

Advisory No: GP18/04

<b>TITLE</b>	Notification of significant risk
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<b>REPLACES</b>	Not applicable
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<b>COMPLIANCE</b>	Mandatory
<b>APPROVED FOR DISTRIBUTION BY</b>	CEO
<b>REVIEW DUE DATE</b>	22 August 2020
<b>INFORMATION IN THIS ADVISORY APPLIES TO:</b>	All approved accrediting agencies assessing general practices
<b>KEY RELATIONSHIP</b>	Not applicable
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<b>TRIM NO.</b>	D17-45231
<b>LINKAGES TO OTHER ADVISORIES and/or DOCUMENTATION</b>	Practice Incentive Program Guidelines Practice Nurse Incentive Program Guidelines <i>Health Practitioner Regulation National Law (2009)</i>
<b>ATTACHMENTS</b>	Attachment 1 – Definition of significant risk
<b>NOTES (if applicable)</b>	Nil

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**PURPOSE:**

To describe the requirements for accrediting agencies to notify the Australian Commission on Safety and Quality in Health Care (the Commission) and relevant state and territory health care complaints bodies of significant risks of patient harm that pose an ongoing risk to public health and safety that are identified during the assessment of general practices.

**ISSUE:**

Clause 4.8.1 of the Guide to the approval process for accrediting agencies assessing general practices requires accrediting agencies to notify the Commission and the relevant state or territory health care complaints body of any significant risk/s identified during the assessment of a general practice.

The Health Minister has tasked the Commission with the coordination of the National General Practice Accreditation Scheme (the Scheme). This includes receiving information about the assessments of general practices, including notification of significant risks.

State and territory health care complaints bodies are independent bodies whose role it is to receive, assess and investigate complaints that raise questions about public health and safety. Health care complaints bodies have a legislative function to act for the resolution, or prosecution, of complaints that endanger public health and safety.

Assessors and accrediting agencies require clarification of the term 'significant risk' to ensure they are able to identify circumstances during an assessment that might constitute a significant risk in a general practice, and to ensure they are able to comply with their reporting obligations under the Scheme. A definition of significant risk for general practice is outlined in Attachment 1.

The *Health Practitioner Regulation National Law 2009* (the National Law) requires registered health practitioners, employers and education providers to report to the Australian Health Practitioner Regulation Agency (AHPRA) any instances of 'notifiable conduct' by individual registered health practitioners. Notifiable conduct by individual registered health practitioners does not fall under the definition of significant risk for the purposes of this advisory and is not required to be reported to the Commission or the relevant state or territory health care complaints body. Assessors and/or accrediting agencies that observe any conduct by individual registered health practitioners that constitutes notifiable conduct during an assessment are required to follow the mandatory reporting processes as outlined by AHPRA.

**REQUIREMENTS:**

Where an assessor is onsite and identifies **one or more significant risks as defined by Attachment 1**, the following series of escalating actions are to be taken:

1. Assessors are to notify both the practice and their accrediting agency that a significant risk of serious patient harm has been identified.
2. Assessors and/or the accrediting agency are to discuss with the practice the immediate action to be taken to mitigate the identified significant risk/s.

3. In circumstances where the mitigation of the significant risk/s requires changes to be embedded in the practice over a period of time, assessors and/or the accrediting agency are required to develop in consultation with the practice an action plan that outlines the actions to be taken and timeframes for these.
4. Assessors and/or the accrediting agency must document the significant risk/s identified during the assessment in the practice's assessment report, including details of the immediate actions taken to mitigate the significant risk/s, as well as any action plan that may have been developed and the timeframes for these actions.
5. Where a significant risk/s was identified during an assessment, the accrediting agency must not award the practice accreditation unless, or until, it has confirmed the significant risk/s have been adequately mitigated. Accrediting agencies may need to conduct further reviews or assessment of the practice, depending on the risk/s identified during the assessment and the planned actions. Any review or re-assessment of the practice must occur within 90 days of the initial assessment.
6. If the accrediting agency is not satisfied that the significant risk/s have been mitigated within 90 days of the initial assessment, the accrediting agency must not award the practice accreditation and is to notify the relevant state and territory health care complaints body and the Commission of the significant risk/s identified.

