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PCEHR/HI Discussion Paper Feedback
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AMA submission: PCEHR/HI Legislation Discussion Paper

The AMA continues to support a properly built and governed PCEHR system as an important tool to improve care provision and thereby improve the healthcare system, despite some concerns with the way in which the PCEHR has been designed and implemented to date.

The AMA welcomes the move towards making consumers' participation in the PCEHR apply on an opt-out basis, and the changes to the PCEHR legislation and HI Service to enable this, subject to the comments provided in this submission.

The AMA's overall interest is that the trials of participation arrangements are well-defined and clearly focused on testing the basis for participation, not complicated or diverted by other issues. The trials must enable timely assessment and decision on moving to an opt-out arrangement for the PCEHR. While the trials may identify other matters, these are by-products of the trials and should not distract from their purpose.

The Legislation Discussion Paper provides useful information on many of the changes proposed to enable the trials. In other cases the information provided is minimal and insufficient to enable due diligence consideration of the proposed 'hard law' changes involved.

The AMA is not able to support proposed changes which are not justified by clear information on the specific problem to be addressed, the evidence that establishes the problem, how this will be addressed by the proposed legislative change, and the full consequences of that change. These areas are identified in this submission.

There are several areas where the specific results of the proposed amendments are not described in the discussion paper. Therefore, the AMA expects an **Exposure Draft** of the legislation will be provided to enable stakeholders to properly understand the obligations on healthcare organisations. This is good legislative practice, and essential where both the principal and amending legislation are complex, impose significant obligations on consumers and healthcare providers, and there is no clear documentation of the justification or consequences of some of the changes proposed. An Exposure Draft is an investment that will repay in the passage of the legislation, the operation of the trials and the ongoing future of the PCEHR.

The success of the trials, and their contribution to a decision on moving to opt-out, will depend to a significant degree on the quality of information and services for awareness,

training, support and resources for consumers and healthcare providers. The AMA notes this has been grossly inadequate in relation to both eHealth foundations and the PCEHR to date.

Learning from this, the trials must be supported by a well-thought-out approach to providing single point access to information that is effective, accurate, up to date, concise, and layered for the needs of different users and different levels of detail. This should comprise a 'trials handbook' available through different media and platforms as required. Material for the handbook should be developed and road-tested with intended users.

The AMA has consistently advocated for core clinical information in the PCEHR to not be subject to patient access controls. This was also a recommendation of the PCEHR Review.

Certainty that PCEHRs contain predictable core clinical information, not affected by the application of access controls, is critical to the achievement of two of the objectives set for the PCEHR in section 3 of the PCEHR Act, ie:

> *(c) reduce the occurrence of adverse medical events and the duplication of treatment; and*
> *(d) improve the coordination and quality of healthcare provided to consumers by different healthcare providers.*

As a starting point, core clinical information could be defined as:

- medications;
- adverse events;
- discharge summaries;
- recent results of diagnostics tests; and
- shared health summaries.

Given the legislative objectives and the promised benefits of the PCEHR system, all healthcare providers involved in providing care to a consumer should have access to the core clinical information, not only those few providers in strictly limited 'break glass' emergency situations.

While it will be useful to test the concept of core clinical information, the AMA recognises that it is likely to be impractical to do so while at the same time testing opt-out. The AMA notes testing of core clinical information could therefore be undertaken as a separate or phase 2 trial, and the current proposed trials will maintain the existing provisions for access controls.

In a broader sense, the AMA notes the trials, the proposed new governance arrangements and the provision of funding for three years operation mark an important transition for the PCEHR and ehealth.

These watershed developments mark a point to deal with other problems that have held back progress unnecessarily.

The PCEHR has suffered from the lack of a clearly articulated and shared goal underpinning the national ehealth system. In the absence of an agreed purpose and documented plan, there has been scope for widely varying interpretations and understanding. The rules and systems for the PCEHR's operation have been seen as arbitrary or misguided, restrictive, and lacking in internal consistency.

These issues have been compounded by the lack of a strategic plan and a clear development program for the PCEHR. There is now a clear need and a perfect opportunity to start with a plan for the period leading up to ACeH's commencement, including responding to the PCEHR Review recommendations.

