



Guidelines for pharmacists providing dose administration aid services

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Executive summary

These Guidelines provide pharmacists with best practice guidance for the delivery of medication adherence services; Dose Administration Aid (DAA) and Staged Supply and medication management services; MedsCheck and Diabetes MedsCheck and Home Medicines Review (HMR).

These are patient-centred clinical services delivered with the aim of improving medicine safety and the quality use of medicines. They integrate with other patient-centred services to enhance a patient's optimal use of medicines. Pharmacists can provide these services to any patient based on their clinical need.

Services provided to eligible patients can be remunerated under the Seventh Community Pharmacy Agreement (7CPA) or the Department of Veteran's Affairs (DVA) DAA service, if pharmacists adhere to the relevant program rules. A summary of these rules can be found throughout this document in the orange and blue boxes respectively. Pharmacists should use these guidelines in conjunction with program rules and resources at www.ppaonline.com.au and www.dva.gov.au.

The delivery of these services encourages pharmacists to work collaboratively with the patient and their carer, prescriber, and other relevant members of the healthcare team to enhance patient care.

Best practice for the delivery of these programs includes:

- establishing patient need
- obtaining patient consent
- ensuring patient safety
- promoting quality use of medicines.

These Guidelines do not replace the need for pharmacists to exercise professional discretion and judgement when delivering these programs in their own unique practice environment. These Guidelines do not include clinical information or detailed legislative requirements. At all times, pharmacists delivering these programs must comply with all relevant Commonwealth, State and Territory legislation, as well as to the overarching and program-specific standards, codes, and rules (see Figure 1).

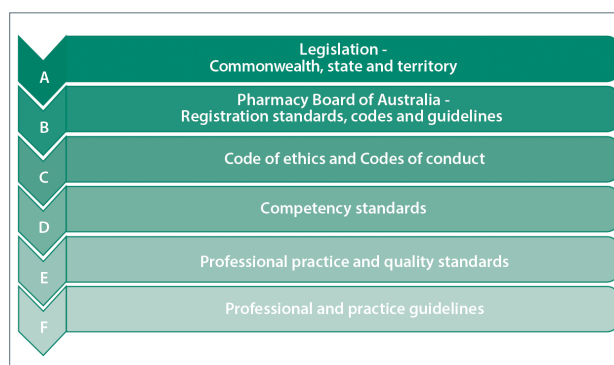


Figure 1. Overarching guidance and regulation of pharmacy service delivery¹

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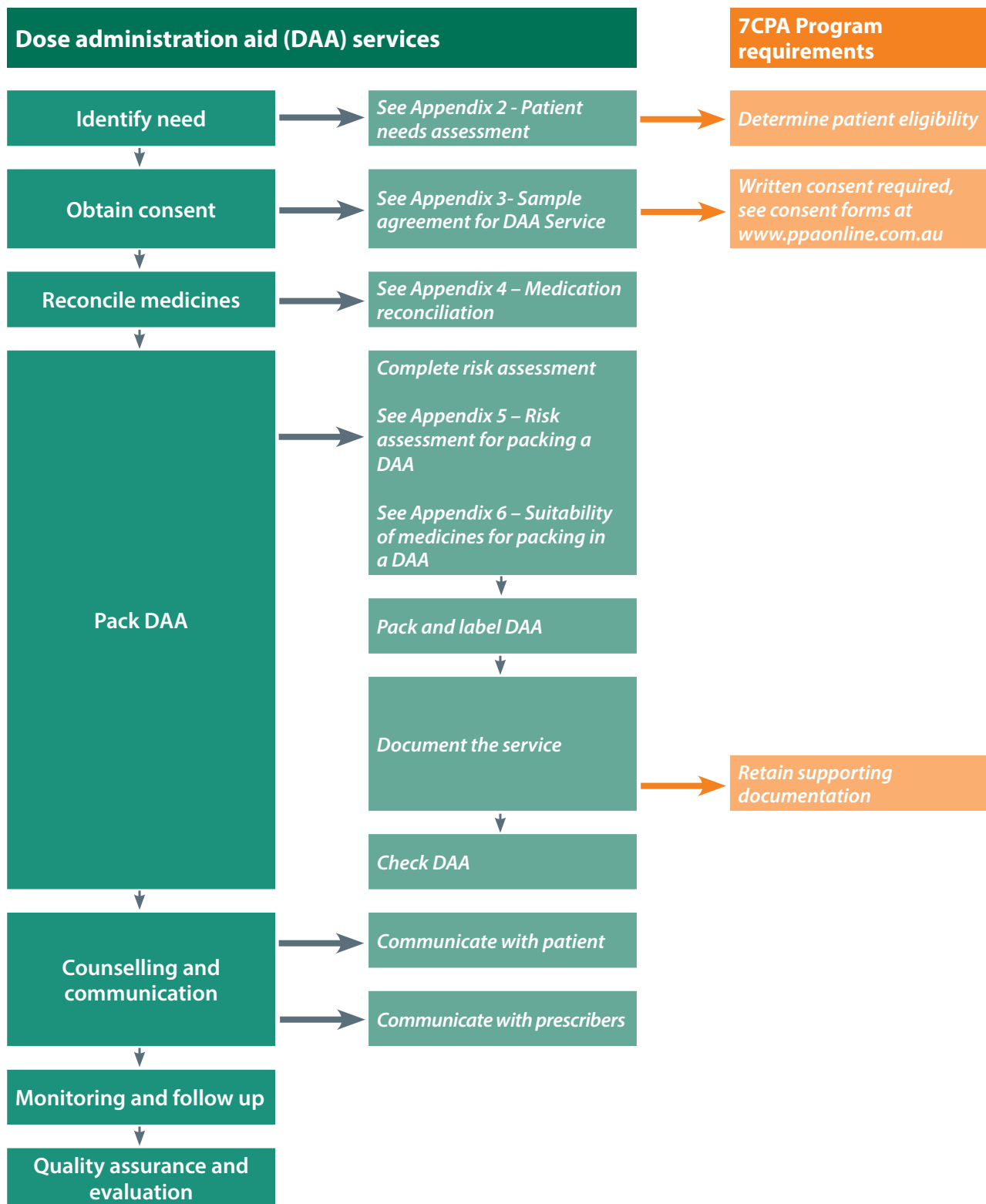
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Service overview



Introduction

A DAA service aims to promote medicine safety and the quality use of medicines by improving adherence and medication management, and reducing medication misadventure. A DAA is a device that can be used as part of a coordinated approach to medication management. By using a DAA, patients can receive the correct medicine, at the correct dose and time, in a safe and hygienic manner.

The provision of a DAA forms part of the medication management pathway, supporting safer care at both the distribution and administration steps of the pathway for certain patients.² DAAs are not suitable for all patients, and do not overcome all barriers to optimal medicines management.^{3,4}

The provision of a DAA is a clinical service, and not simply a supply function. Patient safety is paramount; pharmacists providing DAA services must follow robust processes that meet relevant professional practice standards.¹

During this service, pharmacists should refer patients to other appropriate clinical services i.e. MedsCheck, Diabetes MedsCheck, Home Medicines Review (HMR), staged supply, Residential Medication Management Review (RMMR), if identified as necessary for continuation of patient care (see Figure 2).

