Response to Request for Comment

on NEHTA's "Electronic Transfer of Prescription - Draft"

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Executive Summary

On review of the 'Electronic Transfer of Prescriptions' document suite, the Australasian College of Health Informatics (ACHI) would like to provide formal feedback in relation to the draft framework proposed.

Firstly, NEHTA should be congratulated for the current and ongoing development of what might be described as one of the cornerstones for moving the Australian healthcare sector into the 21st century. These significant advances will likely touch all Australians and have far reaching impacts for the future of healthcare delivery. As such, it cannot be emphasised strongly enough that the platform and framework being developed now must be characterised as being; comprehensive, exhaustive in its detail, robust in nature, receiving appropriate 'buy-in' from all stakeholders and must be delivered in a manner which is achievable, measureable and outcome driven. Overriding these factors, this platform, framework and implementation must be achieved within a defined period of time and within the allocated budget resource. It is well understood that there are significant complexities and hurdles that must be overcome to achieve these objectives. Equally, it also understood and appreciated that no one person, group or organisation is going to have all the answers in isolation. To this end, ACHI wish extend their support, so that together and with all other stakeholders, we can build a future healthcare system that all Australians can be proud of.

It is noted that NEHTA will provide a forum to give the opportunity for interested parties to seek clarification on the specifications. ACHI representatives would be happy to meet with NEHTA representatives to further discuss this framework initiative and to provide advice and support where appropriate.

Salient points raised in this document primary relate to clarity on scoping decisions made; or in other words, why particular areas have been defined as being 'in scope' or 'out of scope'. Similarly, there are also questions and concerns raised, relating to the process of relative prioritisation given to what should be included in the initial stages of implementation (Release 1) and what should be implemented during a later, undefined, period of time (goal-state).

Further to these broad matters of scoping, prioritisation and timelines, there has also been concern raised regarding uncertainty in the level of stakeholder input in the development of this framework. The draft framework is commended for being a great starting point for discussion; however ACHI would have concerns if only minimal exposure had been given to stakeholder groups prior to finalisation of this framework. If there is an expectation that much of the change necessary to achieve the stated goals is going to be self regulated with little or no financial support for software vendors and other stakeholders, it will be essential that very high levels of 'buy-in' are achieved across all of these initiatives. ACHI would certainly not want to see a framework of standards developed in isolation of the 'grass roots' users and stakeholders, such that the framework becomes largely redundant as the free market decides to pursue its own alternate, or incongruent set of standards.

Finally, ACHI feel that there were some sections within the document suite which contained insufficient detail to gain a proper understanding on what is actually being proposed. As the old adage states 'the devil is in the detail' and it is felt that in a complex, high risk, multi stakeholder environment, where failure is not an option, it pays that all parties have a good and thorough understanding of this detail.

Scope of Feedback

The Australasian College of Health Informatics (ACHI) is pleased to provide input into the process of developing an appropriate environment for E-Health in Australia. Before offering comment, ACHI notes that NEHTA's prioritisation for feedback includes, though not limited to, 'errors of omission or commission, inconsistent descriptions and editorial rule concerns'.

ACHI believes a more valuable response could be provided had the scope of feedback been sought on the wider aspects of NEHTA's present Electronic Medications Management initiative. ACHI is thus concerned that at present, adequate details of the overall Electronic Medications Management proposal may not have received sufficient exposure in the public domain and as a result our response is provided in this context.

In submitting this response, ACHI is keen to suggest that the proposed Electronic Medications Management initiative proceeds in the spirit of the clinical maxim, *primum non nocere* (first, do no harm). Government, healthcare providers and consumers must each find the correct balance between; improved access and responsiveness to healthcare; personal information being properly protected and at the same time ensuring the broader community objectives are achieved. Getting the planning, public education, governance or implementation processes wrong could have long term negative consequences for the future progression of e-Health in Australia.

ACHI was formed in 2002 to be Australia's peak health informatics professional body, representing the interests of a broad range of clinical and non-clinical professionals working within the health informatics sphere. ACHI is committed to quality, standards and ethical practice.

