Pilot Handbook

Queensland Community Pharmacy Hormonal Contraception Pilot

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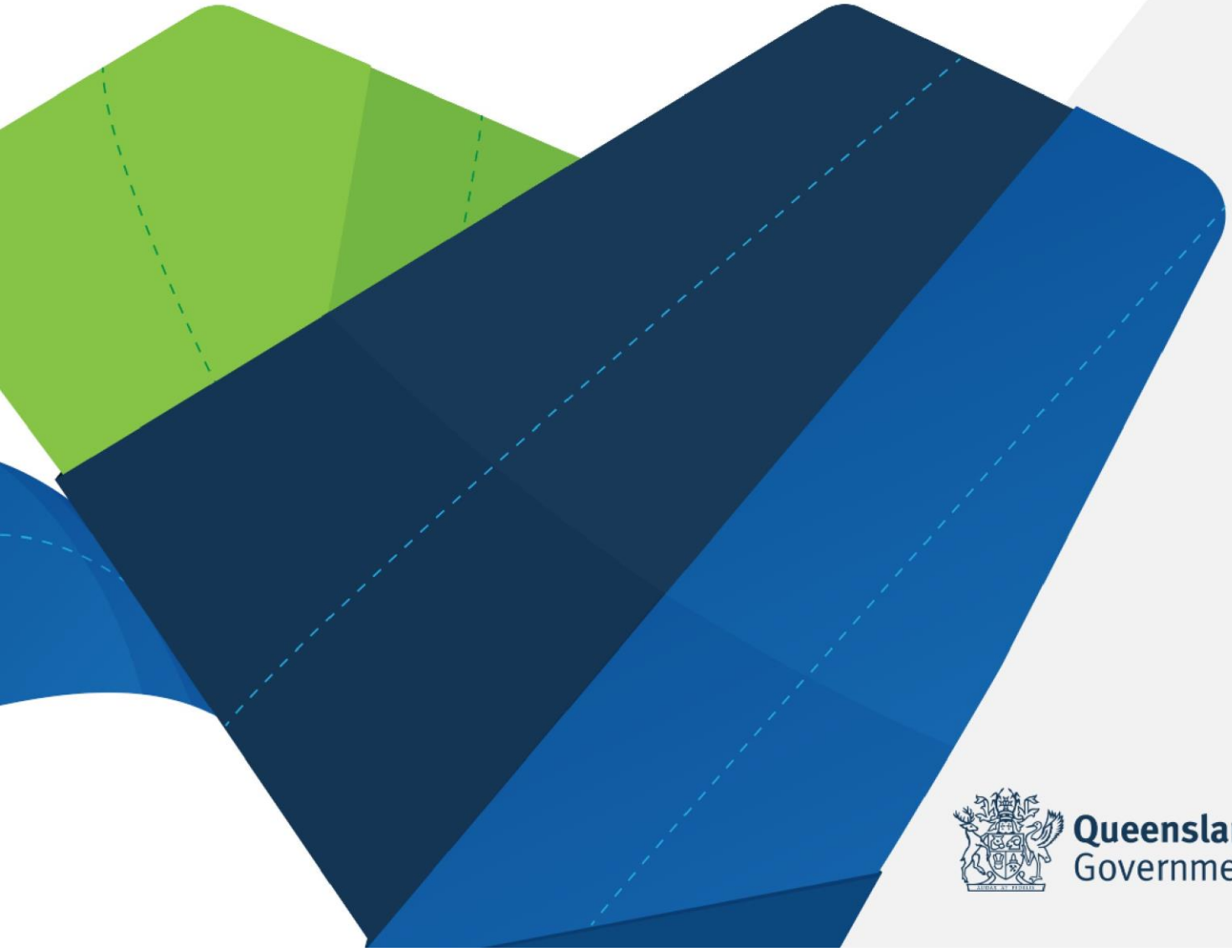

Queensland Government

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Version 1.0	09.07.2024	Approved
Version 1.1	16.10.2024	Administrative update

1 Overview

1.1 Document purpose

The Queensland Community Pharmacy Hormonal Contraception Pilot Handbook (the **Handbook**) provides pharmacists and pharmacy staff who are participating in the Queensland Community Pharmacy Hormonal Contraception Pilot (the **Hormonal Contraception Pilot**) with a reference guide to information and resources which support their participation in the Hormonal Contraception Pilot.

The Handbook provides information regarding participation requirements, patient eligibility and management, and other operational requirements and processes. It aims to support the provision of safe and high-quality services, in accordance with the legislative provisions that enable service delivery for the Hormonal Contraception Pilot.

The Handbook is a living document and will be updated as revisions are made to improve content and processes. When updates to the Handbook are made, the version on the Queensland Community Pharmacy Pilots website will be replaced.

2 Conditions of participation

To ensure that pilot services are delivered to a high-quality and safe standard, participating pharmacies and pharmacists are required to adhere to the conditions of participation. In addition, there are criteria that patients must meet to be eligible to receive a service as part of the Hormonal Contraception Pilot.

2.1 Participation requirements: pharmacies and pharmacists

Prior to providing services as part of the Hormonal Contraception Pilot, pharmacies and pharmacists must receive authorisation from Queensland Health.

The requirements that must be met by pharmacies and pharmacists to be authorised are outlined on the Queensland Community Pharmacy Pilots website. These requirements include that the pharmacy holds current Quality Care Pharmacy Program accreditation.

Pharmacy owners, or an authorised delegate, are required to complete the registration form on behalf of their pharmacy, as well as on behalf of the participating pharmacists working within their pharmacy/ies.

The pharmacy owner, or an authorised delegate, must provide a number of declarations throughout the registration process, in relation to the readiness of the pharmacy and the pharmacists that intend to provide pilot services at that pharmacy. Pharmacies and pharmacists will be authorised by Queensland Health to commence delivery of pilot services following the successful completion of the registration process.