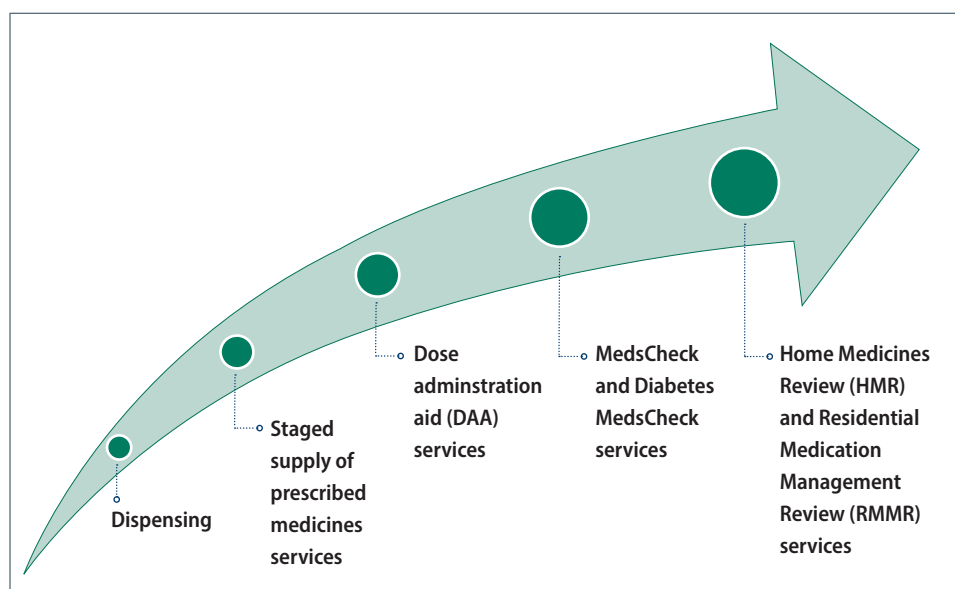


Figure 2. Medication management services across the continuum of patient care

Terminology

For a number of terms used in these guidelines, several related terms with equivalent or similar meaning may be equally appropriate in certain contexts (see Table 1).

Table 1. Guideline terms, definitions and equivalent or related terms		
GUIDELINE TERM	DEFINITION	EQUIVALENT OR RELATED TERMS
Adherence	A qualitative measure of the extent to which a patient's behaviour corresponds with the recommendations agreed with a healthcare provider, ideally through a concordant approach ¹	Compliance, concordance
Automated dose-packaging system	A computerised and automated system that execute tasks such as medicine counting, packing into sachets, labelling and electronic documentation	Semi-automated dose-packaging system
Carer	An individual responsible for, or taking part in, the provision of care for another person through either a formal or informal arrangement ⁵	Agent, authorised representative, case worker, guardian
Controlled drug	A medicine listed in schedule 8 of the SUSMP	Schedule 8 medicine, schedule 8 poison
Dose administration aid (DAA)	A tamper-evident, well-sealed device or packaging system that allows for organising doses of medicine according to the time of administration ¹	Blister pack, bubble pack, medicine sachet
DAA medication profile	A document prepared by a pharmacist which sets out information relating to the patient (e.g. age, allergies, comorbidities) and their current medication regimen, including medicines that are not packed in the DAA	Medicines list, medication profile, medication record
Healthcare provider	A practitioner who provides services to individuals or communities to promote, maintain, monitor or restore health (such as a general practitioner, dentist, physiotherapist or case worker) ¹	Health professional, healthcare practitioner, healthcare professional
Informed patient consent	The patient agrees to a healthcare provider providing treatment and care after receiving understandable and clear information including the options, risks, benefits and purpose of the action ⁶	Consent
Medicine	A prescription, non-prescription, or complementary or alternative medicine	Drug, medication, product
MedsIndex	A score reflecting how closely patient adhere to their medication regimen	N/A
My Health Record	An electronic summary of a person's health information maintained by the Australian Government ⁷	Digital health record, eHealth record
Patient	A person who uses, or is a potential user of, health services, including their family and carers ¹	Client, consumer, individual, person
Pharmacist	An individual holding provisional or general registration with the Pharmacy Board of Australia, as recorded on the online Register of practitioners on the Australian Health Practitioner Regulation Agency (AHPRA) website. A pharmacist holding provisional registration must be supervised by a pharmacist holding general registration at all times in the pharmacy ⁸	Intern, registered pharmacist
Prescriber	A health provider who is responsible for patient care, specifically medicines	Doctor, general practitioner (GP), nurse practitioner, other approved prescribers, specialist
Stability	The extent to which a medicine retains the drug substance content, and drug product properties and characteristics that it possessed at the time of its manufacture within specified limits and throughout the storage and use (i.e. its shelf life) ⁹	N/A

Establishing the service

Policies and procedures

Pharmacists should establish policies and procedures to govern the provision of DAA services. They must adhere to all legislative requirements, and meet relevant professional practice standards. See *Standard 15: Dose Administration Aid Service in Professional Practice Standards, version 5*.¹

Policies and procedures should be systematically reviewed and updated as required as part of quality assurance and evaluation process. See *Quality assurance and evaluation*.

Preparation area

All DAA should be packed in a dedicated area of the pharmacy, or an area outside the pharmacy that meets pharmacy registering authority requirements. The preparation area should provide sufficient space to pack DAAs, have good lighting, and be clean, tidy and orderly.

The preparation area must not be accessible to the public, and must offer freedom from interruption during the packing process.¹⁰

Selecting a DAA system

A DAA must be capable of providing the correct medicine, at the correct dose and time, in a safe and hygienic manner. A DAA may be in the form of either:

- unit-dose packing (where the dose [single or multiple units] of a single type of medicine is packed in each compartment, blister or sachet)
- multi-dose packing (where doses of more than one medicine can be packed in one compartment, blister or sachet).

Ideal features of a DAA system are outlined in Box 1.

Automated dose-packaging systems are available to pack DAA. See *Appendix 1 - Automated dose-packaging technology* for requirements of these systems.

All DAA packing systems, including automated dose-packaging technology, must meet relevant professional practice standards.

Training

All staff involved in providing a DAA service must have training and practical experience relevant to their role and the packing system used. Due to the role requirement of handling medications and prescriptions, as well as technical nature of processing DAA devices, this training should be similar to that of a dispensary technician.

Staff should understand their role and responsibilities in the delivery of the DAA service, and the policies and procedures used.¹

Training, and assessment through supervised practice, should be recorded (e.g. in a personal training record, or manual).

Patient privacy

Pharmacists must respect and safeguard patient privacy and confidentiality at all times, including in relation to any information acquired when providing DAA services. This applies to interactions with the patient in the pharmacy, as well as the proper handling of healthcare records.¹ Pharmacists must meet the relevant *Professional Practice Standard (1.3 Privacy and Confidentiality)* in the provision of a DAA service.

Box 1. Features of an ideal DAA system

- Easy to use with clear and complete labelling and instructions for when medicines should be taken
- Enables medicines to be set out in a manner appropriate for the prescribed dosing schedule
- Secures the medicine from moisture and contamination
- Be easily accessed by the patient
- Limits ready access by children
- Includes labelling that identifies all individual medicines packed in the DAA
- Includes patient information about how to administer medicines not packed in the DAA
- Provides a structure capable of maintaining the integrity of medicine (during transport, storage, regular distribution and the potential for accidents such as being dropped)
- Supports a mechanism, or a system, that can show evidence of tampering

Providing the service

Identify need

The need for a DAA can be identified by the prescriber, pharmacist, patient/carer, or by another healthcare provider.

There is no single set of criteria for identifying patients likely to benefit from a DAA. Some patients on one regular medicine may benefit from the use of a DAA, while others taking a large number of medicines may have no problems managing their medicines.

A DAA is likely to be most effective for motivated patients who want to take their medicines, and who have adequate vision, cognition and dexterity to use the DAA, or for patients who have a carer assisting them or administering their medicines.⁴ See Box 2.

