

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance Regulations 2018

Subsection 133(1) of the *Health Insurance Act 1973* (the Act) provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters required or permitted by the Act to be prescribed, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Purpose

The purpose of the *Health Insurance Regulations 2018* (the Principal Regulations) is to repeal and remake the *Health Insurance Regulations 1975* (the Previous Regulations). The Previous Regulations are required to be remade before 1 October 2018, which is when the instrument will sunset under the *Legislation Act 2003*.

The Principal Regulations support the provision of appropriate Medicare services through:

- setting out the mechanisms to support recognition of medical practitioners for the purposes of Medicare;
- setting out the calculation of benefits in relation to certain general practitioner, pathology and diagnostic imaging services;
- providing administrative rules for clarity around electronic requests for pathology services;
- providing restrictions on practitioners that request diagnostic imaging services;
- setting out applicable processes and registration rules regarding diagnostic imaging premises and radiation oncology equipment;
- setting out administrative rules for the submission of Medicare claims to the Department of Human Services; and
- providing information on quality assurance activities.

The Principal Regulations have updated the Previous Regulations to reflect current drafting standards whilst maintaining the original overarching policy framework.

Consultation

As the Principal Regulations maintain the overarching policy framework no formal consultation was undertaken on this regulation. The MBS Review Taskforce has reviewed and reinforced many of the principles that underpin Medicare which are contained within the Principal Regulations. The Taskforce is a clinician-led review which is considering how services can be aligned with contemporary clinical evidence and practice to improve health outcomes for patients. Recommendations from the Taskforce go through extensive consultation prior to being presented to the Government for consideration. The Taskforce is currently examining areas around diagnostic imaging, pathology and general practitioner services.

Additional consultation is currently underway to implement the 2018-19 Budget Measure ‘Stronger Rural Health Strategy’ which is designed to improve access to doctors, nurses and other health care services for all Australians, especially those in the regions. This will consider the mechanisms for the support of recognition of medical practitioners for the purposes of Medicare.

Details of the Principal Regulations are set out in the Attachment.

The Act specifies no conditions which need to be met before the power to make the Principal Regulations may be exercised.

The Principal Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Principal Regulations commence on 1 October 2018.

Authority: Subsection 133(1) of the *Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance Regulations 2018***PART 1—PRELIMINARY****Section 1 – Name**

This section provides for the Principal Regulations to be referred to as the *Health Insurance Regulations 2018*.

Section 2 – Commencement

This section provides that the Principal Regulations commence on 1 October 2018.

Section 3 – Authority

This section provides that the Principal Regulations are made under the *Health Insurance Act 1973*.

Section 4 – Definitions

This section provides for definitions used in the Principal Regulations.

PART 2—DEFINITIONAL MATERIAL**Division 1—Participating midwives**

Subsection 3(1) of the Act defines ‘participating midwife’ as an eligible midwife who is rendering a service in a kind of collaborative arrangement with a kind of medical practitioner. Division 1 of the Principal Regulations specifies these kinds of collaborative arrangements. These arrangements were previously prescribed in sections 2B, 2C, 2D, 2E and 2EA of the Previous Regulations.

Participating midwives can render Medicare-eligible services including antenatal and postnatal care in a hospital. Participating midwives may also request certain diagnostic imaging and pathology services.

Section 5 - Participating midwives—specified collaborative arrangements and medical practitioners

Section 5 of the Principal Regulations specifies the kinds of collaborative arrangements, the kinds of medical practitioners for the purpose of collaborative arrangements, and the requirements collaborative arrangements must comply with.

Kind of medical practitioners

Subsection 5(2) specifies the kinds of medical practitioners with whom an eligible midwife may participate in a collaborative arrangement in order to render a subsidised service. The kinds of medical practitioners specified are ‘obstetric medical practitioner’ (an obstetrician or a medical practitioner who provides obstetric services) or a ‘hospital-authorized medical practitioner’ (a medical practitioner authorised by the hospital authority who employs or engages the practitioner to participate in collaborative arrangements).

Kind of collaborative arrangements

Subsection 5(2) specifies the kinds of collaborative arrangements that an eligible midwife can participate in to be a participating midwife.

Paragraph 5(2)(a) provides for a kind of collaborative arrangement where:

- the eligible midwife is employed or engaged by one or more obstetric medical practitioners;
- the eligible midwife is employed or engaged by an entity that employs or engages one or more obstetric medical practitioners; or
- the eligible midwife has an agreement in writing with an entity other than a hospital (such as a medical practice).

The reference to ‘employs or engages’ covers both employees and contractors.

Paragraph 5(2)(b) provides that an eligible midwife is participating in a collaborative arrangement if an obstetric medical practitioner or a hospital-authorised medical practitioner refers a patient in writing to the midwife for midwifery treatment.

Paragraph 5(2)(c) provides that an eligible midwife is participating in a collaborative arrangement if they make an arrangement with one or more obstetric medical practitioners or hospital-authorised medical practitioners. The arrangement must be in writing and signed by the eligible midwife and each medical practitioner who is a party to the arrangement.

Paragraph 5(2)(d) provides that an eligible midwife is participating in a collaborative arrangement if they:

- have acknowledgement from one or more obstetric medical practitioners or hospital-authorised medical practitioners who will be participating in a collaborative arrangement that allows for consultation, referral and transfer as required in subsection 5(3);
- have informed the patient that the midwifery services will be provided in accordance with an arrangement, with one or more medical practitioners, which meets the requirements of subsection 5(3); and
- makes the records required by section 6 for each patient.

If a hospital employs or engages one or more obstetric medical practitioners, paragraph 5(2)(e) provides that an eligible midwife will be participating in a collaborative arrangement if:

- the eligible midwife has successfully completed a formal process to assess their ability to provide safe, high quality maternity care at the hospital;
- the eligible midwife is granted clinical privileges for a defined scope of clinical practice for the hospital which dictates the parameters of care the eligible midwife can provide; and
- the eligible midwife is authorised to provide midwifery care to their own patients on a private basis at the hospital.

For the purpose of paragraph 5(2)(e), the hospital can be either a public or private hospital. An eligible midwife may only treat a private patient in a public hospital if the patient has elected to be treated as a private patient.

Clinical requirements of collaborative arrangements

Subsection 5(3) provides that each kind of collaborative arrangement specified in subsection 5(2) must provide for:

- a) consultation between the midwife and an obstetric medical practitioner;
- b) referral of a patient by the midwife to an obstetric medical practitioner or a hospital-authorized medical practitioner; and
- c) transfer of a patient's care by the midwife to an obstetric medical practitioner.

Section 6 - Midwife record keeping requirements for certain collaborative arrangements

Section 6 of the Principal Regulations specifies the record requirements for an eligible midwife who is providing midwifery services in accordance with a collaborative arrangement in paragraph 5(2)(d).

Subsection 6(1) of the Principal Regulations specifies the general record requirements in relation to each patient within such an arrangement.

Paragraph 6(1)(a) requires the eligible midwife to record the name of at least one obstetric medical practitioner or hospital-authorized medical practitioner who will be participating within an arrangement which meets the requirements of subsection 5(3).

Paragraph 6(1)(b) requires the eligible midwife to record that they informed the patient they will be providing midwifery care as part of an arrangement, with one or more medical practitioners, which meets the requirements for consultation, referral and transfer as required in subsection 5(3).

Paragraph 6(1)(c) requires the eligible midwife to record plans for the circumstances in which the midwife will consult with an obstetric medical practitioner, refer the patient to a obstetric medical practitioner or a hospital-authorized medical practitioner, and transfer the patient to an obstetric specified medical practitioner.

Subsection 6(2) of the Principal Regulations specifies the particular record requirements in relation to each patient under such an arrangement. These matters must be recorded by the eligible midwife as they occur during the patient's care. The matters should be recorded as soon as practicable.

Paragraphs 6(2)(a) to (c) relate to recording the instances of consultation, referral and transfer as they occur during the patient's care.

Paragraph 6(2)(d) requires the eligible midwife to record an acknowledgement that a named medical practitioner has received, when provided by the eligible midwife, a copy of a hospital booking letter (however described) for the patient.

Paragraph 6(2)(e) requires the eligible midwife to record an acknowledgement that a named medical practitioner has received, when provided by the eligible midwife, a copy of the maternity care plan that the eligible midwife has prepared for the patient.

Paragraph 6(2)(f) requires the eligible midwife to record when the results of any diagnostic imaging or pathology services for the patient, initiated by a request by the eligible midwife, were provided to a named medical practitioner by the eligible midwife.

Paragraph 6(2)(g) requires the eligible midwife to record that the eligible midwife has given a discharge summary (however described) to a named medical practitioner or the patient's usual general practitioner, following the end of the midwife's care of the patient.

Division 2—Participating nurse practitioners

Subsection 3(1) of the Act defines 'participating nurse practitioner' as an eligible nurse practitioner who is rendering a service in a kind of collaborative arrangement with a kind of medical practitioner. Division 2 of the Principal Regulations specifies these kinds of collaborative arrangements. These arrangements were previously prescribed in sections 2B, 2F, 2G and 2H of the Previous Regulations.

Participating nurse practitioners can render certain Medicare-eligible services and can request certain diagnostic imaging and pathology services.

Section 7 - Participating nurse practitioners—specified collaborative arrangements and medical practitioners

Section 7 of the Principal Regulations specifies the kinds of collaborative arrangements, the kinds of medical practitioners for the purpose of collaborative arrangements, and the requirements collaborative arrangements must comply with.

Kind of medical practitioners

Subsection 7(1) specifies that all kinds of medical practitioners are specified for the purpose of nurse practitioner collaborative arrangements.

Kind of collaborative arrangements

Subsection 7(2) specifies the kinds of collaborative arrangements that an eligible nurse practitioner can participate in to be a participating nurse practitioner.

Paragraph 7(2)(a) provides that an eligible nurse practitioner is participating in a collaborative arrangement if they are employed or engaged by one or more medical practitioners or by an entity that employs or engages one or more medical practitioners. The reference to 'employs or engages' covers both employees and contractors. This covers an eligible nurse practitioner who is employed or engaged by a medical practice so long as that medical practice employs or engages at least one medical practitioner.

Paragraph 7(2)(b) provides that an eligible nurse practitioner is participating in a collaborative arrangement if a medical practitioner refers a patient in writing to the nurse practitioner for treatment.

Paragraph 7(2)(c) provides that an eligible nurse practitioner is participating in a collaborative arrangement if they make an arrangement with one or more medical practitioners. The agreement must be in writing and signed by the eligible nurse practitioner and each medical practitioner who is a party to the arrangement.

Paragraph 7(2)(d) provides that an eligible nurse practitioner is participating in a collaborative arrangement if they:

- have acknowledgement from one or more medical practitioners who will be participating in an arrangement which meets the requirements in subsection 7(3);

- have informed the patient that the nurse practitioner services will be provided within an arrangement, with one or more medical practitioners, which meets the requirements of subsection 7(3); and
- makes the records required by section 8 for each patient.

Clinical requirements of collaborative arrangements

Subsection 7(3) provides that each kind of collaborative arrangement specified in subsection 7(2) must provide for:

- a) consultation between the nurse practitioner and a medical practitioner;
- b) referral of a patient by the nurse practitioner to a medical practitioner; and
- c) transfer of a patient's care by the nurse practitioner to a medical practitioner.

Section 8 - Nurse practitioner record keeping requirements for certain collaborative arrangements

Section 8 of the Principal Regulations specifies the record requirements for an eligible nurse practitioner who is providing services within a collaborative arrangement in paragraph 7(2)(d).

Subsection 8(1) of the Principal Regulations specifies the general record requirements in relation to each patient within such an arrangement.

Paragraph 8(1)(a) requires the eligible nurse practitioner to record the name of at least one medical practitioner who has given an acknowledgement to collaborate in the care of the patient (a 'named medical practitioner').

Paragraph 8(1)(b) requires the eligible nurse practitioner to record that they informed the patient they will be providing care in accordance with an arrangement, with one or more medical practitioners, which meets the requirements for consultation, referral and transfer as required in subsection 7(3).

