are Standards 1.2, 1.3 and 1.4. The standards relate to the following matters:

- Part 1 – Organisational Standards
- Part 2 – Pre-procedure Standards
- Part 3 – Procedure Standards
- Part 4 – Post-procedure Standards

Minor changes have been made to the standards to:

- replace all references to the ‘Department of Human Services’ with ‘Services Australia’ following the recent name change
- replace references to the *Health Insurance Regulations 1975* with *Health Insurance Regulations 2018* following the remake of the regulations
- include references to Commonwealth radiation safety legislation in Standard 1.3 and Standard 1.5 to enable practices providing diagnostic imaging services on Norfolk Island to comply with the requirements.

Schedule 2

Schedule 2 defines each of the diagnostic imaging modalities which fall within the scope of the accreditation scheme (ultrasound, computed tomography, diagnostic radiology including general radiology (x-ray), mammography, angiography, fluoroscopy and orthopantomography, nuclear medicine imaging and magnetic resonance imaging) and is unchanged from the 2010 instrument.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Health Insurance (Diagnostic Imaging Accreditation) Instrument 2020

This instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the instrument

This instrument repeals and replaces, with some changes, the *Health Insurance (Diagnostic Imaging Accreditation) Instrument 2010* (2010 Instrument) which was otherwise due to sunset on 1 April 2020 in accordance with the sunset provisions in the *Legislation Act 2003*. Changes have been made to ensure the scheme established by the instrument remains fit for purpose.

The instrument sets out the requirements for the operation of the accreditation scheme for practices seeking to provide Medicare funded diagnostic imaging services. Under the scheme, the proprietor of a diagnostic imaging practice may apply to an approved accreditor for accreditation of the practice. Imaging practices are assessed against accreditation standards specified in the instrument. First time applicants are assessed against a set of entry level standards, with other imaging practices assessed against the full suite of standards. Imaging practices approved under the Medical Imaging Accreditation Program (MIAP) may be granted accreditation on that basis.

The purpose of this Instrument is to repeal and remake the 2010 Instrument to enable the continued operation of the accreditation scheme. This will ensure that accreditation granted under the 2010 instrument is preserved and patient access to Medicare funded diagnostic imaging services is not disrupted.

Human rights implications

This instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the UN Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The UN Committee reports that the ‘*highest attainable standard of health*’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every

effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

Analysis

The instrument maintains and promotes rights to health and social security by ensuring that patients can continue to access Medicare funded diagnostic imaging services which are provided by practices that have been assessed as meeting safety and quality accreditation standards by competent and credible organisations approved for that purpose.

Conclusion

The instrument is compatible with human rights as it has a positive effect on the right to health and the right to social security.

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