The ACHI membership strives to work as a change agent in the health system, encouraging the appropriate use of health informatics methods and technologies. ACHI has the expertise to advise government and the professions on e-Health matters, in particular the national direction, implementation and support for health informatics and educational and capacity building, innovation and diffusion, standards development, research, performance and quality management. ACHI's expertise ranges from university-based health informatics R&D and education to implementation and systems analysis consultancies with health services and government. Fellows of the ACHI have been involved in a range of large scale projects such as the implementation of the Regenstrief EMR system in Africa, MediConnect, HealthConnect, National EDS Taskforce, National HER Taskforce, Patient ID, Clinical Terminology and a range of national and international projects.

Electronic Transfer of Prescription Draft Release 1.0 – Release Notification v 0.6

The 'Electronic Transfer of Prescription Draft Release 1.0 – Release Notification v 0.6' document provides the reader with a 'high level' view of the various functional specifications that together, form the framework for what is envisaged to be the eventual Electronic Medications Management system used throughout Australia. For this reason, it is essential that such framework is rigorously reviewed by a wide audience of stakeholders. On this basis ACHI wishes to express some level of concern that although the following documentation has been released; 'Concept of Operations'; 'Business Process and Requirements Specification'; 'Technical Requirements Specification'; 'Technical Architecture' and a 'Logical Information Model', feedback for these documents has been sought in the absence of

the complete suite of documents, which include the 'e-Prescribing Structured Document Template', the 'Dispensing Record Structured Document Template' and the 'Secure Messaging End Point Specification'. Obviously the availability of these documents as part of the review process would be of benefit not only so that the document itself can be reviewed in its appropriate context, but also to ensure that there is an appropriate level of congruence between the entire suite of documents and that contradictions or ambiguity do not exist between documents. It is vital to be able to see both the whole system framework and also how this fits into the broader e-Health vision for other applications. As the old adage states 'the devil is in the detail' and therefore it is felt important that both high level and granular detail can be reviewed in context.

ETP Concept of Operations Release 1 Draft v1.0

There is obviously a necessary period of time where paper-based processes are to continue (Release 1), however over what period of time does NEHTA envisage moving from paper-based prescriptions (Release 1) to paperless prescriptions (goal-state)? Will there is be 'drivers' put in place to promote his transition, or will this largely be left to the free market to adopt?

What level of discussion has been undertaken with Medicare Australia regarding their requirements for a future paperless prescription system? It is difficult to comment on the validity of such as system until a major stakeholder such as Medicare Australia has declared their position and clearly articulated how they would envisage the prescribing, dispensing and claiming process to work. To expand on this point, for many years now Medicare Australia have continued to be insistent on paper prescriptions being submitted together with the electronic dispensing record from pharmacies because they feel that an electronic dispensing record alone does not provide sufficient ability to audit and scrutinise prescriptions being claimed. Does NEHTA know if this position has changed? Does NEHTA know what position Medicare Australia are taking with the 'goal-state' proposal? Will Medicare Australia be requiring pharmacies to print out a paper copy of the electronic prescription for patients to sign (similar to current process) or will receipt of medications now occur via some type of electronic signature received by the patient to indicate that the prescription has been collected?

ETP Goal-State Processes

Text under the 'ETP goal-state processes' header makes reference to the need for capturing the patient's signature electronically and also for 'managing notifications that inform individuals of important milestones in the life-cycle of an e-Prescription (e.g. last repeat dispensed, impending expiry of an e-Prescription, etc)'. It is good that the abovementioned points have been captured for consideration, however it would seem that given their level of relative importance, more detail surrounding these points should be included within the draft proposal documentation.

Prescription Exchange Service (PES)

The Release 1 proposal indicates that there are 'no changes required to the existing Medicare Australia claiming or compliance assurance processes, neither are any system interface changes required', however, it is unclear via what means the 'PES document access key' will be delivered to pharmacies. Assuming in the first instance that this access key is delivered to the pharmacy via the patient as part of the paper prescription, how will this be validated in pharmacy without a new or modified system interface and / or relevant software modifications? Has the government agreed to

pay for these software modifications and upgrades? If it were assumed that these changes would be adopted by the free market, what incentives and/or punitive measures would be put in place to ensure this change in process occurred?

Cancelling an e-Prescription

If prescriptions are cancelled electronically, who or by what means are patients informed of this process? What happens if an electronic prescription is cancelled, however the patient later takes this paper prescription to be dispensed in a pharmacy which is not participating in the ETP initiative?

