

# Policy Frameworks Mandatory Policy

MP 0163/21

Effective from: 11 June 2021 Amended on: 8 October 2024

# **Newborn Bloodspot Screening Policy**

### 1. Purpose

The Newborn Bloodspot Screening Policy (the policy) sets the mandatory requirements that outline roles, responsibilities and reporting requirements for Health Service Providers that provide maternity, neonatal, clinical specialist and pathology services for newborn babies in the WA health system as part of the WA Newborn Bloodspot Screening Program.

The aim of the WA Newborn Bloodspot Screening Program is to improve the health of babies by identifying those at risk of developing a serious condition early, generally before symptoms present.

This policy is consistent with the Australian Health Ministers' Advisory Council, <u>Newborn Bloodspot Screening National Policy Framework (2018)</u> which provides best practice guidance to deliver newborn blood screening in Australia.

This policy is a mandatory requirement for Health Service Providers under the *Public Health Policy Framework* pursuant to section 26(2)(c) of the *Health Services Act 2016*.

### 2. Applicability

This policy is applicable to Health Service Providers that provide maternity, neonatal, clinical specialist and pathology services.

The requirements contained within this policy are applicable to the services purchased from contracted health entities where it is explicitly stated in the contract between the contracted health entity and the State of Western Australia or Health Service Provider. The State of Western Australia or Health Service Provider contract manager is responsible for ensuring that any obligation to comply with this policy by the contracted health entity is accurately reflected in the relevant contract and managed accordingly.

# 3. Policy Requirements

Health Service Providers providing maternity, neonatal, clinical specialist and pathology services must ensure local policies and procedures are in place that align with the requirements of this policy and the <a href="Newborn Bloodspot Screening Procedure">Newborn Bloodspot Screening Procedure</a>.

### 3.1 PathWest Laboratory Medicine WA

PathWest Laboratory Medicine WA must provide the following services for the WA Newborn Bloodspot Screening Program:

administrative and management services

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- pathology services
- quality assurance.

PathWest Laboratory Medicine WA must document:

- the responsibilities of the Head of the WA Newborn Bloodspot Screening Laboratory
- the administrative support provided to Health Service Providers
- newborn bloodspot screening results management including:
  - notification to Health Service Providers about babies requiring repeat testing
  - o referral of babies to clinical specialist services
  - recording and reporting of data using the <u>Performance Indicators Form Newborn Bloodspot Screening</u>
- pathology procedures for processing newborn bloodspot screening cards.

PathWest Laboratory Medicine must develop an implementation plan detailing how new conditions approved by the WA Minister for Health, as part of the national decision-making pathway for the addition of new conditions to Australian NBS Programs, are to be included within the WA Newborn Bloodspot Screening Program.

### 3.2 Health Service Providers providing maternity and/or neonatal services

Health Service Providers that provide maternity and/or neonatal services must:

- have procedures in place detailing the roles and responsibilities within their organisation as outlined in the <u>Newborn Bloodspot Screening Procedure</u>
- nominate at minimum one contact position at each site who will be the point of contact with PathWest Laboratory Medicine WA
- ensure optimal collection of bloodspot samples for all eligible newborns at 48-72 hours post birth
- ensure sample collection staff are appropriately trained and have access to relevant educational resources.

#### 3.3 Health Services Providers providing clinical specialist services

Health Service Providers that provide clinical specialist services must:

- have procedures in place detailing the roles and responsibilities within their organisation as outlined in the <u>Newborn Bloodspot Screening Procedure</u>
- provide clinical guidance for the care of any baby referred to their service through the WA Newborn Bloodspot Screening Program
- review diagnostic outcomes, in conjunction with PathWest Laboratory Medicine WA, for all babies with abnormal screening results referred to the clinical specialist service
- report any baby or child with a bloodspot screened condition that presented after the bloodspot screening period to the Newborn Bloodspot Screening Program.