The Queensland Community Pharmacy Pilots website provides information related to the registration process for pharmacy owners and pharmacists seeking to participate in the Queensland Community Pharmacy Hormonal Contraception Pilot as well as access to the registration form.

Pharmacy owners (or authorised delegates) with a pharmacy that has already been authorised to participate in the Hormonal Contraception Pilot should email the Pilot Coordination Team at qld-pharmacyscopepilot@health.qld.gov.au if they wish to register additional pharmacists to participate in the Hormonal Contraception Pilot, at that pharmacy.

Participating pharmacists and pharmacy owners are responsible for ensuring that participation requirements are met and maintained for the duration of pilot service delivery.

A Check-in process has been developed to provide ongoing assurance that mandatory requirements are being met and to identify areas for ongoing improvement of the pilot services. More detail about the Check-in process can be found in Section 9.1.

2.2 Patient eligibility

To receive a service as part of the Hormonal Contraception Pilot, patients (and/or substitute decision-makers) must comply with the following requirements:

- Be physically present at the pharmacy for the consultation.
- Provide informed financial and clinical consent to participate in the Pilot service.
- Provide consent to participate in the evaluation for the Hormonal Contraception Pilot, including agreeing to having their administrative health service data analysed for evaluation purposes and to be contacted to participate in surveys about the Hormonal Contraception Pilot.

Prior to a patient being booked in for a consultation, pharmacy staff are required to determine if a patient is eligible to receive a service that is within the scope of the Hormonal Contraception Pilot. This includes understanding patient details that may prevent participation, such as age, pregnancy status, existing comorbidities etc. These details are outlined as 'refer when' criteria in the Hormonal Contraception Clinical Practice Guideline. The Hormonal Contraception Clinical Practice Guideline can be found on the Queensland Community Pharmacy Pilots website.

Patients (and/or substitute decision makers) must also be provided with information regarding the financial, clinical and evaluation implications of participating in the Hormonal Contraception Pilot, as per the patient consent information sheets. More detail can be found in Section 3.

Should a situation occur where a patient who is clearly ineligible has been booked into a consultation then they should not be billed any fees. Where a patient has decided not to proceed with receiving some part of a service or becomes ineligible during the consultation, they may still be required to pay for services that have already been provided.

3 Patient consent

3.1 Patient consent

Informed consent is an essential component of person-centred healthcare and ensures that a patient has sufficient information about the proposed treatment to understand and make an appropriate decision about their care. Further information about informed consent can be found in the Queensland Health *Guide to Informed Decision-making in Health Care*.

To participate in the Hormonal Contraception Pilot, patients (and/or their substitute decision maker) must provide three types of consent prior to receiving a hormonal contraception pilot service: 1) clinical consent, 2) financial consent and 3) evaluation consent. All three types of consent are to be recorded in the Pilot Clinical Information System (Pilot CIS).

The consent process is supported by patient consent information sheets that are located on the Queensland Community Pharmacy Pilots website.

It is the responsibility of the participating pharmacist to ensure that all three types of consent have been communicated to the patient and recorded in the Pilot CIS prior to commencing the consultation.

3.1.1 Clinical consent

Prior to receiving a pilot service, patients (and/or their substitute decision maker) must be made aware of the scope of the pilot service being provided, including potential tests or treatments involved and the risks and benefits of the service.

Information that should be discussed as part of obtaining informed clinical consent includes:

- The scope of the service that may be delivered and what is involved in the service.
- Consent for the participating pharmacist to confidentially record and store patient information in the Pilot CIS.
- Consent for the participating pharmacist to share information as necessary with other members of the patient's health care team including with their usual General Practitioner (GP) or care provider.
- Advice that prescriptions issued under the Queensland Community Pharmacy Pilots may not be able to be dispensed outside of Queensland.

Where a patient has nominated a usual GP or care provider, the participating pharmacist should obtain consent from the patient prior to sharing the service consultation summary.

Patients have the right to change their mind regarding clinical consent for some or all of their treatment at any time, including after providing initial consent. Patients may also refuse consent for the sharing of their information with other practitioners. The patient's decision to withdraw or refuse consent should be documented in their clinical record in the Pilot CIS.

3.1.2 Financial consent

Prior to receiving a pilot service, patients (and/or their substitute decision maker) must be made aware of the costs associated with the service being provided, including the consultation fee and any other costs associated with the service.

Information that should be discussed as part of obtaining financial consent includes:

An estimate of the consultation fee.

- Other potential cost associated with the service such as the cost of consumables, prescribed medicines, and additional investigations that may be required. Pharmacy staff should advise patients that any medicines prescribed as part of the Queensland Community Pharmacy Pilots will be charged as a private prescription, are not subsidised by the Pharmaceuticals Benefits Scheme (PBS) and do not count towards the PBS Safety Net.

- An indication of whether a follow-up consultation may be required and an estimate of what this would cost.

- Other options for accessing care at a lower or no cost (e.g., through a GP or Aboriginal Community Controlled Health Service (ACCHO)).

All consultation fees charged must align to the Queensland Community Pharmacy Pilots fee schedule outlined in Section 4.

It Is essential that patients (and/or their substitute decision maker) are explicitly made aware and understand that the consultation with a participating pharmacist and any medicines prescribed or pathology tests requested are not subsidised by the Medicare Benefits Schedule (MBS) or the PBS. All components of consultation, medicine and consumable costs for the Queensland Community Pharmacy Pilots services are out of pocket expenses and must be paid in full by the patient.

A patient may retract their financial consent, including after providing initial consent. Patients should be made aware that if they decide not to proceed with receiving some part of a service, they may still be required to pay for services that have already been provided.

The clinical and financial consent information sheet can be found on the Queensland Community Pharmacy Pilots website.

3.1.3 Evaluation consent

Prior to receiving a pilot service, patients (and/or their substitute decision maker) must be informed of the pilot service evaluation and asked to provide evaluation consent. All patients (and/or their substitute decision maker) should receive a copy of the evaluation consent information sheet.