Paragraph 8(1)(c) requires the eligible nurse practitioner to record plans for the circumstances in which the nurse practitioner will consult with a medical practitioner, refer the patient to a medical practitioner, and transfer the patient to a medical practitioner.

Subsection 8(2) of the Principal Regulations specifies the particular record requirements in relation to each patient within such an arrangement. These matters must be recorded by the eligible nurse practitioner as they occur during the patient's episode of care. The matters should be recorded as soon as practicable.

Paragraphs 8(2)(a) to (c) relate to recording the instances of consultation, referral and transfer as they occur during the patient's episode of care.

If the eligible nurse practitioner provides the named medical practitioner or the patient's usual general practitioner a copy of a document in subsection 8(4), paragraph 8(2)(d) requires the eligible nurse practitioner to record when the copy was given.

Subsection 8(3) of the Principal Regulations specifies that an eligible nurse practitioner must provide the following documents to a named medical practitioner, upon request:

- copies of documentation in subsection 8(4) relating to referrals to specialists or consultant physicians, diagnostic imaging or pathology services, and records services rendered by the nurse practitioner; and
- copies of documentation regarding consultation, referral or transfer relating to a patient to a named medical practitioner.

Subsection 8(3) of the Principal Regulations specifies that an eligible nurse practitioner must provide copies of documentation in subsection 8(4) to the patient's usual general practitioner if:

- a) that practitioner is not the named medical practitioner; and
- b) the patient consents.

Division 3—Definition of services

Section 9 - Professional services—medical services rendered by approved dental practitioners

Paragraph (b) of the definition of professional service in subsection 3(1) of the Act allows dental practitioner who have been approved by the Minister to render prescribed medical services. Section 9 of the Principal Regulations prescribes the medical services as any item in Group O1 to O11 of the general medical services table.

This was previously prescribed within section 3 of the Previous Regulations.

Section 10 - Meaning of specialist trainee

Subsection 3(17) of the Act provides that a service is only taken to have been provided 'on behalf of' a medical practitioner if the service is provided on behalf of the practitioner by someone who is not themselves a medical practitioner. Accordingly, there are general limitations on a medical practitioner directly claiming benefits for a service provided by another medical practitioner.

Subsection 3(18) of the Act specifies the arrangements where a 'specialist trainee' renders a service under supervision of another medical practitioner. These arrangements allow a trainee medical specialists to provide a professional service prescribed by regulations (see section 11 of the Principal Regulations) under the direct supervision of a supervising medical practitioner, with the supervising practitioner deemed to perform the service and claiming any Medicare benefit for the service in his or her own right.

For the purposes of subsection 3(20) of the Act, section 10 prescribes that a specialist trainee means a medical practitioner who is enrolled in and undertaking a training program with a medical college in paragraph 10(a) or (b).

This was previously prescribed within subsection 2(2) of the Previous Regulations.

Section 11 - Professional services rendered by specialist trainees

Section 11 prescribes the services which can be rendered by specialist trainees.

This was previously prescribed within subsection 3(2) of the Previous Regulations.

Section 12 - Health service not specified in an item—meaning of health service

Subsection 3C(1) of the Act enables the Minister to make a written determination in respect of a health service, or a health service in a specified class of health services, for the purposes

of payment of Medicare benefits. Subsection 3C(8) specifies the types of health services that may be subject to a determination under subsection 3C(1). Paragraph 3C(8)(b) of the Act enables other types of health services to be prescribed by regulations.

Section 12 of the Principal Regulations prescribes classes of health services in paragraphs (a) to (s). This enable Medicare benefits to be payable for these prescribed allied health services, including psychology, physiotherapy and podiatry services.

This was previously prescribed within section 3A of the Previous Regulations.

Division 4—Recognition of medical practitioners as specialists and consultant physicians

Section 13 - Recognition of medical practitioner domiciled in Australia as specialist—meaning of relevant organisation and relevant qualification

Section 3D of the Act provides for the recognition of medical practitioners as specialists. Subsection 3D(1) of the Act provides that a medical practitioner is recognised as a specialist in a particular specialty if the Chief Executive Medicare receives written notice from a ‘relevant organisation’ that the medical practitioner has obtained a ‘relevant qualification’ in relation to that organisation. Subsection 3D(5) of the Act provides a regulation making power to declare a relevant organisation and relevant qualification.

Section 13 of the Principal Regulations declares that Schedule 1 lists the relevant organisations (column 1) for each speciality (column 2) and the relevant qualification for that organisation (column 3). For each speciality, the relevant organisation is a specialist medical college and the relevant qualification is fellowship of that college.

This was previously prescribed within section 4 and Schedule 4 of the Previous Regulations. Former qualifications (qualifications which are no longer awarded), which were previously listed in Part 2 of Schedule 4, are now listed as a relevant qualification for the relevant organisation.

Section 14 - Alternative method of recognition of medical practitioner domiciled in Australia as specialist or consultant physician—application fee

Section 3DB of the Act provides medical practitioners with:

- an alternative method for recognition as a specialist; or
- recognition as a consultant physician.

A medical practitioner may apply to the Minister for a determination that the medical practitioner is a specialist or consultant physician in a particular specialty if the medical practitioner is domiciled in Australia and the medical practitioner is registered under a law of a State or Territory as a specialist in a particular specialty. A medical practitioner may also apply to the Minister for a determination that the medical practitioner is a specialist or consultant physician in a particular specialty if the medical practitioner meets the criteria for the specialty, within the meaning of subsection 3D(2) of the Act.

For these two classes of practitioners, subsection 3DB(3) requires a written application must be accompanied by the prescribed fee. Section 14 of the Principal Regulations prescribes the fee as \$30.

This was previously prescribed within section 5 of the Previous Regulations.

Section 15 - Recognition of medical practitioner who is not domiciled in Australia—application fee

Section 3E of the Act provides for the recognition of medical practitioners, who are not domiciled in Australia, as a specialist or consultant physician for a specified period. The purpose of this section is to increase the supply of medical practitioners in areas of Australia where there is a shortage of specialists and consultant physicians in comparison to the population.

Such a medical practitioner may apply to the Minister for a determination that the medical practitioner should be recognised as a specialist or consultant physician. For this class of practitioner, subsection 3E(2) requires a written application must be accompanied by the prescribed fee. Section 15 of the Principal Regulations prescribes the fee as \$30.

This was previously prescribed within section 6 of the Previous Regulations.

Division 5—General practitioners

Section 3 of the Act defines ‘general practitioner’ as:

- a medical practitioner to whom there is a determination under section 3EA;
- a medical practitioner who is vocationally registered under section 3F; or
- a medical practitioner of a kind specified in the regulations

This Division is made for the purpose of those sections.

Subdivision A—Recognised Fellows of the Royal Australian College of General Practitioners

Subdivision A is made under section 3EA of the Act which provides a determination making power to recognise medical practitioners as Fellows of the Royal Australian College of General Practitioners. These arrangements were previously prescribed in sections 6A, 6B and 6C of the Previous Regulations.

Section 16 - Eligibility for determination as recognised Fellow of RACGP

Section 3EA of the Act provides for the recognition of medical practitioners as fellows of the Royal Australian College of General Practitioners. Subsection 3EA(2) of the Act prescribes that after receiving an application, the Chief Executive Medicare must, within the required period under subsection 3EA(3) of the Act, determine that the applicant is a recognised Fellow of the Royal Australian College of General Practitioners if the Royal Australian College of General Practitioners gives the Chief Executive Medicare written notice stating that the applicant:

- a) is a Fellow of the Royal Australian College of General Practitioners; and
- b) is eligible, in accordance with the regulations, for a determination under this section.

Section 16 of the Principal Regulations is made for the purpose of paragraph 3EA(2)(b) of the Act. Section 16 requires that an applicant must meet the Royal Australian College of General Practitioners minimum requirements for continuing medical education and quality assurance.

Section 17 - Notice from RACGP to Chief Executive Medicare if RACGP does not consider applicant eligible for determination

Section 17 of the Principal Regulations deals with situations where the Royal Australian College of General Practitioners declines to provide a notice to the Chief Executive Medicare under subsection 3EA(2) of the Act.

Section 3EA of the Act does not specifically provide for circumstances where the Royal Australian College of General Practitioners fails or declines to provide a notice supporting a medical practitioner's application for a determination that the practitioner is a recognised Fellow of the Royal Australian College of General Practitioners (a Fellow). That notice is required for the Chief Executive Medicare to make a determination. Section 17 of the Principal Regulations complements the decision making process under section 3EA of the Act by providing a process to inform applicants that the Royal Australian College of General Practitioners has declined or refused to provide a notice that the applicant is a Fellow of the that body and eligible, in accordance with the regulations, for a determination under section 3EA(2) of the Act. The refusal to provide a notice by that body would likely indicate that the practitioner does not meet eligibility and Fellowship requirements. Thus, section 17 is supported by the necessary or convenient regulation making power under subsection 133(1) of the Act for carrying out or giving effect to section 3EA of the Act.

Subsection 17(1) of the Principal Regulations requires the Royal Australian College of General Practitioners to notify the Chief Executive Medicare, in writing, if it declines to provide notice. This additional requirement provides transparency of the decision making process under section 3EA because it requires the Royal Australian College of General Practitioners to also notify the Chief Executive Medicare in writing where it declines to support the recognition of a particular practitioner as a Fellow. Subsection 17(2) requires that the Chief Executive Medicare must give the applicant written notice that such a notice has been received from the Royal Australian College of General Practitioners.

A medical practitioner may contact the Royal Australian College of General Practitioners to ask it to reconsider its decision to decline certification.

Section 18 - Revocation of determination as recognised Fellow of RACGP

Paragraph 3EB(1)(c) of the Act provides a regulation making power to provide for the revocation of a determination. Section 18 of the Principal Regulations specifies that a determination under 3EA of the Act must be revoked if the Royal Australian College of General Practitioners certifies that a medical practitioner does not meet its minimum standards for continuing medical education and quality assurance.

Subsection 3EB(2) of the Act provides that the Chief Executive Medicare must provide the relevant medical practitioner written notice that it has received a revocation notice from the Royal Australian College of General Practitioners.

Subsection 3EB(3) of the Act provides that the notice must specify the day on which a determination is to be revoked, and subsection (4) specifies such a date must not be less than 14 days after the date on which the notice was given. In practice, the Chief Executive of Medicare provides a period of 28 days for the medical practitioner to receive notification prior to revocation of the determination. This period is intended to allow an affected medical practitioner time to contact the Royal Australian College of General Practitioners to ask it to reconsider its decision.

Subdivision B—Vocationally registered general practitioners

Subdivision B is made under section 3F of the Act which provides for the vocational registration of general practitioners. These arrangements were previously prescribed in the *Health Insurance (Vocational Registration of General Practitioners) Regulations 1989*.

Section 19 - Eligibility for vocational registration

Section 3F of the Act provides for the registration of certain medical practitioners as vocationally registered general practitioners. Subsection 3F(6) outlines the requirements applicants for vocational registration must meet in order to be entered on the Vocational Register of General Practitioners, which includes a provision that the applicant is eligible for registration, in accordance with the regulations.

Section 19 of the Principal Regulations sets out the criteria for the readmission to the register of a practitioner whose name has previously been removed from the Register. A practitioner will be eligible for registration if the Royal Australian College of General Practitioners gives written notice:

- a) the individual practitioner's medical practice has been or is about to be predominantly general practice (as defined in the definitions parts of the Regulations); and
- b) the medical practitioner meets the Royal Australian College of General Practitioners minimum requirements for taking part in continuing medical education and quality assurance programs.

Section 20 - Notice from RACGP to Chief Executive Medicare if RACGP does not consider applicant eligible for vocational registration

Section 20 of the Principal Regulations deals with situations where the Royal Australian College of General Practitioners declines to provide notice under subsection 3F(6) of the Act.

Similar to section 3EA of the Act as discussed above, section 3F of the Act does not specifically provide for circumstances where the Royal Australian College of General Practitioners declines or refuses to provide a written notice to the Chief Executive Medicare of a particular practitioner's eligibility for registration as a vocationally registered practitioner. A notice supporting a practitioner's eligibility is required for the Chief Executive Medicare to make a registration decision under section 3F. Section 20 of the Principal Regulations complements the decision making process in section 3F by providing a process to inform applicants that the Royal Australian College of General Practitioners has declined or refused to provide a notice supporting their application for vocational registration. Thus, section 20 is supported by the necessary or convenient regulation making power under subsection 133(1) of the Act for carrying out or giving effect to section 3F of the Act.