# 4. Compliance Monitoring

The Office of Population Health Genomics, on behalf of the System Manager, will monitor compliance with this policy by conducting periodic audits of internal procedures and/or guidelines to ensure alignment to these policy requirements.

### **PathWest Laboratory Medicine WA**

PathWest Laboratory Medicine WA must use the <u>Performance Indicators Form - Newborn</u> <u>Bloodspot Screening</u> to collate data and submit an annual report to the Department of

Health via the Office of Population Health Genomics <u>genomics@health.wa.gov.au</u> at the end of the financial year.

The System Manager may also request additional information to ensure alignment with policy requirements.

#### 5. Related Documents

The following documents are mandatory pursuant to this policy:

- Performance Indicators Form Newborn Bloodspot Screening
- Newborn Bloodspot Screening Procedure

### 6. Supporting Information

The following information is not mandatory but informs and/or supports the implementation of this policy:

- WA Newborn Bloodspot eLearning Package (King Edward Memorial Hospital)
- WA Newborn Bloodspot Screening brochure (Healthy WA)
- Your baby's newborn bloodspot screening test (Healthy WA)
- WA Newborn Bloodspot Screening Program (WA Department of Health)
- National Health Genomics Policy Framework and Implementation Plan 2018-2021
- What is screened in the program (Australian Government Department of Health and Aged Care)
- Our national decision-making pathway (Australian Government Department of Health and Aged Care)
- National Strategic Action Plan for Rare Diseases 2020

#### 7. Definitions

The following definition(s) are relevant to this policy.

Term	Definition
Abnormal result	A result of the screening test that indicates the newborn is at increased risk of having a tested condition.
Bloodspot sample	The blood that is taken from the heel prick of a newborn.
Bloodspot card	The card on which the bloodspot samples are collected and identifying information about the baby being screened is entered.
Neonatal	Relating to newborn babies.
Newborn	A baby from the time of birth up to 28 days of age.
Newborn bloodspot screening	This includes all processes associated with taking a bloodspot sample from newborn babies and testing it to identify babies at increased risk of a number of rare but serious conditions. It is also known as the Guthrie test and the 'heel-prick test'.

Sample collection staff	A suitably trained professional who takes the newborn bloodspot sample including midwives, nurses, child health nurses, Aboriginal Health Practitioners and phlebotomists.
WA health system	The WA health system is comprised of:  (i) the Department;  (ii) Health Service Providers (North Metropolitan Health Service, South Metropolitan Health Service, Child and Adolescent Health Service, WA Country Health Service, East Metropolitan Health Service, PathWest Laboratory Medicine WA, Quadriplegic Centre and Health Support Services); and  (iii) contracted health entities, to the extent they provide health services to the State.

### 8. Policy Contact

Enquiries relating to this policy may be directed to:

Title: Manager, Screening Policy

Directorate: Office of Population Health Genomics

Email: genomics@health.wa.gov.au

#### 9. Document Control

Version	Published date	Review date	Amendment(s)
MP 0163/21	11 June 2021	June 2024	Original version
MP 0163/21	8 October 2024	October 2027	Policy review and amendments as
v.1.0			listed below.

- Title amended with the removal of 'Program.'
- Purpose section refined.
- Policy requirements section refined and updated.
- Compliance monitoring update to reflect the policy owner's responsibility to monitor policy compliance.
- Related document: Newborn Bloodspot Screening Procedure updated.
- Supporting information updated (removed Newborn Bloodspot Screening National Framework and added the national decision-making pathway for new conditions)
- Definitions for 'consent,' 'diagnosis' and 'Health Service Provider' removed from the policy. Definitions for 'false negative' and 'unsuitable sample' moved to the Newborn Bloodspot Screening Procedure. Definition for 'WA health system' inserted.

Note: Mandatory policies that exceed the scheduled review date will continue to remain in effect.

# 10. Approval

Approval by	Nicole O'Keefe, Assistant Director General, Strategy and Governance Division, Department of Health
Approval date	6 June 2021

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