Information that should be discussed as part of obtaining evaluation consent includes:

- That routinely collected administrative health service data necessary to ensure the appropriate monitoring of the quality and safety of the Queensland Community Pharmacy Pilots will be used for evaluation purposes. This includes routinely collected activity records and analysis of routinely collected data by Queensland Health and the Commonwealth Government about health services received before and after participation in the Queensland Community Pharmacy Pilots. **Patients must provide consent for the use of their data for the evaluation, to be eligible to receive a pilot service.**

- Consent for the patient's contact details to be shared with the evaluation team so that follow-up surveys can be sent, and the evaluation team can contact the patient (and/or their substitute decision maker) regarding other evaluation activities. **Patients must provide consent to be contacted to be eligible to receive a pilot service. Patients do not have to participate in any of the evaluation activities if contacted.**

- Once they receive a service, patients will be invited to participate in a range of evaluation activities as part of the Queensland Community Pharmacy Pilots. Consent for participation in these additional evaluation activities will be collected directly by the evaluation team at the point of contact. **Patients do not have to participate in any of the evaluation activities if contacted.**

A checklist of the key points to cover with the patient in relation to the evaluation consent is provided as a guide at Appendix B: Evaluation consent checklist.

Once patients (and/or their substitute decision maker) have been provided the information relating to evaluation consent, the pharmacy staff will confirm this consent in the Pilot CIS. In doing so, pharmacy staff are declaring that the patient (and/or their substitute decision maker) has understood key aspects of the evaluation information outlined above and in the evaluation consent information sheet.

Section 10 provides further details about evaluation activities.

4 Consultation fee schedule

Consultation fees for pilot services have been determined based on the complexity and duration of the service being provided. Participating pharmacists are required to adhere to the fee schedule, set out in Table 1.

Table 1: Consultation fee schedule

	Brief consultation	Standard consultation	Long consultation
Duration	<10 minutes	Between 10 and 20 minutes	>20 minutes
Description	Consultation for a patient presenting with an obvious problem characterised by the straightforward nature of the consultation that requires a short patient history, and if required, limited examination and management.	Consultation for a patient presenting with clinical signs and symptoms with an easily identifiable underlying cause that requires a standard consultation including any of the following: taking a history, undertaking clinical examination, arranging any necessary investigation, implementing a management plan, and providing appropriate preventative healthcare.	Consultation for a patient presenting with multiple clinical signs and symptoms that requires a more detailed consultation including any of the following: taking a history, undertaking clinical examination, arranging any necessary investigation, implementing a management plan, and providing appropriate preventative healthcare.
Price	$18.85 (GST not included)	$35.45 (GST not included)	$68.10 (GST not included)

Time taken to complete the following activities should not be included in the consultation time:

- writing clinical notes and completing forms, reports, or other documentation
- uploading records into the Pilot CIS.
- talking to carers or relatives when the patient is not present.

The Pilot consultation fees outlined in Table 1 do not include any taxes, fees or charges (such as GST).

Consultation fees will be subject to annual fee indexation which will occur in line with MBS fee indexation.

5 Hormonal Contraception Pilot services overview

5.1 Transition from usual care to Hormonal Contraception Pilot care

Pharmacists have a strong reputation for delivering health care advice and support to their patients as well as providing information about the safe and effective use of medicines. This forms part of their everyday pharmacy service. As part of usual care, pharmacists within their current scope of practice may provide services for hormonal contraception including:

- Provision of the Schedule 3 emergency contraception.
- Continued supply of Schedule 4 oral hormonal contraceptive medicines under Section 156 of the Medicines and Poisons (Medicines) Regulation 2021 where the patient has not been able to obtain a prescription before needing to continue treatment with the medicine.

Where appropriate, these services may be integrated into, or provided instead of a pilot service based on the patient circumstances and preferences.

Usual care is defined as the standard scope of practice that pharmacists deliver as usual business, outside of the Hormonal Contraception Pilot scope. In defining and understanding the difference between usual care and Hormonal Contraception Pilot care and what the transition involves, it is important to acknowledge that not all customers seeking pharmacist advice will wish to participate in the Hormonal Contraception Pilot.

A pharmacist's duty of care prevails for all pharmacy customers and usual pharmacy services and care should continue to be provided when the patient is offered pilot services but chooses not to participate. The transition to pilot services should only proceed when the patient has been made aware of pilot services and has provided all three types of consent.

5.2 Hormonal Contraception Pilot service

Pharmacists participating in the Hormonal Contraception Pilot may provide a service for hormonal contraception in line with the Hormonal Contraception - Clinical Practice Guideline which is located on the Queensland Community Pharmacy Pilots website. The service includes:

- patient history taking, including a sexual and reproductive history.
- screening and identification of relevant patient-risk factors.
- assessing of the patient's contraceptive and sexual health needs.

- development of a hormonal contraception and sexual health plan in collaboration with the patient, and where appropriate, prescribing of an appropriate hormonal contraceptive medicine.
- providing education and counselling.
- effective documentation.
- communication to other healthcare professionals.

The Medicines and Poisons (Medicines) Regulation 2021 and the Extended Practice Authority 'Pharmacists' (the Pharmacists EPA) provides the legislative authority for pharmacists to provide a service as part of the Hormonal Contraception Pilot. These documents are available online at the Legislation, standards and extended practice authorities site.

A participating pharmacist may prescribe hormonal contraception to a patient in accordance with the Pharmacists EPA where this is required for the management of the patient's condition. All prescribing must be completed as part of a consultation and must have a corresponding clinical record within the Pilot CIS. See Section 6.2.1 for clinical documentation for prescribing services.

When selecting hormonal contraception to manage the patient's condition, the pharmacist must choose from the classes of scheduled substances mentioned within the Pharmacists EPA in line with the current online version of the *Therapeutic Guidelines: Sexual and Reproductive Health: Contraception*. The pharmacist must consider any restrictions stated within the Hormonal Contraception Clinical Practice Guideline.

