



## **AMA SUBMISSION TO THE OFFICE OF THE FEDERAL PRIVACY COMMISSIONER'S REVIEW OF MBS AND PBS PRIVACY GUIDELINES**

The following paper responds to the November 2004 invitation by the Office of the Federal Privacy Commissioner (OFPC) for individuals and organisations to provide submissions to a review of the Medicare and Pharmaceutical Benefits Programs Privacy Guidelines. These Guidelines, which came into effect on 15 April 1994 are issued by the OFPC under section 135AA of the National Health Act 1953.

The comments in this submission are linked to the OFPC's Issues paper headings under Section D "Issues for Consideration".

### **Introduction**

It is the AMA's view that the development in information and communications technology has created a significantly greater potential for privacy intrusion through data linking. In that context it is of more importance today that the law and, in particular the MBS and PBS Privacy Guidelines, continue to stringently protect the separation of MBS and PBS data. In light of current technological developments and the potential risks to privacy from a greater capacity for data linkage, there may in fact be a case for strengthening the Guidelines.

The AMA is of the view that resources should be allocated to the OFPC to review the guidelines to identify further improvements to security of information held on these data bases above the minimum standards.

### **The Health Environment**

The OFPC issues paper notes that the potential for privacy intrusion through the data linkage strongly influenced the law and the development and structure of the current Guidelines that create somewhat of a firewall between the MBS and PBS data bases and stringently restrict data linkage.

It is acknowledged that the changes in information technology have had significant impact on the health sector. In particular, it provides access to a wide range of information that can contribute to improvements in the delivery of healthcare and health outcomes for patients. The ultimate development of a national electronic health record has the potential to provide the means to share an individual's health information for the purposes of their health care needs throughout their lifetime. Access to a reliable, historical record of an individuals' encounters with the health system throughout their lifetime can contribute to safety and quality in the delivery of health care, particularly as the patient moves in and out of different parts of the health system, and can thus improve individual health outcomes.

However, such systems also provide a source of data on individuals that has never before been available in a form that can be interrogated and linked so easily and so widely. This new environment, while creating the potential for significant positives in improving health



care, has at the same time created significant potential risks to the privacy of individual health information and the independence of a medical practitioners' clinical decision making.

The AMA supports the drive to create a financially efficient health system. This must not be done without adequate regard to clinical quality issues or the independence of clinical decision making.

The linking of individual patient MBS and PBS data potentially provides the means for Government to "interfere" in the clinical management of specific health issues, particularly in relation to prescribing practices. The current prescription authority system, as a financial management measure as opposed to a clinical measure, is evidence of the disconnect that arises between the priorities of good clinical management and Government cost control.

For many years, and throughout the development of different aspects of e-health in Australia, the Government has consistently "sold" e-health as having an objective of improving health outcomes. Its focus on the access to electronic health information data for its own secondary, unrelated purposes, however, has at times overshadowed and undermined the credibility of its stated objective on health outcomes. Function creep and a low priority approach to the establishment of key building blocks in e-health to protect privacy has been a highlight of Government initiatives to date.

Under the National Electronic Health Transition Authority we are finally seeing real progress on the key building blocks to a national electronic health record. While many relate to national functionality and interoperability many of the building blocks, and the some of the key stumbling blocks in e-health, relate to policy issues surrounding the protection of privacy and individual patient information.

Any suggestion at this stage that stringent protection of individual health information held on PBS and MBS data bases should be relaxed represents poor judgement in the current environment. It creates potential risks to current and future progress on electronic health records, particularly in relation to consumer confidence and overall "acceptance" by consumers and doctors.

Secondary purposes, particularly unrelated secondary purposes, should not drive the design direction or priorities in e-health. An emphasis on secondary uses has the potential to erode the confidence of patients in their doctor's capacity to protect their personal health information. Regardless of what form the information takes – de-identified or otherwise. The successful implementation of a national electronic health care record will depend on both patients and providers finding it acceptable.

Further broad secondary uses that might arise from data linkage have implications for the consent processes at the medical practice level. NPP10 governs the collection of information by doctors and NPP1 the obligation on doctors to inform their patients of **all** potential and actual purposes for which the information is collected. NPP2 deals with the use and disclosure of that information with reference to the rules on collection and consent requirements.



When discussing secondary purposes to which even de-identified patient information may be put Government and industry tend to speak in very broad terms and this level of “vagueness” is in our view inadequate for consent processes.

For example, the use of de-identified data for health research sounds good to the consumer and even the medical profession but a more detailed description may reveal that in fact the data is used for market research and financial gain. This is likely to provoke a very different response from consumers and the profession on the use of de-identified patient information.

