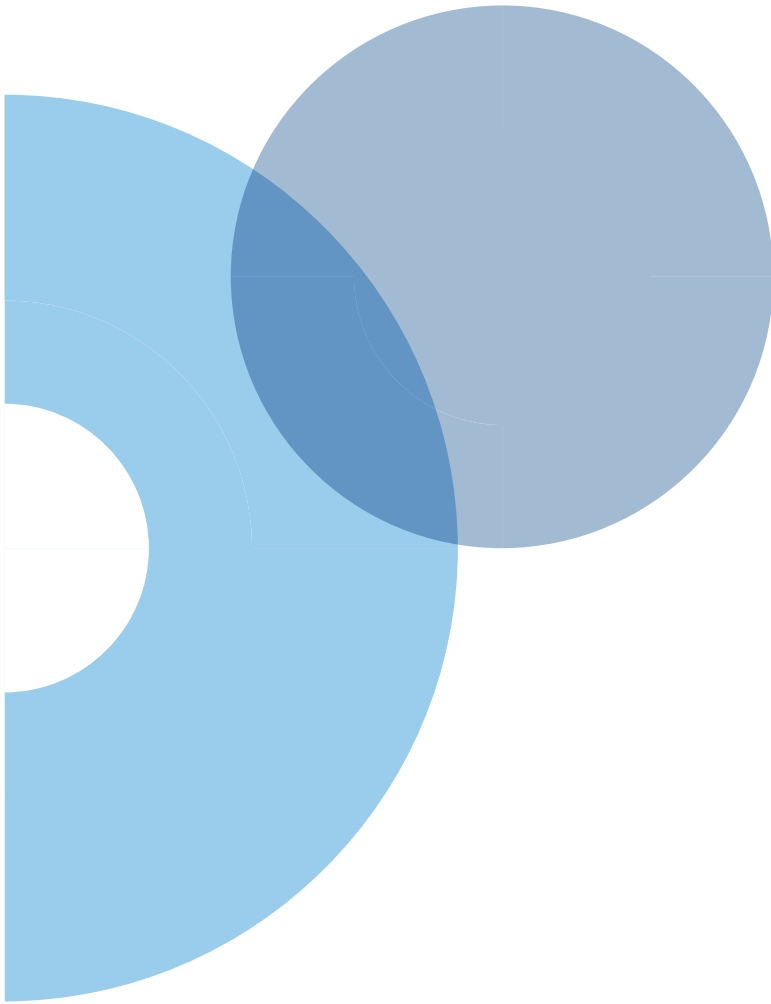




March 2019

Certifying Digital Mental Health Services

Discussion paper for consultation participants



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Supporting safe, high-quality digital mental health services

The Australian Commission on Safety and Quality in Health Care (the Commission) is seeking to develop ways to assist people who want to use digital mental health services.

In referring to digital mental health services, we are including the following ways by which consumers and carers can access treatment and care:

- Internet-based services
- Mobile health applications (apps)
- SMS counselling services
- Telephone services
- Videoconferencing services.

Electronic medical record software and programs are not included in our definition.

We know that for many people, treatment and care that is provided through these digital services can be as effective as face-to-face services. Digital services may be easier to access, and sometimes can be accessed anonymously to protect user identity.

If we can develop ways to assure people that digital mental health services are safe and effective, it will increase:

- The trust and confidence of consumers, carers and clinicians in these services
- Adoption rates of these services
- User choice.

The Commission is exploring the development of a certification framework to achieve these aims.

How you can help

We are seeking input from consumers, carers, clinicians, service providers and other stakeholders in the digital mental health sector to inform the development of the certification framework.

We are consulting people across Australia in March and April 2019. This includes holding face-to-face workshops in six locations and some online workshops. There will also be a written survey that people can complete if they wish during this period.

Through this consultation process we are asking you to share your thoughts, knowledge and experience about digital mental health services. It does not matter if you have never used digital mental health services. Your thoughts about this form of service delivery and what might be needed to assure you that services are safe and effective will be helpful.

The workshops and survey provide the opportunity for you to share your thinking with the Commission about the topics outlined in this paper. We look forward to you sharing your views on this important topic.

To get the best outcome, ThinkPlace will be assisting the Commission in this consultation process.

About this document

This discussion paper presents three topic areas that will be explored through the consultations:

TOPIC 1 What expectations and preferences of consumers, carers and clinicians does the certification framework need to meet?

TOPIC 2 What are the options being considered within the certification framework?

TOPIC 3 How might the certification framework be implemented, governed and funded?

If you are planning to participate in the consultation workshops, or to complete the survey, this discussion paper will provide guidance. It includes some information and questions about the three topic areas.