Prescriptions must be compliant with all other requirements outlined within the *Medicines and Poisons (Medicines) Regulation (2021)* and *Medicines and Poisons Act 2019*. Refer to the *Writing Lawful Prescriptions* factsheet for information.

Prescriptions for services delivered through the Hormonal Contraception Pilot will be generated from the Pilot CIS. Participating pharmacists may choose to generate an electronic or paper prescription for the patient. Hormonal Contraception Pilot prescriptions will be provided to patients and can be presented at any pharmacy to be dispensed including the pharmacy where the pilot service was delivered. For both paper and electronic prescriptions, verification of the participating pharmacist prescriber is confirmed via the eRx Script Exchange, using the barcode located on the script.

Patients prescribed hormonal contraception who may be travelling interstate should be advised that their prescription may not be able to be dispensed outside of Queensland.

The Hormonal Contraception Clinical Practice Guideline has been informed by and developed in alignment with the Therapeutic Guidelines, the Australian Medicines Handbook (AMH), and other relevant resources.

6 Clinical record keeping

Clear, thorough, and timely clinical documentation is critical to delivering and facilitating safe and quality healthcare services and is proven to improve patient outcomes by ensuring that essential information about a patient's care is available to all members of the patient's care team.

Ensuring the completeness and accuracy of documentation in the clinical record is important for good clinical communication across care providers and forms the basis of safe transitions of care between treating clinicians and with the patient and their carer/family.

Quality clinical documentation also ensures that the participating pharmacist is protected in the event of any complaint or allegation about the care provided. If the documentation is missing or incomplete, the participating pharmacist may be at risk of being unable to support their clinical decision-making or explain the action taken.

A bespoke Pilot CIS has been developed for collecting, storing, and sharing patient records. Every patient seen through the Hormonal Contraception Pilot must have a clinical record that supports effective patient care during and following the consultation and enables collaborative communication and/or referral between healthcare providers.

Participating pharmacists are required to **finalise all clinical records within 24 hours of the consultation** to ensure clarity and completeness of the clinical documentation. It is important to avoid saving clinical records as drafts, as this helps maintain quality and safety standards for the Hormonal Contraception Pilot. In addition, **draft records may not be compliant with professional and legal requirements**. Pharmacists should implement a process to review and finalise clinical records at the end of each day.

High-quality clinical documentation should be informed by the principles outlined in Table 2 which have been adapted from the *Australian Commission on Safety and Quality in Healthcare*.

Table 2: Principles of high-quality clinical documentation

Principle	Outcome
Person-centred	• The patient's goals for their care are reflected in the care provided. • Documentation is tailored to the care needs of the patient, taking into consideration what practical information is needed to support safe care.
Compliant	• Privacy and confidentiality requirements are met.

	• Patient consent documentation requirements are met. • Standardised terminology and approved abbreviations are used for both general health terms and medications.
Complete, accurate and readable	• Relevant information is captured, including clinical history, treatment plan and information and advice (including communication with other healthcare practitioners). • Documentation is accurate, objective and shows respect for the patient. • Documentation can be understood by other health practitioners. This includes the patient's management plan and any other details in the clinical record necessary to facilitate continuity of care.
Integrated and up to date	• Relevant information is shared with other health practitioners securely and in a timely manner. • Consultation summary documentation is provided to the patient where relevant. • Information is up to date. Clinical records, consultation summaries and referrals are completed contemporaneously with the consultation.
Accessible	• The needs and capabilities of those who will use the information are considered, including language barriers. This may include the patient and their family and/or carer. • Documents are available to patients and clinicians that need them, when they need them (physical accessibility).

6.1 Data privacy

Participating pharmacists are required to comply with *Queensland health record legislation*, to ensure that clinical records are held securely and that unauthorised access to such records is prevented, including protecting the privacy and integrity of electronic records. Participating pharmacists must also comply with relevant State and Commonwealth legislation and guidelines pertaining to the privacy and confidentiality of personal information.

Pharmacy staff must also recognise that patients have a right to access information contained within their clinical record and should facilitate access to the required information in a timely manner where appropriate.

It is a pharmacy owner's responsibility to ensure that all participating pharmacists and pharmacy staff uphold the privacy and confidentiality of collected and stored data and ensure

that only authorised staff have the ability to view, input, amend and distribute clinical information collected as part of a Hormonal Contraception Pilot consultation.

6.2 Patient clinical record

The patient clinical record will include general administrative, patient-specific and consultation specific information that is taken prior to, during and following consultation.

Patient clinical records must be contained within the Pilot CIS. In the event that the Pilot CIS is unavailable due to unexpected system downtime, a paper clinical record should be used. A template that can be used for this purpose has been included at Appendix A: Paper clinical record.

It should be noted that in the event of the Pilot CIS being unavailable, participating pharmacists will not be able to generate Hormonal Contraception Pilot prescriptions.

6.2.1 Clinical documentation for prescribing services

Participating pharmacists are required to complete a clinical record where a consultation is provided. A comprehensive clinical record is required to detail the following information:

- the patient's personal details including their name and address
- a record of the patient's financial, clinical and evaluation consent
- a comprehensive history, including reproductive and sexual history
- details of the assessment conducted, including examinations and measurements
- any diagnosis or working diagnosis made.
- the contraception and sexual health management plan, including therapeutic and non-therapeutic management
- all referrals or notifications made to other healthcare professionals
- any plans made for clinical review and follow-up with the patient.

Table 3 provides an example clinical consultation record for a general consultation for a patient requesting a prescription for hormonal contraception.

Table 3: Example clinical consultation record for a general consultation

Field	Example information
Past medical history	Nil.
Past surgical history	C-Section 2023.