The current major developments should also mark a new way of progressing ehealth with clinical and other stakeholders, based on a cooperative and collaborative approach, rather than defaulting to compulsion and coercion.

The PCEHR is reliant on the good will of the private sector healthcare provider community. These healthcare provider organisations and individual healthcare providers are already experienced and proficient at handing a wide range of sensitive information and making timely and accountable decisions on the basis of it, including in relation to clinical information about the needs and treatments for their patients, and responsible referral of patients for other healthcare services, including access to scarce and expensive health resources. Medical practitioners act on an unpaid basis as an agent of Government to submit patients' claims for Medicare rebates.

Imposing additional and often gratuitous statutory obligations in this environment is not required and often counter-productive.

Detailed comments

Name

The AMA supports the proposed change of name from PCEHR to My Health Record.

3.1.2 Definitions

Alignment between HI and PCEHR Acts

The intermingling of proposed legislative changes to both the PCEHR and the HI Acts in a single discussion paper does not actually assist a careful consideration of the different changes involved in the specific context of the principal legislation. Two separate discussions of the changes proposed to each Act, supplemented with a concise statement of changes made to both Acts, specifically for consistency or overlap etc, would have been more useful.

Regardless of method of presentation, simply identifying differences between the two Acts does not provide sufficient information of itself to justify proposals to align or standardise the approaches, terminology or other legislative constructs currently used. What apparently looks simply like different terminology may be actually based on a different legislative intent in two Acts prepared for different purposes. Where changes are proposed, the reasons for the existing variation should be identified.

Clarification of "healthcare"

The AMA notes the definitions and the proposed change to include health related disability, palliative care or aged care service providers in the definition of 'healthcare', and the intention to align 'healthcare' and 'health information' with the Privacy Act.

New definition: "Core Clinical Information"

The AMA acknowledges the concerns that patient privacy is paramount, but this should and can be balanced with the need for electronic health records to make healthcare safer, more efficient and more effective.

Doctors treat patients most effectively when they have access to all the necessary clinical information. Patient safety and the quality of care will be improved if treating doctors can access and contribute to core clinical information about the patients they are treating in their PCEHR.

The availability of reliable and predictable core clinical information in a PCEHR, not affected by the application of access controls, is critical to the PCEHR's effectiveness in reducing adverse medical events, duplication of treatment and improving coordination of care by different healthcare providers.

As described in the general comments above, a new definition of '**core clinical information**' should be included in the PCEHR Act, with arrangements to trial the operation of this concept to be developed as a Phase 2 trial of the PCEHR:

Section 5 Definitions

After 'contracted service provider' insert

'**core clinical information'** means information about the consumer's state of health in relation to:

- medications;
- adverse events;
- discharge summaries;
- recent results of diagnostics tests; and
- shared health summaries.

Additional consequential amendments could be made in other relevant sections of the PCEHR Act as appropriate to operationalise this concept of core clinical information.

3.1.2 Distinguishing health care providers and organisations

As noted, the AMA considers that mixing together descriptions of proposed amendments to separate legislation enacted for different purposes is not helpful for a clear consideration of the different legislative changes involved.

The Legislation Discussion Paper claims the HI Review recommended this change because treating them together gives organisations the same level of privacy protection as individuals, but the Privacy Act does not treat information about organisations as personal information.

This does not make a sufficient case for legislative changes to distinguish between healthcare providers and organisations.

If the reason or consequence of the proposed change, as highlighted in the example, is to enable the System Operator to advise consumers which organisations participate in the PCEHR, legislative change is not required and is not the most/an effective way of achieving this objective.

Rather than a blanket approach based on legislative compulsion, it would be more effective to engage directly and work with healthcare provider organisations to consciously and willingly provide their details for public access by agreement.

3.2 Governance

Governance and establishment of ACeH

The AMA welcomes the proposed new governance structures and looks forward to stakeholder involvement and consultation in the work of the implementation taskforce, ACeH itself, and with the Department of Health in relation to national ehealth policy.

A key requirement for the new governance arrangements is for the ACeH Board to include the types of expertise and experience that span across its responsibilities.