Subsection 20(1) of the Principal Regulations provides that the Royal Australian College of General Practitioners must give the Chief Executive Medicare written notice that it declines to provide support regarding the eligibility of an applicant for registration under section 3F of the Act. This additional requirement provides transparency of the decision making process because it requires the Royal Australian College of General Practitioners to also notify the Chief Executive Medicare in writing where it declines to support the registration of a particular practitioner under section 3F. Subsection 20(2) of the Principal Regulations provides that the Chief Executive Medicare must give the applicant written notice if the Royal Australian College of General Practitioners does not certify a medical practitioner under subsection 20(1).

A medical practitioner may contact the Royal Australian College of General Practitioners to ask it to reconsider its decision to decline certification.

Section 21 -Removal from Vocational Register of General Practitioners

Subsection 3G(1) of the Act provides that the Chief Executive Medicare must remove a medical practitioner from the Vocational Register of General Practitioners if the Royal Australian College of General Practitioners gives written notice that the regulations require that the medical practitioner's name be removed from the Register.

Section 21 of the Principal Regulations provides for the removal of a medical practitioner from the register if their practice is not predominantly in general practice. Specifically it is intended that where an individual practitioner is not working predominantly in general practice for the previous quarter of the year, then they must be removed from the register. The Royal Australian College of General Practitioners may also give notice to remove a practitioner's name from the register where he or she has failed to meet the minimum requirements of the Royal Australian College of General Practitioners for taking part in continuing medical education and quality assurance programs.

Subsection 3G(2) of the Act provides that the Chief Executive Medicare must provide the relevant medical practitioner written notice that it has received a revocation notice from the Royal Australian College of General Practitioners.

Subsection 3G(3) of the Act provides that the notice must specify the day on which a determination is to be revoked, and subsection (4) specifies such a date must not be less than 14 days after the date on which the notice was given. In practice, the Chief Executive of Medicare provides a period of 28 days for the medical practitioner to receive notification prior to removing the medical practitioner's name from the Register. This period is intended to allow an affected medical practitioner time to contact the Royal Australian College of General Practitioners to ask it to reconsider its decision.

Subdivision C—Recognised fellows of the Australian College of Rural and Remote Medicine

Subdivision C is made for the purpose of paragraph (c) of the meaning of 'general practitioner' in the Act. Subdivision C of the Principal Regulations provides a determination making power for the Chief Executive of Medicare to recognise medical practitioners as Fellows of the Australian College of Rural and Remote Medicine. These arrangements were previously prescribed in sections 2A, 6DA, 6DB and 6DC of the Previous Regulations. As the determination making power is derived from the instrument and not the Act itself, a transitional provision has been inserted into the Principal Regulations in Part 12. The primary purpose of this transitional provision is to ensure that medical practitioners with a determination made under the Previous Regulations are treated as if the determination had been made under the Principal Regulations. This will ensure they will continue to be recognised fellows of the Australian College of Rural and Remote Medicine.

Section 22 - Determination as recognised Fellow of ACRRM

Section 22 of the Principal Regulations describes the process by which a medical practitioner can be recognised for the purposes of paragraph (c) of the definition of 'general practitioner' in section 3 of the Act.

A medical practitioner who wishes to be recognised under this section needs to apply to the Chief Executive Medicare for a determination that the medical practitioner is recognised as meeting the fellowship standards of the Australian College of Rural and Remote Medicine.

The Chief Executive of Medicare must make a determination within 14 days of being given written notice by the Australian College of Rural and Remote Medicine that the medical practitioner is eligible for a determination under section 23 of the Regulations. The Chief Executive Medicare must notify the applicant in writing noting the day on which the determination will enter into force.

The Chief Executive Medicare or an authorised officer, as defined in subsection 22(8), may give information about determinations in force for particular persons to the Australian College of Rural and Remote Medicine. The names and addresses of practitioners who are the subject of determinations under this section may be made available to the public on request.

Section 23 - Eligibility for determination as recognised Fellow of ACRRM

Section 23 describes the criteria for eligibility considered by the Australian College of Rural and Remote Medicine. An applicant must have attained fellowship of the Australian College of Rural and Remote Medicine to be eligible.

Subsection 23(2) requires that a medical practitioner who attained fellowship after the Australian Medical Council accredited training was introduced will be eligible for a determination if:

- a) they have completed Australian Medical Council accredited training program in its entirety or has been assessed by Australian College of Rural and Remote Medicine as having training and experience equivalent to the successful completion of the accredited training; and
- b) they meet the Australian College of Rural and Remote Medicine minimum requirements for taking part in continuing medical education and quality assurance programs.

Subsection 23(3) requires that a medical practitioner who attained fellowship before the Australian Medical Council accredited training was introduced will be eligible for a determination if:

- a) if Australian College of Rural and Remote Medicine certifies that the applicant has training and experience equivalent to the successful completion of Australian Medical Council accredited training or they are a vocationally recognised general practitioner; and
- b) they meet the Australian College of Rural and Remote Medicine minimum requirements for taking part in continuing medical education and quality assurance programs.

Section 24 - Revocation of determination as recognised Fellow of ACRRM

Section 24 of the Principal Regulations provides for a process for the revocation of determinations. Under subsection 24(1) the Chief Executive Medicare must revoke a determination made under section 22 if:

- a) the medical practitioner provides in writing a request for it to be revoked;

- b) the Australian College of Rural and Remote Medicine provides written notice that the medical practitioner has not met minimum requirements for continuing medical education and quality assurance or is not a fellow; or
- c) the Chief Executive Medicare becomes aware that the medical practitioner is no longer a medical practitioner.

Subsection 24(2) requires that the Australian College of Rural and Remote Medicine must inform a medical practitioner and allow at least 14 days for that practitioner to show why the notice should not be made, before notifying the Chief Executive Medicare.

Subsections 24(3), (4) and (5) of the Principal Regulations requires the Chief Executive Medicare to inform the medical practitioner in writing that the determination will be revoked. The notice must specify the day on which the determination will be revoked. The day of revocation must be at least 14 days after the day the notice was given.

Subdivision D—General practitioners for the purposes of section 20 of the Act

Section 25 - Medical practitioner who practises in general practice

Subdivision D is made for the purpose of paragraph (c) of the meaning of ‘general practitioner’ in the Act. Section 25 of the Principal Regulations provides that a medical practitioner (other than a specialist or consultant physician) who practices in general practice is a ‘general practitioner’ for the purpose of section 20 of the Act. This determines their eligibility for the 90 day pay doctor via cheque scheme. See sections 63 and 64 of the Principal Regulations for more information.

This was previously prescribed within subsection 13AA(3) of the Previous Regulations.

Division 6—Register of Approved Placements

Section 19AA of the Act prohibits access to a Medicare provider number to persons who have become, or have been deemed to become, medical practitioners on or after 1 November 1996. The effect of the prohibition is that such a medical practitioner, and their patients, cannot claim a Medicare benefit in respect of professional services performed by the practitioner.

However, subparagraphs 19AA(1)(b)(iv) and 19AA(2)(b)(iv) contain an exception to the prohibition for the duration of a period for which a medical practitioner is registered under section 3GA of the Act. This Division in the Principal Regulations is made for the purpose of section 3GA. This was previously prescribed in sections 6E, 6EA, 6EB and Schedule 5 of the Previous Regulations.

Section 26 - Specified bodies, courses and programs

Section 3GA of the Act establishes a Register of Approved Placements. Paragraph 3GA(5)(a) provides that a medical practitioner can apply if they are enrolled in, or undertaking, a course of program of a kind with specified bodies.

Subsection 26(1) of the Principal Regulations specifies the bodies and respective courses. The bodies are medical colleges and the courses are vocational training courses which lead towards fellowship.

Subsection 26(2) of the Principal Regulations specifies the bodies and respective programs – which include vocational training programs and programs to increase access to medical practitioner services.

Section 27 – Removal from the Register

Subsection 3GB(1) of the Act requires the Chief Executive of Medicare to remove a medical practitioner from the Register of Approved Placements if:

- a) the person asks to be removed;
- b) a body specified in regulations gives written notice that the person is not enrolled in, or undertaking, the course or program in relation to which he or she was registered; or
- c) the regulations require the person's name be removed.

Section 27 of the Principal Regulations prescribe the criteria for the removal of medical practitioners from the Register of Approved Placements.

PART 3—MEDICARE BENEFITS

Division 1—Amounts of medicare benefit

Section 28 - Entitlement to medicare benefit—services for which medicare benefit is 100% of Schedule fee

Section 28 of the Principal Regulations provides that, for the purposes of paragraph 10(2)(aa) of the Act, the items which are prescribed as having a benefit equal to 100% of the fee in respect of the service are the general practice attendance items specified in the table at subsection 28(1) and the bulk-billed diagnostic imaging services in subsection 28(2).

Subgroups 2 to 12 of Group A7 in the table are specified in a determination made under subsection 3C(1) of the Act. This determination is the *Health Insurance (Section 3C General Medical Services – Other Medical Practitioner) Determination 2018*.

This was previously prescribed in section 6EF and Schedule 6 of the Previous Regulations.

Division 2—Medicare benefits in relation to pathology services

Subdivision A—Simplified outline of this Division

Section 29 - Simplified outline of this Division

Section 29 of the Principal Regulations provides a simplified overview of Division 2. Division 2 deals with the requirement for the payment of Medicare benefits for certain pathology services. The power to prescribe these requirements is in section 16A of the Act.

Subdivision B—Specifying services

Section 30 - Pathology service determined to be necessary by participating midwife

Subsection 16A(3) of the Act provides that a Medicare benefit is not payable for a pathology service (which is not a pathologist-determinable service) rendered by an approved pathology practitioner unless it has been requested by a 'treating practitioner'.

Paragraph 16A(1)(aa) of the Act provides a regulation making power to list the kinds of services which can be considered necessary by 'treating practitioners', who are participating

midwives. Section 30 of the Principal Regulations specifies the pathology services that may be requested by a participating midwife. Participating midwives can request certain pathology services in groups P1, P2, P3, P6 and P8 of the pathology services table.

This was previously prescribed in subsection 11A(1) of the Previous Regulations.

Section 31 - Pathology service determined to be necessary by participating nurse practitioner

Subsection 16A(3) of the Act provides that a Medicare benefit is not payable for a pathology service (which is not a pathologist-determinable service) rendered by an approved pathology practitioner unless it has been requested by a ‘treating practitioner’.

Paragraph 16A(1)(ab) of the Act provides a regulation making power to list the kinds of services which can be considered necessary by ‘treating practitioners’, who are participating nurse practitioners. Subsection 31 of the Principal Regulations specifies the pathology services that may be requested by participating nurse practitioners. Participating nurse practitioners can request any pathology service in groups P1 to P8 of the pathology services table.

Subsection 31 of the Principal Regulations also specifies the pathology services in group P9 which can be considered necessary by participating nurse practitioners. Participating nurse practitioners can render these ‘prescribed pathology services’ subject to certain circumstances under subsection 16A(7A) of the Act.

This was previously prescribed in subsection 11A(2) of the Previous Regulations.

Subdivision C—Requirements for requests for pathology services

Section 32 - Purpose of Subdivision

Section 32 of the Principal Regulations provides that Subdivision C is made for the purposes of paragraph 16A(4)(b) of the Act. Subsection 16A(4)(b) provides a regulation making power to specify the requirements of pathology requests.

These sections were previously prescribed in the *Health Insurance (Pathology Services) Regulations 2018*.

Section 33 – Information about requesting practitioner

Section 33 of the Principal Regulations specifies the information which must be included in a request for a pathology service about the requesting practitioner. This includes:

- a) the requesting practitioner’s name; and
- b) the address for their place of practice or their provider number, if the request was made a place of practice; or
- c) the address of any place of practice or the provider number for that place of practice, if the request was not made at such place of practice.