Field	Example information
Medication history	Nil current regular medicines. Has previously used Yaz (Ethinylestradiol/Drospirenone) and Implanon prior to first pregnancy.
Allergies and adverse reactions	Amoxicillin - Hives (from childhood).
Smoking, alcohol and recreational drugs history	Nil smoking. Infrequent alcohol 2-3 standards per week.
Relevant family history	Nil significant family history including clotting disorders.
Obstetric history	3 pregnancies, 2 births (2020 and 2023), 1 termination (2018). Up to date with screening. 4 months postpartum, currently breastfeeding.
Relevant sexual activity	Married, single partner for 6+ years. Previously taken OCP before transitioning to Implanon (removed 2019). Barrier method used since 2020.
Relevant work, hobbies and other information	Mother of 2 children. Working part time.
New service/follow-up	New service.
Presenting symptom	Contraception oral.
Subjective assessment	Requested prescription for hormonal contraception. No issues reported with previous contraception medicines used (Implanon/Yas). Currently breastfeeding, intending to continue for approx. 3 months. Reports normal menstrual cycle, restarted 4 months postpartum, nil heavy/irregular bleeding. No signs of androgenisation/hirsutism. Can exclude pregnancy. Last period 2/52 and has reliably used barrier method since. No other signs and symptoms. Nil reported Hx of STIs. Nil other genitourinary symptoms present. Low STI risk.
Objective assessment (including measurements)	Conducted measurements as follows: Weight: 73kg Height: 173cm BMI: 24.4 Blood pressure: 126/73 mmHg.
Diagnosis	Hormonal contraception service
Treatment and plan	Discussed hormonal contraception options while breastfeeding. Patient would prefer to commence POP and reassess options at the next appointment.

Field	Example information
	Prescribed levonorgestrel 30microg tablets - Take 1 tablet at the same time each day (qty 112), nil repeats. Discussed the importance of taking the same time each day, use of barrier method until effective, management of missed doses and the expected side effects. Reminded patient of recommended sexual health screening.
Follow-up/clinical review	Clinical review booked for 3 months. Consult summary to GP.

7 Professional communication

7.1 Consultation summary

Timely and comprehensive sharing of information with other members of the patient's health care team is critical for ensuring continuity of safe and high-quality care for the patient and supports reduction in duplication of tests and investigations.

Following a consultation, a consultation summary should be provided to the patient and, with patient consent, electronically shared with the patient's usual GP or care provider(s) via secure messaging within the Pilot CIS. Where this is not possible, alternative secure transfer of patient information may be used. Ideally, this communication should occur within 48 hours of the consultation.

Where a GP or usual care provider is not nominated, the patient should be provided with a digital or hardcopy of the consultation summary to be given to the care practitioner of their choice.

The consultation summary can be generated within the Pilot CIS and must include relevant details including personal and clinical patient information, relevant history, presenting symptoms, information on the treatment plan and advice on ongoing care and management of the patient.

7.2 Referrals

Patients accessing pilot services may require referral to other healthcare providers for further investigation, treatment or management including collaborative management. The Hormonal Contraception Clinical Practice Guideline provides guidance and criteria to aid clinical decision-making in determining when a patient may require a referral.

A referral may occur concurrently with commencement and/or ongoing management of the patient by the participating pharmacist. Alternatively, a referral may result in the transfer of care for the patient to another healthcare provider. Timely and comprehensive referrals are critical to ensuring continuity of safe and high-quality care for the patient.

A copy of the referral should be shared with the patient. Where possible referrals should be sent to the nominated provider via secure messaging within the Pilot CIS. Where this is not possible, alternative secure transfer of patient information may be used. Where a usual care provider is not nominated, the patient should be provided with a digital or hardcopy of the referral to be given to the care practitioner of their choice.

Where the clinical practice guideline requires a referral to be made, the participating pharmacist must ensure that a written referral is provided to the patient and/or their designated primary care provider.

The referral/s can be generated within the Pilot CIS and must include patient identification details, referring practitioner details, relevant clinical information about the condition, treatment provided including any medication prescribed or changed and the reason for the referral.

8 Clinical incident and feedback management

Ensuring that lessons learned are captured, communicated, and applied is an important part of creating a system that enables continuous improvement and informs better clinical practice and service delivery. This includes having a culture that encourages patients and staff to report incidents and share learnings.

8.1 Feedback and incident reporting

Feedback from participating pharmacists, pharmacy staff, health practitioners and consumers regarding their experience of the Hormonal Contraception Pilot is strongly encouraged to support continuous improvement of pilot service delivery. The Queensland Community Pharmacy Pilots Quality and Safety Framework articulates a systems approach to understanding and analysing clinical incidents.

A process for monitoring and maintaining an effective feedback and incident management system within the Hormonal Contraception Pilot has been developed to provide an accessible, responsive, and fair process for consumers, providers and all stakeholders involved.

The Queensland Community Pharmacy Pilot online feedback and incident form, located on the Queensland Community Pharmacy Pilots website, has been designed for consumers and stakeholders to provide general feedback, report a clinical incident, give a compliment, or make a suggestion for improvement. Complaints and incidents are also able to be reported via the Office of the Health Ombudsman (OHO) and the Australian Health Practitioners Regulation Agency (Ahpra).

This online feedback and incident reporting mechanism is in addition to existing business as usual feedback and incident management policies and processes for the pharmacy.

The process for participating pharmacist and/or pharmacy owners to report feedback or incidents are outlined below in Section 9.2.3.

The Pilot Coordination Team will register submissions received via the online feedback and incident form or via email into a central register where they will be triaged, reviewed and then referred and managed through the appropriate avenue.

Through the triage and review processes, submissions will be categorised as:

- Compliments – are communicated back to the participating pharmacist where relevant and noted in reporting.
- Suggestions for improvement – are assessed for potential improvements for the Hormonal Contraception Pilot, and/or communicated back to the pharmacist if relevant.

- Complaints – are referred (if appropriate) to the relevant participating pharmacist for management via local policies and processes. Depending on the nature of the complaint, it may also be referred through other quality and safety pathways for action and resolution, including to the Queensland Community Pharmacy Pilots Quality and Safety Subcommittee.

