Australian Government
Professional Services Review

Information gathered by the Director and Associate Director of Professional Services Review

Guidelines for notices to produce

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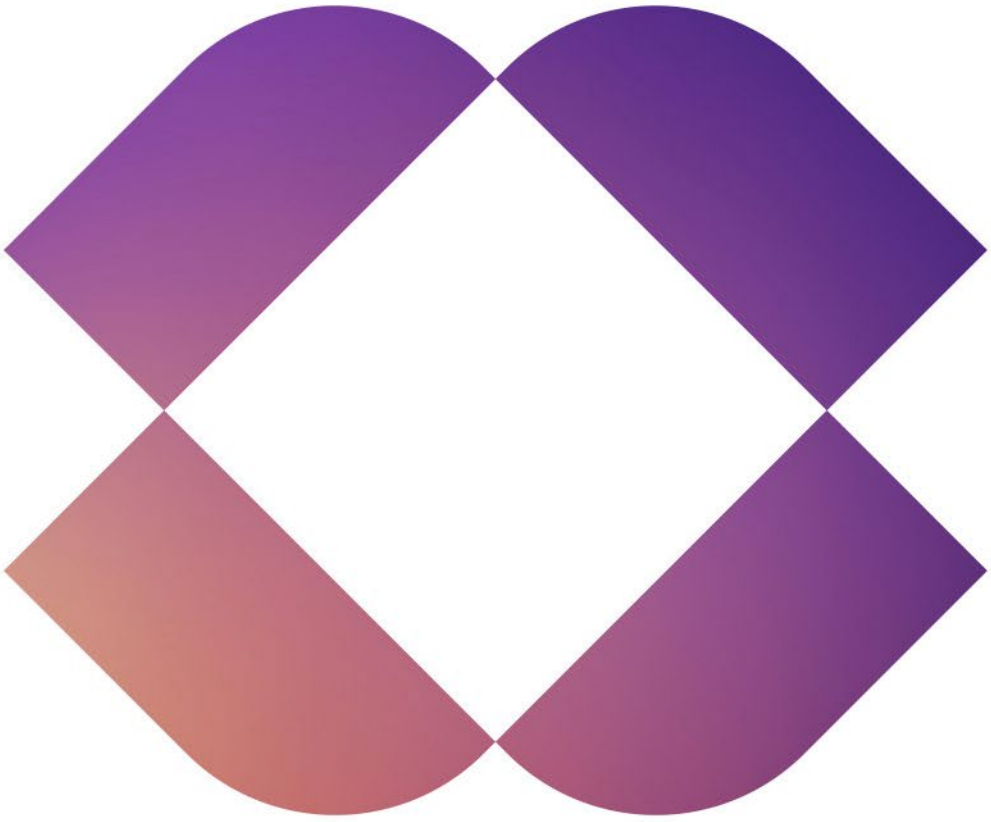

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1. Summary

1.1 The Professional Services Review (PSR) is established under the *Health Insurance Act 1973* (HI Act). The HI Act confers a range of functions and powers on the Director and Associate Directors of PSR in relation to reviewing the conduct of prescribed health practitioners.

1.2 The Director and any Associate Directors of PSR may each review the provision of services for which benefits have been paid under the Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS), and the Child Dental Benefits Schedule (CDBS). For the purposes of such reviews the Director and Associate Director may issue a notice to produce (notice).

1.3 If the Director or Associate Director issues a notice to a person, that person must comply with that notice by producing the specified documents and/or giving any requested information. Failure to comply with a notice may be an offence. A notice may be issued to a person under review or any other person if the Director or Associate Director considers the person has possession, custody or control of documents relevant to the review, being documents that are relevant to an assessment of whether the person under review has engaged in inappropriate practice.

1.4 These notice guidelines provide information about notices to produce for recipients and their legal representatives. Unless otherwise indicated, all section references in these guidelines are to the HI Act.

Generic medical image

2. Background

2.1 In 1999, the Professional Services Review (PSR) scheme was amended to introduce a power for the Director of PSR to be able to require the production of documents and the giving of information. This recognised that the Director needed to be able to examine medical records, and practice and other relevant documents, as part of conducting reviews under the PSR scheme.[1] In 2023, the PSR Scheme was amended to establish the role of Associate Director and to extend the Director's powers in conducting reviews, including the power to require the production of documents and the giving of information, to the Associate Director.[2] Multiple Associate Director's may be appointed.