Cancelling a Dispense Record

Is it envisaged that this will be an 'active' process requiring the pharmacist to take additional steps beyond the standard (current state) dispensing process or will this be a 'passive' process whereby the pharmacist cancels / modifies a prescription with these changes automatically being passed through to the ETP system 'behind the scenes'? In public hospitals up to 40% of discharge prescriptions items require modification or change by a pharmacist. Obviously systems that require modifications to be manually updated in an 'active', duplicated fashion could potentially lead to significant workload issues.

EPS Clinical Terminologies

Text under 'EPS Clinical Terminologies' state that there will be 'optional use of national standard clinical terminologies including SNOMED-CT and the Australian Medications Terminology (AMT) in e-prescriptions'. The 'goal-state' is however to 'make the use of standard clinical terminologies mandatory.' Based on this premise, it would seem to indicate that for Release 1, there would be the potential for the existence of a non-standardised means of communicating drug names and terminology. Does this statement need to be more clearly articulated as to what 'optional use of national standard clinical terminologies' actually refers to in real terms? By extension, does this mean Release 1 could potentially just use plain text?

Assuming that SNOMED-CT and the Australian Medications Terminology (AMT) were not yet available at the time of Release 1 implementation, what would be exact time period envisaged between Release 1 implementation and reaching 'goal-state' where SNOMED-CT and the Australian Medications Terminology (AMT) were being fully utilised? What risks would NEHTA foresee for the Australian Healthcare sector if we travelled down this path? What steps would be put in place to mitigate any such risks?

Security Controls

Text under 'Security Controls' states that 'all access to the ETP repositories will be recorded within an audit log. From time to time this log may be audited to identify improper use of the ETP services'.

Has consideration been given to how 'time to time' will be defined? Who would be the controlling body who would carry out this work? How is 'improper use' to be identified or defined? This document seems to indicate that it would largely be up to the owners of the respective data repositories

to self regulate much of this process. Would this lead to the potential that inherent variations in process and data integrity may result? This might by extension, leads to broader governance issues across the whole implementation and ongoing maintenance process. Where does data integrity and broader governance issues start and stop between the patient, care providers, private hardware and software vendors, government agencies, government bureaucrats and ultimately government ministers? We don't need to search too far for lessons learned (Victoria Police IT systems) to see and appreciate the importance for good data storage integrity and a robust governance framework to be in place prior to implementing mass data storage of confidential information.

Change Management

The change management process described in this document sounds quite reasonable. However, it is not clear whether the intention of these 'change management' groups are to seek stakeholder feedback with the aim of modifying fundamental areas of the ETP framework, or whether it more to simply identify persons or groups to 'champion the cause', with little capacity to modify or change decisions already made. Obviously ACHI would like to think NEHTA is aiming for the former.

Technical Architecture Release 1 Draft v1.0

The executive summary states that the 'proposed ETP solution assumes that there will be no one organisation that is given the responsibility of building or operating the components that provide this integration.' From this statement several logical questions might flow, namely; will NEHTA act as the ongoing governing body to 'keep the glue in place' between these organisations? Secondly, where private vendors and operators form part of this collaborative, who will be funding these organisations? Thirdly, has there been any thought given to which components of this collaborative are better to stay in public hands versus private hands? Fourthly, is there the potential for business monopolies or duopolies to exist whereby government has no means of exiting from these relationships once the system is up and running and the processes have matured? How will individual (private) operators be dealt with if it is found that there are data leaks containing private information? In summary, it is important these (and other) governance questions are addressed prior to implementing any such systems as it would be analogous to 'unscrambling the proverbial egg' if major governance changes need to be made post implementation and contractual agreements are already in place.

Scope

It is interesting to note that prescribing and dispensing in acute care settings, which includes both public and private hospitals, together with prescribing and dispensing decision support functionality have been classified as being 'out of scope'.