Pharmacists should undertake a needs assessment to identify any factors that may be contributing to non-adherence or medication errors, and to determine if a DAA is suitable and appropriate.³ A patient's attitude to medicine-taking and individual preferences can be useful in determining how effective a DAA is likely to be.⁴ See *Appendix 2 - Needs assessment for a DAA*.

For patients living in residential care facilities (RCF), use of a DAA may be mandated.

Box 2. Patients who may benefit from a DAA

- Patients with a medical history suggesting problems managing medicines (e.g. prior hospitalisation due to poor adherence)
- Patients who forget if they have taken their medicines, and who would benefit from a visual cue
- Patients who have a carer who monitors their medicine taking
- Patients with a complex regimen of medicines with a regular dosing schedule of solid oral dosage forms suitable for packing in a DAA
- Patients with signs of cognitive or physical impairment, which may affect their ability to effectively manage medicines (there needs to be an adequate level of cognition to manage the DAA)
- Patients taking five or more medicines daily (including non-prescription medicines)

References: Elliott¹; Stuck¹; Lecouturier²

7CPA and DVA eligibility criteria

Under 7CPA and DVA DAA programs, pharmacies may be funded for providing the service to eligible patients.^{13,14} Patients who are ineligible under these programs but who may benefit from a DAA can still be offered the service.

7CPA DAA Program patient eligibility criteria

- Medicare and/or Department of Veterans' Affairs (DVA) cardholder or a person who is eligible for a Medicare card
- Living at home in a community setting
- Current government issued concession cardholder; **and**
- Difficulties managing their medicines due to literacy or language issues, physical disability or cognitive difficulties; **or**
- Taking five or more prescription medicines and is experiencing difficulties with medication management

Note:

- A person who identifies as an Aboriginal or Torres Strait Islander person, who is eligible for a Medicare card, but who does not hold either a Medicare card or Concession card will still be eligible for this program.
- DAA services funded under 7CPA Program are not available to in-patients of public or private hospitals, Day hospital facilities, transitional care facilities, to residents of a government funded aged care facility or patients in a correctional facility.
- DAA services funded under 7CPA Program are not available to patients receiving DAA services funded under other Federal or State and Territory government programs. Claims cannot be made for DAA services provided as part of the DVA DAA service or the 7CPA QUMAX program.

Reference: 7CPA Program Rules¹³

DVA DAA Program patient eligibility criteria

- Gold, White or Orange DVA Health Card holder
- Living in the community and not in a residential care facility, or hospital
- Assessed by a GP or pharmacist as likely to benefit from a DAA service
- Eligible for a Home Medicines Review
- Using medicines that are suited to a DAA
- Have authority prescriptions for the DAA and Veteran's 6-monthly review

Note: Patients must consent to the sharing of information about their use of the DAA service, and to the collection and provision to DVA of data arising from the service.

Reference: DVA DAA¹⁴

Consent

Informed patient consent must be obtained and documented prior to providing a DAA service. This may include a formal agreement between the patient and pharmacy providing the DAA service that documents the details of the service. See *Appendix 3 – Sample agreement for DAA service*.

For patient living in a RCF, consent for a DAA service may be obtained during admission.

As part of the consent process, patients may choose not to have certain medicines packed in a DAA. See *Communication with patient*.

7CPA DAA Program patient consent

Pharmacists must obtain written patient consent for DAA services provided under 7CPA. See www.ppaonline.com.au for patient consent forms

Reference: 7CPA Program Rules¹³

Medication reconciliation

Prior to packing a DAA, the pharmacist must reconcile the patient's medicine to create an accurate medication profile that includes all prescription, non-prescription and complementary and alternative medicines including those not packed (see Box 3). An HMR, RMMR, MedsCheck or other medication review service may be a valuable way to conduct this assessment.¹

Box 3. DAA Medication profile

- Brand name*
- Generic name*
- Form*
- Strength*
- Dose and dosage regimen*
- Indication and special instructions
- Dates started/duration
- Prescriber

*Required under 7CPA program rules

The medication profile should be confirmed with the prescriber, who should then be given a copy. The patient should also be provided with the medication profile, if appropriate.

Regular reconciliation is required to promote medication optimisation and ensure any subsequent changes to the patient's medication regimen are reflected in the DAA medication profile.

Pharmacists should use information from the patient's *My Health Record*, where available, to inform the reconciliation process.¹ See *Appendix 4 – Medication reconciliation* for further information.

Packing a DAA

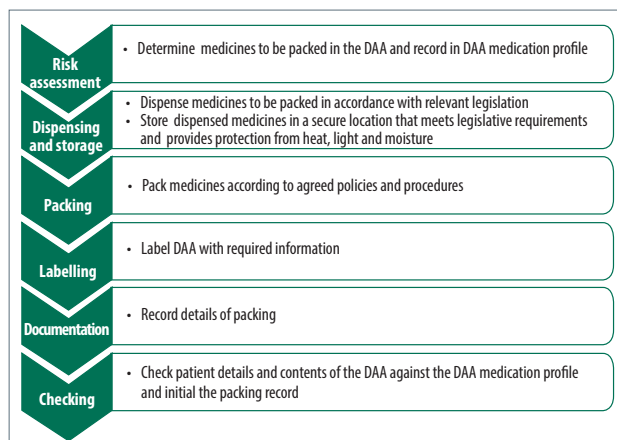


Figure 3. DAA Packing process

Risk assessment

Pharmacists should complete a risk assessment to determine what medicines are suitable for packing in a DAA. See *Appendix 5 – Risk Assessment for packing a DAA*.

There is a lack of information available on the stability of medicines stored outside of the manufacturer's original packaging. Removing medicines from original packaging for packing in a DAA is often considered an off-label use as it is not consistent with the manufacturer's approved product information.^{15,16} See *Appendix 6 – Suitability of medicines for packing in a DAA*.

Pharmacists must use professional judgement to decide which medicines should be packed in a DAA and any related actions to be taken.¹ When deciding which medicines to pack, the pharmacist must weigh the risk of potential medicine instability against the risk of non-adherence.

Details of medicines to be packed or not packed should be reflected in the DAA medication profile.¹

A list of medicines not to pack and special storage conditions for others should be maintained by the pharmacy, as part of DAA policies and procedures.

Packing

Medicines should be packed according to the DAA medication profile.¹ When packing a DAA, the number of medicines in each compartment should enable clear visibility of each item. Consideration should be given to possible physical or chemical interaction between medicines in close proximity to each other.

If using a heat-seal system, use a proprietary heat sealing device to produce a quick and reliable heat seal and minimise medicine exposure to high temperatures. Packing heat-sensitive products (e.g. capsules) at the base of the packing compartment may reduce any deleterious effect of heat sealing devices.^{9,17}

After packing, and prior to supply to the patient, the DAA should be stored in an area protected from heat, light and moisture, which meets relevant legislative requirements.¹

Staff who pack DAAs should follow appropriate hand hygiene processes (see *Appendix 7*) and not be responsible for other duties at the time of packing to minimise interruptions and packing errors.¹

Child-resistant packaging

A DAA must adhere to Therapeutic Goods Administration (TGA) child-resistant packaging requirements. Blister-sealed DAA, cold-sealed cassettes, and sachets produced by automated dose-packaging systems meet these requirements. Blisters and sachets are permitted as child-resistant packaging provided they are not formed from cellulose film or unlaminated paper. Some DAA do not meet the requirements for child-resistant packaging, including dosette-type tablet organisers (or similar devices) where lids can be easily flipped open or where lids become worn and may fall open.¹⁸

Changing a DAA

Changes to the contents of a DAA after it has been packed, other than corrections, should only occur following confirmation with the prescriber in accordance with legislation and guidelines. All changes should be documented in the DAA medication profile and be initialled by the pharmacist.¹

Professional judgement is required to determine the best way to implement changes to a DAA. This may include consideration of the urgency of the required change, and the number of packs affected.