Accrediting agencies are to inform their client, and include relevant clauses in any contractual arrangements, about the process that will be followed if a significant risk/s are identified during assessment, including the possibility that information about the significant risk/s will be provided to the Commission and to relevant state or territory health care complaints bodies if the practice fails to adequately mitigate the risk/s.

Accrediting agencies are not required to report to the Commission or to relevant state or territory health care complaints bodies' instances of notifiable conduct of individual registered health practitioners.

A definition of significant risk for the purposes of this advisory is included in Attachment 1

## Attachment 1

Few, if any, Australian general practices pose a significant risk of harm to patients. However, from time to time, lapses and errors may occur that result in an increased risk of harm to patients accessing care from that practice.

A significant risk is one where there is a high probability of a substantial and demonstrable serious adverse impact for patients who access care from the general practice undergoing assessment. In each case, a significant risk will be sufficiently serious to warrant an immediate response to reduce the risk to patients. This may include interventions or changes to the practice’s policies, procedures or management systems; the clinical care environment; or clinical practice.

Risks that have already been identified by the practice, such as those identified through the review of a near miss or critical incident, and which are subject to existing quality improvement plans and effectively mitigated, would not be considered a significant risk for the purposes of this advisory.

Significant risks for the purposes of this advisory are those risks that at the time of the assessment have not previously been identified by the practice; are systemic in their origin; are not currently controlled; or have not been sufficiently mitigated so as to prevent the possibility of serious patient harm.

Assessors and/or accrediting agencies can use the following sample risk matrix to help determine if an identified risk/s of patient harm constitutes a significant risk/s as defined by this advisory.

**Table A2.1: Risk analysis matrix**

Likelihood	Consequences				
	Negligible	Minor	Moderate	Major	Extreme
Rare	Low	Low	Low	Medium	High
Unlikely	Low	Medium	Medium	High	Very high
Possible	Low	Medium	High	Very high	Very high
Likely	Medium	High	Very high	Very high	Extreme
Almost certain	Medium	Very high	Very high	Extreme	Extreme

<b>Low risk</b>	Manage by routine procedures.
<b>Medium risk</b>	Manage by specific monitoring or audit procedures.
<b>High risk</b>	This is serious and must be addressed immediately.
<b>Very high risk</b>	The magnitude of the consequences of an event, should it occur, and the likelihood of that event occurring, are assessed in the context of the effectiveness of existing strategies and controls.
<b>Extreme risk</b>	

Source: Australian Guidelines for the Prevention and Control of Infections in Health Care (Table A2.1)

The following list provides some examples of significant risks for general practices. They are intended to be examples only. This list is not exhaustive and should not be exclusively used to identify significant risks.

Examples of significant risks in a general practice may include, but are not limited to:

<b>Risks</b>	<b>Impact</b>
Staff do not routinely use processes to correctly identify a patient before care is administered or before personal information is accessed and used	Patients are misidentified and experience preventable harm, such as an allergic reaction to prescribed medications or inaccurate referrals
Processes for correctly cleaning, disinfecting and sterilising reusable medical devices are not performed to the required standard	Preventable infections are transmitted to patients
Medicines that are required to be stored in a secure location are left unlocked and are accessible to the general public	Patients or staff may inappropriately access controlled medicines and experience an adverse reaction
Processes for managing temperature-sensitive medicines do not exist or are not followed by staff	Vaccines or other patient medicines cannot be dispensed or administered because they are not available, or they are administered but are ineffective
Processes to check and follow up clinically significant test results do not exist or are insufficient	Patients do not receive necessary follow up care and experience preventable harm