The trust placed in the doctor by the patient that their personal health information will be protected is the key enabler in being able to deliver the primary purpose of electronic health records to improve patient care and health outcomes. A quote from the National Electronic Records Taskforce’s July 2000 report on a health information network for Australia says it all:

“The degree to which individual consumers’ privacy is protected and is seen to be protected is critical to the success of initiatives aimed at greater sharing of personal health information by electronic means. Virtually unconditional trust placed by a consumer in his or her health care provider that information imparted to the profession will remain confidential, is fundamental to the consumer’s relationship with the provider as well as the quality and appropriateness of the care received.”

The AMA considers that in the current environment any relaxation of the Guidelines that separate the PBS and MBS data bases represents a risk to that trust which will be so vital in the early stages of introducing national electronic systems.

In relation to data linkage the OFPC paper states that a more complete picture for direct health service provision can lead to efficiencies and better treatment for the individual. AMA would argue, however, those efficiencies and improved patient care can be derived by the linkage of health service provision data at the level of an individual electronic patient health record across the service provision sector. At this level data linkage is not an issue because the function is in fact access to existing data and the capacity to incorporate new data within the record. For example, an electronic health record may contain medication, treatment, diagnosis and a range of health information and that information is incorporated within the record in a linked manner with the consent of the patient. The data exists as a linked data in an electronic record and ultimately can only be accessed by other health providers on the basis of consent and on the basis that the information contained within the record is used for the purposes for which it was collected – that is the care of the patient. Any other use of the data contained in such a record would be classified as a secondary use and must remain accessible only with the consent of the patient whether that data is de-identified or otherwise.

There is an assumption that access to and linking of de-identified data is not an issue for debate. The AMA acknowledges the value of linking de-identified data but is not satisfied that there is a national standard or definition as to what constitutes de-identified data. The



Government argues that it can lawfully collect de-identified information without consent. However, that ignores the breaches of privacy that occur in the disclosing by doctors of that information to the Government without full compliance with the collection rules in the NPPs. Doctors can be misled into assuming that it is lawful to disclose that information simply because the Government is empowered to collect it. Unless Government fully discloses the purposes for which this material will be used, even in de-identified form, doctors are unable to meet their compliance obligations at the point of collection.

A requirement on Government to provide a clear statement of approved uses of de-identified data, the use of which has been consented to by the patient may operate to prevent function creep in secondary uses of de-identified data.

AMA does not support any expansion of the Guidelines that would permit the HIC to retain linked PBS/MBS data for longer than three months. The Coordinated Care trials will be finalised this year with four of the trials concluding on 30 June and the fifth concluding on 30 September. It is the AMA's view that the Guidelines should be amended accordingly to remove the reference to the coordinated care trials in relation to exemptions to data linking.

### **Secondary Uses of Information**

The AMA does not support the view that the secondary uses listed in the OFPC paper are limited by the current Guidelines.

Medicare is a financial billing and payment system. Linking this information to the PBS does not and cannot serve any credible clinical purpose. The linking of MBS and PBS data for the purposes outlined in items **1-3 and 5** in particular has little or no clinical value. MBS data contains no diagnostic information.

*1. Assess the effectiveness of a particular drug or treatment for a medical condition on the life expectancy of those suffering from the condition.*

The effectiveness of a particular drug or treatment is best assessed under the strict standards applied to randomised controlled trials. MBS and PBS data would not provide adequate or reliable data to make such assessments. Further a linking of such data would not contribute to such assessments.

*2. Assess Adverse Drug Reactions, Including Where a Drug May Have an Unforeseen Side Effect.*

A national system exists for the reporting and assessment of adverse drug reactions. The reporting system does appear to take a disjointed approach at the national level and progress to improve the above objective may best be achieved by measures that either standardise and/or centralise the reporting system. Currently the Adverse Drug Reactions Advisory Committee (ADRAC) receives reports on unexpected and serious adverse events for all medicines, including vaccines. In the Northern Territory, Queensland and Western Australia, adverse events following immunisation are notifiable. Medical practitioners and



other health professionals report adverse events directly to their respective State or Territory Health Department, who will notify ADRAC. In South Australia and the Australian Capital Territory adverse events are not notifiable, but may be reported to the respective State or Territory Health Department. Reports of adverse events in New South Wales, Victoria and Tasmania can be forwarded directly to ADRAC.

Section A 1.4 (d) of the Guidelines would appear to allow linkage of data in circumstances where an adverse drug reaction or problems with treatments or equipment, where they represent a serious and imminent threat to the life or health of the individual.

### *3. Monitor treatments and equipment*

Neither MBS or PBS data provide the level or quality of data that could reliably contribute to the monitoring of treatments of equipment.