2.2 The Director and Associate Director each have a broad discretion about how to conduct a review, including in relation to investigative methods and procedures, and what documents may be relevant will depend on the circumstances of this review. There are some matters which are likely to be of interest across many reviews and these are set out here to assist an individual under review to understand the review process.

[1] The Report of the Review Committee of the Professional Services Review Scheme (March 1999), p 27.

[2] Health Insurance Amendment (Professional Services Review Scheme) Act 2023; see also s83A of the HI Act (as amended).

2.3 While there is general information about notices within these guidelines which may be of assistance to a company under review, the vast majority of PSR reviews to date have related to individuals, and the information here is intended for individual persons under review.

2.4 Reviews of companies are considered to fall outside the scope of these guidelines and the details of any review of a company will guide decisions by the Director or Associate Director regarding the use of information gathering powers in those circumstances.

3. Part VAA of the HI Act and its objects

3.1 Part VAA of the HI Act establishes the PSR scheme. The object of part VAA is to protect the integrity of the Commonwealth Medicare benefits, dental benefits and pharmaceutical benefits programs and, in so doing:

a. protect patients and the community in general from the risks associated with inappropriate practice

b. protect the Commonwealth from having to meet the cost of services provided as the result of inappropriate practice.[3]

4. The Director and Associate Director of PSR

4.1 The PSR agency is headed by the Director of PSR. The Director and Associate Directors each perform certain review functions of the PSR agency. Under the Act, the Director and any Associate Director have a range of powers and functions in relation to conducting reviews.

4.2 The Director and Associate Director only have the power to conduct a review if the Chief Executive Medicare (CEM) has made a request to review the provision of services by a person (the person under review) during the period specified in the request (the review period). The Director or Associate Director has a month after receiving the request to decide whether to conduct a review.

[3] Section 79A.

5. Reviews

5.1 If the Director or Associate Director decides to conduct a review, they have formed the view that there was a possibility that the person under review engaged in inappropriate practice in providing services during the review period.[4]

5.2 In conducting a review, the Director and Associate Director have to apply a higher bar. Under the Act, the Director and Associate Director are required to consider whether there are insufficient grounds on which a Committee could reasonably find that the person under review has engaged in inappropriate practice in providing services during the review period.[5]

5.3 The Director or Associate Director may undertake a review in such manner as they see fit,[6] subject to practical considerations like having to complete that review within 12 months[7] and taking appropriate steps to give the person under review procedural fairness. Generally, the Director or Associate Director will choose to collect sufficient information to get a detailed and accurate picture of the conduct of the person under review during the review period.

5.4 One of the ways that the Director or Associate Director may collect information for a review is by issuing a notice to produce under section 89B of the Act.

6. Issuing a notice to produce

Who can receive a notice?

6.1 For the purpose of undertaking a review, the Director or Associate Director may require documents and/or information relevant to the review to be produced to them by:

a. the individual under review, or

b. any other person (including a company) who the Director or Associate Director believes to have possession, custody or control of, or to be able to obtain, relevant documents.[8]

[4] Section 88A.

[5] For information about the role of Committees in the PSR scheme, please see the *Your Guide to the Professional Services Review Process* at https://www.psr.gov.au/publications-and-resources/publications/resources-regarding-psr-process/your-guide-professional-services-review-process.

[6] Section 88B(b) of the Act.

[7] Section 94 of the Act.

[8] Section 89B of the Act.

Form of a notice to produce

6.2 The Director or Associate Director can require the production of these documents and/or the giving of information by giving a written notice to the person. The notice has to allow the person at least 14 days to produce the documents and/or give the information, and must include important information about how to comply with the notice and the consequences of non-compliance. The notice may specify that original documents are required by the Director or Associate Director,[9] but the Director or Associate Director will usually be satisfied with copies.

How many notices will be issued for each review?

6.3 How many notices the Director or Associate Director issues, and to whom, varies from review to review. This can be affected, for example, by the number of different settings at which a person under review provided services during the review period, and who holds relevant records for each setting.

6.4 Information in the request for review received from the CEM about where the person under review provided services during the review period, and information provided by the person under review about who holds records for the services provided at each location, can assist the Director or Associate Director to identify who is the custodian of relevant documents.

At which point in the process will a notice be issued?