As well as healthcare recipients, the Board should include a minimum of healthcare provision expertise. This should include Board members from publicly and privately practicing clinicians, covering specialist and primary care healthcare provider backgrounds.

The whole ehealth system relies on private sector healthcare providers and private sector health ICT providers, yet neither have been involved as representatives of their sectors in ehealth governance arrangements to date. There has also been insufficient focus on medical specialists other than general practitioners in PCEHR and ehealth implementation.

This span of expertise should be reflected in a single advisory committee to provide stakeholder advice and input to the ACeH Board. The proposed ACeH Jurisdictional Advisory Committee should be renamed the ACeH Stakeholder Advisory Committee and its membership re-specified to match with representation of the same stakeholders on the ACeH Board. Although not mentioned at section 3.2.1, this will presumably include expertise in aged care and disability care, given the other changes proposed in the discussion paper.

The proposal to replace the IAC with an 'independent assurer' would not be supported without the above governance arrangements. The IAC and the independent assurer appear to have different objectives, functions, viewpoints and scale of operations. Important functions of the IAC would be lost without the establishment of an ACeH Stakeholder Advisory Committee.

Under these arrangements, the ACeH Stakeholder Advisory Committee would become a very useful and critically-important resource for stakeholder input to ehealth more broadly, whether through the ACeH Board or to the Department in terms of national ehealth policy. The distinction between these two policy domains can and has been a relatively artificial construct, and investment in the SAC as a source of stakeholder advice will repay itself in both domains through improved policy and implementation over time.

3.2.2 HI Service Operator

The AMA does not see any justification for, nor does it support, any proposal to make provision for an open-ended, undefined future change to prescribe a different but unspecified entity to be the HI System Operator. There is no information to justify why the HI System Operator should be disconnected from the Medicare system. If at some future point a specific proposal is made to change the HI System Operator, it should be put with full information for consideration by Parliament as a specific amendment to the principal legislation, not as a disallowable instrument.

3.3.1 An Opt-out PCEHR system?

The AMA welcomes the move to trial opt-out arrangements for consumer participation in the PCEHR. It looks forward to well-defined, tightly-controlled trials to be completed in a timeframe that allows for evaluation and timely migration to full implementation of opt-out arrangements.

The selection of geographical locations for the trials will no doubt take a range of factors into account, including how geographically well-defined the trial populations are, the concentration and linkages between healthcare facilities (including aged care services), and the current level of ehealth usage as a platform to trial use of the PCEHR on an opt-out basis.

The quality and availability of awareness, education, training and support services will be critical to the success of the trials. These services should be described in the trials handbook referred to above. Among many other issues, this should include how local healthcare providers will be contacted, engaged and involved in the trials, and any specific implications for them (such as patients wishing to discuss their participation, selection of healthcare provider or access controls with their GP etc).

It would be useful for the trial handbook or other information to outline the main steps following completion of the trials, including how national roll-out of opt-out arrangements would be undertaken.

Opting out in trial regions

There will need to be a mechanism to deal with situations where a person may choose to opt-out of a PCEHR in part to protect their identity. If the System Operator sends a letter confirming this to the latest address held by Medicare it may immediately defeat this purpose.

Individual consent

The proposal for 'legislative authorisation' under opt-out arrangements in relation to uploading records (in place of actual patient consent) is welcomed.

Legislative authorisation must be designed to ensure that standing consent for health professionals to upload data continues unchanged as for current opt-in arrangements, unless the individual consumer asks a health professional not to upload something.

This will need be covered in the proposed trials handbook and other information to make clear that legislative authorisation means consumers have given standing consent to uploading of their health information, exactly as applies under the PCEHR Act under current opt-in arrangements.

Secondary use of information

The AMA notes there are no proposed changes to how information in the system can be used for secondary purposes. It is unclear exactly what is intended by the statement that processes and systems for secondary use of information 'have still to be developed'. There are well-established protocols and resources for the use of health information for secondary purposes, including those produced by the:

- NHMRC (see eg *Guidelines approved under Section 95A of the Privacy Act 1988);*
- Office of the Australian Information Commissioner (see Privacy Fact Sheet 17 (January 2014) and Australian Privacy Principles)
- World Medical Association (see eg WMA Declaration on Ethical Considerations regarding Health Databases).

