



**Australian Government**  
**Department of Health**  
Office of Drug Control

# Consultation – Single Licence Model

Consultation paper

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## Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

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## Introduction

The Government proposes to implement a single medicinal cannabis licence under the *Narcotic Drugs Act 1967* (the Act) and other associated reforms to the licence application process. These amendments will bring into effect Recommendation 7 from the Review of the Narcotic Drugs Act (the Review).

**Subject to Government's final consideration, the precise terminology of the matters set out below in the legislation to be put to Parliament will be finalised during the legislative drafting process. We ask that you give us your feedback on the policy discussed below. Concepts will be explored further during consultation sessions (information on these sessions is outlined below).**

## Providing feedback

The Office of Drug Control (ODC) will conduct further face to face consultations on the proposed reforms below – these sessions will provide an opportunity for the ODC to explain in more detail the proposed reforms. Feedback on the proposed amendments will also be sought at this time.

It is anticipated that forums will be held in Sydney, Melbourne and Brisbane in mid-late January 2020. Further information on these sessions will be published shortly.

Direct stakeholder feedback at these sessions is welcomed. However, if you are unable to attend these sessions and wish to lodge a written submission on this paper, please contact the ODC at [mcs@health.gov.au](mailto:mcs@health.gov.au).

## About this paper

This paper is divided into two sections. Following a brief overview of the background, Part 1 will explain the high level design of the proposed single licence model. Part 2 will explain reforms relating to the process of applying for a medicinal cannabis licence.

## Background

In 2019, Professor John McMillan AO undertook a Review of the *Narcotic Drugs Act 1967* (the Review) in accordance with section 26A of the Act. In conducting the Review, Professor Mc Millan engaged in an extensive public consultation process and also liaised directly with key stakeholders through the publication of a discussion paper which invited submissions.

The result of the Review was the publication of the Report on the Review into the *Narcotic Drugs Act 1967* (the Report), which was tabled in Parliament on 5 September 2019.

In the Report, Professor McMillan made 26 recommendations which have been accepted in principle by The Honourable Greg Hunt MP, Minister for Health.

The reform process has been undertaken in two stages. The regulation amendments for stage 1 of the reform process are set out in the *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019*, which will commence on 1 January 2020. The specific amendments implement recommendations 2, 8 and 11 of the Review and involve revisions mostly aimed at simplifying the information provision requirements for a licence application and clarifying and aligning terminology with the Act. The *Narcotic Drugs Amendment (Review Recommendations) Regulations 2019* can be found at: <https://www.legislation.gov.au/Details/F2019L01485>.

The second stage of the reforms are those changes that require amendments to the Act, which include but are not limited to, the implementation of a single medicinal cannabis licence.

This reform implements Recommendation 7 of the Report, which states:

*The Narcotic Drugs Act 1967 be amended to establish a new licence structure applying to medicinal cannabis products. The Narcotic Drugs Act 1967 should provide for the issue of a single licence to authorise all or some of cultivation, production, manufacture and research of such products.*

Detailed discussion related to this recommendation can be found in Chapter 6 of the Report <https://www.odc.gov.au/news-media/news/tabling-report-review-2016-medicinal-cannabis-amendments-narcotic-drugs-act-1967> (p.p.56 -59).