6.5 The Director and Associate Director generally prefer to issue notices early in the review process, which allows the most time for relevant documents to be examined, and for any issues they raise to be put to the person under review for their consideration and response. This means that a notice may be issued when the Director's or Associate Director's inquiry is still broad, and the relevant documents may then assist to refine the scope of the review. In some cases, relevant documents and/or information may identify new lines of inquiry which the Director or Associate Director may pursue through further information gathering, including by issuing further notices.

7. Scope of reviews and notices to produce

Notices in the context of inquisitorial proceedings

7.1 The Director and Associate Director of PSR do not perform a judicial function or make findings in regard to civil or criminal liability. Notices are part of an investigation process, with

[9] Item 36, Schedule 1, *Electronic Transactions Regulations 2020*.

the purpose of enabling the Director or Associate Director to be informed on relevant matters in order to properly discharge their statutory function.

The threshold for the Director or Associate Director to issue a notice

7.2 The Director or Associate Director will form a view about whether documents are relevant and whether it is appropriate to issue a notice by reference to their task of inquiring into whether a person under review may have engaged in inappropriate practice in connection with the provision of services during the review period.

7.3 'Inappropriate practice' is defined in section 82 of the HI Act and covers a broad range of conduct[10] and the categories of what might constitute inappropriate practice are not closed. At a high level, however, it is conduct in connection with rendering or initiating a service that a Committee could reasonably conclude would be unacceptable to the general body of the person's profession or specialty.

7.4 Some kinds of conduct are expressly addressed in the definition of inappropriate practice, that is:

a. in forming a view about whether a person has engaged in inappropriate practice, a Committee is required to have regard to whether or not they kept adequate and contemporaneous records of the rendering or initiation of the services

b. where the person has rendered or initiated a 'prescribed pattern of services', they have engaged in inappropriate practice unless a Committee reasonably concludes that there were relevant exceptional circumstances.

7.5 Other conduct which has been found to be inappropriate practice in relation to a service includes:

a. not meeting the relevant legislative requirements for the service[11]

b. rendering or initiating a service that was not clinically relevant[12]

c. inappropriate billing of a service[13]

d. not providing an adequate level of clinical input.[14]

7.6 More practical examples of conduct constituting inappropriate practice can be found in the case outcomes report on the PSR website as published from time to time at https://www.psr.gov.au/case-outcomes.

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[10] *Selia v Commonwealth of Australia* [2017] FCA 7 at [79]–[89].

[11] *Health Insurance Commission v Grey* [2002] FCAFC 130 at [189].

[12] *Sevdalis v Director of Professional Services Review* [2017] FCAFC 9.

[13] *Selia v Commonwealth of Australia* [2017] FCA 7 at [83].

[14] *Traill v McRae* [2002] FCAFC 235.

8. Examples of relevant documents and information

8.1 Section 89B of the Act makes it clear that clinical or practice records of services rendered or initiated during the review period by a person under review are relevant documents.[15] These allow the Director or Associate Director to consider a range of matters, including whether there is an adequate and contemporaneous record for a service provided during the review period.

8.2 When issuing a notice to the person under review, the Director or Associate Director is likely to require the records of services they provided during the review period as part of the complete clinical file (i.e. the complete patient record) held by the person under review for the patient. When the Director or Associate Director requires a complete patient record, they are having regard to the kinds of information that allow them to get a clear understanding of services provided during the review period.

8.3 For example, information in the patient record from outside the review period:

a. shows the Director or the Associate Director the information about the patient available to the person under review at the time of the service

b. puts the service in the context of the patient's medical history and courses of treatment.

8.4 In most cases, having the complete patient record available as part of the review enables the Director or Associate Director (or a consultant engaged under section 90) to step into the shoes of the individual who provided the service. This ensures the Director or Associate Director (or a consultant), understands the clinical context in which the service was provided when assessing whether the individual's conduct in connection with the service constituted inappropriate practice.

8.5 Without the full record being available there may be insufficient information available to explain the service under review provided by the individual. For example, an individual may have ordered pathology on a date of service, which based on the record of the year under review did not have a reasonable clinical indication. However, the full record may disclose relevant clinical history such as previous diagnoses, previous surgery or previous family history which could justify the ordering of such investigations.