The purposes for which information can be collected need to be clearly explained in terms that are meaningful to patients and clinicians.

Registering healthcare provider organisations in opt-out trials

The commitment that healthcare provider organisations etc will continue to participate on an opt-in basis is welcomed. This should not be changed.

3.4 Obligations of parties

3.4.1 Obligation to enter into participation agreement

The proposed removal of participation agreements is welcomed. Many HPOs saw the agreements as a heavy-handed and one-sided set of obligations that appeared to be driven by the needs of government but actually discouraged participation of healthcare provider organisations.

Government will need to produce information that provides a simple explanation of the obligations on healthcare providers who choose to use the PCEHR, eg what information, undertakings, preconditions etc are required, where will these requirements be documented,

what will HPO or other entities be required to do to accept any such conditions, what will be the consequences of not meeting a condition etc.

This needs to be documented in clear plain English and readily accessible to healthcare providers.

The removal of the agreements should not involve continuation of any unnecessarily onerous provisions of the agreements in another form. Equally, the indirect benefit of identifying obligations in one readily locatable place should not be lost (currently in participation agreements, in future in readily available information as proposed here, and in the trials handbook etc).

3.4.1 Liability

The proposal to make the System Operator subject only to liability under the common law and not under provisions in the participation agreement is noted. However, it is not clear what the text box note actually means and what specific limits it refers to, ie:

Note: The common law applies limits to loss and damage that can be recovered.

To increase the proposed legislation's clarity and usefulness on this point, the AMA recommends the System Operator's legal duties be clearly set out in the legislation. The legislation should identify the heads of liability which the system operator bears in relation to the PCEHR and include an indemnity clause covering users in case of the system operator's negligence.

Reconciliation of provisions in Participation Agreements and proposed future treatment

From the discussion paper we are not able to explicitly identify which obligations that fell on healthcare providers under the participation agreements will be carried into the legislation or let go completely. For example:

- the PCEHR Act should place an obligation on the System Operator to provide information on request about any times when the PCEHR system was unavailable (clause 3.4 of the PA)
- there should be prompt notification of change in System Operator contact details (clause 3.6)
- data quality (clause 4.1) – presumably what is intended to be addressed at paragraph 3.4.3 in the discussion paper – see comments below
- obligations to notify the System Operator of certain matters (clause 4.4) – are these to be preserved, if so, where, in what form and how is it proposed a HPO will undertake these obligations?
- intellectual property - the proposal for the PCEHR Act to provide that use of a document in the PCEHR or downloaded from the PCEHR does not infringe copyright is welcomed. In relation to uploading material to the PCEHR system (clause 7.2) – the provision in the PA that a HPO can only upload material where certain IP conditions are met does not appear to be explicitly addressed in the discussion paper, which focuses on use of documents *after* they have been uploaded (and presumably relates to clauses 7.2 and 7.3); what IP conditions apply to uploading documents, where will they be defined and how will they operate?
- assistance in relation to enquiries (clause 8.1) – is this obligation to continue, if so, how and where will it be defined once the PA is ceased?
- termination of ability to continue to participate (clause 12) – where will actions that cause/enable termination be defined?

3.4.1 Data breach notifications

While the AMA is happy for a requirement to report data breaches to be carried over from the participation agreements, it should not involve a new penalty. The consequences of a failure to report a breach under the Act should be no greater or different in nature than the consequences under the participation agreement.

The participation agreement imposes obligations on HPOs to promptly notify the System Operator of system related errors or where security has been compromised (clause 4.4). The System Operator has the right to terminate the agreement if provisions have been breached and the breach is not remedied within 28 days of a notice to rectify, or the breach is not capable of being remedied (clause 12.3). The same penalty should apply when participation agreements are removed.

The proposal to amend the PCEHR Act to require reporting of data breaches by HPO's and contracted service providers is not supported if it involves different penalties than the participation agreements.

3.4.2 Centralising and simplifying participant obligations

Section 78 of the PCEHR Act currently provides that *'A person that is, or has at any time been, a registered repository operator or a registered portal operator must not contravene a PCEHR Rule that applies to the person.'*

Civil penalty: 80 penalty units.