## Part 1 – Proposed single licence model – high level design

### Current processes – multiple licences

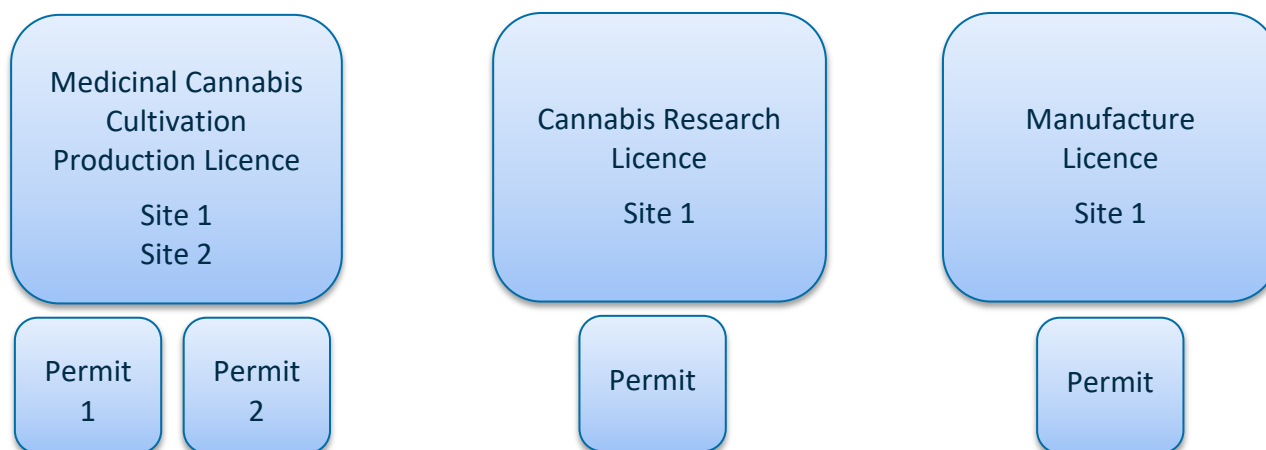
Presently, there are three different licences that can be granted under the Act:

- Medicinal cannabis licence and/or
- Cannabis research licence; and/or
- Manufacture licence.

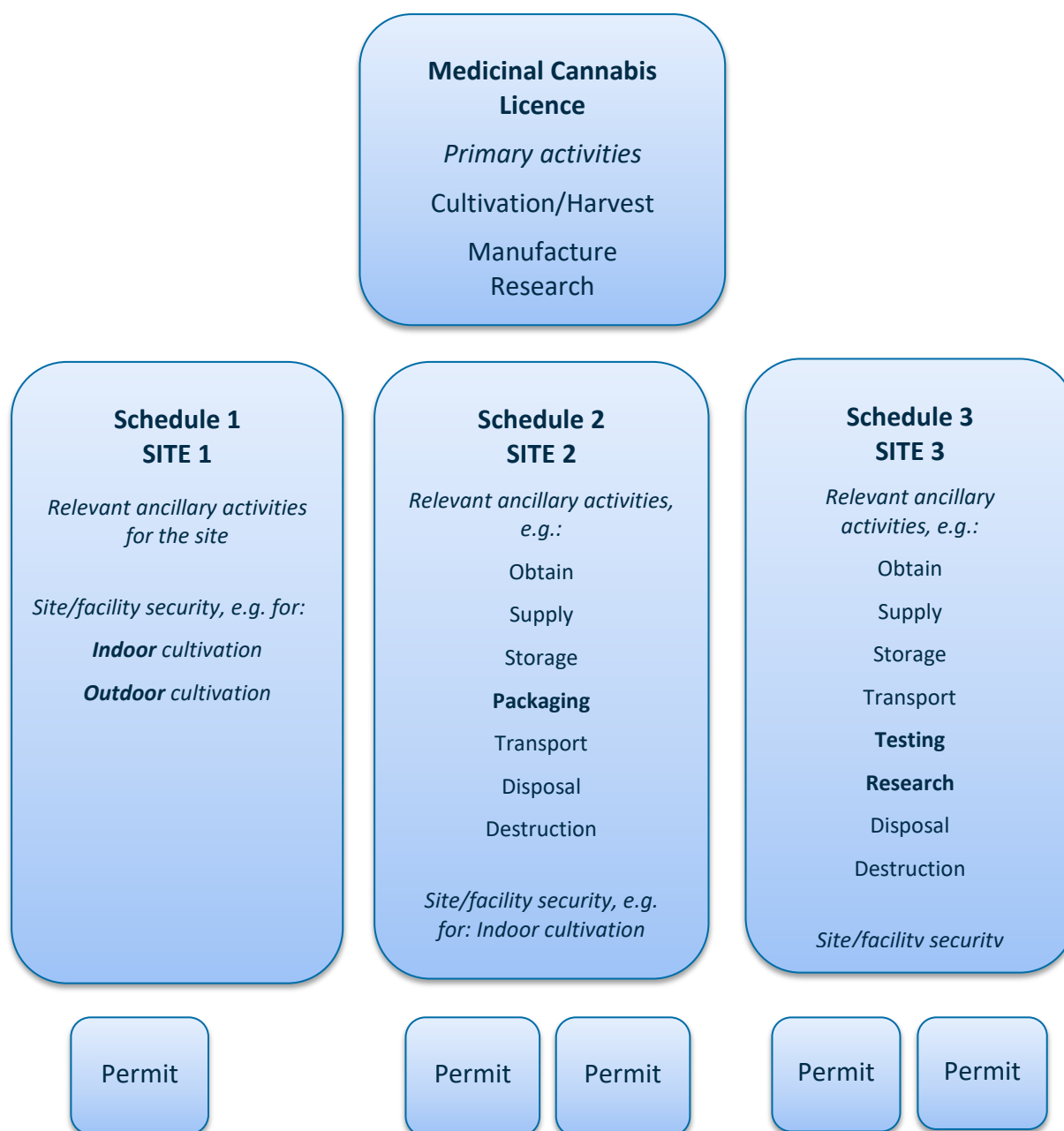
Given the current three licence structure, an applicant may be required to submit three different applications in order to obtain a licence that authorises the activities associated with operating its business.