Re-use of medicines

Any unused medicines in DAA that are returned to the pharmacy or have not been collected from the pharmacy, should be disposed of in accordance with relevant legislation and not be re-used.¹⁹ Any DAA materials should be disposed of in a way that protects a patient's privacy.¹

Pharmacists should use professional judgment to determine whether medicines supplied by the patient, hospital or other facility, should be packed into a DAA, with consideration of storage and stability, urgency of supply, patient safety, and other relevant patient factors. Medicines not in original containers or that have illegible or missing expiry dates should not be packed.¹

See *Monitoring* for action to be taken in regard to unused medicines.

Advanced packing

A DAA should be packed as close as possible to the date of use.¹ Packing DAA in advance of expected use may be associated with increased risk where subsequent changes to the patient's medication regimen are made. Pharmacists must have a system for ensuring all medication changes are incorporated into any DAA already packed.¹

Pharmacists should note that 7CPA DAA Program rules require provision of a weekly DAA service.¹³

Third-party packing

Pharmacists may engage a third-party provider (i.e. TGA licenced facility or another pharmacy) to pack DAA. The packing pharmacist at the third party packing facility is responsible for ensuring DAA are prepared in a timely and accurate manner according to the patient's current medication regimen. However, it is the supplying pharmacist who is ultimately responsible for the service. They must assess the measures, techniques and technology used by the third party packing facility to check packed DAA for accuracy, to determine whether additional checking of a DAA is required prior to its supply to a patient or their agent. A third-party provider is not permitted to provide a DAA directly to the patient.^{10,20}

The pharmacist engaging a third-party provider should ensure²⁰:

- responsibilities of each party are set out in a written agreement including dispensing, packing and urgent changes
- patient rights to privacy are understood by each party
- informed patient consent is obtained for third-party packing and documented in the service agreement
- third-party provider has access to the patient's current DAA medication profile
- patients are adequately supported to use the DAA.

Labelling

A DAA must be labelled with all required information (see Box 4).¹⁰ Consideration should be given to whether any additional information is required on the label.

It is considered best practice to include the initials of the checking pharmacist on the DAA label.

If space does not permit all required information to be included directly on the DAA, pharmacists should consider other mechanisms to ensure patients receive adequate instruction.

Box 4. DAA labelling requirements

- Patient name
- Name, address and telephone number of the pharmacy or pharmacy department who supplied the DAA
- Brand and active ingredient names, strength and form of all medicines supplied in the DAA
- Information about the colour, shape, size and manufacturer's marks for each medicine, and/or a coloured picture/photo of each medicine
- Directions for use of each medicine (including frequency and dose) in plain English (if space permits, other languages that are accurate translations of English may be used on the DAA label if beneficial for optimising the medication management of the patient)
- Date the DAA was packed and the expiry date of the DAA
- Any applicable storage instructions
- Any cautionary advisory labels (CALs) required or recommended for individual medicines¹⁶
- Date and day of the week when the DAA is to be used^{1,3}
- The words *Keep out of reach of children*
- If more than one DAA is being used, clear directions that there are more medicines in another DAA (e.g. *DAA 1 of 2*)³

Cautionary advisory labels

Relevant cautionary advisory labels (CALs), as determined by clinical assessment, should be supplied with the DAA. This can be achieved by applying CALs either directly to the DAA or on a separate document such as a DAA medication profile. Patients should be able to determine which label applies to which medicine.¹⁰ CALs required by legislation must be applied directly to the DAA.¹

See the *Australian Pharmaceutical Formulary and Handbook (APF)*¹⁶ for recommended CALs for individual medicines.

DAA expiry dates

Pharmacists should apply professional judgement, and be guided by current evidence, when deciding on appropriate expiry dates.¹ International guidance recommends that medicines should not be left in a DAA for longer than eight weeks.^{15,16} This maximum time may be reduced by the inclusion of medicines with known storage limitations (e.g. thyroxine sodium [levothyroxine sodium] tablets), or environmental conditions such as humidity.⁴ See *Appendix 6 - Suitability of medicines for packing in a DAA* for information regarding expiry dates for prn packs.

PSA is aware of the various views on the issue of assigning an expiry date to a packed DAA and will continue to monitor new information as it becomes available.

Checking

All DAA packed must be checked by a pharmacist with general registration to ensure patient details are correct and the medicines packed are consistent with the DAA medication profile. The pharmacist responsible for checking the DAA must initial the DAA packing record and should initial the DAA label. At the time of checking, the checking pharmacist should not be responsible for dispensing or undertaking other professional duties.¹

Where DAA have been packed by a third-party packing facility, the supply pharmacist retains responsibility for checking the pack.¹⁰

Documentation

A DAA patient profile (see Box 5) and records of each DAA packing (see Box 6) should be maintained for every patient.¹ *Appendix 8 - Sample record of packing dispensed medicines into a DAA* provides a template record suitable for recording DAA packing. Packing records should be retained for at least six months.¹⁰

If possible (i.e. software permitting), pharmacists should upload, and update as required, the patient's DAA medication profile in their *My Health Record* as an event summary.¹ See www.digitalhealth.gov.au/using-the-my-health-record-system/how-to-use-the-my-health-record-system/uploading-an-event-summary

Pharmacists should store all supporting documentation for audit purposes.¹ See *Quality Assurance and evaluation*.

Box 5. Information documented in DAA Patient profile

- Patient details
- Patient's current medication regimen, including all prescription and non-prescription medicines packed and not packed (DAA medication profile)
- Physical constraints of the patient that may affect their medication management abilities (e.g. impaired vision), and other medication aids that are used
- Specific prescriber requests (if any) in regard to the way the patient should take a specific medicine
- Type of DAA and packing interval
- Verification that the prescribed medicines have been checked as suitable for packing in a DAA
- Risk-benefit assessments and decisions made by the pharmacist, and the rationale upon which the decisions were made
- Date the DAA patient profile was compiled or updated/reviewed
- Records of changes that have been made, name of the person who requested the change, and initials of the pharmacist who made the change (see *Changing a DAA*)

Reference: Stokes¹⁷

Box 6. Information to include in a DAA packing record

- Patient's name and address
- Date of packing, or repacking as a result of changes
- Date of provision
- Details of the medicine provided (with cross reference to prescription numbers where appropriate) including each medicine's name, form, strength and dose
- Quantity of a patient's medicine that remains after packing
- Initials of the person who packed the DAA and the pharmacist who checked the DAA

Reference: Pharmacy Board of Australia¹⁹

For services claimed under 7CPA or DVA DAA programs, further documentation is required.¹³

7CPA DAA Program supporting documentation

The following information must be retained for seven (7) years:

- Section 90 number at the time of the provision of the service
- Pharmacy accreditation ID at the time of the provision of the service
- Registered pharmacist identifier (e.g. AHPRA registration number)
- Copy of the patient consent form, where relevant
- Patient's name and address
- Patient's Medicare/DVA card number
- Patient's concession card number
- Copy of the patient consent form
- How the patient has satisfied all eligibility criteria
- Copy of the DAA medication profile
- Date(s) of provision of the DAA

Reference: 7CPA Program Rules¹³

Communication

Communication with patients

Pharmacists should encourage patients using a DAA to participate in their medication management by providing regular counselling opportunities to discuss medication safety, and their medicine regimen. Counselling should include¹:

- discussion of all medicines packed in DAA, particularly any new medicines
- use of the DAA including how to avoid rupturing blister seals prematurely, and using devices to assist extracting medicines from blisters
- storage of the DAA
- what to do if the DAA is damaged, or if medicines in the DAA change appearance
- advice on medicines that are not packed, and how these should be stored and used
- arrangements for ongoing supply of medicines (i.e. prescription requests and refills).