The discussion paper doesn't provide any specific justification and specification of the proposed changes to section 78, or to the other unspecified, 'minor amendments' that are referred to as being proposed to the legislation. Therefore the AMA can't assess the impact for medical practitioners.

If the purpose is to make healthcare providers and other participants subject to compliance with the PCEHR Rules, this should be clearly stated and the reasons why this is required (ie the justification) should be explained. Specifying that legislation will be amended so that it applies 'appropriately' to all participants is not informative.

Further, if the proposed amendments would make healthcare provider organisations or providers subject to penalties which they are not currently subject to, the AMA cannot support the proposed amendments without clear information.

3.4.3 Obligation for organisations to have PCEHR policy

The AMA does not support the inclusion of an additional undescribed and non-specific requirement for a HPO's PCEHR policy to address how the organisation will address data quality.

As part of input to the Department on the draft participation agreement, including in written feedback on the draft agreement (see AMA comments on the draft participation agreement provided on 19 June 2012), the AMA achieved the removal of a proposed requirement to 'ensure the quality and content of any records...uploaded to the PCEHR system', for the same reasons as outlined below.

Healthcare provider organisations that are medical practices are already required to meet a range of provisions that directly address data quality, including:

- AMA Code of Ethics
- Medical Board of Australia Good medical practice: a code of conduct for doctors in Australia

- Health Insurance Act 1973 - medical practitioners are required to keep adequate and contemporaneous records of the rendering or initiation of services.

There is no information justifying this proposed additional and redundant requirement, no description of what "data quality" actually means, or may be intended to mean, and no explanation of how such a provision would make any difference to the quality of clinical information which is already required. The discussion paper does not help by seemingly equating data quality with 'appropriate security and information handling practices'.

In terms of current requirements, for example, the Australian Council on Healthcare Standards EQuIP 5 Standards Criterion 1.1.8 requires that 'the health record ensures comprehensive and accurate information is collaboratively gathered, recorded and used in care delivery'.

The Medical Board's Good medical practice: a code of conduct for doctors in Australia provides at section 8.4 Medical records:

Maintaining clear and accurate medical records is essential for the continuing good care of patients.
Good medical practice involves:

8.4.1 Keeping accurate, up-to-date and legible records that report relevant details of clinical history, clinical findings, investigations, information given to patients, medication and other management in a form that can be understood by other health practitioners.
8.4.2 Ensuring that your medical records are held securely and are not subject to unauthorised access.
8.4.3 Ensuring that your medical records show respect for your patients and do not include demeaning or derogatory remarks.
8.4.4 Ensuring that the records are sufficient to facilitate continuity of patient care.
8.4.5 Making records at the time of the events, or as soon as possible afterwards.
8.4.6 Recognising patients' right to access information contained in their medical records and facilitating that access.
8.4.7 Promptly facilitating the transfer of health information when requested by the patient.

Obligations to use PCEHR system

The AMA looks forward to the time when the PCEHR system is operating universally with optimum ease of use and seamless integration across health care providers.

This is in fact the situation desired by clinicians and the point at which there will be a universal, automatic and effective incentive for all clinicians to participate in the PCEHR.

At this point, and only at this point, will it be sensible to make uploading of clinical information to the PCEHR a condition of accessing Medicare rebates for certain health services/items.

Healthcare providers should only be required to upload the results of specific Medicare services as a condition of accessing a Medicare rebate for the service when all of the following are in place:

1. all patients and all providers who could potentially use the relevant items are actively using the PCEHR;
2. operation of the PCEHR is simple, seamless, integrated with clinical software tools and works with maximum ease of use; and

3. use of the PCEHR is integrated across all healthcare provider organisations and healthcare providers, including primary care, specialists, hospitals, aged care, disability, palliative care providers.

Until these conditions are achieved there are a number of issues that are relevant:

- If healthcare providers have already chosen to opt-in to the system then logically there is likely to be little need for an additional incentive tied to Medicare fee for service items.
- Imposing an upload requirement on universally available health insurance/Medicare rebatable services is inconsistent with an opt-in system for healthcare providers.
- The information that is required to be documented to attract Medicare benefits for health assessments, medication reviews and care planning services does not contemplate full publication via the PCEHR. The shared health summary was designed specifically to provide useful clinical information for the patient and other users of the PCEHR and will often contain some, but not all, information from these other documents. A shared health summary prepared with or resulting from such services is likely to be much more useful to upload to the patient's PCEHR.
- The need for other healthcare providers in addition to medical practitioners to be required to upload information to the PCEHR.

