

2 March 2018

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Sydney NSW 2000

cc Bec Sykes  
Department of Health  
GPO Box 9848,  
Canberra ACT 2601

*CHF's Follow-up to the 23 February 2018 Workshop on the  
Development of a Framework for the Secondary Uses of My  
Health Record Systems Data*

Dear Dr Fodero

Thank you for the opportunity to attend the workshop held on 23 February 2018 at the Grace Hotel in Sydney on the Development of a Framework for the Secondary Use of My Health Record Systems Data in Australia.

We understand that this was the last scheduled opportunity for stakeholders to provide feedback before the Department of Health releases the final document to the public. We appreciate being able to submit this follow-up letter to provide more detail on some of the statements we made at the workshop and share statements there was not time to make on the day.

We support My Health Record and recognise the potential for the public to benefit from Secondary Uses of My Health Record System Data. The potential will only be realised with clear security and privacy safeguards that meet high standards and sound data governance and stewardship around appropriate use in the public interest. Building and maintaining public trust and confidence is essential to the delivery of digital health programs.

As stated at the workshop, HealthConsult is delivering a high-level implementation plan to the Department along with the Framework document. We ask that when the Department makes public the Framework that:

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- a version of the Implementation Plan also be shared publicly. It will be important for stakeholders to have a sense of implementation intent and timeframes
- there is a clear and timetabled consultation and review process on both the Framework and the Implementation Plan
- sufficient time and scope be given to the legal and privacy communities to investigate the implications of the Framework for consumers
- consumers are consulted on the Implementation Plan
- consideration is given to the concerns of NACCHO, and whether there are other vulnerable populations who would benefit from a moratorium on being included.

We also ask that, in recognition of the time it will take to get the 'core' of the Data Governance Board up and running, the Department set a date before which no secondary uses of data will be possible. Providing clarity on this, as well as holding a robust consultation and review process will go a long way to assuring consumers and the wider public that appropriate governance is being put in place, including risk management. This will also help separate the issue of secondary use from this years opt-out expansion program.

We now support the position in the draft Framework draft that the Australian Institute of Health and Welfare (AIHW) should be the auspicing organisation for the Data Governance Board.

Attachment A has our more detailed comments organised by the sections of the Framework draft. If you would like to discuss this matter further, please contact Dean Hewson, Digital Health Adviser on 0262735444 or [d.hewson@chf.org.au](mailto:d.hewson@chf.org.au).

Yours sincerely



Leanne Wells  
CHIEF EXECUTIVE OFFICER

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ATTACHMENT A

### *3 – Governance model for secondary use of MHR system data*

We believe there should be a key role for CHF as the national peak in developing the functions of the consumer panel specifically as well as providing input to the design of the Data Governance Board in general. We ask that:

- there be a clear framework for selecting consumers to the panel developed to ensure diversity and capability
- scope be given to members of the consumer panel to consult more widely with other consumers
- there be an open process for the development of the terms of reference for the Panel and Board
- depending on the size of the Data Governance Board, it should include 2-3 consumers/community representatives, not just the panel chair
- at least some of those consumers should be sourced through CHF as the national peak, similar to how we nominate for PBAC. We do not yet have a position on whether there should be a CHF representative on the panel.
- the NHMRC Community and Consumer Advisory Group not be considered a suitable proxy for the consumer panel. The panel and its terms of reference need to be fit-for-purpose
- further guidance on what 'core elements' are needed before the Board becomes operational and secondary uses are allowed is given.

### *4 – Secondary uses of MHR system data*

Thank you for agreeing to consider changing the language in this section from 'include' to 'includes but is not limited to'.

We would like to reiterate that there be further clarity given on uses that a consumer may view as secondary that are already allowed as a primary use through legislation governing My Health Record.

For example, a secondary use considered non-health related and hence not appropriate in the Framework draft is 'Assessment of eligibility for benefits'. However, item c in section 70 - Disclosure for law enforcement purposes, etc. of the My Health Records Act 2012 (version C2016C01104) states that the System Operator can authorise disclosure for 'the protection of the public revenue'. A

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consumer understanding of that may be that assessment of benefits may be allowed, and explaining why or if it would or wouldn't be should be done at the same time as release of the Framework.