Patients should be encouraged to discuss any difficulties (e.g. physical, visual) in using the DAA, or adhering to their medication regimen (e.g. swallowing difficulties) with the pharmacist.

Patients should be advised to return unused medicines in the DAA to the pharmacy for safe disposal.

Written information such as a medication profile, CALs, and consumer medicine information (CMI) leaflets should be used to support verbal counselling.¹⁶

The patient's use of a DAA should be discussed as part of any MedsCheck, HMR or RMMR service. These services may provide an opportunity to discuss and resolve any ongoing issues.

Patients have the right to choose not to take a prescribed medicine. If the patient does not want certain medicines to be packed in a DAA, the pharmacist should discuss the reasons with the patient and encourage them to discuss their choice with the prescriber, if relevant. Any decisions about medicine use and medication management should be made in partnership with the patient, pharmacist and where relevant, the prescriber. Pharmacists should ensure the patient has made an informed decision about their medication management, while also respecting patient autonomy. The results of any discussions should be reflected in the DAA medication profile.

Communication with prescribers

Pharmacists should communicate regularly with the prescriber, or other healthcare providers involved in the patient's care, with patient's consent accurate transfer of medicines information, and to address medication management issues that arise during service delivery (see Box 7).¹

Patient consent to share information related to the DAA service with other healthcare providers should be obtained when commencing the service, as part of the DAA service agreement.

Any communication between the pharmacist and prescriber or other healthcare providers should be recorded.¹

Box 7. Reasons to communicate with prescribers

- Initiating a DAA for a patient
- Maintaining an accurate DAA profile including medicines that have not been packed in a DAA
- Organising new prescriptions
- Verifying medication orders
- Suggesting alternative options for medicines not suitable for packing into a DAA
- Optimising medicine directions (e.g. dosing times)
- Changing a DAA on receipt of a new prescription or medication order
- Managing non-adherence
- Managing difficulties the patient may be experiencing with using a DAA
- Managing transitions of care
- Discussing concerns for patient safety

References: PSA¹; Department of Health³; Elliott⁴

Monitoring and follow up

The prescriber and pharmacist should monitor patients to detect and assess any issues or problems that patients have when starting to use a DAA. Ongoing monitoring should occur once a DAA is established (see Box 8).¹

There may be reduced opportunity to review and counsel patients who have their DAA delivered or live in a RCF. Pharmacists should ensure procedures are in place to identify these patients, and ensure appropriate monitoring and follow up is provided.^{4,15}

Services funded under certain third-party arrangements (i.e. DVA DAA service) include formal patient follow up at 6-monthly intervals to enable pharmacists to monitor patient health outcomes.¹³ See *Data collection*.

Box 8. Pharmacist's role in monitoring patients using DAA

The pharmacist's role in monitoring should involve:

- asking the patient to return used DAA to the pharmacy to prevent accumulation or hoarding of unused medicines and to allow for adherence monitoring
- undertaking regular re-assessments at agreed intervals to assess adherence, medicine management ability, medicine knowledge, concordance with medicine regimen records, and reiterate correct handling and storage directions of DAA.^{21,22} This could involve a HMR or other medication review. Re-assessment should be formally documented and may include items required under funded programs
- undertaking medication reconciliation following medication changes or transitions of care
- assessing whether improved adherence as a result from using the DAA has led to increased adverse effects, and counselling patients and/or carers on what to do if this occurs

Data collection

DAA services that are funded under the DVA DAA service require patient data to be collected at the commencement of the service and the 6-month follow up to evaluate the impact of the DAA service on patient health outcomes.¹³

Pharmacists should consider collecting data for all DAA patients to inform quality assurance and service evaluation. See *Quality assurance and evaluation* (see box 9).

DVA DAA Service data collection

Pharmacists are required to collect information relating to the patient's DAA service at a six-monthly Veteran's Review and provide this to the prescriber for continuation of the service. See www.dva.gov.au/providers/provider-programmes/dose-administration-aid-daa-service for information

References: DVA DAA¹⁴

Box 9. DAA Program data collection

After obtaining consent, the following data is useful for collection as part of the DVA DAA service. Collection of this data for other DAA recipients can also inform quality assurance and service evaluation.

At commencement of participation in DAA service

- Patient details: Date of birth, gender, Medicare number and/or Department of Veterans' Affairs file number, postcode, concession details
- What is the referral source for the DAA?
- What was the date the referral/plan was made?
- Total number of prescription and non-prescription medicines
- Does the patient have a history of non-adherence?
- Is the patient experiencing difficulties with medication management?
- Does the patient have a disability that makes them eligible for a DAA?
- Is English the patient's primary language at home?
- Does the patient identify as Aboriginal and/or Torres Strait Islander?
- What health conditions/co-morbidities is the patient taking medicines for?
- Does the patient have support with managing medicines?
- What is the patient's average *MedsIndex* score?
- Date of initial contact
- Number of DAA packs packed per week
- Frequency of collection
- How will the patient mainly obtain the DAA?
- In the last six months, did the patient go to their GP, or hospital, because of problems with their medicine?
- Was the patient using a DAA prior to this visit?
- Type of DAA packed by pharmacy

At six-month follow up contact with patient

- Date of follow up consultation
- Total number of prescription and non-prescription medicines
- How many times have there been changes to the DAA in the previous six months?
- What was the reason for the change?
- During the past six months, what are your observations of the patient's medicine use?
- What activities have been undertaken by the pharmacy to support the DAA service?
- What is the patient's average *MedsIndex* score?
- In the last six months, did the patient go to their GP, or hospital, because of problems with their medicine?
- Is continuation of the DAA service recommended for this patient?
- If the DAA service is not recommended for continuation, what is the reason?

Quality assurance and evaluation

To ensure a DAA service meets the safety and quality requirements of professional practice, pharmacists should introduce procedures for quality control, quality assurance and monitoring of DAA provision.¹

Audits should be carried out prior to the commencement of a DAA service and at 6-monthly intervals. *Professional Practice Standard 15: Dose Administration Aid Service* should be used as a tool for self-assessment. The performance and results should be recorded together with any action taken, and the resulting outcome. Any changes should be reflected in updated policies and procedures.¹

Data collected for patients receiving DAA services can be used to inform quality assurance and service evaluation.

Managing a recall

Pharmacists must ensure procedures allow for accurate tracking of medicines, and appropriate management of recalls, sources of error and system review. All medicines packed in DAA must be traceable.

Best practice involves recording batch numbers and expiry dates of all medicines that are packed in DAA to enable identification and isolation of a medicine in the event that a medicine is recalled.