In Victorian both public and private hospitals access the PBS for outpatient, discharge and day chemotherapy medications. In fact this is the primary source of funding for medications used in these circumstances. In the case of discharge and day chemotherapy prescriptions, the majority of these prescriptions will be both prescribed and dispensed within the same institution. However, this is not the case with hospital outpatient clinics. Within public hospitals there are two types of outpatient clinics; public clinics and Medicare funded clinics (private clinics). In the case of the Medicare funded (private) clinics, patients are not permitted to access PBS via the public hospital pharmacy and must seek their medications from an outside community pharmacy. Patients from public clinics have the choice as to whether they obtain their medications from the public hospital or the commu-

nity. Further to this, patients will often see GP and specialist under the auspices of a 'shared care' type arrangement and hence it would seem that the benefits born from implementing ETP in hospitals would potentially be stronger than if implemented in the community setting alone. Therefore rationale for excluding hospitals is unclear.

One of the benefits championed with the adoption of electronic prescribing is the inherent patient safety due to increased decision support. Again it is unclear as to why such a fundamental component of electronic prescribing has been removed from scope.

Key Assumptions

Text under 'Key Assumptions' state that 'the solution will support a competitive commercial environment in which operators of Prescription Exchanges will compete to store e-Prescriptions. The Technical Architecture provides an environment where commercial Prescription Exchange Service operators can exchange records directly between their respective repositories.' Is this type of arrangement going to lead us to an analogous situation that we have with banks and ATMs where charges and fees spring up everywhere if you don't make a withdrawal from the 'correct' ATM machine? How will this charging or fee structure work? Will the consumer, health service provider or government pay these costs?

'ETP will, in some circumstances, reduce the cost of dispensing a medicine but will not significantly affect (either way) the cost of prescribing a medicine'. Is there any evidence or experience from other countries to indicate that the cost of dispensing is reduced? On what basis is this statement made?

'Time will be required for vendors to modify their existing products to directly implement the following at all their exposed product interfaces.' Time is mentioned, however money is not. Who does NEHTA envisage will pay for these software and integration modifications? The reason this question is raised is that in the Victorian Public Hospital Sector there was a 'request' for community pharmacies to modify their software so that the government had the ability to track hospital prescriptions being dispensed in community pharmacies. Suffice it to say that because there was not any money provided as an incentive for software vendors to make these modifications, it took several years before these modifications started to flow through. What is to prevent a similar situation from occurring here? Will there be mandated timelines put in place to prevent one or several key stakeholders from unduly holding up the transition process for the wider health care sector?

'Provided clinical safety is maintained and NEHTA defined national foundation services are used appropriately, clinical information systems can participate in ETP Services prior to achieving full compliance with AMT and clinical document specifications. A specified level of compliance will still be required.' What is the 'specified level of compliance' and who or how would this be determined?

Solution States

'Original and duplicate prescriptions are generated as before but, in addition, the Electronic Prescribing System prints the "Document access key" as a barcode and text string on the duplicate prescription'. When a prescription arrives at pharmacy and the pharmacist identifies an error with the prescription, for example the doctor prescribes the incorrect dose of a medication, how would this situation be resolved? Is the doctor expected to correct the electronic version of the prescription immediately? If the doctor does not correct this immediately and the original repeat is dispensed,

does the doctor have the capacity to just cancel the repeats (given the original prescription has already been dispensed?) Is there a risk that we end up with the paper and electronic script looking different somehow? i.e. slightly different directions etc. Which prescription would then take precedence as being correct? It is noted that in the 'Technical Requirements Specification' document it states 'Paper prescriptions remain the authoritative version of the prescription'. However, if this is the case, what status does the paper script have if the electronic script has been is cancelled?

Key Design Decisions

'Allow the solution to transition over time to rely less on paper documents'. Does this mean that the overall transition toward electronic prescribing is being acting upon passively as opposed to an active approach with clear timelines? Will we end up with a scenario as is the case with utility bills, where the technology is available to send bills electronically or automatically deduct the correct amount of money form an account via direct debit, however despite this being available, many people choose to remain with receiving the traditional paper-based bill in the mail. Would such as scenario with electronic prescribing hinder electronic prescribing reaching its full potential?

Business Process and Requirements Specification Draft v1.0

Nil comments. (Any comment(s) relevant to the abovementioned document have already been highlighted in other sections of this feedback response). The stated specifications overall look quite reasonable.