You may not want to respond to all of the topics that are discussed. That's OK. If you wish, please just focus on the areas that are of interest to you, or where you feel your experience and knowledge are relevant.

Key terms

Before you start, it may be useful to familiarise yourself with the definitions below as they relate to this project.

What is a digital mental health service (DMHS)?

For this project, a digital mental health services, or DMHS, is defined as a mental health, suicide prevention or alcohol and other drug service that uses digital technology to facilitate engagement and the delivery of care.

DMHS may be provided via an online channel, such as a website or an app, email, SMS, telephone, or videoconferencing. It can be a stand-alone service, or may be blended with face-to-face services.

On the Australian Government's [Head to Health](#) website, DMHS are grouped into four categories:

- Information and education (e.g. websites and apps)
- Digital counselling (e.g. telephone, email and SMS)
- Treatment programs (e.g. websites and apps)
- Peer support (e.g. moderated online forums).

What is a DMHS certification framework?

A DMHS certification framework should include the following:

- The aim of certification and the principles that underpin it
- What certification means, including the level of warranty that certification offers to DMHS users
- How the certification will be carried out (including any rules, technical requirements and procedures)
- Clearly assigned roles and responsibilities for the governance and administration of the certification scheme.

The certification framework will support ongoing safety and quality assurances for DMHS, including those listed on the Australian Government's digital mental health gateway [Head to Health](#).

What is certification?

Certification of products and services aims to provide quality assurance to consumers, and ensure that potential safety risks are managed.

Examples relevant to the digital health space include:

- Tools and resources to assist users to choose services
- Rating or endorsement of services based on standard criteria
- Independent assessments of the safety and quality of services against defined guidelines or standards
- Mandatory regulation of services.

Acronyms

DMHS – Digital Mental Health Service

NSQHS Standards – National Safety and Quality Health Service Standards

AHSSQA Scheme – Australian Health Service Safety and Quality Accreditation Scheme

Topic areas

1. What expectations and preferences of consumers, carers and clinicians does the certification framework need to meet?

Benefits of certification

The potential benefits of DMHS certification include:

- Increased user confidence in the quality of DMHS
- Greater protection of privacy and data security
- Reduced risk of harm to users
- Enhanced consumer and carer empowerment and choice
- Increased quality of DMHS
- Increased access to DMHS
- Program development that reflects user perspectives and experiences
- A culture of continuous improvement and enhanced usability
- Clear clinical governance structures for DMHS.

DISCUSSION POINT

Of all the potential benefits of the certification framework, what matters most to you?

Aspects to be considered

In addition to understanding the experience of users, the certification framework should also take into account:

- **Evidence base:** there is evidence available that the DMHS is safe and effective
- **Clinical governance:** the DMHS has systems in place to provide safe and high-quality care
- **Monitoring safety and quality:** the DMHS monitors its content, usability and performance, including any incidents of harm to users
- **Partnering with consumers:** the DMHS provides the opportunity for consumers and carers to engage in planning their treatment and care
- **Continuity and transitions of care:** the DMHS provides referrals to other service providers and shares relevant health information accordingly
- **Responding to deterioration in a person's mental state:** the DMHS can detect deterioration in a person's mental state and respond appropriately
- **Data security and management:** the DMHS protects user privacy and confidentiality, and controls the access, usage and storage of user data
- **Usability:** the DMHS functions as intended and is fit-for-purpose
- **Accessibility:** the DMHS makes it as simple as possible for users to locate and access appropriate services
- **Interoperability:** the DMHS can connect to other health records effectively and securely
- **IT infrastructure stability and security:** the DMHS works efficiently, reliably, and securely

- **Change management:** the DMHS manages changes so as to minimise the impact on users
- **Target population:** the DMHS makes it easy for users to determine whether the service is appropriate to meet their needs
- **User engagement:** the DMHS is co-designed with users
- **User satisfaction:** the experience of users who have engaged with the DMHS.

DISCUSSION POINTS

What does the certification process need to cover to meet the needs and expectations of consumers, carers and clinicians?

Thinking about the range of DMHS identified on page 2, do all service categories need to be certified?

Are there some types of DMHS that are a higher priority for certification than others?

2. What are the components being considered within the certification framework?

Components of a certification framework

The certification framework could be formed by a range of components including:

National standards for DMHS

National standards may help protect the public from harm and improve the quality of DMHS provision.

Each standard would contain a list of criteria that describe the key areas covered by the standard as well as the actions required to meet the standard.

The national standards would provide a quality assurance mechanism that allows DMHS developers and providers to test whether relevant systems are in place to meet expected standards of safety and quality.

Tools and resources

Tools and resources would assist potential users to know what to look for when making a choice about a DMHS. Toolkits could be designed to meet the needs of consumers, carers and clinicians.