### *5. Population health oversight, including planning, delivery and monitoring of health outcomes through studies and analysis of data.*

The Department of Health and Ageing currently has access under the Guidelines to de-identified data that would contribute to this purpose. It is difficult to comprehend how any linking PBS and MBS data would assist in this regard, particularly the clinical information that would be required for population health oversight.

Overall in relation to **Items 1-3 and 5** the AMA would argue that PBS and MBS data alone or linked represent poor quality data to undertake such tasks and in some case the data linking would simply not provide the information required for the purported purposes. There is significant doubt about how “clean” the data is in the context of its value to suggested secondary uses. The Australian National Audit Office’s (ANAO) recent report on the integrity of Medicare enrolment data found that while overall the data held by HIC was of sufficient quality for the purposes of administration of Medicare there had been only marginal improvement in the quality of data residing in the new Consumer Directory system that replaced the Medicare Enrolment File originally established in 1984. ANAO found some inconsistent recording of data related to personal information, some data, particularly in fields containing various dates was logically inconsistent or in error and that up to half a million active Medicare enrolment records were probably for people who are deceased. Further data cleansing was one of the 6 recommendations ANAO made to HIC.

The current Guidelines consistently acknowledge the desirability of linking data for specific purposes and set out these exemptions and limitations on retention of such data. The Guidelines do allow the linking of de-identified data for specific health policy purposes and in that context the purposes outlined are not limited by the Guidelines but prevents permanent linking in conjunction with the personal identification number.

Maintaining the principle of functional separation of the MBS and PBS data bases does not in the AMA’s view unreasonably limit the capacity of the Commonwealth to use such data for the purposes suggested, except for those limitations imposed by the quality of the data itself.



*4. Determining the best way to achieve efficiencies in health outcomes delivery and directions in health care*

This is a financial management objective and is not limited by the current Guidelines. The linking of PBS and MBS data provides no clinical basis for determining community health needs or the efficient allocation of resources. AMA is of the view that the linking of such data has the potential to contribute to rationing of health resources on the basis of cost containment rather than the provision of quality clinical care and/or patient need.

*6. Promote Statistical Research through the provision of de-identified information; and  
7. Aid population and other forms of health research through the provision of identified information.*

It is the AMA's view that these secondary uses are not limited by the current Guidelines. Under section 4A of the Guidelines disclosure of identified information is based on secrecy provisions and under the strict conditions of individual patient consent or conformity with National Health and Medical Research Guidelines.

In relation to the question of linking PBS and MBS data for these purposes, AMA is of the view that given the access to other sources of data of higher quality, neither warrant any amendment to the Guidelines that permits data linking.

With reference to section 4A.2 of the Guidelines the AMA does have some concerns at the lack of accountability imposed on researchers, who have been provided with identified data, to destroy such information at the end of the research project.

### **Community Attitudes**

The AMA contends that the developments in information and communication technology have in fact made consumers much more aware of the privacy issues around their health information and the potential for that privacy to be breached. Community attitudes certainly differ between age groups with younger patients demonstrating a great deal more wariness about release of and access to their personal information. Issues of data linkage, particularly in the context of insurance and employment, are of increasing concern. Any amendment to the stringent protection of privacy of personal information provided by the Guidelines would in our view be a matter for community concern.

In the current environment, with initiatives such as release of the Medicare Smart Card, there is a growing concern at the extent to which the Government could potentially link data without the current limitations imposed by the Guidelines. As technology develops further there is reason to consider that the current Guidelines may need to be strengthened. The Government announced the implementation of the Smart Card initiative, including functionality for a consumer identification number, without any consultation with the wider community. It is incorporating the number in new Medicare Cards and has not yet undertaken discussion on its purpose. A stated purpose is fundamental to providing privacy protection related to the uses of such a number. The implementation of any functionality for



the Smart Card, particularly using the consumer identification number, will have very significant ramifications for threats to privacy should any requirements related to the functional separation of the PBS and MBS data be relaxed. Any relaxation of the Guidelines would in turn impact on acceptability of the additional functionality of the Medicare Smart Card by both consumers and the medical profession.

### **Data Retention**

Any review of the Guidelines in relation to retention of data and an appropriate period for retention must be related to decisions on the capacity to link PBS and MBS data. AMA would be of the view that as long as the Guidelines continue to prevent the capacity to link PBS and MBS data an extended retention period may be an issue worthy of consideration, particularly in relation to PBS data. An extended retention period may be of assistance to consumers for a range of reasons but a decision to alter the Guidelines could only be justified on the basis of current consumer demand or evidence that such demand is likely to increase.

Should any change to the current Guidelines that alters current arrangements that separate PBS and MBS data occur, AMA would not support an expanded retention period, and in fact would consider a reduced retention period appropriate.