The Review found that applicants find this to be time consuming and required submission of duplicate information that must be provided with each application.

Discussion of the difficulties raised by the current three licence model is discussed further in the Report and is not repeated again here.



**Diagram 1: Current 3 licence structure**



**Diagram 2: Proposed single licence structure, involving multiple sites**

### Proposed reform - A single licence

Recommendation 7 proposes there to be a single licence. However, given experience to date in the Australian medicinal cannabis industry, it is recognised that that some licensed entities may seek to have more than one site. It is envisaged that the single licence model should be flexible enough to accommodate licence holders with single sites, and those with broader interests and multiple sites.

The potential complexity raised by such a diverse industry can nevertheless be addressed in a single licence structure where the application, assessment process and licence itself can focus on issues relevant to the activities at a particular site and facility. It is therefore envisaged a licence will authorise an entity to undertake any one or more of the primary activities identified in recommendation 7, and also specify relevant ancillary activities and security arrangements for each site/facility in a schedule.



It is proposed that there will be only one medicinal cannabis licence application form. The form will require applicants to specify the activities they propose to undertake in relation to cultivation and/or research and/or manufacture of medicinal cannabis. Please note, further information in regard to proposed reforms to the application process are explored below.

### Primary and ancillary activities

If a licence is granted it may authorise the licence holder to undertake some or all of the primary activities associated with a medicinal cannabis licence. Ancillary activities are those that support the conduct of the primary activities.

The present caution that a licence holder cannot carry out any of these activities without first obtaining a permit will remain.

The tables below list the primary and ancillary activities. However, the ODC will seek feedback on the practical application of these groupings during consultation sessions.

<b>Primary activities</b>
Cultivation of cannabis plants and harvest of cannabis
Manufacture of cannabis or cannabis resin into drugs
Research relating to one or both of the above
Other, where prescribed by regulation

<b>Ancillary activities</b>
Obtain
Supply
Packaging
Transport
Storage
Possession
Control
Disposal
Destruction
Testing
Research (where the primary activity is not research)
Others, where prescribed by regulation

## Amendments to definitions of primary activities

It is proposed that the meaning of certain terms will be clarified within the Act. These terms are used to describe activities associated with primary and ancillary activities. Review of these terms also implements Recommendation 5 of the Review which assists in reflecting language used in the medicinal cannabis sector.