Section 34 – Information about patient

Section 34 of the Principal Regulations specifies the information which must be included in a request for a pathology service about the patient (subject to the requirements applying to certain ‘further requests’ under section 37). The request must include:

- the name of the patient;

- the address of the patient; and
- if the person is a patient in relation to a hospital, particulars about the hospital.

Subsection 34(2) specifies that the request can include the person's private health insurance information, if the patient is a private patient in a hospital and has consented to the inclusion of that information.

Subsection 34(3) prohibits the information in subsection 34(2) from being included on the request without the patient's consent. A patient who does not consent will not affect their entitlement to Medicare benefits and/or private health insurance benefits for that service.

Section 35 – Information about pathology service

Section 35 of the Principal Regulations specifies the information which must be included in a request for a pathology service in respect of the service (subject to the requirements applying to certain 'further requests' under section 37). The request must include:

- a) a description of the service;
- b) the date when it was determined to be necessary; and
- c) whether the service relates to a bodily specimen obtained from a person while they were an in-patient of a hospital and is to be performed after the person ceases to be an in-patient of a hospital.

Section 36 – Requests that specify an approved pathology practitioner

Section 36 of the Principal Regulations requires the treating practitioner to provide the clinical grounds, or a statement that the specification is on clinical grounds, if an approved pathology practitioner is specified on the request for pathology services.

Section 37 – Further requests

Section 37 of the Principal Regulations applies to 'further requests' for pathology services. A further request is a request for pathology services which is made by an approved pathology practitioner who received the initial request (the 'first request') from a treating practitioner.

Subsection 37(2) requires that the further request must include the information about the treating practitioner that was included in the first request, per the requirements in section 33.

Subsection 37(3) requires that the further request is not required to comply with the request requirements about the patient in section 34 or the pathology service particulars in section 35 if:

- a) it relates only to the pathology service to which the first request relates; and
- b) the first request is provided with the further request.

Division 3—Medicare benefits in relation to R-type diagnostic imaging services

Subdivision A—Simplified outline of this Division

Section 38 – Simplified outline of this Division

Section 38 of the Principal Regulations provides a simplified overview of Division 3. Division 3 deals with the requirement for the payment of Medicare benefits for certain diagnostic imaging services. The power to prescribe these requirements is in section 16B of the Act.

Subdivision B—Specifying services for effective requests

The diagnostic imaging provisions in section 16B of the Act provide that, except in certain circumstances, Medicare benefits are only payable for a diagnostic imaging service if it is rendered by a medical practitioner pursuant to a written request from another medical practitioner. The services which are subject to the written request requirement are classified as "R type" services.

There are a number of regulation making powers in section 16B of the Act to allow certain types of health professional to request specified diagnostic imaging services. The sections in Subdivision B are made for the purpose of those powers.

Section 39 - Requests by dental practitioners

Subsection 16B(2) of the Act provides a regulation making power to list the kinds of services which can be requested by dental practitioners, which are defined in subsection 3(1) of the Act.

The list of diagnostic imaging services which can be requested by any dental practitioner is prescribed in subsection 39(2) of the Principal Regulations.

Certain dental practitioners are approved by the Minister under paragraph (b) of the definition of "professional service" in subsection 3(1) of the Act. These approved dental practitioners can request the prescribed diagnostic imaging services in subsection 39(3) of the Principal Regulations.

Certain dental practitioners are registered or licensed as prosthodontists under a law of a State or Territory or recognised by the registering or licensing authority as a specialist of prosthodontics. Subsection 39(4) of the Principal Regulations prescribes the diagnostic imaging services which can be requested by these prosthodontists.

Certain dental practitioners are registered or licensed as periodontists, endodontists, pedeodontists or orthodontists under a law of a State or Territory or recognised by the registering or licensing authority as a specialist of periodontics, endodontics, pedoedontics or orthodontics. Subsection 39(5) of the Principal Regulations prescribes the diagnostic imaging services which can be requested by these dental practitioners.

Certain dental practitioners are registered or licensed as oral medicine specialists or oral pathology specialists under a law of a State or Territory or recognised by the registering or licensing authority as a specialist of oral medicine or oral pathology. Subsection 39(6) of the Principal Regulations prescribes the diagnostic imaging services which can be requested by these dental practitioners.

This was previously prescribed in section 10 of the Previous Regulations.

Section 40 - Requests by chiropractors

Section 16B(3) of the Act provides a regulation making power to list the kinds of services which can be requested by chiropractors, which are defined in subsection 3(1) of the Act. The list of diagnostic imaging services which can be requested by these providers is prescribed in section 40 of the Principal Regulations.

This was previously prescribed in subsection 11(1) of the Previous Regulations.

Section 41 - Requests by physiotherapists or osteopaths

Subsections 16B(3A) and 16B(3C) of the Act provide regulation making powers to list the kinds of services which can be requested by physiotherapists and osteopaths respectively, which are defined in subsection 3(1) of the Act. The list of diagnostic imaging services which can be requested by physiotherapists and osteopaths are prescribed in section 41 of the Principal Regulations.

This was previously prescribed in subsection 11(2) of the Previous Regulations.

Section 42 - Requests by podiatrists

Subsection 16B(3B) of the Act provides a regulation making power to list the kinds of services which can be requested by podiatrists, which are defined in subsection 3(1) of the Act. The list of diagnostic imaging services which can be requested by podiatrists is prescribed in section 42 of the Principal Regulations.

This was previously prescribed in subsection 11(3) of the Previous Regulations.

Section 43 – Requests by participating midwives

Section 16B(3D) of the Act provides a regulation making power to list the kinds of services which can be requested by participating midwives, which are defined in subsection 3(1) of the Act. The list of diagnostic imaging services which can be requested by participating midwives is prescribed in section 43 of the Principal Regulations.

This was previously prescribed in subsection 11B(1) of the Previous Regulations.

Section 44 - Requests by participating nurse practitioners

Subsection 16B(3E) of the Act provides a regulation making power to list the kinds of services which can be requested by participating nurse practitioners, which are defined in subsection 3(1). The list of diagnostic imaging services which can be requested by participating nurse practitioners is prescribed in section 44 of the Principal Regulations.

This was previously prescribed in subsection 11B(2) of the Previous Regulations.

Subdivision C—Specifying services for pre-existing diagnostic imaging practices**Section 45 -Exemption from subsection 16B(1) of the Act—pre-existing diagnostic imaging practices**

Subsection 16B(11) of the Act provides an exemption to the general diagnostic imaging request requirements for practitioners who rendered at least 50 services between 17 October 1988 and 16 October 1990. Section 45 of the Principal Regulations provides a list of specified Medicare items that are exempt from subsection 16B(1) of the Act to allow for the continued payment of benefits for the listed services.

This was previously prescribed in section 12 of the Previous Regulations.

Division 4—Medicare benefits in relation to radiation oncology services

Section 46 - Meaning of radiation oncology service

Subsection 16F of the Act prevents Medicare benefits from being paid for radiation oncology services, unless the radiation oncology service is undertaken on equipment ordinarily located at the premises or base and equipment of that type is listed on the Register for the registered premises or mobile base. Section 46 of the Principal Regulations specifies the groups of items that this rule applies to.

The items prescribed are the 'megavoltage' (subgroup 3), 'brachytherapy' (subgroup 4) and 'computerised planning' (subgroup 5) items currently listed in the general medical services table.

This was previously prescribed in section 12B of the Previous Regulations.

Division 5—Particulars of professional services

Subsection 19(6) of the Act, provides that a Medicare benefit is not payable in respect of a professional service unless prescribed particulars are recorded on the account or receipt, or on the form of the assignment or agreement (where relevant), in relation to the professional service. The sections in Division 5 of the Principal Regulations prescribe these particulars.

Section 47 - Simplified outline of this Division

Section 47 of the Principal Regulations provides a simplified overview of Division 5.

Section 48 - Purpose of Division

Section 48 provides that all of the sections in Division 5 of the Principal Regulations are prescribed particulars of professional services made for the purpose of subsection 19(6) of the Act.

Section 49 - All services—particulars of patient, date of service and fees

Section 49 of the Principal Regulations prescribes the general requirements which apply to all Medicare services. This includes:

- a) the name of the patient;
- b) the date the service was rendered;
- c) the amount charged for the service
- d) the amount paid for the service; and
- e) the outstanding balance in respect of the service.

This was previously prescribed in subsection 13(1) of the Previous Regulations.

Section 50 - All services—particulars of professional service rendered

Subsection 50(1) of the Principal Regulations prescribes that all Medicare services require a description of the professional service sufficient to identify the item that specifies the service.

Subsections 50(2) and (3) prescribe the particulars that are required in relation to professional services rendered as part of an episode of hospital or hospital-substitute treatment.

This was previously prescribed in subsections 13(2), (2A) and (3) of the Previous Regulations.

Section 51 - Most general medical services and Group P9 pathology services—particulars of person rendering service

Section 51 of the Principal Regulations prescribes the particulars of the person rendering general medical services (except radiation or nuclear services) and services in group P9 of the pathology services table.

Subsection 51(2) prescribes the particulars as:

- the name of the person who rendered the service; and
- information about where the service was rendered:
 - if the service was rendered at a place of practice, the address of the place of practice or the provider number for the place of practice; or
 - if the service was not rendered at a place of practice, the provider number allocated to any place of practice; and
- a statement that the person rendered the service.

Section 51(3) prescribes the particulars for overseas medical trained doctors or a foreign graduate of an accredited medical school. While these are generally the same as the particulars for domestic medical practitioners in subsection 51(2), overseas trained doctors must provide the provider number or place of practice where the service was rendered. These doctors can only render Medicare services at certain location if they are granted an exemption under subsection 19AB(3) of the Act.

This was previously prescribed in subsections 13(1A), (1B) and (1C) of the Previous Regulations.

Section 52 - Certain radiation or nuclear services—particulars of person rendering service and person claiming or receiving fees

Subsections 52(2) and (3) of the Principal Regulations prescribe particulars required for certain radiation and nuclear medical services which are specified in items 12500 to 12533, 15000 to 15600 and 16003 to 16015 in the general medical services.

This was previously prescribed in subsection 13(11) of the Previous Regulations.

Section 53 - Certain radiation oncology services —use of equipment

For the purposes of subsection 19(6) of the Act, section 53 of the Principal Regulations prescribes that the location specific practice number must be recorded for radiation oncology services rendered on equipment registered at radiation oncology premise or a registered base for mobile radiation oncology equipment.

This was previously prescribed in subsection 13(22) of the Previous Regulations.

Section 54 - Pathology services (other than Group P9)—particulars of person rendering service

Section 54 of the Principal Regulations prescribes the particulars of the person rendering pathology services (except services in group P9). Subsection 54(2) prescribes the particulars as the:

- the name of the person who rendered the service; and
- information sufficient to identify where the service was rendered:
 - the address of the place of practice; or
 - the provider number for the place of practice.

The rendering provider is:

- a) the approved pathology provider who rendered the service, or on whose behalf the service was rendered; or
- b) if the service was rendered completely in a single accredited pathology laboratory – any approved pathology practitioner rendering professional services in the accredited pathology laboratory; or
- c) if the service was rendered in more than one accredited pathology laboratory owned and controlled by an approved pathology authority – any approved pathology practitioner rendering professional services in one of the laboratories where the service was partly rendered.

Other particulars for pathology services are prescribed in section 55.

This was previously prescribed in subsections subsection 13(12) of the Previous Regulations

Section 55 - Pathology services—other particulars

For the purposes of subsection 19(6) of the Act, section 55 of the Principal Regulations prescribes the particulars required that relate to requested pathology services, pathologist-determinable services, services rendered by a member of a group of medical practitioners and the initiation of a patient episode by collection of a specimen.

Subsection 55(2) prescribes particulars for requested pathology services, including:

- a) the name of the treating practitioner who requested the service;
- b) the provider number for their place of practice, if the request was made at the place of practice;
- c) if the request was not made at such place of practice, the provider number of any place of practice; and
- d) the date of the request.

Subsection 55(3) prescribes that it is a particular to indicate that a pathologist-determinable service was considered necessary by the rendering approved pathology practitioner. This applies if the service was rendered on behalf of that approved pathology practitioner.

Subsection 55(4) prescribes that it is a particular to indicate the name of the requesting practitioner and the date on which the treating made the request, for a prescribed pathology service in paragraph 16A(7)(b) of the Act.