If the batch numbers and expiry dates of medicines used are not recorded, pharmacists must ensure they have another mechanism in place that allows for medicines to be accurately recalled and isolated if there is a medicine recall.¹

Appendix 1–Automated dose-packaging technology

Automated dose-packaging systems enable computerised and automated medicine counting, packing into sachets, labelling and electronic documentation. Facilities using an automated dose-packaging system may need licensing by the Therapeutic Goods

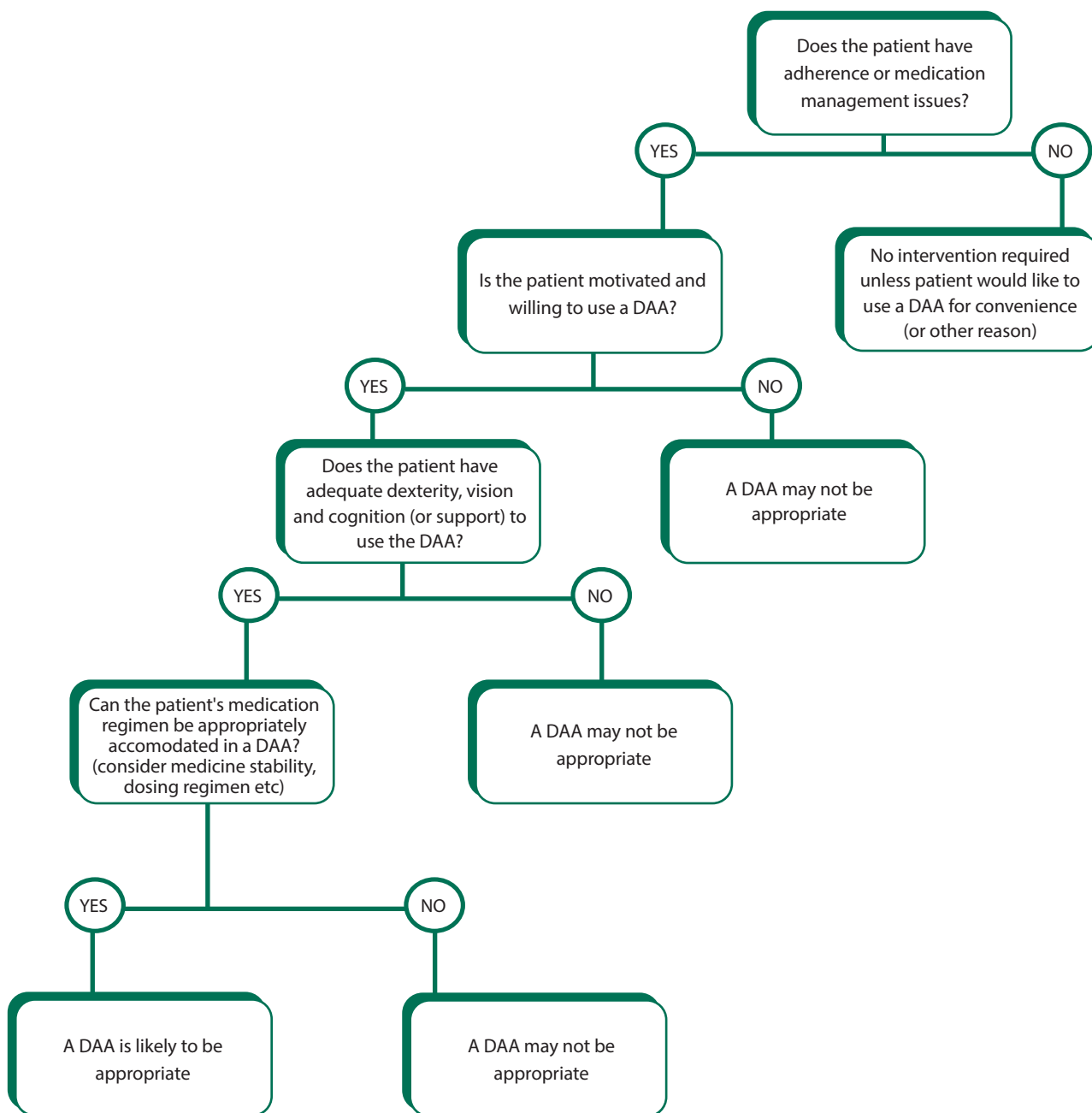
Administration (TGA).^{10,20}

Pharmacists should use professional judgement to determine medicines that may be unsuitable for loading into automated dose-packaging systems (e.g. cytotoxics, thyroxine sodium [levothyroxine sodium]). Advice may also be available from suppliers of automated dose-packaging systems.

Pharmacists using automated technology to pack medicines for patients must ensure²³:

- machines are operated in a clean environment, away from the dispensing computer and bench area of the dispensary
 - temperatures are maintained below 25°C
 - all staff involved in using the machine receive initial and ongoing training and demonstrate competency in its use, and this training is documented
 - a cleaning and maintenance protocol is strictly followed
- testing is carried out at the start of each day, and at other times where it may be required
 - there is a written procedure that describes the use of the machines, including maintenance and error records, and a written quality assurance program that includes the refilling of bulk canisters
 - quality control processes for checking data entry, loading medicines, and checking final products are followed
 - irregularities detected during the quality control processes are documented and resolved.

Appendix 2 – Patient needs assessment for a DAA



Adapted from Elliott⁴

Appendix 3 – Sample agreement for a DAA service

Pharmacists are encouraged to modify this sample agreement to meet their DAA service needs.

Patient	Pharmacy providing the DAA service	
Name:.....	Name:.....	
Address:.....	Address:.....	
Phone No.:.....	Phone No.:.....	
Email:.....	Email:.....	
Medicare number:.....	Name of pharmacist:.....	
Concession card details:.....		
Name of carer and phone No.:.....		
Emergency contact name and phone No.:.....	Patient's prescriber	
Other details:.....		Name:.....
		Address:.....
	Phone No.:.....	

Note: The options given in parentheses under 'Issues' are examples only.

Issues	Agreed terms
Consent	
Patient consents to the sharing of medicine-related information between the pharmacist and the patient's prescriber(s), hospital or community nurse as relevant (yes/no):	
Patient consents to an assessment of their management of the DAA every 6 months (yes/no) or at agreed intervals of:	
Patient consents to relevant information being shared with a third-party packing provider (yes/no/not applicable):	
DAA service costs	
The Australian Government is contributing approx \$6 per week towards the cost of DAA services for eligible patients as part of the 7CPA DAA Program. Your pharmacist will discuss your eligibility.	
Cost of medicines is additional to the DAA service. The person responsible for payment of medicines that are to be packed in a DAA is (patient/carer/other):	
Cost of the DAA service (per week/per month/per DAA/other) is:	
Payment for the DAA service will be (invoiced/on account/paid at time of collection of DAA):	
Prescriptions	
Person responsible for providing a valid prescription (where required) for medicines to be packed in a DAA (patient/prescriber/facility staff/other):	
Pharmacist will remind the patient to obtain a new prescription from the prescriber (yes/no):	
Pharmacist will generate reminder notices to the prescriber to provide prescription(s) (yes/no):	
Patient consents to brand substitution for medicines packed in a DAA (yes/no):	
Prescriber is willing to provide a prescription for ongoing medicines without a formal consultation (appointment) with the patient (yes/no):	
If prescriptions are dispensed at another pharmacy or pharmacy department, the procedure to ensure that this pharmacy has the medicines for packing into the DAA is:	
Procedure to be followed if there is no prescription available for the pharmacist to dispense is:	

<i>DAA service details</i>	
Brand or type of DAA supplied is:	
Number of days supply of regular medicines for each DAA packed is:	
Specific storage conditions for the DAA are:	

Medicines to be packed in DAA	
-------------------------------	--

1.	6.
2.	7.
3.	8.
4.	9.
5.	10.

Medicines not packed in DAA	Reason for not packing
-----------------------------	------------------------

1.	
2.	
3.	
4.	
5.	
6.	