<b>Cultivation and Harvest</b>
<i>Cultivation</i> will be clarified to include <i>harvest</i> . Harvest will be defined as removal of cannabis flowers from the plant.
<b>Manufacture</b>
The definition of <i>manufacture</i> will align with the definition of that term in the Single Convention and will be extended to include all <i>production</i> activities that occur post-harvest. This will be inclusive of, but not limited to, activities such as dry ice extraction, alcohol or water baths and any other extraction method.
<b>Research</b>
It is anticipated that _____ will be both a primary and an ancillary activity. Research could be a primary activity whereby the applicant seeks a licence for the purpose of undertaking research as it relates to the development of new strains of cannabis or to improve the yield of a cannabis crop by altering environmental factors. Research that is an ancillary activity could be research into the stability of a product, analysis of samples to determine the cannabinoid levels of the plant or product development.

## Research institutions

We note that research institutions undertaking scientific research into cannabis undertake the same primary activities (e.g. cultivation/harvest and/or manufacture) and most of the same ancillary activities (e.g. obtain, supply, transport, storage, waste disposal etc.) as other licence holders who are commercial entities. Additionally, they may undertake additional ancillary activities (e.g. testing).

However, a key difference between research institutions and other licensed entities is often that the volumes of cannabis to be handled/managed at the facility are smaller.

Consideration is therefore being given by the ODC to the risks to be managed by regulating such entities, for example the appropriate level of information required in a licence application where the primary activity under the licence is only research, the risks of diversion where small volumes are involved, and ongoing compliance monitoring and enforcement considerations.

## Part 2 – Reforms to the process of considering a licence application

In progressing the single medicinal cannabis licence model, the ODC identified a number of processes in the existing licence application framework that could be enhanced. This part of the paper proposes a number of changes that expand upon the scope of Recommendation 7 of the Report.

### Two step application process

Generally, medicinal cannabis industry participants begin construction of the relevant facilities after a licence has been granted. This is because the grant of the licence is critical to the financier's decision. As the information provided at the licence application assessment stage often does not reflect the final circumstances for an applicant following renting or construction and commissioning of a site, the licence requires variation, and the ODC must reassess key information before a permit can be granted. As a practical matter there is some not inconsiderable 'back and forth' between the licence holder and the Secretary to finalise the required variation and permits. There is an opportunity to introduce efficiencies.

To address these difficulties, it is proposed that the assessment of a medicinal cannabis licence application will occur in 2 steps. The information that is considered in each step is will not differ significantly to current requirements for a licence application, rather, it has been separated into 2 steps.

Accordingly, the preference is to provide for there to be separate consideration of the suitability criteria and the location-specific criteria through a two stage process, which would:

- minimise the possibility of applying an evaluation and risk assessment of obsolete or incorrect data, ensuring the integrity of the licensing scheme;
- reduce duplication of effort involved in making an application for a licence (including the application for a variation) as well as considering whether to approve the licence and the variation authorising the subsequent construction of the facilities; and
- ensure that the Secretary has express statutory authority to carry out the separate processes.

**Work on key concepts and terminology will be progressed throughout the drafting process. Further details on the proposed approach will be provided at the consultation sessions.**

**STEP 1** of the application would include assessment of:

- a. whether the applicant is a 'fit and proper' person<sup>1</sup>
- b. the consistency of the proposed activities with the Single Convention,
- c. whether the proposal meets applicable standards
- d. whether required fees have been paid
- e. if the information is correct and accurate, and
- f. that all required information has been provided including that the site has been selected (eligibility criteria).

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<sup>1</sup> The requirements for a 'fit and proper person' will remain as provided for by Part 2 of Chapter 1 of the ND Act.

A decision to refuse may be made at Step 1. This would allow the ODC to eliminate applications on the basis of eligibility before moving on to the more detailed assessment of security in step 2.

**STEP 2** would only commence once the site and/or facilities have been constructed and can be inspected by the ODC. Step 2 would include assessment of the following:

- a. whether the applicant has taken all relevant measures to ensure the physical security of cannabis plants, cannabis, cannabis resin, extracts and drugs derived from cannabis, and
- b. that the location, facilities and / or security arrangements at the land, premises or facilities are appropriate
- c. the outcomes of a site inspection.