Subsection 55(5) prescribes the particulars for pathology specimen collection points.

This was previously prescribed in subsections 13(9), (10) and (10A) of the Previous Regulations.

Section 56 - Diagnostic imaging services—particulars of person rendering service and person claiming or receiving fees

Section 56 of the Principal Regulations prescribes the particulars required for diagnostic imaging services.

Other particulars for diagnostic imaging services are prescribed in section 57.

This was previously prescribed in paragraph 13(14)(c) and subsections 13(16).

Section 57 - Diagnostic imaging services—other particulars

For the purposes of subsection 19(6) of the Act, section 57 of the Principal Regulations prescribes the particulars required that relate to requested diagnostic imaging services, diagnostic imaging equipment and exemptions from the general request requirements.

Subsection 57(2) prescribes particulars for requested diagnostic imaging services, including:

- a) the name of the person who requested the service;
- b) information sufficient to identify the place of practice of the requestor:
 - a. the address of the place of practice; or
 - b. the provider number for the place of practice; and
- c) the date of the request.

Subsection 57(3) prescribes that the location specific provider number must be recorded, if the diagnostic imaging procedure (the scan) was done at a registered diagnostic imaging premise or a registered base for mobile diagnostic imaging equipment.

Subsections 57(4) to (7) prescribe the particulars for services which are exempt from the general diagnostic imaging request requirements.

This was previously prescribed in subsections 13(14), (15), (16) (17), (17A), (18), (19) and (22) of the Previous Regulations.

Section 58 - Services provided upon referral

For the purposes of subsection 19(6) of the Act, section 58 of the Principal Regulations prescribes the particulars for referred services rendered by a specialist or consultant physician.

Subsection 58(2) prescribes the general particulars for referred services. These particulars apply to referred services, subject to the circumstances in subsections 58(3) to (5). The general particulars include:

- a) the name of the referring practitioner;
- b) information sufficient to identify the place of practice of the referring practitioner:
 - a. the address of the place of practice; or
 - b. the provider number for the place of practice.
- c) the date of referral; and
- d) the period of validity of the referral under section 102 of the Principal Regulations.

Subsections 58(3) to (5) prescribe the particulars for referred services rendered by a specialist or consultant physician where the referral is lost, a hospital patient is referred within a hospital, or the service is rendered in an emergency.

This was previously prescribed in subsections 13(4), (5), (6) and (7) of the Previous Regulations.

Section 59 - Multiple professional services in a single day

For the purposes of subsection 19(6) of the Act, section 59 of the Principal Regulations prescribes that when more than one service is provided to a person on the same day by the

same provider, the time at which each attendance on that day commenced must be recorded. These particulars apply to:

- a) medical practitioners, dental practitioners and optometrists rendering a consultation service in items 3 to 10948 of the general medical services table; and
- b) a consultation service rendered by a participating midwife or participating nurse practitioner.

This was previously prescribed in subsections 13(8), (8A) and (8B) of the Previous Regulations.

Section 60 – Anaesthesia

For the purposes of subsection 19(6) of the Act, section 60 of the Principal Regulations prescribes the particulars required for items listed in subgroup 21 of Group T10 of the general medical services table.

Paragraph 60(2)(a) prescribes the general particulars for management of anaesthesia services (other than anaesthesia in connection with dental services – items 22900 and 22905). The prescribed particulars are the name of each medical practitioner who performed a procedure in which anaesthesia was administered.

Paragraph 60(2)(b) provides that if the after hours emergency anaesthesia item 25025 applies to the service, the particulars include the time the service began, the time the service ended, and the duration of the service time.

Subsection 60(3) provides that if the after-hours perfusion item 25050 applies to the service, the particulars include the time the service began, the time the service ended, and the duration of the service time.

Subsection 60(4) provides the particulars for services rendered by an assistant anaesthetist. The general particulars include the names of the principle anaesthetist and each medical practitioner who performed a procedure in which anaesthesia was administered. Paragraph 60(4)(c) provides that if the after hours emergency assistance anaesthesia item 25030 applies to the service, the particulars include the time the service began, the time the service ended, and the duration of the service time.

This was previously prescribed in subsections 13(20) and (21) of the Previous Regulations.

Division 6— Professional services rendered by or on behalf of certain medical practitioners

Section 61 - Other circumstances in which subparagraphs 19AA(1)(b)(iv) and (2)(b)(iv) of the Act apply

Section 19AA of the Act provides that medical practitioners who were registered or in training on or after 1 November 1996 cannot render Medicare-eligible services unless they have completed vocational training.

However, section 19AA allows for certain exemptions for certain cohorts of doctors who have not completed their vocational training, including allowing medical practitioners to participate in Medicare under section 3GA of the Act. This allows specialist and general

practitioner trainees to provide Medicare-eligible services while undertaking their post graduate training.

Medicare-eligibility is conditional on the medical practitioner practising in the period and location in which they are registered under section 3GA, or subject to any such conditions as specified in regulations made under paragraph subparagraph 19AA(3)(b).

For the purposes of paragraph 19AA(3)(b) of the Act, section 61 of the Principal Regulations provides for the continued payment of Medicare benefits where a medical practitioner who was in an approved placement under section 3GA of the Act provides services at that same location for a short period beyond the end date for the approved placement.

This was previously prescribed in section 6F of the Previous Regulations.

Section 62 - Meaning of *intern*

For the purposes of subsection 19AA(5) of the Act, section 62 of the Principal Regulations lists the relevant State and Territory laws under which a medical practitioner is an "intern". Intern is used to determine if a medical practitioner, who was a trainee as at 1 November 1996, is subject to the minimum proficiency requirements of section 19AA of the Act.

This was previously prescribed in section 6G of the Previous Regulations.

Division 7—Payments to medical practitioners and approved billing agents

Section 63 - Circumstances for electronic payments to medical practitioners

Subsection 20(3) of the Act deals with circumstances where a patient has not forwarded a cheque to the rendering medical practitioner under the pay doctor via claimant arrangements. It allows the Chief Executive Medicare to electronically transfer the balance owed to the rendering practitioner if the patient has not forwarded the cheque within 90 days (known as the 90 day pay doctor cheque scheme).

Subsection 20(5) of the Act provides a regulation making power to prescribe the conditions for use of the 90 day pay doctor via cheque scheme.

Subsection 63(2) of the Principal Regulations prescribes that electronic claims made through the Medicare Online (EFT), Medicare Easyclaim (EFTPOS) or ECLIPSE (billing agent) claiming channel are applicable for the 90 day pay doctor via cheque scheme. Subsection 63(3) of the Principal Regulations prescribes that general practitioners are also eligible for the 90 day pay doctor via cheque scheme if the claim is made by other claiming channels (manual claims), providing they have enrolled with the Department of Human Services.

Allied health providers cannot access the 90 day pay doctor via cheque scheme arrangements.

This was previously prescribed in sections 13AA and 13AB of the Previous Regulations.

Section 64 - Requirements for payments to specialists and consultant physicians

Subsection 20(6) of the Act provides that subsections 20(3) to 20(5) of the Act do not apply to a professional service rendered by or on behalf of a specialist or consultant physician, unless the claim for Medicare benefit for that service is made in an electronic manner mentioned in subsection 63(2) of the Principal Regulations.

This was previously prescribed in sections 13AC of the Previous Regulations.

Section 65 - Approved billing agents—application requirements and fee

Simplified billing is an initiative of the Australian Government and is administered by the Chief Executive Medicare. Approved billing agents act on the patient's behalf to claim un-paid, in-hospital Medicare and private health insurance medical benefits. The patient does not need to be involved in the process unless there is an agreed out-of-pocket expense. In order to be registered as an approved billing agent, prospective billing agents must submit an application to the Chief Executive Medicare for approval.

Section 20AB of the Act allows the Chief Executive Medicare to approve applications for billing agents made by a person or body. Subsection 20AB provides a regulation making power to specify requirements for the application and to set a fee (if any) to accompany the application.

For the purposes of paragraph 20AB(2)(a) of the Act, subsection 65(1) of the Principal Regulations prescribes that an application for approval as a billing agent must be in the form approved by the Chief Executive Medicare.

For the purposes of paragraph 20AB(2)(b) of the Act, subsection 65(2) of the Principal Regulations sets out the fees applicable for application as a billing agent.

This was previously prescribed in section 13B of the Previous Regulations.

Division 8—Eligible midwives

Section 66 - Meaning of *eligible midwife*—requirements

Under section 21 of the Act, an 'eligible midwife' is a midwife who has met the requirements specified in regulations. Section 66 of the Principal Regulations requires eligible midwives to meet the registration standard for an endorsement for scheduled medicines developed by the Nursing and Midwifery Board of Australia (the Board) for the purpose of section 38(2) of the National Law. This standard was approved by the Australian Health Workforce Ministerial Council and is publicly available on the Board's website at: <https://www.nursingmidwiferyboard.gov.au/registration-and-endorsement/endorsements-notations.aspx#eligible>.

In order to satisfy the requirements in section 66 of the Principal Regulations, a midwife must provide evidence that he or she satisfies the Board that he or she has the relevant qualifications and experience required by the registration standard. The Board may notate the Register of Midwives, provide a letter of assessment or other form of evidence once satisfied that the standard has been met.

This was previously prescribed in section 14A of the Previous Regulations.

PART 4—SPECIAL PROVISIONS RELATING TO PATHOLOGY

Section 67 - Giving notice of termination of undertaking

Subsection 23DB(1) of the Act provides for the Minister to approve, by legislative instrument, forms of undertakings to be given by persons who wish to become approved pathology practitioners or approved pathology authorities.

Sections 23DE and 23DH of the Act prescribe particulars for approved pathology practitioners and approved pathology authorities who wish to submit an application to terminate their undertaking. Section 67 of the Principal Regulations provides the address a notice of termination must be sent to.

This was previously prescribed in the *Health Insurance (Pathology Services) Regulations 2018*.

Section 68 - Approved pathology authorities—other records of pathology services

Subsection 23DKA(1) of the Act provides that regulations may require approved pathology authorities to prepare and maintain records of pathology services rendered in accredited pathology laboratories of which they are proprietors.

Section 68 of the Principal Regulations prescribes that an approved pathology authority must prepare and maintain a record of each pathology services rendered in accredited pathology laboratories it owns. The record must include a copy of the report and be kept in a manner that enables the retrieval of information using the name of the patient and the date of the service.

This was previously prescribed in section 16A of the Previous Regulations.

Section 69 - Offences in relation to request forms—branded pathology request forms

Subsection 23DP(3) of the Act provides that it is an offence for an approved pathology practitioner or an approved pathology authority to directly or indirectly distribute to a medical or dental practitioner, participating midwife or participating nurse practitioner a branded request form that is not in accordance with regulations made for the purpose of the subsection.

Subsection 69(1) of the Principal Regulations specifies that pathology request forms are subject to subsection 23DP(3) of the Act if it includes the registered name or trading name of an approved pathology authority and the location of one of more collection centres.

Subsection 69(2) of the Principal Regulations requires such a pathology request form much include a statement which informs a patient of the effects of subsections 16A(3) and (3A) of the Act. These provisions in the Act require that, where a treating practitioner has specified a particular pathologist on the request on clinical grounds, the service must be provided by that pathologist for Medicare benefits to be payable. This is to ensure that patients are aware of their right to take the request to a provider of their choice, and the limitations on that right where the treating practitioner has specified a particular pathologist on clinical grounds.

This was previously prescribed in section 18A of the Previous Regulations.

PART 5—SPECIAL PROVISIONS RELATING TO DIAGNOSTIC IMAGING SERVICES

Regulation 70 - Requests for diagnostic imaging services—information and form requirements

Subsection 23DQ(1) of the Act provides that regulations may specify the form in which a requested diagnostic imaging service must be made and the information that must be included.

Subsection 70(2) of the Principal Regulations requires that the information that must be included is:

- a) the name of the person who requested the service;
- b) information sufficient to identify the place of practice of the requestor:
 - a. the address of the place of practice; or
 - b. the provider number for the place of practice;
- c) the date of the request; and
- d) a description of the diagnostic imaging service which is sufficient to identify the item in the diagnostic imaging services table that relates to the service.