Assessments

Assessments could be conducted as self-assessments or independent third-party assessments, and could be at the level of the individual DMHS or at the level of the service provider.

Options for types of assessment include:

Self-Assessment

DMHS would self-assess their conformance with the national standards and make this information available to potential users.

Independent Assessment

An assessment of a DMHS against the national standards would be conducted by an independent agency. The outcome of the assessment could be made available in a user-friendly format to potential users of the service.

Assessment of Service Providers

This option would take into account the service provider's approach to developing, procuring and operating their DMHS. If the service provider could demonstrate a culture of quality and organisational excellence, then it is likely that they would produce DMHS that meet the appropriate standards.

Certifying service providers with 'trusted provider' status would allow those services which offer multiple DMHS to minimise the cost and administrative burden of certification. Clear criteria would need to be developed on what is required to demonstrate a culture of quality and organisational excellence.

A Blended Assessment

An alternative approach may be to require those providers holding trusted provider status to still have each individual DMHS assessed but with a lighter assessment process. This could be based on a self-assessment or an assessment that focuses only on the key elements of interest to consumers and carers (which would need to be determined).

User reviews

DMHS users, including consumers, carers and clinicians, could describe their experience using the service and offer a rating, either as an overall rating of the service or a rating of each of the key domains or criteria set out in the national standards.

Rating systems

There are a number of ways in which the outcome of an assessment could be depicted:

- A star rating, similar to what is seen in an app store, showing an overall assessment of achievement against the national standards
- A multi-dimensional rating system that rates each domain or criteria of the national standards separately
- A simple trust mark (analogous to the Heart Foundation 'tick') that indicates a product conforms to the national standards.

Ratings could be:

- Displayed by the DMHS when marketing their service, or
- Used to develop curated libraries of DMHS as a resource for consumers, carers and clinicians.

The rating system should resonate with DMHS users. The system should enable users to make more informed and confident choices about which DMHS to use, without requiring expertise in the certification system as a whole.

DISCUSSION POINTS

What are the most important components for consumer, carers and clinicians?

What is your preferred method of assessment and why?

3. How might the certification framework be implemented, governed and funded?

Creating a system that builds consumer, carer and clinician trust

Building trust and confidence in the framework is essential to its success. For this reason the implementation, governance and administration of the certification framework are important dimensions to get right.

Governance and management of certification

The recommended model would be one where a government agency manages the certification scheme and undertakes periodic reviews of the national standards to ensure that they remain relevant in an agile and innovative digital world.

This approach mirrors the governance of the National Safety and Quality Health Service (NSQHS) Standards under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme.

Conduct of assessments and monitoring of DMHS

Options for how assessments are governed and DMHS are monitored could include:

- A **centralised model** where the assessment and monitoring is undertaken by a government agency
- A **de-centralised model** where government delegates the assessment and monitoring to trusted third parties like accredited NGOs
- An **integrated model** where assessment is undertaken through pre-existing, trusted certification programs, such as the AHSSQA Scheme.

DISCUSSION POINTS

Who should govern the certification scheme?

Do you support a centralised model for governing the certification framework and for setting and reviewing the national standards as proposed?

Is a centralised, decentralised or integrated model preferred for delivering assessments and monitoring DMHS under the certification framework?

Integration with existing regulation

The design of the certification framework and national standards would take account of the existing statutory and regulatory requirements across health, mental health, and digital health. The national standards would use existing standards where possible, to reduce duplication of effort and minimise the administrative burden for service providers.

There would be synergy between the national standards for DMHS and the NSQHS Standards and the National Standards for Mental Health Service (NSMHS).

Some DMHS may fall within the scope of the Therapeutic Goods Administration's (TGA) existing regulatory framework for medical devices and would be listed on the Australian Register of Therapeutic Goods.

DISCUSSION POINT

Where are the opportunities for existing standards to align with a certification framework for DMHS?

The benefits of participation for DMHS providers and developers

Certification should increase safety and improve the experience for DMHS users without reducing the diversity of available services, or impacting on the ability of DMHS providers and developers to be agile and to innovate.

To ensure that the certification framework is well-adopted, it is important to understand the:

- Benefits a DMHS developer or service provider may expect from certification
- Obstacles that may deter them from entering into the certification process.

Potential benefits

- Enhancing the brand of the DMHS
- Increasing the likelihood of endorsement from government agencies, clinicians and/or community organisations
- The potential link between certification and funding opportunities (e.g. with governments, Primary Health Networks or private health insurers).

Potential obstacles

- Unreasonable cost and complexity associated with certification
- Availability of resources to meet the requirements of certification, particularly for smaller organisations or services
- Availability of existing websites or gateways that do not require certification to list a DMHS (e.g. App Store or Google Play)
- Lack of available support and guidance for DMHS about the certification process.