Step 2 would require the presentation of site and floor plans, a description of the security arrangements in place and relevant standard operating procedures to the ODC. Once Step 2 is finalised the licence holder can apply for a permit.

Particular requirements will apply in circumstances where the applicant chooses not to give information required to be considered at stage 2 when making its application for stage 1. It is intended that there will be a maximum period of time between the ODC's assessment and approval of step 1 (re eligibility matters), and the time when the applicant is required to give information relevant to step 2 (re location specific matters). Failure to give this information within the prescribed timeframe will have the effect that the licensing process cannot proceed. If the applicant wants to proceed with the primary activities it will have to make a fresh application for a licence. The ODC is seeking feedback on what a reasonable timeframe would be, with initial consideration being a 2 year period is suitable.

This approach seeks to:

- a. ameliorate the risk of the information provided at step 1 of the application becoming obsolete;
- b. prevent the speculative entry into the medicinal cannabis scheme by those without a genuine interest and plan to undertake authorised activities; and
- c. provides an incentive for industry participants to progress the construction of a facility within a reasonable time frame.

Nothing in the granting of a licence is to preclude the Secretary from having regard to changes in the applicant's circumstances that may affect the Secretary being satisfied that it is a fit and proper person for a medicinal cannabis licence while the licence is in force.

### **Benefits of a 2 step process**

The 2 step process will reduce the regulatory burden on applicants and allow the ODC, by reducing the required effort to revisit an applicant's circumstances, to redirect its resources and achieve efficiencies in the time taken to process an application for a licence. This may be further enhanced by the removal of the requirement for a licence holder to reapply for or a renew a licence (see discussion below on licence periods).

## Questions and Answers

- [Will I receive a licence during step 1 or step 2?](#)

The precise name of the authorisation that you will be given if the ODC approves your application at stage 1 is still to be finalised. One possibility is that it will be called an eligibility assessment. The intention is to make it clear that the applicant has been approved at stage 1 so as to enable the applicant to finalise its financial arrangements with its financiers. It would be useful to hear from you whether one term or another would work better. Ultimately, at stage 2, an approval will bear the name licence.

- [How long do I have after I have received an approval at stage 1 before I must submit information to complete step 2 of the application process?](#)

Two years however the ODC seeks feedback in relation to this timeframe

- [Can I apply for stages 1 and 2 at the same time?](#)

Yes

- [Did the ODC consider other options in relation to Recommendation 7?](#)

Yes, a model requiring that an application could only be made if the applicant had both selected a site and constructed facility was initially considered. But progressing with this model seemed unnecessary noting the proposal above that applicants can submit information relevant to stages 1 and 2 together.

## Matters that will remain similar to existing arrangements

Subject to the approach to managing the two stage process (and any amendments to implement other recommendations from the Report), it is proposed to maintain the same or broadly similar arrangements as currently apply under the Act for:

- the circumstances in which the Secretary must refuse to grant a medicinal cannabis licence (see e.g. s 8H and extend this to cover manufacturing)
- the exceptions to the circumstances in which the Secretary must refuse to grant a medicinal licence (see eg s 8J and extend this to cover manufacturing)
- the power for the Secretary to impose conditions in granting a medicinal cannabis licence (see s 8K)
- the requirement for the Secretary to notify an applicant of decision (see s 8L)
- the matters to be specified in a licence (see s 8M)
- variations to a medicinal cannabis licence and permits that apply to cannabis licences and permits (see ss 10M and 10N)<sup>2</sup>
- revocation of a medicinal cannabis licence or permit (see ss 10P and 11)<sup>3</sup>
- surrender of a medicinal cannabis licence or permit (see s 11A)
- unauthorised activities (including breach of conditions in a medicinal cannabis licence) (see ss 11B-11E).

<sup>2</sup> Amendments to s 10M are proposed to implement recommendation 12.

<sup>3</sup> Amendments to s 10P are proposed to implement recommendation 19.

## Conditions

It is proposed to maintain the existing power for the Secretary to impose conditions in granting a medicinal cannabis licence (see s 8K).