- Clinical incidents – are managed through the appropriate quality and safety pathway, depending on the nature of the incident. This may include referral to the Queensland Community Pharmacy Pilots Quality and Safety Subcommittee or to the OHO.

All feedback and incident reports are used to inform quality and safety management and reporting and continual quality improvement processes, as well as to inform the evaluation of the Hormonal Contraception Pilot.

9 Pilot administration and support

The Pilot Coordination Team provides support to participating pharmacists and pharmacies and ensures that reporting requirements for the Hormonal Contraception Pilot are met.

In addition to providing support for Hormonal Contraception Pilot related queries and questions, the Pilot Coordination Team is responsible for conducting the Check-in process and maintaining up to date information on the Queensland Community Pharmacy Pilots website.

The sections below provide an overview of what support to expect and the resources available to pharmacies and pharmacists for the duration of the Hormonal Contraception Pilot.

9.1 Contraception Pilot Check-in process

The approach to conducting the Check-in process aims to create minimal workload for pharmacies and pharmacists while ensuring a regular and comprehensive assessment of compliance with service delivery and operational requirements. There are several components to the Check-in process for both participating pharmacists and pharmacy owners that are highlighted below in Table 4.

Table 4: Stages of the Check-in process

Stage	Description	What should you expect
Selection and notification	Hormonal Contraception Check-in assessments are conducted on a monthly cadence, whereby each pharmacy will become eligible to participate in the Check-in process for the Hormonal Contraception Pilot 1 month following authorisation.	As part of this process, the pharmacy owner and participating pharmacists will receive a notification email that the pharmacy has been selected. The email will invite you to work with the Pilot Coordination Team to find a suitable time to conduct the Check-in conversation. Within the notification email, you will be provided with a link to the **Pilot evaluation survey** for completion and requested to provide an **image/s of your private consultation room.**
Compliance check	A review will be undertaken to ensure that the participation	This will be done as pre-work by the Pilot Coordination

	requirements continue to be met, including having a private consultation room and AHPRA registrations.	Team ahead of the Check-in conversation.
Patient record auditing	A sample of patient records will be selected to be reviewed for alignment with the clinical practice guideline and completeness of the clinical record.	The outcome of the patient record audit will be included in your post-check-in summary.
Check-in conversation	Check-in conversations provide a proactive approach to understanding the operational impacts, challenges and experience of delivering pilot services.	These sessions will be scheduled for approximately 30 minutes and will be either through teams or in-person with a member of the Pilot Coordination Team. A number of key questions and items will be discussed during the Check-ins, to understand if you have any concerns or require any additional support.
Post-Check-in summary	A summary of the Check-in will be generated for each pharmacy.	You will receive a copy of the summary through email and will have the opportunity to clarify or discuss any component of the summary with the Pilot Coordination Team.

9.2 Pilot website

A Queensland Community Pharmacy Pilots website has been established to assist with the management of information and resources. The Queensland Community Pharmacy Pilots website provides access to the registration process and a range of pilot resources.

9.2.1 Registration process

A Registration Information Pack has been developed to support pharmacy owners in completing the registration process. This document outlines what is involved in completing the registration form, details the information that will be requested as part of the registration process and answers a number of frequently asked questions.

Pharmacists wishing to participate in the Hormonal Contraception Pilot should work with the relevant pharmacy owner to confirm adherence to the participation requirements and to complete the registration process.

9.2.2 Accessing Hormonal Contraception Pilot resources

Pilot resources that have been developed to assist with the delivery of pilot services are located on the Queensland Community Pharmacy Pilots. It is important to note that printed versions of these documents are uncontrolled and that documents located on the website may be updated throughout the Hormonal Contraception Pilot.

Resources that are available on the Queensland Community Pharmacy Pilots website include:

- The Hormonal Contraception Pilot Handbook (this document)
- The Hormonal Contraception Clinical Practice Guideline
- In-store promotional resources
- Queensland Community Pharmacy Pilots Registration Information Pack
- The clinical and financial consent information sheet.

9.2.3 Reporting a clinical incident

Participating pharmacists and/or pharmacy owners are required to report the following via email to the PCT at qld-pharmacyscopepilot@health.qld.gov.au:

- all clinical incidents relating to the Pilot that are reported to a pharmacist's indemnity insurer; and
- any instances where the OHO or Ahpra are investigating a clinical incident or complaint about a Hormonal Contraception Pilot service.

Reporting of clinical incidents via email to qld-pharmacyscopepilot@health.qld.gov.au is essential to ensure central visibility of all clinical incidents relating to the Hormonal Contraception Pilot.

9.2.4 Participating Pharmacies look-up directory

The 'Pilot pharmacy look up directory' is an online tool that allows consumers to search for pharmacies that are taking part in the Hormonal Contraception Pilot. This directory is located on the Queensland Community Pharmacy Pilots website.

The Participating pharmcies look-up directory includes a phone number and address of the pharmacy, and a link to the Hormonal Contraception Pilot booking portal for that pharmacy, if provided through the registration process. If a pharmacy owner wishes to update the

phone number and address that is displayed on the Participating pharmacies look-up directory, they can contact the Pilot Coordination Team via email to qld-pharmacyscopepilot@health.qld.gov.au.

Pharmacists are responsible for reporting all changes to participation for the duration of the Hormonal Contraception Pilot. If a participating pharmacist stops providing Hormonal Contraception Pilot services, it is the responsibility of the pharmacist to report this to the Pilot Coordination Team via email to qld-pharmacyscopepilot@health.qld.gov.au. This is important so that pharmacies who do not have pharmacists who are authorised to provide pilot services do not appear in the Participating pharmacies Pilot look-up directory.

9.3 Key contacts

There are a number of key contacts available for participating pharmacists to access support throughout the delivery of pilot services (see Table 5).