Logical Information Model Draft v1.0

Scope Exclusion

'Information associated with potential future eMM projects, e.g. prescriber dispense notification, medication adherence monitoring, current medication list, etc', is listed as being out of scope. It is understandable why these items might be excluded for the purposes of simplicity, however items such as the availability of 'current medications list' is currently a major issue for the hospital community interface resulting in huge inefficiencies for both parties. Has there been any thought to how these initiatives could be included in earlier rather than later stages of the implementation process as these are the type of issues that will really highlight and champion the benefits of a true electronic prescribing environment?

AMT & SNOMED CT Availability

Text under the AMT & SNOMED CT header state that 'fully resolved modelling for support of AMT is not present'; this is also the case for SNOMED CT. This would raise the question as to how it would be envisaged that a standardised method of communicating prescription information would successfully be implemented without first having these two data sets available. (Discussion on this matter has already been covered in prior sections of this paper).

Healthcare System Identifiers

'To support this identification process, NEHTA has secured the services of Medicare Australia to design and build Australia's first national healthcare identification service. The resulting Healthcare Identifiers (HI) Service will provide the requisite identification service for the people and organisations involved in healthcare across Australia.

Initially, however, it is assumed that local system identifiers (including Medical Record Numbers [MRNs] and Unique Patient Identifiers [UPIs]) and the national Healthcare Identifiers (HIs) will coexist. In the longer term, IHIs and HPIs are expected to replace these local identifiers, providing an interoperable approach to identification.'

The abovementioned vision is certainly a logical direction to take, however it should be noted that there are an enormous number of legacy systems across the healthcare sector that would need to be upgraded to facilitate this process. What exactly is meant by the term 'co-exist' in this statement? i.e. will these legacy systems need to be all be modified to hold each of these numbers within their database, or does this mean any one of these identifiers will be able to be used and the identifiers will be matched when information is submitted to the central repositories? Either way, this is monumental task, the effort (and cost) on which should not be underestimated.

ETP Logical Information Model

The model indicates that there will be appropriate fields to capture, store and transmit Medicare, concession and safety net card details which is entirely appropriate based on current paper-based processes. However, does broader consideration need to be made as to whether this information continues to be requested from the patient and entered into the prescribing or dispensing system, or is it possible that if all this information is already linked to the Individual Healthcare Identification (IHI) the requirements could be cut down to the provision of a single IHI and remove the need for patients to manage and provide what would otherwise be an IHI, a Medicare card, a concession card, and a safety net card. This currently wastes an enormous amount of administrative time manually feeding these details into systems, which is already known by government agencies anyway.

Technical Requirements Specification Release Draft v1.0

Nil comments. (Any comment(s) relevant to the abovementioned document have already been highlighted in other sections of this feedback response). The stated specifications overall look quite reasonable.

Conclusion

The overall suite of documents and the framework to which they refer has been well considered and structured. The main comments for feedback or areas of concern perhaps surround what has been defined 'in scope' and 'out of scope'. There are several items such as; AMT and SNOMED CT availability; the exclusion of public and private hospitals; the exclusion of 'current medication lists' and the exclusion of decision support that have been highlighted. It is understandable that such a decision has been made from a project management perspective; however equally, many of these features form the fundamental basis upon which the perceived benefits of electronic prescribing are underpinned. Therefore it will be important that if these features and functionality are not rolled out in the initial release, there is concerted effort to have them implemented in a timely manner soon after the first release. Again, reference to any timelines governing implementation of electronic prescribing in this suite of documents appears a little vague at best; however there was indication that a passive, free market type approach was going to be used. There was also little detail relating to how costs would be shared or allocated amongst stakeholders. Both timelines and costs quite reasonably may sit outside the scope of such a document suite, however if it is determined that this is the case, it might be useful to explicitly mention this fact along with details regarding which government bodies or groups would ultimately be responsible for allocation of funds, coordination of timelines and also any punitive / 'carrot and stick' measures which might be instituted to ensure that the full benefits of this implementation are realised in a timely fashion.

As briefly outlined in the Executive Summary, ACHI representatives are happy to meet with NEHTA representatives to further discuss the issues raised. Given the number and magnitude of some of the issues still requiring resolution, ACHI would like to ensure that ongoing dialogue continues throughout the draft and finalisation processes of this framework.

Thank you for your consideration in these matters highlighted.