It is also proposed to maintain a range of appropriate prescribed/statutory conditions on licences in the Act and Narcotic Drugs Regulation 2016 (the Regulation).

However, the precise nature and scope of conditions to be prescribed or imposed will be considered in light of the implementation of recommendation 13 of the Report, which will involve reviewing the standard licence conditions that are imposed on licences to ensure that conditions are not imposed unnecessarily and that conditions are appropriately framed. Further information on licence conditions will be provided at the consultation forums.

## Period of the licence

The Report includes a recommendation that the Act be amended so that licences are issued for a maximum 5 year term, and a licence holder may apply for renewal of the licence at the expiration of that licence term in accordance with the Regulation (see recommendation 10). The ODC is interested in stakeholder feedback on the recommended 5 year term, or whether a perpetual licence would be preferable for medicinal cannabis licences, subject of course to a sufficiently robust compliance and enforcement framework which includes appropriately framed suspension and revocation powers. The ODC notes that licences or authorisations have effect perpetually in other Commonwealth regulatory contexts, including under the *Therapeutic Goods Act 1989*. Feedback on licence periods will therefore be a topic for discussion at the stakeholder forums in January 2020.

## Medicinal cannabis permits

**It is expected that arrangements for permits will remain similar to the existing arrangements. This is reflected in the discussion on permits below. Permit arrangements will require review, and could change, once the single licence model is finalised. Further details about permits will be provided at the consultations.**

It is proposed to maintain the same approach for **granting a medicinal cannabis permit** under the existing Act (see ss 8P-9A), including:

- a holder of a medicinal cannabis licence may apply for a medicinal cannabis permit in relation to activities authorised in the medicinal cannabis licence (see s 8P).
- the Secretary must make a decision on an application for a medicinal cannabis permit (see s 9).
- if the Secretary decides to grant a permit, the Secretary must notify the applicant in line (see s 9A).

In relation to the **matters that are to be included in a permit**, it is proposed to maintain the same approach as for a manufacturing permit under the existing ND Act (see s 12C), as this covers matters that are common to each of the permits issued under the 3 existing licences. Additional matters that are currently prescribed for a medicinal cannabis permit (s 9B(1)) or for a cannabis research permit (s 10A(1)) will instead be specified in the Regulation.

Accordingly the matters to be specified in a medicinal cannabis permit, without limiting the matters that the Secretary may specify, may include one or more of the following:

- the maximum quantity of cannabis plants, cannabis, cannabis resin or drugs or narcotic preparations at the site specified in the permit
- the maximum quantity of cannabis plants, cannabis, cannabis resin or drugs or narcotic preparations the Secretary considers is necessary for the licence holder to possess or control for the normal conduct of business
- the period for which an activity authorised by the permit may be conducted
- the period for which the permit is in force (see below)
- any other matter prescribed by the Regulation.

In relation to the period a medicinal cannabis permit may be in force, it is proposed to maintain a similar approach that which applies under existing s 9C of the Act (with appropriate modifications for a single licence).

As such, a medicinal cannabis permit ceases to be in force at the end of the period for which it is expressed to be in force or, if it is revoked or taken to be revoked earlier, when it is revoked or taken to be revoked in line with the Act. Noting the precise nature of any amendments is a matter of drafting, for completeness, the permit could also cease to be in force when it is surrendered.

Should a perpetual licence period be adopted (see above), a similar modification is not required for medicinal cannabis permits, as a permit is:

- issued under a licence and is, therefore, limited to the period a licence is in force
- issued in relation to specific activities authorised under a licence, which may be limited in the time, seasonal or stage of a production process it is required for.

### Transitional arrangements

Along with other matters noted in the discussion above, ODC transitional arrangements for existing licences and permits and existing applications will be informed by the drafting approach adopted for the 2 stage licence process. Further information on transitional arrangements is expected to be provided during the consultation sessions in January 2020.

**The consultation sessions will provide more information on various matters, that will be informed by the drafting process and other recommendations, including:**

- **licence conditions**
- **permits**
- **transitional arrangements**