Table 5: Key contacts for pilot service-related queries and issues

Contact	Key Contact	Contact Details	Support Provided
Queensland Health	Pilot Coordination Team	E: qld-pharmacyscopepilot@health.qld.gov.au	Primary point of contact for queries and requesting further information.
Clinical Information System provider	MedAdvisor Qld support	P: 1300 909 917	Technical support with the booking system and Pilot CIS used for pilot services.
Pilot evaluation team	Pilot Evaluation Team	E: QCPSPPevaluation@deloitte.com.au P: (07) 3003 8230	Primary point of contact for questions relating to the evaluation and ongoing monitoring of the Pilot.

10 Evaluation

Queensland Health has commissioned an external evaluation of the Hormonal Contraception Pilot. The evaluation is being conducted by an external evaluation team (Deloitte in partnership with Griffith University academics). The evaluation has received ethical approval through Griffith University's Human Research Ethics Committee.

This mixed-methods evaluation will collect and analyse data from a range of sources, including activity and administrative records and additional data collected from all stakeholders involved in the delivery of the Hormonal Contraception Pilot. Stakeholders include participating pharmacists, patients, other healthcare practitioners, and other relevant stakeholders (e.g., peak bodies, government, and consumer representative groups).

The following section provides an overview of the additional data that is collected by the evaluation team from pharmacists and patients who choose to participate in the evaluation activities.

All data collected for the evaluation is kept private and stored in secure online environments, held by Deloitte and Griffith University. This information is only accessible to the evaluation team. More information about risks, privacy, and data storage is outlined in the evaluation consent information sheet which is located on the Queensland Community Pharmacy Pilots website.

There are a range of other stakeholders who may be consulted as part of the evaluation (see Table 6).

Table 6: Consultations for other stakeholders

Group	Purpose
Other Healthcare Practitioner Survey	To collect information about their experience of the Contraception Pilot.
Other key stakeholder consultations	To collect insights from other key stakeholders, including peak bodies, and other representative groups.

If you have any questions about evaluation activities, please contact the evaluation team directly using the details provided in Section 9.3.

10.1 Evaluation data collection – pharmacists and pharmacy owners/managers

There are a number of opportunities for participating pharmacists to contribute their views about the Hormonal Contraception Pilot to the evaluation team. These are outlined in Table 7 which describes the purpose and timeframe of each evaluation activity.

While participating pharmacists, pharmacy owners and other pharmacy staff will be invited to complete all of the following evaluation activities, you can choose whether or not to participate in one or all of these evaluation activities.

Table 7: List of pharmacist evaluation activities

Evaluation activity	Purpose	Timeframe
Post Training survey	To collect data about to what extent the training was a barrier or enabler to delivery of pilot services and participating pharmacist's experiences of training.	Six weeks after authorisation to commence pilot services.
Pharmacy Pilot survey	To collect data about participating pharmacist's experiences with the delivery of pilot services.	Surveys will be sent as part of the Check-in process.
Option for follow up interviews/focus groups	An optional interview with the evaluation team to provide further feedback about experiences participating in the Hormonal Contraception Pilot. Participating pharmacists can express interest in these follow-ups by indicating their interest as part of the Pharmacist Pilot survey.	Interviews will be offered after the Pharmacy Pilot survey.
Formal withdrawal survey	Captures participating pharmacists' self-reported reasons for withdrawing from the Hormonal Contraception Pilot (or from Contraception Pilot training).	Once a participating pharmacist has withdrawn from the Contraception Pilot or from Contraception Pilot training.

10.2 Evaluation data collection – patients

A condition for participation in the Hormonal Contraception Pilot is that patients are required to consent to the provision of routinely collected activity data for evaluation purposes. This includes the collection and analysis of data relating to the services patients receive, along with data about a patient's health service utilisation more broadly (e.g., MBS, PBS, and hospitalisation data). The evaluation team ensures that appropriate privacy and security processes are in place to access this information, in line with ethical guidelines.

Patients will also be sent a Patient Experience Survey within seven days following each pilot service consultation. These surveys will collect information regarding the patient's experience accessing care under the Hormonal Contraception Pilot (booking, convenience, cost etc.) and the care that they received (interactions with pharmacy staff, confidence and trust and patient centred care). Patients will also be able to provide further feedback and insights about the pilot services through the opportunity to participate in other evaluation activities.

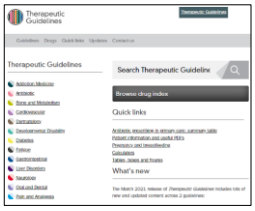
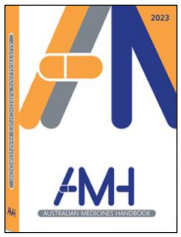
11 Key documents and resources

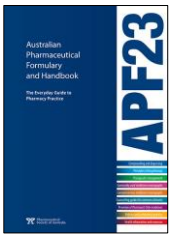
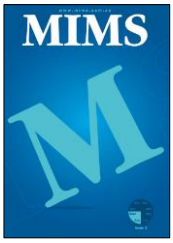
The delivery of pilot services is supported by key documents and resources which can be used by participating pharmacies and pharmacists to support effective and high-quality service delivery.

In addition, there are a number of resources that have been used to inform the Hormonal Contraception Pilot Clinical Practice Guidelines and may be useful to reference throughout pilot service delivery.

These resources are summarised in Table 8.

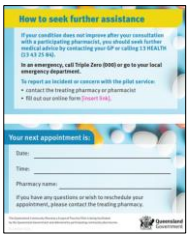
Table 8: Key resources and documents

Resource	Description
	Relevant Queensland Legislation Medicines and Poisons (Medicines) Regulation 2021 Extended Practice Authority – "Pharmacists"
	**Hormonal Contraception Clinical Practice Guideline** The clinical practice guideline guides participating pharmacists' management of the hormonal contraception service. This includes detailing the parameters of the intervention or service.
	**Therapeutic Guidelines** The Therapeutic Guidelines is an online data base that provides practical treatment advice to assist practitioners with decision making at the point-of-care.
	**Australian Medicines Handbook and the AMH Children's Dosing Companion** The AMH is an independent, evidence-based, national drug reference, for health practitioners concerned with the quality use of medicines.