We also request that:

- further guidance be included or shared alongside the Framework on what informed consent of people's data for secondary use will look like
- some guidance is included or shared alongside the Framework about how key features of the Productivity Commission's 2017 report into Data Availability and Use would be incorporated into the Framework, especially the proposed Consumer Data Right

### *5 – Organisations/individuals who could apply to access MHR system data for secondary use*

We acknowledge that consideration of placing some text from the Five Safes Framework's 'Safe Person' principle into this section of the framework is being given. It is important for consumers to have a clear understanding of the protection this 'fit and proper person' principle gives to the Framework.

We ask that consideration be given to how clear the wording can be around commercial access in order to give consumers confidence that public benefit and personal protections will be applied effectively.

### *6 – Access to, or release of, MHR system data for secondary use*

We strongly call for adequate funding to be secured for the organisation who auspices the Data Governance Board, and for the organisations that ensure effective consumer protection, such as the OAIC.

We also ask that:

- where guidelines between this and other decision-making processes around public health system clash, the more conservative should be applied
- the Framework include guidance on what rules already protect health data and the linking thereof, by specifically making example of PBS and MBS data

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- since some type of controlled access like SURE seems to be the most likely way to gain access to de-identified information, that this information be included in the Framework
- specifying a general approach to how fees should work or the process for deciding on how they will be approached be included in the Framework
- guidance on the types of research the auspicing organisation (AIHW) could do for a fee without releasing the secondary data to researchers

### *7 – Process for requesting and accessing data*

We generally support this section. We would like to add that we think that:

- HRECS must be NHMRC approved, and consideration given to whether all NHMRC HRECS should be automatically judged competent, especially after the Productivity Commissions Data Availability and Use report is responded to by government, as it suggests all HRECS should become NHMRC registered
- consideration should be given to whether the appeal mechanism of writing to the Secretary of the Health Department is sufficient, what mechanisms for reapplication there are, and whether there needs to be a process the Data Governance Board is responsible for in the first instance
- that the Framework makes clear the answer to the concern that in some cases multiple HREC approvals are needed, for example of both a University and a remote community, and that the answer be that the approval of both will still be required.

### *8 – Data Linkage*

We are satisfied with the answers we received at the workshop on Privacy Impact Assessments. We ask that clarity be provided in the Framework of the likelihood of the use of secure research environments over more open sharing. Allaying consumer concerns on My Health Record in general will be aided by clear statements here.

### *9 – Processes to ensure protection of the privacy of individuals*

We strongly request that sufficient time and support be given to the legal and privacy communities to respond to the Framework, especially on whether further legislative changes are needed to sufficiently protect consumers. The OAIC requested in their submission that the Privacy Act 1988 be extended to cover

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secondary uses, as their current remit only extends to the point at which My Health Record data leaves the system. We also ask:

- where one nominated expert on de-identification processes is enough
- that CUA's be consumer readable, or include a consumer readable 'explanatory statement' and the be included on the public register
- that mechanisms through which it can be ensured data is not used for other processes is made clear in the Framework or its Appendices

### *10 – Preparing and making data available, and data quality*

We ask that it be made clearer in the Framework that any reuse of secondary data requires a new application to the Data Governance Board, as the decision on whether is sufficiently de-identified is a risk assessment made at a singular point in time, not perpetuity. We also ask that the Framework provide guidance on the responsibilities for preparing and making data available between the Board and the auspicing organisation be made clearer, if only through the Implementation Plan.

### *11 – Monitoring and assurance processes*

We, as far as our expertise allows, support the OAIC's position on extending the Privacy Act to cover secondary uses of data and ask that this be considered more fully in a consultation process following the Framework's initial release. We also ask that it be considered again as to whether exception reporting of breaches is enough, and whether the Board or another organisation has a responsibility to actively monitor uses of secondary data.

### *12 – Risk mitigation strategies and imposed penalties*

We strongly ask that there be transparency in the public register on how and why a decision was made to accept or reject an application for secondary use. Both PBAC and the TGA Scheduling decisions provide guidance to the public, and this level of transparency is becoming the expectation of consumers. We also ask that:

- the internal processes, benchmarks and guidelines the Board uses to guide their be made public
- that consideration be given to the potential privacy impacts of a public register for studies that could lead to a risk for communities or individuals

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- that the Framework state as a future goal that a consumers My Health Record will include an audit log of secondary uses, and the research created from those uses
- that the register include mechanisms to gather feedback and the Data Governance Board and/or auspicing organisation have a process for responding to it
- that further advice is gathered on whether the current penalties in legislation are sufficient to deter misuse
- that the Framework make it clear who is responsible for enforcement

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