8.6 Eligibility for some services is also dependent on things that may have happened outside of the review period. For example, whether an MBS rebate is payable:

a. for certain chronic disease management services depends on the patient having at least one medical condition that has been present (or is likely to be present) for at least 6 months

[15] Section 89B(1).

b. for a review of a general practitioner management plan depends on a plan having been prepared at least 3 months earlier

c. for services rendered by a specialist, may depend on when the patient was referred to the specialist

d. for skin excision items, may depend on the pathology results only available after the date of service

e. for mental health services, depends on the patient having a diagnosis of a mental disorder

f. for some imaging services, depends on the service not having previously been provided or provided within a timeframe extending beyond the review period.

8.7 Some medicines also have restrictions or conditions that must be met before they can be prescribed to a patient on the PBS. For example:

a. some antibiotics are only available under the PBS for specific types of infections or where resistance to a different class of antibiotic is suspected or proven

b. some medicines are restricted under the PBS to conditions that are chronic or have persisted for specified periods of time, or where other medicines are contraindicated or intolerance is proven

c. some medicines are subject to strict State based legislative controls due to their high potential for misuse, abuse and dependence (for example, opioids such as morphine, fentanyl, oxycodone) and evidence of State based authorities may be required.

8.8 When issuing a notice to a hospital or medical practice where services were provided during the review period, the Director or Associate Director is also likely to require the production of the complete patient file, having regard to the same matters.

8.9 The notice may also require a person to give information to the Director or Associate Director about other persons that hold the relevant documents requested in the notice. For example, as well as requiring a person to produce any documents specified, the notice may also require a person under review to identify any patients in relation to whom a residential aged care facility (RACF) holds part of the patient record and to provide the contact details of that RACF. This enables the Director or Associate Director to issue a separate notice to a RACF to ensure that they have access to relevant patient records to enable them to conduct their review.

8.10 For RACFs, the Director or Associate Director is more likely to request the patient's clinical file for only a specific period proximate to and covering the review period, rather than the complete clinical file. This is because of the volume of information collected about the health of residents on a daily basis in a RACF setting and the decreasing likelihood of the relevance of information in RACF records as they are less proximate to the review period.

8.11 The Director and Associate Director each recognise that health practitioners, and the businesses they work with, are routinely required to produce documents to courts and regulators, and often have software and other systems to manage this. However, when determining the scope of a notice to produce the Director or Associate Director will take into account the administrative load likely to be caused by a notice. Generally, this balancing by the Director and Associate Director is reflected in the number of patients for whom the complete patient file is required and for RACFs, the period of time for which records are required.

8.12 Just like the kinds of conduct that may be inappropriate practice, the categories of documents which could potentially be relevant documents are not closed.

9. Complying with a notice to produce

Privacy considerations

9.1 A notice from the Director or Associate Director creates a requirement to disclose information under an Australian law, within the meaning of the *Privacy Act 1988*.[16] This means that complying with the notice is consistent with privacy requirements, including those that apply to businesses that provide health services.

Practical considerations

9.2 When the Director or Associate Director sends out a notice, they also send a letter which provides direct contact details for PSR staff who can assist with the collection or electronic transfer of the required documents.

9.3 Generally, the Director and Associate Director each prefer to receive documents electronically and PSR maintains a secure document sharing platform for this purpose. If hard copy documents are being produced, PSR will provide tamper evident containers for the records and arrange for their collection by courier.

9.4 Where PSR receives all documents and/or information required by a notice, PSR will provide written acknowledgement of receipt of these materials and/or information. If PSR is not satisfied there has been full compliance, PSR will write advising of what information has been received and which information covered under the notice remains outstanding. In such a case the notice recipient is encouraged to contact the PSR staff member identified in the notice.

[16] Australian Privacy Principle 6.2(b), Schedule 1, Privacy Act.

Time allowed for compliance

9.5 A notice will specify a time period in which the notice must be complied with, which must be at least 14 days from the date the notice is given to the person. Subject to the comments below, strict adherence to this deadline is expected and immediate consideration will be given to pursuing cases of non-compliance.

9.6 The Director or Associate Director can decide not to take action for non-compliance for a specific period, if satisfied there are good reasons for doing so. Requests for the Director or Associate Director to delay taking compliance action should set out in full the reasons why the notice cannot be complied with within the specific period and indicate a date when compliance will be achieved.

9.7 Difficulties meeting the deadline set out in the notice should be raised with PSR as early as possible in order to allow time for the Director or Associate Director to give proper consideration to the request to delay compliance action. Requests received on or after the date the documents are due should be accompanied by an explanation of why it was not practicable to have brought these issues to the attention of the Director or Associate Director earlier.