Subsection 70(3) defines the types of diagnostic imaging requests which are subject to the rule regarding branded request forms in subsection 70(4). The forms which are applicable to subsection 70(4) are:

- a) diagnostic imaging request forms supplied, or made available to, a requesting practitioner by a diagnostic imaging provider on or after 1 August 2002; if
- b) the request form includes the registered name or trading name of a diagnostic imaging provider, as defined in subsection 70(5), and the location of one or more locations where diagnostic imaging services are rendered.

Subsection 70(4) of the Principal Regulations requires that such a diagnostic imaging request form must include a statement which informs a patient of the effect of subsection 16B(4) of the Act. This provision specifies that, where a request is addressed to a specified practitioner providing diagnostic imaging services, the service can be rendered by another practitioner.

This is to ensure that patients are aware of their right to take the request to a provider of their choice. The exact wording of the patient advisory statement to appear on branded diagnostic imaging request forms is not prescribed.

This was previously prescribed in section 19 of the Previous Regulations.

Section 71 - Medical practitioners rendering diagnostic imaging services—other records of services

Subsection 23DS(1) of the Act provides that regulations may require medical practitioners to prepare and maintain records of diagnostic imaging services rendered by them, and, in particular, may impose requirements relating to:

- (a) the form in which the records are to be prepared;
- (b) the information that must be included in the records; and
- (c) the manner in which the records must be kept.

Section 71 of the Principal Regulations specifies the records which must be prepared and maintained by the medical practitioner who renders the service. These record requirements are described in subsections 71(3) and (4). Subsection 71(5) prescribes that the records must be kept in a manner that enables the retrieval of information using the name of the patient and the date of the service.

This was previously prescribed in section 20 of the Previous Regulations.

Section 72 - Diagnostic Imaging Register—other information to be included in application for registration

Section 16D of the Act requires that Medicare benefits are not payable (unless otherwise directed by the Minister) for diagnostic imaging services unless the diagnostic imaging procedure (the capturing of the image) used in rendering the service is:

- undertaken on equipment ordinarily located at registered diagnostic imaging premises or a registered base for mobile equipment; and
- the service undertaken is of type listed for that premise or base.

A premise or base is registered at a particular time if a registration under Division 4 of Part IIB is in effect at that time. The Division sets out a scheme for the registration of diagnostic imaging practices and the collection of information about these practices, including the diagnostic imaging equipment located at or connected with them.

Proprietors of diagnostic imaging premises or a base for mobile equipment may apply to the Minister for registration under section 23DZN of the Act. Section 23DZP of the Act specifies the requirements for the application. The application must include the primary information specified in section 23DZR and other information prescribed pursuant to paragraph 23DZP(1)(d).

Section 72 of the Principal Regulations prescribes the additional information which is required to be included in an application for registration of diagnostic imaging premises or a base for mobile diagnostic imaging equipment.

Paragraph (a) requires information to be supplied about the nature of the practice. As indicated in the example shown in the Principal Regulations, the information that may be collected under this paragraph could include whether the practice is a base for mobile equipment, a specialist diagnostic imaging medical practice (either on a stand-alone practice site or co-located with a primary care practice of group), a primary care practice, a sports medicine clinic or a public hospital.

Paragraphs (b) to (e) require information to be provided about the types of equipment ordinarily located at the practice. It would include such things as the number of each type of equipment, the age of the equipment where there are Medicare eligibility requirements in relation to the equipment (eg computed tomography equipment), the functionality of the equipment (eg for ultrasound equipment, whether the equipment has an echocardiography capability), and identifying numbers such as serial number.

Paragraph (f) prescribes the information about the accreditation that is required in an application for registration. The information about the accreditation is only necessary if the premises or base is accredited under a diagnostic imaging accreditation scheme at the time of the application.

This was previously prescribed in section 20A of the Previous Regulations.

Section 73 - Diagnostic Imaging Register—other information to be included on Register

Section 23DZQ of the Act provides that if an application has been properly made, the Minister must register certain details of the premises or mobile base on the diagnostic imaging register established for this purpose under section 23DZK. This includes other information prescribed pursuant to subparagraph 23DZQ(1)(b)(iv).

Section 73 of the Principal Regulations prescribes the additional information that is to be included on the diagnostic imaging register is the information that is mentioned in section 72 of the Principal Regulations.

This was previously prescribed in subsection 20B(1) of the Previous Regulations.

Section 74 - Primary information—types of diagnostic imaging equipment

Subsection 23DZR(2) of the Act provides a regulation making power to prescribe types of diagnostic imaging equipment that is primary information.

Section 74 of the Principal Regulations prescribes the types of diagnostic imaging equipment used (column 1) for specific services listed in the diagnostic imaging services table (column 2). The purpose of recording equipment by type is to ensure that a practice has equipment that is appropriate for use in the rendering of particular diagnostic imaging services.

This was previously prescribed in section 20C of the Previous Regulations.

Section 75 - Diagnostic imaging accreditation—information to be included on Diagnostic Imaging Register

Section 16EA of the Act requires that Medicare benefits are not payable (unless otherwise directed by the Minister) for diagnostic imaging services unless the diagnostic imaging procedure (the capturing of the image) used in rendering the service is:

- undertaken at premises that are accredited under a diagnostic imaging accreditation scheme to undertake the particular type of diagnostic imaging procedure; or
- if the scan is taken off-site, on equipment that is ordinarily located at a base for mobile diagnostic imaging equipment or diagnostic imaging premises accredited to undertake the procedure

Diagnostic imaging premises and bases for mobile diagnostic imaging equipment are accredited under Division 5 Part IIB of the Act. Section 23DZZIAB of the Act requires that the Minister must record prescribed information about accreditation status on the diagnostic imaging register.

Subsection 75(1) of the Principal Regulations prescribes the required information. The required information is the name of the approved accreditor; the commencement date for the accreditation; the diagnostic imaging procedures for which the premises are, or base is, accredited; and the date on which (if the premises or base has not been accredited again) accreditation was revoked. Subsection 75(2) of the Principal Regulations prescribes the required information if the diagnostic imaging equipment for which the premises or a base is accredited is varied.

This was previously prescribed in subsection 20B(2) of the Previous Regulations.

PART 6—PROHIBITED PRACTICES IN RELATION TO PATHOLOGY SERVICES AND DIAGNOSTIC IMAGING SERVICES

Part 6 of the Principal Regulations set out a method for determining the amount that is to be the market value of property, goods or services; and a method of working out whether the amount of a payment or of consideration for property, goods or services is substantially different from the market value of the property, goods or services.

Subsection 23DZZIF(5) of the Act sets out the circumstances where a benefit that consists of a payment (whether or not made to the beneficiary) for property, goods or service that are not shared between the beneficiary and another person is a permitted benefit. Paragraph (b) provides that the amount of the benefit must not be substantially different from the market value of the property, goods or services.

Subsection 23DZZIF(6) sets out the circumstances where a benefit that consists of the provision of property, goods or services to the beneficiary is a permitted benefit. Paragraph (b) provides that the benefit must be provided for consideration that is not substantially different from the market value of the property, goods or services.

Subsection 23DZZIF(9) provides that, for the purposes of paragraphs 23DZZIF(5)(b) and 23DZZIF(6)(b), the regulations may prescribe a method of working out whether the amount of a payment or of consideration is substantially different from the market value, or an amount determined by a method prescribed in the regulations to be the market value, of a specified class of property, goods or services.

Section 76 - Meaning of permitted benefit—method for determining substantial difference from market value

For the purposes of subsection 23DZZIF(9) of the Act, section 76 of the Principal Regulations provides method for determining substantial difference from market value.

Example 1:

Payment: \$1000
Market Value: \$850

Difference between market value and payment = \$150.
20% of the market value = \$170.

In this example, the amount of the payment is not substantially different from the market value because the difference between the market value and the payment is not more than 20% of the market value.

Example 2:

Payment: \$600
Market Value: \$700

Difference between market value and payment = \$100
20% of the market value = \$140

In this example, the amount of the payment is not substantially different from the market value because the difference between the market value and the payment is not more than 20% of the market value.

Example 3:

Payment: \$550

Market Value: \$300

Difference between market value and payment = \$250

20% of the market value = \$60

In this example, the amount of the payment is substantially different from the market value because the difference between the market value and the payment is more than 20% of the market value.

This was previously prescribed in section 20CA of the Previous Regulations.

Section 77 - Meaning of permitted benefit—method for determining market value

For the purposes of subsection 23DZZIF(9) of the Act, subsection 77(1) of the Principal Regulations specifies the amount determined by what a willing purchaser will have to pay, at the time mentioned in subsection (2), to a vendor who was willing, but not anxious to sell, being the method, is the market value of property, goods or services.

Subsection 77(2) specifies the time at which the amount referred to in subsection 77(1) is to be assessed for the purposes of ascertaining the market value.

Subsection 77(2) provides that the time is:

- for an offence or a contravention of asking for a benefit that is not a permitted benefit – when the person asked for the benefit;
- for an offence or a contravention of accepting a benefit that is not a permitted benefit – when the person accepted the benefit;
- for an offence or a contravention of offering a benefit that is not a permitted benefit – when the person offered the benefit; or
- for an offence or a contravention of providing a benefit that is not a permitted benefit – when the person provided the benefit.

The method set out in this section is intended to reflect the common law meaning of market value as found in the High Court decision of *Spencer v The Commonwealth of Australia* (1907) 5 CLR 418.

The following may be relevant to the application of the method in section 77:

- the amount or price is the best price that may reasonably be obtained for the property, goods or services, if sold in the ‘general market’. In considering what is the ‘general market’:
 - if there is no general market, for example in the case of shares in a private company, such a market is to be assumed;
 - all possible purchasers are to be taken into account;

- where the vendor knows that the potential purchaser values the property, goods or services in a special way, this usually means that the property, goods or services will sell and the market value will be at the higher end of the usual market value range.
- the transaction should be at arm's length and should take place in an environment where the purchaser and vendor each act knowledgeably (including in regard to current market conditions), prudently and without compulsion; and

Where the property is either land or some interest in land such as a lease, evidence of market value may be obtained from the following:

- a report by a registered valuer that identifies the particular land or interest in land;
- a valuation required by a financial institution for financial purposes, noting that such valuations may be conservative and may indicate that the property has a higher unencumbered value;
- a valuation by a registered real estate valuer being a comprehensive valuation of the property at the date of transaction indicating an inspection of the property had been undertaken; or
- other offers to purchase or lease.

Where the property is not an interest in land or where the benefit is a good or a service, evidence of market value may be obtained from the following:

- a report by a registered valuer that identifies the particular property, good or service;
- any valuation of the particular property, good or service for insurance purposes; or
- other offers to purchase.

Where the benefit being examined is the purchase of shares, units or options evidence of market value might be obtained from a review of the latest balance sheet and supporting notes of the particular entity in which the interest is being or may be purchased.

This was previously prescribed in section 20CB of the Previous Regulations.

PART 7—RADIATION ONCOLOGY REGISTER

Section 78 - Radiation Oncology Register—other information to be included in application for registration

Section 16F of the Act requires that Medicare benefits are not payable (unless otherwise directed by the Minister) for radiation oncology services unless the service is:

- undertaken on equipment ordinarily located at registered radiation oncology premises or a registered base for mobile equipment; and
- the service undertaken is of type listed for that premise or base.

A premise or base is registered at a particular time if a registration under Part IIC is in effect at that time. The Division sets out a scheme for the registration of radiation oncology practices and the collection of information about these premises, including the radiation oncology equipment located at or connected with them.

Proprietors of radiation oncology premises or a base for mobile equipment may apply to the Minister for registration under section 23DZZM of the Act. Section 23DZZO of the Act specifies the requirements for the application. The application must include the primary information specified in section 23DZZQ and other information prescribed pursuant to

paragraph 23DZZO(1)(d).

Section 78 of the Principal Regulations prescribes the additional information which is required to be included in an application for registration radiation oncology premises or a base for mobile radiation oncology equipment.