In the meantime, if increased uploading of clinical documents to the PCEHR is desired, it should be incentivised as an activity in its own right through a separate payment, not attached inappropriately to an existing Medicare rebate designed for an entirely separate purpose.

A clearly more effective solution to populate the PCEHR with useful clinical information is to provide a Medicare rebate specifically for the uploading of a shared health summary or event summary.

3.4.7 Obligation for System Operator to notify decisions

This proposal is unsupported by any specific and quantified information why the current system requires change. Giving hypothetical examples of potential problems with current notification requirements, with no information about whether they have in fact occurred and what the consequences of this have actually been, does not justify a change.

Instead, this proposal seems to be entirely driven by the need to simplify processes for government. The current legislative provisions were designed to have balanced regard to need for the individual or entity concerned to actually receive a communication with certainty, compared with imputed receipt of a token communication such as an unnoticed email.

This proposal could have significant implications for healthcare providers being forwarded an important notification, such as a notification affecting their continued participation in the PCEHR system, by email.

Not only would such a decision, which could be about cancelling or suspending their PCEHR registration, be deemed to have effect at the time the decision is emailed by the System Operator, but as an email to a (large) health provider organisation it could easily go astray and not be received by the person who was intended to receive it and who is in a position to take action about it.

Furthermore, if the communication dealt with a reviewable decision, the date that notification of the decision was received (via an insecure and unreliable email) determines the period in which the HPO or other recipient must commence action.

*[See, for example, PCEHR Act s97(4): A person who is given a written notice under subsection (2) may, by written notice given to the System Operator within 28 days **after receiving the notice**, ask the System Operator to reconsider the decision.]*

The AMA does not support giving the Systems Operator flexibility to choose how notifications would be made.

3.4.8 Retaining records

The trial of opt-out arrangements highlights there should be a streamlined, uncomplicated procedure for patients who want data removed (under certain specified circumstances and/or after a certain time).

3.4.9 Obligation for System Operator to provide system testing

It is not clear from the discussion paper why this requires legislative change nor what such a change would actually be, given the test environment would not use real information and be isolated from the live system.

How this relates to the provision of a user testing environment in which clinicians can 'try out' the PCEHR should be clarified. The AMA strongly supports a user testing environment. More information is needed to clearly establish whether this proposed legislative change is required to enable user or system testing.

3.5 Privacy

3.5.1 Notification of PCEHR use

The AMA is not convinced the proposal - to provide an access control allowing alerts to be sent to individuals by SMS or email every time their PCEHR is opened - is sensible or practical.

It is not clear what problem this proposal is intended to address, or even that it would address effectively any (as yet unspecified) problem. There is no equivalent facility applying to paper records or e-records within an organisation.

Being informed who has accessed your PCEHR may be sensible and useful in the right circumstances. These are already defined in the PCEHR Act. The AMA *Guide to using the PCEHR* recommends that if a medical practitioner accesses a patient's PCEHR when the patient is not present the medical practitioner should inform the patient during any subsequent consultation that their PCEHR was accessed.

Being informed every time your PCEHR is opened is not sensible. What actions would a patient take on receipt of such information and in what timeframe (other than likely concern/anxiety)?

Would a patient presenting to an Emergency Department, unconscious or with limited capacities due to trauma or serious illness, be in a position to welcome and/or take action on multiple SMS notifications as a result of their PCEHR being opened by multiple members of the ED team?

Many GPs and other medical practitioners do documentation and other work-ups for patients with eg chronic disease after normal surgery hours. Opening a patient's PCHR should not generate an automatic notification at that time.

3.5.3 Collection, use and disclosure of information

As noted, the intermingling of HI and PCEHR changes throughout the Legislation Discussion Paper has some advantages but also some drawbacks. Drawbacks include creating an

expectation that the two separate and distinct pieces of legislation, prepared for different purposes and at different times, should use the same legislative constructs and terminology at all points.