DISCUSSION POINTS

What are the biggest potential benefits for DMHS developers and service providers and how could these be supported?

What are the biggest potential obstacles for DMHS developers and services providers and how could these be mitigated?

Funding certification

To achieve optimal uptake and sustainability, a certification scheme must be cost-effective and represent good value for government and DMHS developers and/or service providers.

Two options have been identified for funding the cost of a certification framework:

Government funded

Government funding, if agreed, may extend to supporting selected components of the certification framework (e.g. the establishment and review of national standards and governance of the certification framework) or the entire certification process (including the assessment of DMHS/DMHS providers).

This option may be supported if it can be demonstrated that maintaining a certification framework and national standards is sufficiently in the public interest or that it is a community service obligation.

Cost recovery

Cost recovery involves an entity charging for some or all of the efficient costs of undertaking an activity. Cost recovery may include the recovery of all costs or only part of the costs.

If a cost recovery approach is taken to funding a certification framework for DMHS, then DMHS developers or DMHS service providers would be required to pay a fee for being assessed under the certification framework.

Experience shows that when an individual or organisation is required to pay for a service, they are more likely to value it.

It is possible that, if required to pay for certification, DMHS developers or service providers may pass these costs on to service users.

DISCUSSION POINT

Do you have a preference between a government funded option (government pays) and a cost recovery approach (DMHS developer or services provider pays)?

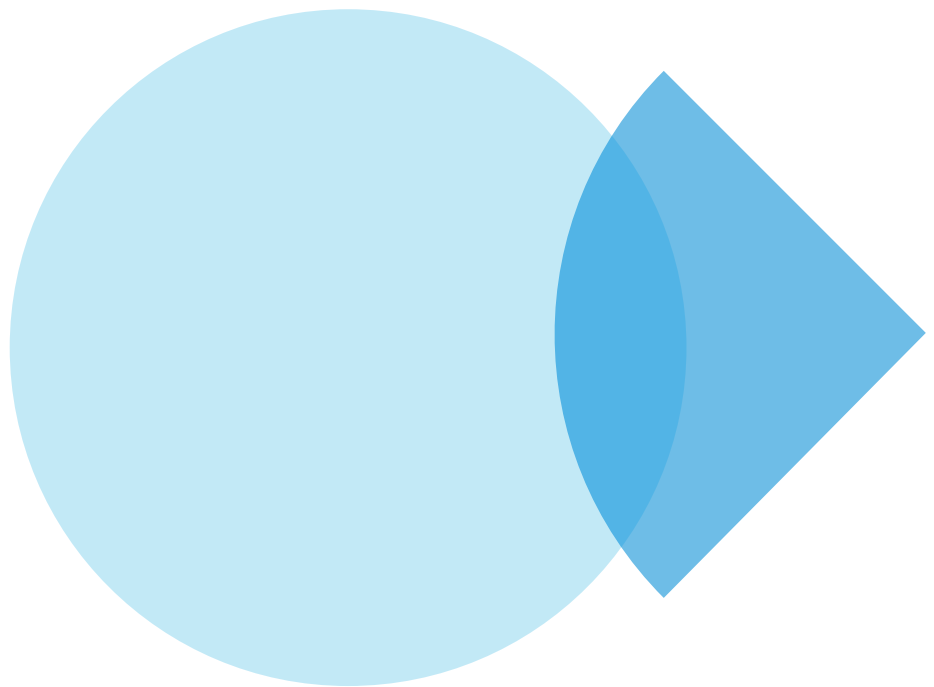
What happens next?

At the end of the consultation, the Commission will provide a report to the Australian Government Department of Health (the Department) on the options for a certification framework for DMHS, including the development of national standards.

Based on the option(s) agreed by the Department, the next phase of the project will progress the development of the framework and the standards. It is anticipated that there will be further consultation when this occurs.

For more information please visit www.safetyandquality.gov.au/dmhs

You can contact the Commission's project team at DMHS@safetyandquality.gov.au



About the Australian Commission on Safety and Quality in Health Care

The role of the Australian Commission on Safety and Quality in Health Care (the Commission) is to lead and coordinate national improvements in the safety and quality of health care.

The Commission works in partnership with the Australian Government, state and territory governments and the private sector to achieve a safe, high-quality and sustainable health system. In doing so, the Commission also works closely with

patients, consumers, carers, clinicians, managers, policymakers and healthcare organisations.

Key functions of the Commission include developing national safety and quality standards, developing clinical care standards to improve the implementation of evidence-based health care, coordinating work in specific areas to improve outcomes for patients, and providing information, publications and resources about safety and quality.

You can learn more about the Commission at: www.safetyandquality.gov.au



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