Paragraph (a) requires information to be supplied about the nature of the practice. As indicated in the example shown in the Principal Regulations, the information that may be collected under this paragraph could include whether the practice is a base for mobile equipment, a specialist radiation oncology practice (either on a stand-alone practice site or co-located with a primary care practice of group), a primary care practice, a sports medicine clinic or a public hospital.

Paragraphs (b) to (d) require information to be provided about the types of equipment ordinarily located at the practice. It would include such things as the number of each type of equipment, the functionality of the equipment, and identifying numbers such as serial number.

This was previously prescribed in section 20D of the Previous Regulations.

Section 79 - Radiation Oncology Register—other information to be included on the Register

Section 23DZZP of the Act provides that if an application has been properly made, the Minister must register certain details of the premises or mobile base on the radiation oncology register established for this purpose under section 23DZZJ. This includes other information prescribed pursuant to subparagraph 23DZZP(1)(b)(iv).

Section 79 of the Principal Regulations prescribes the additional information that is to be included on the radiation oncology register is the information that is mentioned in section 78 of the Regulations.

This was previously prescribed in section 20E of the Previous Regulations.

Section 80 - Primary information—types of radiation oncology equipment

Subsection 23DZZQ(2) of the Act provides a regulation making power to prescribe types of diagnostic imaging equipment that is primary information.

Section 80 of the Principal Regulations prescribes the types of radiation oncology equipment used. The purpose of recording equipment by type is to ensure that a practice has equipment that is appropriate for use in the rendering of particular radiation oncology services.

This was previously prescribed in section 20F of the Previous Regulations.

PART 8—HEALTH PROGRAM GRANTS

The Radiation Oncology Health Program Grants Scheme offers funding for eligible high-cost equipment used in the delivery of radiation therapy to approved providers. The Scheme is administered under Part IV of the Act and is open to ‘approved organizations’ that are recognised as providing an ‘approved health service’.

Section 81 - Form for application for approval as an organization under Part IV of the Act

Section 40 of the Act allows an organization to apply to the Minister for recognition as an ‘approved organization’. Subsection 40(1) of the Act requires that organizations apply to the Minister for approval as an organization under Part IV of the Act in accordance with the prescribed form.

Section 81 of the Principal Regulations provides that the application for approval as an organization under Part IV of the Act can be found in Form 1 in Schedule 2 to the Regulations.

Subsection 81(2) of the Principal Regulations requires that the application must be signed by a person who is:

- one of the persons responsible for the management of the organization; and
- authorised in writing by the organization to sign that application.

In order to provide for clarity and efficiency in relation to the making of an application by an organization under section 40 of the Act, subsection 81(2) makes it clear who can sign the application form. This is necessary as applicants would be mostly bodies, including bodies corporate and not individuals. As subsection 81(2) complements and is ancillary to section 40 of the Act, subsection 81(2) is supported by the necessary or convenient regulation making power under subsection 133(1) of the Act for carrying out or giving effect to section 40 of the Act.

Section 81 reflects section 21 of the Previous Regulations.

Section 82 - Form for application for approval of health service

Section 41 of the Act allows an approved organization to apply to the Minister for approval of health services provided, or to be provided. Subsection 41(1) of the Act requires that organizations apply to the Minister for an ‘approved health service’ in accordance with the prescribed form.

Section 82 of the Principal Regulations provides that the application for approval of a health service under Part IV of the Act can be found in Form 2 in Schedule 2.

Subsection 82(2) of the Principal Regulations requires that the application must be signed by a person who is:

- one of the persons responsible for the management of the organization; and
- authorised in writing by the organization to sign that application.

In order to provide for clarity and efficiency in relation to the making of an application by an organization under section 41 of the Act, subsection 82(2) makes it clear who can sign the application form. This is necessary as applicants would be mostly bodies, including bodies corporate and not individuals. As subsection 81(2) complements and is ancillary to section 41 of the Act, subsection 81(2) is supported by the necessary or convenient regulation making power under subsection 133(1) of the Act for carrying out or giving effect to section 41 of the Act.

Section 82 reflects section 22 of the Previous Regulations.

PART 9—MEDICARE PARTICIPATION REVIEW COMMITTEES

Section 83 - Meaning of professional organisation

Section 83 of Principal Regulations prescribes the professional organisations for the purposes of the definition of ‘professional organisation’ in subsection 124B(1) of the Act. These professional organisations are the Australian Dental Association Incorporated, the Australian Medical Association Limited, and Optometrists Association Australia.

This was previously prescribed in section 25 of the Previous Regulations.

PART 10—QUALITY ASSURANCE CONFIDENTIALITY

Part VC of the Act encourages efficient quality assurance activity in connection with the provision of certain health services. Section 124X of the Act empowers the Minister to declare an activity as a quality assurance activity. The declaration is a legislative instrument for the purposes of the *Legislation Act 2003*.

Part 10 the Principal Regulations is made for the purpose of section 124X of the Act. Part 10 was previously prescribed in sections 23A, 23B, 23C, 23D, 23E, 23F and 23G of the Previous Regulations.

Section 23G of the Previous Regulations is not remade as on review it was not found appropriate to declare quality assurance activities involving the assessment or evaluation by a person of the services, skill or performance of a health care practitioner for the purpose of determining a health care practitioner’s clinical practicing rights, and any appeal process associated with this assessment

Division 1—Quality assurance activities—application for declaration

Section 84 - Application for a declaration that a quality assurance activity is an activity to which Part VC of the Act applies

A declaration under subsection 124X of the Act may describe a quality assurance in any way, including by reference to the nature of the activity, by reference to a person who is engaging or proposes to engage in the activity, or by reference to circumstances in which the activity is being or is proposed to be, engaged in.

Subsection 84(1) of the Principal Regulations requires that an applicant seeking a declaration of a quality assurance activity under Part VC of the Act must apply to the Minister using the form approved by the Minister.

Section 84 complements the making of a declaration by the Minister of a quality assurance activity under section 124X of the Act. In addition, Section 84 does not extend the scope or general operation of Part VC of the Act or the Act itself, but is strictly ancillary. Section 84 requires the applicant to apply to the Minister using the form approved by the Minister for the purposes of this section. Requiring the applicant to provide the relevant information that the Minister is required to consider in making the declaration makes the decision making process timely, lawful, relevant and efficient. Relevant information is required to be provided by the applicant to enable the Minister to appropriately describe the activity to be declared to be a quality assurance activity, to be satisfied that the person who is engaging or proposes to engage, in the activity is authorised to do so and the basis of that authority, and the proposed quality assurance activity is in the public interest having regard to the any criteria prescribed

in the Principal Regulations. It is not unusual to have an application process prior to the making/amending of the relevant legislative instrument. For example refer to the making and amending of the Poisons Standard under the *Therapeutic Goods Act 1989*, and also the listing of a kind of prosthesis under the Private Health Insurance (Prosthesis) Rules under section 72-10 of the *Private Health Insurance Act 2007*.

Subsection 84(1) of the Principal Regulations requires that the form must require the applicant to give an undertaking that:

- a) the applicant will inform the Minister if there is a change to the purpose of the activity; and
- b) the applicant will inform the Minister if there is any significant change to the body undertaking the activity which may impact on the activity.

Quality assurance activities under Part VC of the Act involve the collection of personal and confidential information about health services provided to patients. A proposed activity, for example, may involve collecting health information and recording of details of activities that had adverse consequences to patients for the overall purpose of improving the quality of health services provided by particular specialists or practitioners. Disclosure of personal information is prohibited and any collection and recording of that information must be for the purposes of the declared quality assurance activity. Declaring such activity as a quality assurance provides certain safeguards by protecting certain information from disclosure, and protecting person engaging in those activities in good faith from civil liability in respect of the activities. It is therefore necessary to require applicants to provide undertakings that the applicant will inform the Minister of a change to the purposes of the quality assurance activity to which the application relates as soon as practicable after the change occurs or of any significant change to the composition or purposes of the body that is likely to affect the activity as soon as practicable after the change occurs.

Thus, both subsections 84(1) and (2) are supported by the necessary or convenient regulation making power under section 133(1) of the Act for carrying out or giving effect to Part VC of this Act.

This was previously prescribed in section 23A of the Previous Regulations.

Division 2—Quality assurance activities—public interest criteria

Section 85 - Purpose of Division

Subsection 124X(3) of the Act provides that the Minister must not make a declaration unless satisfied as to certain matters. Paragraph 124X(3)(b) of the Act requires the Minister to be satisfied that it is in the public interest, having regard to such criteria as are prescribed by the regulations. Section 85 of the Principal Regulations provides that the purpose of Division 2 is to prescribe the criteria to which the Minister must have regard in deciding whether it is in the public interest.

Section 85 reflects section 23B of the Previous Regulations, except that it makes clear and reflects the wording of paragraph 124X(3)(b) of the Act that the Minister only has regard to the criteria in deciding whether the activity to be declared is in the public interest.

Section 86 - Disclosure of information about quality assurance activities

In deciding whether the activity to be declared is in the public interest for the purposes of paragraph 124X(3)(b), the Minister must have regard to the disclosure of information about the quality assurance activities set out in section 86. Subsection 86(1) provides that the activity must include the disclosure of information described in paragraphs (a) or (b), unless it is not appropriate to disclose such information. The information described in paragraphs (a) and (b) concerns the quality of services assessed, evaluated or studied, and conditions or circumstances affecting the quality of the service. The disclosure of the information under subsection 86(1) must not identify individuals, expressly, indirectly or through implication. The timing and manner of disclosure of information must be acceptable to the Minister.

Section 86 reflects section 23C of the Previous Regulations.

Section 87 - Quality assurance activities engaged in in a single State or Territory

Section 87 of the Principal Regulations builds on the priority given by section 124ZC of the Act to State or Territory legislation having the same general purpose as the relevant provisions of the Act by limiting declarations of quality assurance activities engaged in only one State or Territory to activities of broader significance. Accordingly, for the Minister to be satisfied that the activity is in the public interest, the Minister must have regard to the following if the activity is to be engaged in a single State or Territory:

- a) the State or Territory government has advised the Minister that the activity is not subject to similar State or Territory legislation, and in the opinion of the State or Territory, it is in the public interest that Part VC of the Act should apply to the activity;
- b) the activity includes a methodology that has not been previously used in Australia;
- c) the activity is a pilot study which is investigating whether a particular methodology can be used in Australia;
- d) the activity addresses new subject matter that has not been previously addressed in Australia;
- e) the activity potentially affects the quality of health care nationally
- f) the activity is a pilot study for the purpose of investigating whether the activity has the potential to affect the quality of health care nationally; or
- g) the activity is of national importance.

This was previously prescribed in section 23D of the Previous Regulations.

Section 88 - Quality assurance activities of a kind that has not previously been engaged in, in Australia

Section 88 of the Principal Regulations provides that for the Minister to be satisfied that the activity is in the public interest, the Minister must have regard to the criterion set out in this section where the quality assurance activities has not previously been engaged in Australia. The application of Part VC of the Act to the activity must be likely to encourage participation in the activity by persons who provide health services and:

- (a) if the activity involves the making of recommendations about the provision of health services – the acceptance and implementation of the recommendation by persons who provide health services; and
- (b) if the activity involves monitoring of the implementation of recommendation about the provision of health services- the participation of persons who provide health services in monitoring the implementation.

This was previously prescribed in section 23E of the Previous Regulations.

Section 89 - Quality assurance activities of a kind that has previously been engaged in, in Australia

Section 89 of the Principal Regulations is to ensure that the protection of the relevant provisions of the Act is reserved to cases where their application is necessary to make the activity effective.

The section provides that the Minister must be satisfied on reasonable grounds that the protection of the Act is necessary to encourage, as specified, the participation of health service providers to a greater extent than under the earlier activity.

This was previously prescribed in section 23F of the Previous Regulations.

PART 11—MISCELLANEOUS PROVISIONS

Division 1—Charging of fees for provision of public hospital services to public patients

Section 90 - Circumstances in which fees must not be charged for provision of public hospital services to public patients

Section 128C of the Act makes it an offence for medical practitioners, participating midwives, participating nurse practitioners (or a person acting on behalf of these persons) to charge a public patient – through a fee, payment or any other consideration (such as a booking fee) – in the circumstances as set out in regulations.