This generally laudable objective must be subject to achieving the specific objectives of each piece of legislation, and careful assessment to see whether what might look like simple or accidental variation in provisions is in fact a sensible variation reflecting the legislative intent.

A general statement flagging a move to a principles-based approach can be supported 'in principle', but cannot be supported in specific terms without a clear justification for the change and a 'before and after' table showing what prescriptions are to be replaced by what principles. The justification for a change in this area must include a specific and quantified statement of the problem.

In the terms of the discussion paper, who has been 'confused about what they can and can't do' under the current arrangements? What are the specific barriers to the effective operation of the HI and PCEHR system that have been encountered? If the nature of the authorisations will not change, but 'simply their representation in legislation', what actual change will have been effected and to what purpose?

The AMA does not support this change without the opportunity to consider this information.

An accurate and well-written prescription can be much easier to comply with than a vaguely expressed set of principles. Moving to a principles-based approach could inadvertently create a new lack of certainty and room for ambiguity in interpretation that could create circumstances for unintended breaches of privacy requirements.

When they are resolved, these and other privacy-related aspects of the PCEHR need to be clearly explained in awareness, education and training material for patients and healthcare providers. One feature of the PCEHR to date has been clinicians and their patients being unclear about the details of current rules regarding collection, use and disclosure of information, and what is required of them.

<u>Third party information</u>

Clarifying that healthcare providers may include relevant third party information in uploads to the PCEHR is welcome. It is sensible to make provisions for situations where part of a patient's clinical information may contain information about someone else.

It is assumed this change, together with the proposed change to treatment of copyright, will replace the current IP provisions in the Participation Agreement as they affect the System Operator. It is not clear whether HPO's still face IP issues when uploading information to the PCEHR *(see above re participation agreement).*

<u>Healthcare Provider Directory (HPD)</u>

Subject to appropriate transition arrangements, the AMA supports the proposals to remove the need for organisations to provide consent before they are listed in the HPD.

Transition arrangements are required to allow time for the Commonwealth to ensure HPOs are aware of their obligations under the Healthcare Identifiers Act and Rules (including s 9B of the Act) to provide professional and business details of their organisation to the Service Operator, which will now be included in the HPD.

Healthcare identifiers by prescribed entities

Allowing other entities to handle healthcare identifiers should be approached carefully. There is potential to significantly dilute and diffuse the purpose of the healthcare identifiers system by allowing other entities to handle HIs. Any such expansion must be considered as an amendment to the principle legislation, not as a delegated legislative instrument.

For example, if there is a clear policy intent to enable one or more of aged care providers, NDIS disability providers, primary health networks, palliative care services, as additional categories to handle healthcare identifiers, these should be specifically included in the legislation.

This will be consistent with the approach proposed to expressly authorise the Information Commissioner to handle healthcare identifiers, by amendment to the Act. The AMA does not agree that a different approach should be used for other providers. A general head of power should not be established in the HI legislation to enable such additional entities to be specified by regulation.

Retaining information for security purposes

What fraudulent activities have generated this proposal? There is no information to establish why the ability to collect personal information by the System Operator is required or how it will actually be used. The PCEHR system was not designed to be a database of personal information about healthcare providers and a much clearer statement of the problem, its frequency and seriousness of any episodes will be needed to justify this change.

Handling by AHPRA

The AMA does not support the proposal for AHPRA to be provided with additional information for the purpose of 'playing a role' in relation to healthcare identifiers. This is not AHPRA's role. AHPRA was established to assist the registration of practitioners, for which it receives funding from the practitioners involved. It is not appropriate to confer new roles on AHPRA that are not directly about APHRA's core functions, and certainly not without specific Government funding of any additional responsibility.

Penalties for misuse of information

The AMA does not agree that the current penalty regime for the PCEHR should be increased. There is no information to justify the imposition of criminal penalties and therefore no requirement or purpose in moving from the current civil penalty structure. Introducing criminal penalties without reason will be a deterrent to participation in the PCEHR.

Without information on the incidence of current breaches leading to penalties there is no justification for the current criminal penalty structure in relation to healthcare identifiers. This should be changed from criminal to civil penalties.

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