9.8 All such requests will be considered within the overarching framework of the PSR scheme, which provides the Director and Associate Director a strict 12-month deadline within which to complete a review.

No requirement to seek documents from third parties

9.9 A person who is issued with a notice must produce the required documents that are in their possession, custody or control, or that they are able to obtain.

9.10 The Director and Associate Director each understands that most persons under review will have clear arrangements with the practices they work with about what records they may obtain from practice systems and for what purpose. If the person who receives the notice does not have the right to obtain the relevant documents, the notice will require them to give the Director or Associate Director the name and address of a person who does (if they know it).[17]

9.11 When the Director or Associate Director issues notices to third parties, care is taken, as far as is practical, not to disclose the identity of the person under review.

9.12 It may be that while a person can take steps towards obtaining a document (for example, they can contact a pathology laboratory and ask them to send a copy of a test result for a patient), this is at the discretion and subject to the priorities of someone else. In those circumstances, the Director and Associate Director each asks that the person contact PSR to

[17] See section 89B(2)(d).

discuss this in the first instance, as it may be more appropriate for a notice to be issued to another party.

No requirement to obtain information from My Health Record

9.13 The Director and Associate Director do not expect and cannot permit a person to obtain any information from a patient's My Health Record[18] for the purposes of complying with a notice. Access to the My Health Record system is subject to significant restrictions and the system is likely to hold information that simply duplicates what is otherwise available in the patient's clinical file.

Requirement not to provide false or misleading documents

9.14 It is an offence to produce a document in response to a notice if a document is false or misleading in a material particular and the person knows that the document is false or misleading in that particular, and the person intentionally fails or refuses to identify to PSR the respects in which the document is false or misleading.[19]

9.15 Examples of the production of false or misleading documents can include producing patient files, either electronically or in handwriting, that have been prepared or modified for the purposes of responding to the notice, and representing that such documents reflect the contemporaneously prepared patient file.

10. Non-compliance with a notice to produce

10.1 Intentional failure or refusal to produce documents and/or give information required under a notice can have serious consequences. For a practitioner being reviewed, this can result in Medicare or dental benefits not being payable in respect of services they provide.[20] For other notice recipients, there are criminal and civil penalties that may apply in those circumstances.[21]

10.2 If a person is having difficulty producing documents and/or giving information by the date specified in the notice, they should contact PSR as early as possible before the due date. Engaging early and explaining the circumstances assists the Director or Associate Director to

[18] For more information about the My Health Record, please see https://www.digitalhealth.gov.au/initiatives-and-programs/my-health-record.

[19] See 106ZPP of the Act.

[20] See section 106ZPM of the Act.

[21] See, for example, sections106ZPN and 106ZPNA.

understand what the person's intent is, and to consider whether to refrain from commencing compliance action at that time.

10.3 If a person does not produce the required documents and/or give the required information by the due date on the notice, then the 12-month period to complete the review can be extended by the period of the delay.[22]

10.4 PSR recommends all persons the subject of a review contact their medical defence organisation (or other professional indemnity insurer), or otherwise engage legal assistance, to help them through the PSR process, including responding to any notices that may be issued. For third parties not under review receiving notices, there is no requirement for them to seek legal advice prior to responding to a notice, although they may choose to do so.

11. Rules of self-incrimination do not apply

11.1 A person cannot decline to produce documents required under a notice because the documents may incriminate them.[23] However, if an individual does produce documents to the Director or Associate Director, those documents and information derived from them cannot be used against them in any criminal proceedings, other than proceedings about the provision of false or misleading records to the Director or Associate Director.[24]

11.2 The HI Act provides for certain disclosures of information which can include materials obtained by the Director or Associate Director under a notice being provided to third parties. In particular, sections 106XA and 106XB require certain information to be provided to Ahpra and section 89A requires certain information to be provided to the Chief Executive Medicare.

12. Handling of produced documents

12.1 Information in documents produced to the Director or Associate Director is protected by secrecy obligations in the Act,[25] as well as the restrictions that apply to handling personal information in the Privacy Act.

12.2 PSR stores and disposes of personal information in accordance with the *Archives Act 1983*. PSR's disposal schedule under this legislation means that it destroys patient information it has gathered as part of a review as soon as practicable after the review is finalised.

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[22] See section 94(3) of the Act.

[23] Section 106ZPQ(1) of the Act.

[24] Section 106ZPQ(2)(a).

[25] See section 130 of the Act.

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