Section 90 of the Principal Regulations specifies these circumstances as an obstetric public hospital service relating to the delivery of a baby, or services associated with the delivery of the baby provided to a public hospital patient.

This was previously prescribed in section 25A of the Previous Regulations.

Division 2—Recovery of amounts

Section 91 - Recovery of debts due to the Commonwealth—prescribed rate of interest

Section 129AC of the Act outlines that where payments or benefits paid under that Act exceeds the amount that should have been paid as a result of a false or misleading statement, the excess is recoverable as a debt due to the Commonwealth. The same section prescribes that if a person does not produce a document in respect of a professional service as required by a notice issued under section 129AAD (or complies with the notice and the documentation does not substantiate the service), then the benefit paid in respect of the service becomes a debt owed to the Commonwealth to the extent the service cannot be substantiated.

Subsection 129AC(2) of the Act provides for an increase in the debt owed by interest where a person (or the estate) who received a notice to repay an amount owed to the Commonwealth has defaulted on their repayment agreement or has not entered into a repayment agreement within a relevant period. Section 91 of the Principal Regulations prescribes the rate of interest as 15% per annum.

This was previously prescribed in section 26 of the Previous Regulations.

Division 3—Divulging and using information

Section 130(1) of the Act requires officers to observe secrecy in relation to any information acquired in the performance of their duties relating to the affairs of another person. Section 130(3A) of the Act permits the Secretary or Chief Executive Medicare to provide specific information to prescribed authorities and persons in specific circumstances. Division 3 is made for the purpose of subsection 130(3A) to prescribe the authorities and persons to whom certain information may be disclosed.

This was previously prescribed in section 27 and Schedule 3 of the Previous Regulations.

Section 92 - Divulging information—treatment provided to veterans

Section 92 of the Principal Regulations specifies:

- a) an APS employee in the Veterans' Affairs Department who performs functions in relation to treatment or medical treatment, under the laws specified in paragraphs (i) to (iv), is a prescribed person; and
- b) the information that may be provided is information that would enable such a person to perform those functions.

The purpose of the section is to enable the Chief Executive Medicare to divulge information to certain employees of the Veterans' Affairs Department in order to:

- ensure the integrity of both Medicare benefits and claims for medical treatment as administered by the Veterans' Affairs Department; and
- enable the disclosure of information to undertake the function of processing claims for compensation.

The Previous Regulations specified the position number of each prescribed person in the Veterans' Affairs Department to whom information could be divulged. The Principal Regulations specify the prescribed persons by employment status and function. This reflects more modern and appropriate drafting; the intention is that the range of prescribed persons to whom certain information is able to be divulged remains the same.

Section 93 - Divulging information—complaints and investigations

Section 93 of the Principal Regulations specifies that the Chief Executive Medicare can divulge certain information to prescribed authorities. The prescribed authorities are disciplinary bodies (Medical Board of Australia and State and Territory Medical Boards), and in the co-regulatory jurisdictions of New South Wales and Queensland, the bodies responsible for managing complaints (NSW Health Care Complaints Commission and the Queensland Office of the Health Ombudsman), in addition to the Veterans' Affairs Department.

Subsections 93(2) and 93(3) provide the circumstances in which certain information may be disclosed to the prescribed authorities listed in paragraphs 93(1)(a)(i) to (iv), which is when a patient has complained to the Chief Executive Medicare about a medical practitioner, and the Chief Executive Medicare reasonably believes that the complaint should be referred to the prescribed authority, or if the prescribed authority tells the Chief Executive Medicare that a patient has made a complaint to the authority about a medical practitioner. Subsection 93(4) provides that certain information may also be disclosed to the Veterans' Affairs Department in the circumstances mentioned in subsections 93(2) and 93(3).

Subsection 93(5) provides that certain information may be provided to the Medical Board of Australia if a medical practitioner is the subject of an investigation by the Chief Executive Medicare relating to the rendering of services. However, subsection 93(6) provides that the information can only be disclosed to a State or Territory authority if the medical practitioner is, was, or is applying to be, registered or licensed to practice, or practising in that State or Territory.

Subsections 93(7) to (10) specify the information which can be divulged to the prescribed authorities.

This was previously prescribed in section 27 of the Previous Regulations and Parts 4 and 5 of Schedule 3 of the Previous Regulations.

The relevant authorities are prescribed in order to enable information to be divulged in certain circumstances in order to ensure the integrity of Medicare benefits. Changes from the Previous Regulations reflect updated drafting styles.

Section 94 - Professional disciplinary and regulatory bodies

Subsection 130(4A) clarifies that a prescribed professional disciplinary or regulatory body is permitted to use the information provided to it under subsection 130(3A) for the purposes of any investigation or inquiry being conducted by the body in the performance of its own functions or the exercise of its powers. Section 93 of the Principal Regulations specifies that the Medical Board of Australia, State and Territory Medical Boards, NSW Health Care Complaints Commission and the Queensland Office of the Health Ombudsman are prescribed bodies for the purpose of subsection 130(4A) of the Act.

Division 4—Manner of patient referrals

Section 132A of the Act provides a regulation making power to prescribe the manner in which a patient can be referred to a medical practitioner. This Division is made for the purpose of prescribing those requirements.

These referral requirements apply to specialist and consultant physician items which specify a service is a referred service. This rule reflects the principle that general practitioners are the gatekeepers of the Australian healthcare system. These arrangements were previously prescribed in sections 29, 30, and 31 of the Previous Regulations.

Section 95 - Purpose and application of Division

Section 95 of the Principal Regulations provides that for the purposes of section 132A of the Act, Division 4 prescribes the manner in which a patient is to be referred to a practitioner. This Division applies to a referral of a patient to a specialist or consultant physician for the purposes of an item in the general medical services table or an item in a determination made under subsection 3C(1) of the Act.

Section 96 - Who can make referral

Section 96 of the Principal Regulations specifies who can make a referral.

This was previously prescribed in the definition of ‘referring practitioner’ in section 2 of the Previous Regulations.

Subsection 96(3) of the Principal Regulations was previously prescribed in paragraph (d) of the definition of ‘referring practitioner’ in Part 3 of the general medical services table. This definition will be removed from the general medical services table by the *Health Insurance (Repeal and Consequential Amendments) Regulations 2018*.

Section 97 - Requirement to consider need for referral

Section 97 of the Principal Regulations requires that the referring practitioner must consider if the patient needs to see a specialist or consultant physician for the treatment or management of their medical condition.

Section 98 - Requirements for form of referral

Subsection 98(1) of the Principal Regulations specifies the general form requirements which referring practitioner must meet when issuing referrals. It provides that a referral must be in writing, signed by the referring practitioner and dated. Electronic referrals can meet these requirements providing the referral complies with the *Electronic Transactions Act 1999*.

Subsection 98(2) of the Principal Regulations provides for an exemption to the general requirements in subsection 98(1) in instances of an emergency. The general requirements do not apply if the referring practitioner considers it necessary for the patient to urgently see a specialist or consultant physician for treatment of a serious or life threatening condition specified in subsection 98(3).

The Division also makes provisions where a specialist or consultant physician considers the patient's condition necessitates emergency treatment and time does not permit compliance with the normal referral requirements. This situation is specified in subsection 101(3) of the Principal Regulations.

Section 99 - Requirements for contents of referral

Subsection 99(1) of the Principal Regulations provides that a referral must explain the referring practitioner's reasons for referring the patient, including sufficient information about the patient's condition.

Subsection 99(2) puts additional requirements on the contents of a referral where the referring practitioner is a specialist or consultant physician. It requires that the referral must include the name of the primary health care provider (general practitioner, participating midwife or participating nurse practitioner) nominated by the patient, if possible. Where the patient is unwilling or unable to nominate a primary health care provider, the referral must include a statement to that effect.

Section 100 - Requirement to record certain referrals in hospital records

Section 100 of the Principal Regulations provides the arrangements when a referral is required for a patient in a hospital (who is not a public patient). Where a referral is generated during an episode of hospital treatment for a service provided or arranged by that hospital, the approval of the referral must be included in the hospital records. The approval must be signed by the referring practitioner.

This arrangement does not apply where a medical practitioner within a hospital is involved in referring a patient to a specialist or consultant physician in private rooms. The normal referral arrangements in section 98 would apply in these circumstances.

Section 101 - Receipt of referral by specialist or consultant physician

Subsection 101(1) of the Principal Regulations specifies the general referral receipt requirement which apply to specialists and consultant physicians rendering referred services. It provides that a referred service cannot be rendered until a referral has been presented for the patient.

Subsections 101(2) and (3) provide for exemptions to the general requirements. Subsection 101(2) prescribes that specialists and consultant physicians can render referred services without a referral if the patient tells the rendering practitioner:

- there was a referral;
- the referral has been subsequently lost, stolen or destroyed, and
- the name of the referring practitioner.

Subsection 101(3) prescribes that specialists and consultant physicians can render referred services without a referral if the patient's condition necessitates emergency treatment within 30 minutes and time does not permit compliance with the normal referral requirements.

Section 102 - Period of validity for referrals

Subsection 102(1) of the Principal Regulations specifies the general period of validity for referrals. The duration of a referral will be:

- a) valid for a fixed period;
- b) valid indefinitely; or
- c) where no period is set would be valid for 12 months.

The commencement of the period for paragraphs (a) and (c) begin after the first service is rendered by the specialist or consultant physician in accordance with the referral.

Subsections (2) to (4) provide for periods of validity for referrals given by certain types of referring practitioners. Subsection (2) provides that a referral originating from a specialist or consultant physician is valid for:

- a) a maximum of 3 months. The commencement of the period begins after the first service is rendered by the specialist or consultant physician in accordance with the referral; or
- b) until the patient is discharged from hospital, if the person is within hospital for more than 3 months.

Subsections (3) and (4) provide the validity for referrals given by a participating midwife and a participating nurse practitioner.

Subsections (5) to (7) provide for periods of validity for referrals given in special circumstances. Subsection (5) provides that a referral for a professional service to a patient in a hospital who is not a public patient is valid until the patient ceases to be a patient in the hospital.

Subsection (6) restricts the validity of an emergency referral given by referring practitioner in accordance with subsection 98(2). Such a referral is valid for only one attendance on the patient.

Subsection (7) restricts the validity of lost, stolen or destroyed referrals to one attendance on the patient.

PART 12—TRANSITIONAL PROVISIONS

Division 1— Transitional matters relating to the repeal of the Health Insurance Regulations 1975

Section 103 – Things done under the *Health Insurance Regulations 1975*

Section 103 of the Principal Regulations provides a general transitional provision. It provides that things which were done under the Previous Regulations are treated as if the thing was done under the Principal Regulations.

SCHEDULE 1—SPECIALISTS

Clause 1

Clause 1 of Schedule 1 lists the organisations, specialities and qualifications for the purpose of sections 10 and 13.

SCHEDULE 2—FORMS

Schedule 2 lists the forms for the purpose of sections 81 and 82.

Statement of Compatibility with Human Rights

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

Health Insurance Regulations 2018

This Legislative 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 Legislative Instrument

The purpose of the *Health Insurance Regulations 2018* (the Principal Regulations) is to repeal and remake the *Health Insurance Regulations 1975* (the Previous Regulations). The Previous Regulations are required to be remade before 1 October 2018, which is when the instrument will sunset under the *Legislation Act 2003*.

The Principal Regulations support the provision of appropriate Medicare services through:

- setting out the mechanisms to support recognition of medical practitioners for the purposes of Medicare;
- setting out the calculation of benefits in relation to certain general practitioner, pathology and diagnostic imaging services;
- providing administrative rules for clarity around electronic requests for pathology services;
- providing restrictions on practitioners that request diagnostic imaging services;
- setting out applicable processes and registration rules regarding diagnostic imaging premises and radiation oncology equipment;
- setting out administrative rules for the submission of Medicare claims to the Department of Human Services; and
- providing information on quality assurance activities.

The Principle Regulations have updated the Previous Regulations to reflect current drafting standards whilst maintaining the original overarching policy framework.

Human rights implications

The Regulations engage 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 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 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 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 Principle Regulations will maintain rights to health and social security by ensuring access to publicly subsidised health services under Medicare continues to be available from 1 October 2018.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

Greg Hunt

Minister for Health