Resource	Description
	**Australian Pharmaceutical Formulary and Handbook (APF)** The APF contains information related to medicines, medicines safety, good dispensing practice, complementary medicines, drug interactions, managing missed doses of contraceptives, wound management and laboratory tests used in clinical practice.
	**Monthly Index of Medical Specialities (MIMS) Australia** MIMS is an online database that provides comprehensive and trusted medicines information to Australian health care professionals.

The resources developed to support and effectively inform consumers on the services available as part of the Queensland Community Pharmacy Pilots are listed in Table 9. Digital versions of these resources are available on the Queensland Community Pharmacy website.

Table 9: Consumer resources

Resource	Description
	**Pilot appointment card** The Pilot appointment card provides succinct and clear information on how to seek further assistance as well as giving patients a physical option for pharmacy staff to record details of their next Pilot service appointment.
	**Pharmacy posters** Pharmacy posters provide simple, succinct, and clear information on what the Pilot is, the services provided and associated costs. The poster is recommended to be used as external signage and throughout the pharmacy.
	**Clinical and financial consent information sheet** The clinical and financial consent information sheet provides information about what constitutes clinical and financial consent, and what information the patient should understand prior to providing clinical and financial consent.

Resource	Description
	**Evaluation consent information sheet** The evaluation consent information sheet provides information about the evaluation process and the evaluation activities patients will be required to participate in as part of accessing a pilot service.

Appendix A: Paper clinical record

Please note that this paper clinical record is only to be used in the absence of the Pilot Clinical Information System (CIS). All details must be entered into the Pilot CIS when available and this paper patient clinical record must be appropriately destroyed.

An editable version of this form is available on the Queensland Community Pharmacy Pilots website.

Consultation Date:	Pharmacist:	Does the patient still consent: Y/N

Patient information:

First name:	Last name:	Date of Birth:	Sex assigned at birth:
Address:	Suburb:	State:	Post code:
Medicare number: □□□□□□□□□□/□□/□□		Medicare expiry:	
Mobile number:		Email:	

Emergency contact:

First name:	Last name:	Relationship:	Contact Number:

Medical and social history:

Past medical history:

Past surgical history:

Allergies and known adverse medication reactions:

Current medications:

Clinical service:

New or follow-up service:

Presenting symptoms:

Subjective assessment:	Objective assessment:

Measures (observations):				
Weight (kg):	Height (cm):	BMI (KG/M2):	Waist circumference:	Temperature:
Systolic blood pressure (mmHg):	Diastolic blood pressure (mmHg):	Heart rate (beats/min):	O2 saturation (%):	

Measures (respiratory function):					
FEV1 (in litres):	FVC (in litres):	FEV:FVC ratio (%):	PEF (L/min):	Asthma control test (5-25):	COPD Assessment test (0-40):

Measures (lipid profile):			
Total cholesterol (mmol/L):	HDL-C (mmol/L):	LDL-C (mmol/L):	Triglycerides (mmol/L):

Measures (glycaemic control):					
hbA1c (mmol/mol):	HbA1c (%):	Blood glucose-Fasting (mmol/L):	Blood glucose- 1 hour post OGTT (mmol/L):	Blood glucose- 2 hour post OGTT (mmol/L):	Blood glucose-Random (mmol/L):

Measures (renal measures):			
Creatinine (urinary) mmol/L:	Albumin (urinary) g/L:	Urinary Albumin-to-Creatinine Ratio (uACR) (mg/g):	Egfr (mL/min/1.72m2):

Pathology:	
Pathology required: Y/N	Pathology test(s) ordered:

Clinical service:
Diagnosis:
Treatment:

Consultation outcome:					
Consultation length: Brief, standard, long		Clinical service type:			
Prescribed Pilot medication:	☐	OTC treatment:	☐	Non-pharmacological management:	☐
Counselling and education:	☐	No intervention:	☐	Other (please specify):	

Appendix B: Evaluation consent checklist

Patient consent will be confirmed by participating pharmacists during patient visits. This will occur at the beginning of a consultation. It is important that participating pharmacists understand that this means they are confirming that patients consent to the following declarations (see Table 10).

Please see the link to the full evaluation consent information sheet. A printed copy could be useful to show patients at the point of collecting evaluation consent.

Table 10: Points for patient consent declaration

Patient consent check points
I understand that the evaluation will include the analysis of my Pharmacy activity data;
I agree that all of my questions related to the pilots and the evaluation have been answered to my satisfaction;
I understand the risks involved;
I understand that there will be no direct benefit to me from my participation in this research;
I understand that my participation in the pilots is voluntary;
I understand that my participation in this research will not be disclosed to anyone outside the independent evaluation team;
I understand that if I do choose to participate or not to participate in follow-up evaluation activities (e.g., survey or interviews), it will have no effect on my relationship with Queensland Health, Deloitte, Griffith University, or any health service provider;
I understand that if I have any additional questions, I can contact the research team;
I understand that I can contact the Manager, Research Ethics, at Griffith University Human Research Ethics Committee if I have any concerns about the ethical conduct of the project; and
I agree to participate in the pilots and agree to: • Being contacted to participate in surveys regarding the pilots • My administrative health service data to be analysed for evaluation purposes.

Glossary

Table 11: Glossary

Acronym	Description
Ahpra	Australian Health Practitioners Regulation Agency
AMH	Australian Medicines Handbook
EPA	Extended Practice Authority
GP	General Practitioners
MBS	Medical Benefits Scheme
MIMS	Monthly Index of Medical Specialties
OHO	Office of the Health Ombudsman
PBS	Pharmaceutical Benefits Scheme
Pilot CIS	Pilot Clinical Information System
QCPP	Quality Care Pharmacy Program