Procedure to be followed if there is a need for more than the usual number of packs to be supplied (e.g. patient going on holidays) is:	
Date and time when DAA can be collected will be advised (by telephone when ready/when the prescription is provided to the pharmacist/other):	
DAA will be (delivered/collected) by (pharmacy staff/patient/facility staff):	
Procedure to be followed if the DAA is damaged, destroyed, or incorrectly opened is:	
Unused medicines in a DAA, empty DAA and expired DAA will be returned to the pharmacy by (patient/carer/facility staff/other):	
Procedure to be followed if the patient/carer has difficulty using the DAA, or if the patient has difficulty taking medicines in the DAA is:	
Changes to medicines	
Procedure to follow if there are medicine changes is:	
Changes to prescribed medicines (i.e. dose, frequency, duration, or commencement or cessation of a medicine) will be conveyed in writing by the prescriber (yes/no):	
Urgency of the need to change DAA to accommodate medicine regimen changes will be conveyed to the pharmacy by (prescriber/patient/facility staff):	
Procedure if changes to medicines in the DAA need to be made before the current DAA pack is finished is:	
Other notes/comments	

Signed:

Patient:..... Pharmacist:.....

Date:..... Date:.....

Appendix 4 – Medication reconciliation

Medication reconciliation is a formal process of verifying a patient's medicines to obtain a complete and accurate list of their current medicines.²⁴ Medication reconciliation can identify medication errors occurring from incomplete or miscommunicated information, especially at points of transition of care²⁵; more than 50% of medication errors occur at transitions of care.²⁶ Errors that can occur include transcription, omission, duplication of therapy, and drug-drug and drug-disease interactions.²⁵

Reconciling a patient's medicines is essential to ensure a patient's medication profile contains accurate information; a vital component of medication adherence and management.

As part of the reconciliation process, pharmacists should take the best possible medication history by²⁷:

- reviewing relevant patient information such as age, and cognitive state and considering what impact these may have on obtaining reliable information and if a carer or family member should be present
- asking the patient about any previous adverse medication events or allergies
- asking the patient to bring all current medicines including prescription, non-prescription and complementary and alternative products to the consultation
- asking the patient to bring all their prescriptions and repeat prescriptions, if not already retained by the pharmacy to the consultation
- assessing the patient's understanding of rationale for treatment, attitude and adherence to prescribed treatment.

Pharmacists should try to confirm the accuracy of the medication history with the prescriber or a recent hospital discharge summary.²⁸ Pharmacists should access the patient's *My Health Record*, if available, for information such as the shared health summary, dispense records and discharge summaries to help in developing the medication profile.

After reconciling a patient's medicines, an accurate medication profile can be prepared including name of medicine, dose (strength, dose form, frequency and route) and details of allergies and adverse reactions.

Pharmacists should inform the prescriber of any discrepancies in the list and document any changes.

If possible (i.e. software permitting), pharmacists should upload this documentation to the patient's *My Health Record* as an event summary. See www.digitalhealth.gov.au/using-the-my-health-record-system/how-to-use-the-my-health-record-system/uploading-an-event-summary.

Appendix 5 – Risk assessment for packing medicines a DAA

If the answer to any of the following questions is 'No', packing of the medicine in a DAA is not recommended.^{17,21} For further information see APF 23 Section A: *Crushing, dispersing or repackaging medicines*.¹⁶

If the medicine poses work, health and safety risks and requires special handling (e.g. solid dose cytotoxic agents, hormones, penicillin derivatives, teratogens), can the dose be packed in the DAA in a way that will offer protection to pharmacy staff and patients?	Yes/No
If the medicine requires protection from heat (e.g. soft gel capsules), will the process used to seal the DAA and/or the storage conditions (temperature) protect the medicine from being adversely affected?	Yes/No
If the medicine requires protection from moisture (e.g. effervescent tablets, dispersible tablets, buccal tablets, sublingual tablets, wafers, and tablets containing hygroscopic or moisture sensitive drugs), does the DAA offer appropriate protection to protect the medicine from being adversely affected? (see Note 1)	Yes/No
If the medicine requires protection from light, is the DAA light proof or can appropriate protective measures be used e.g. placing the DAA in a light-protective sleeve and advising the patient/carer about storage of the DAA to protect it from light? ²⁹ (see Note 2)	Yes/No
If the medicine is of a size or in a form that requires containment (e.g. a liquid) or a large compartment, can the DAA provide this?	Yes/No
If the medicine requires protection from air (oxygen), does the DAA offer appropriate protection from air? (Prompt sealing of DAA after packing is essential when any medicines are packed. Patients should also receive regular education about how to open individual DAA compartments to ensure the seal of other compartments is not compromised)	Yes/No
If there are known interactions between the medicine and the packaging materials used in the DAA or potential interactions with other medicines packed in the DAA, can the medicine be protected from these interactions? ^{15,29} (see Note 3)	Yes/No
If medicines to be packed in a DAA require refrigeration, can they be kept in appropriate storage conditions that won't impact on the stability of other medicines packed in the DAA? ³⁰	Yes/No

Note 1: The following factors may suggest that medicines are sensitive to moisture¹⁵:

- Packaging composed entirely of foil is an indication that the medicine is sensitive to moisture.
- Packaging that contains desiccants suggests that the product is sensitive to moisture.
- Degradation of medicines is most commonly due to hydrolysis, which requires water. Hydrolysis is most likely to occur in medicines with functional groups such as (carboxylic) esters (e.g. aspirin). Being aware of the chemical structure of a medicine and being able to identify the presence of these functional groups may assist in determining which medicines may be moisture-sensitive.

Environmental conditions of temperature and humidity, which impact on the stability of repackaged medicines, will vary across different regions of Australia and at different times of the year.

Note 2: The following factors may suggest that medicines are sensitive to light¹⁵:

- Dark-coloured (i.e. not white or clear) blister packs indicate that the medicine requires protection from light.

Note 3: The following factors need to be considered when packing certain medicine formulations¹⁵:

- The drug release for modified-release tablets may be affected by the presence of moisture if formulation excipients swell or gel when coming into contact with water.
- Gelatin capsules (both hard and soft forms) have high water content, meaning that mixing capsules with tablets can lead to water transferring from capsules to tablets. This has the potential to affect the chemical stability (by hydrolysis) and the physical stability (hardness, friability, disintegration and dissolution) of susceptible medicines (moisture sensitive and hygroscopic). However, the impact of this on the patient is not known. It is recommended that mixing capsules with modified-release tablets in particular should be avoided where possible due to the potential for the modified-release characteristics to be altered.
- If both hard and soft gelatin capsules are present in a DAA, there is a risk of transfer of moisture content between the two. This can increase the risk of capsule brittleness or capsule softening and distortion. While it is not known to what extent this occurs when packed in a DAA, it is recommended that the inclusion of both in the same compartment be avoided.

Appendix 6 – Suitability of medicines for packing in a DAA

Regimen suitability

When deciding whether medicines should be packed, the following regimen issues may need to be considered³:

- If medicines are used on an 'as required' basis, will packing this into a DAA lead to confusion and potential overuse?
- If medicines are used for a defined short-course treatment, does the risk of possible non-adherence if not packed in a DAA outweigh the risk of possible inappropriate use or using the medicine for a longer period of time than intended if it is packed?
- If medicines are part of a complicated regimen or have specific requirements around the timing of administration in relation to food or other medicines, is the DAA able to adequately incorporate these requirements?

'As required' medicines

If a decision is made to pack a medicine that is taken on an irregular or as required ('prn') basis, it must be packed separately and clearly labelled. When assigning expiry dates to 'prn' packs, pharmacists should consider the stability of medicines packed in the DAA as well as the need to review 'prn' use on a regular basis.

Stability

There is little available data regarding the stability of medicines during packing or storage in DAA. In addition, there is no information on the stability of medicines when packed in close physical contact with other medicines. While pharmacists would be aware of general principles regarding the stability of medicines, there are no decisive rules that can be applied for each medicine to determine its suitability for packing in a particular DAA.

Transfer of a medicine to a DAA, or canisters for automated dose-packaging systems, is outside the terms of each product's registration licence required by a manufacturer. When repacking a medicine into a DAA (and refilling canisters for automated dose-packaging systems), a pharmacist must consider the impact on stability.^{9,16,21}

A decrease in the stability of medicines can have numerous consequences, including³¹:

- a loss of potency due to a decrease in the active pharmaceutical ingredient (API) content
- changes in bioavailability due to altered tablet or capsule hardness, friability and disintegration or dissolution rate
- formation of toxic degradation products, potentially leading to adverse effects
- changes in the physical appearance of a medicine, leading to patient concern about the quality of the medicine, which could potentially impact on adherence.

A pharmacist must make an informed judgement as to the suitability of any medicine for inclusion in a DAA, taking into account guidance from current resources where available.^{17, 21} The pharmacist should carefully assess a medicine's stability in a DAA against the risks of non-adherence if that medicine is not packed, and discuss with the prescriber if required. See *Appendix 5 - Risk assessment for packing a medicine in a DAA*.

The DAA medication profile should include medicines to be packed, and medicines not to be packed, as well as evidence of the application of professional judgement to the decision process.

Examples of medicines that may not be suitable for packing in a DAA

Type of tablet	Examples
Effervescent tablets	Effervescent forms of potassium chloride, soluble aspirin tablets
Dispersible tablets	Piroxicam dispersible tablets
Buccal tablets	Amphotericin B (amphotericin) lozenges
Sublingual tablets	Glyceryl trinitrate sublingual tablets, buprenorphine HCl sublingual tablets
Chewable tablets	Vitamin C
Hygroscopic tablets	Sodium valproate
Tablets exceedingly susceptible to light degradation	Nifedipine, tamoxifen
Tablets containing aluminium hydroxide, magnesium trisilicate	<i>Gaviscon</i> tablets
	Hexamine hippurate (methenamine hippurate) tablets
	Omeprazole (unless packed monthly)
Moisture-sensitive medicines	Wafer presentations (e.g. olanzapine)
Other medicines where limited time in DAA may be appropriate	Thyroxine sodium (levothyroxine sodium)
Other medicines where there are specific contraindications for repacking from the manufacturer	Dabigatran (<i>Pradaxa</i>)

References: Sansom¹⁶; Haywood²⁰; Church³⁰; eMIMS³²; Llewelyn³³; Loscertales³⁴

Retaining original packaging

It is not recommended that medicines are packed in their original packaging due to the risk of patients swallowing medicines in their original strip or blister packaging.¹⁰

Where manufacturers advise that a medicine must remain in its original packaging (e.g. foil) until just prior to ingestion, the risk of poor adherence must be weighed against the risk of swallowing the medicine still in its packaging. In consultation with the prescriber, an alternative medicine that is not required to be kept in its original packaging could be considered.^{4,16}

If a medicine is packed in its original packing, a risk management strategy should be documented in the DAA medication profile. For example, clear and specific instructions for the patient to remove the medicine from its foil or blister pack prior to administration. Patient understanding of these instructions should be confirmed.

Cytotoxic and other hazardous medicines

Oral cytotoxic and other hazardous medicines should only be packed into a DAA if there is a clear benefit of improved adherence from using a DAA, which outweighs the risk of exposure during packing or administration.

Patients need to be aware of correct handling and storage of these medicines. Warning statements included on the manufacturer's original packaging (e.g. warnings about teratogenicity if used in pregnancy) should also be included on the DAA label.¹⁰ CAL 21 should be used to identify all hazardous medicines.¹⁶

Due to the narrow therapeutic index of cytotoxic medicines, Pharmacy Board of Australia provides the following guidance if these medicines are to be packed into a DAA¹⁰:

- Pharmacists must exercise extra vigilance when dispensing and packing cytotoxic medicines into a DAA.
- Other non-cytotoxic medicines for a patient must not be packed in the same DAA.
- A cytotoxic warning label must be included on the DAA containing cytotoxic medicines.
- Staff packing cytotoxic medicines should have appropriate training.

Relevant professional guidelines and work, health and safety (WHS) standards should be observed when cytotoxic substances are handled.³⁵ See APF Section A: *Crushing, dispersing or repackaging medicines*¹⁶ for further information on safety considerations when packing solid dose forms of cytotoxic and other hazardous medicines in DAA.

Controlled drugs

DAA containing controlled drugs (including those in returned DAA) must be packed, stored handled and disposed of, in compliance with relevant legislative requirements.

If a DAA containing a controlled drug is packed for a patient in a hospital or residential care facility, the facility should be advised so that the DAA can be stored in accordance with relevant legislative requirements.¹⁰

Appendix 7 – Hand hygiene procedures

Hand washing with soap

Sample procedure for hand washing with soap and water

1. Remove jewellery from the hands and wrists.
2. Wet hands thoroughly and apply a liquid soap with a neutral pH ensuring there is enough soap to adequately clean all hand surface areas.
3. Lather hands vigorously with soap for 15–30 seconds.
4. Rub hands palm-to-palm.
5. Continue rubbing hands with the right palm over the top of the left hand and with fingers interlaced, then repeat with hands in the opposite position.
6. Rub hands palm-to-palm with fingers interlaced.
7. Rub the backs of fingers to the opposite palms with fingers interlocked.
8. Rub the left thumb clasped in the right palm in a rotational manner, then repeat with the opposite hands.
9. Rub the tops of clasped fingers of the right hand in the left palm in a rotational manner backwards and forwards, then repeat with opposite hands.
10. Rinse hands under running water.
11. Dry hands thoroughly with a single-use paper towel.
12. Use a paper towel to turn off the taps if other methods (e.g. automatic hand sensors, elbow or foot controls) are not available.

This procedure should take 40–60 seconds.

Reference: Adapted from Hand Hygiene³⁶

Hand rubbing with alcohol-based product

Sample procedure for rubbing hands with an alcohol-based hand product

1. Remove jewellery from the hands and wrists.
2. Apply a quantity of alcohol-based hand product according to the manufacturer's directions into a cupped hand, ensuring there is sufficient product to adequately cover all hand surface areas.
3. Rub hands palm-to-palm.
4. Continue rubbing hands with the right palm over the top of the left hand and with fingers interlaced, then repeat with hands in the opposite position.
5. Rub hands palm-to-palm with fingers interlaced.
6. Rub the backs of fingers to the opposite palms with fingers interlocked.
7. Rub the left thumb clasped in the right palm in a rotational manner, then repeat with the opposite hands.
8. Rub the tops of clasped fingers of the right hand in the left palm in a rotational manner backwards and forwards, then repeat with opposite hands.
9. Rub hands together until hands are dry before touching any medicines. Do not rub off excess product.

This procedure should take 20–30 seconds.

Appendix 8 – Sample record of packing dispensed medicines into a DAA

Name: Address:

Living arrangements (community, facility, etc.):

DAA packing	Date of supply																
	Date when DAA is intended to start																
	Initials of packer & pharmacist																
	Quantity remaining																
	Quantity packed																
	Date																
Prescription dispensed	Batch no. and expiry date																
	Quantity dispensed																
	Date dispensed & prescription no.																
Medicine name/ form/ strength/ dose																	

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