

AUSTRALIAN MEDICAL ASSOCIATION

SUBMISSION TO

THE COMMONWEALTH DEPARTMENT OF HEALTH AND AGED CARE

THE BETTER MEDICATION MANAGEMENT SYSTEM

DRAFT EXPOSURE LEGISLATION

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OVERVIEW

The AMA supports the stated primary objective of the Bill. It, cannot, however support the Bill in its present form. The AMA's position is that the flaws in the scheme as reflected by the provisions of the Bill can not be satisfactorily rectified by amendment. We make the following comments.

The Objects and Scheme of the Bill

1. The benefits of the Bill to the consumer are limited. This is reflected in the title of the Bill in the use of "Better" to qualify the Medication Management System to be established under the proposed enactment. Section 5 of the Bill is modest in stating its primary object to be "to improve levels of access to medication information ...". Achieving this object is limited because:

- The development of "complete" patient records are not possible in a consumer/provider "opt-in" system for each medication episode.
- The effectiveness of the system is dependent upon the will of the consumer to participate, vigilance with regard to entering every medication episode and consumer will not to suppress entry of some medications.
- Consumer participation is dependent upon the cooperation of the pharmacists and doctors, assuming that participation is truly voluntary.

2. The scheme of the Bill purports to be "opt-in" so far as consumers, doctors and suppliers are concerned. In relation to consumers, participants are limited to those who have Medicare numbers. In relation to doctors and suppliers, it is unlikely that participation will be truly voluntary:

- If the Bill is to achieve its object to any significant extent, consumers will in fact "opt-in". If this is the case, participation by doctors and suppliers will be dictated by the market forces. Doctors have to participate, or lose patients.
- The anti-discrimination provisions of the Bill (Section 144) do not prevent access to Government incentives, such as PIP, being tied to doctor participation under the Bill. Further, the Bill allows the Board absolute discretion to dictate conditions upon which participation is permitted by doctors and pharmacists, and to effectively exclude participation. At the same time the Board is to be appointed by the Minister with little constraint upon him of nature and mix of appointments.

3. What then are the secondary objects, if any? These are not stated. However, they are obvious and achievable:

- The record will establish a large nation-wide database of medications prescribed and supplied to consumers.
- The data will be collected at low cost to the Government, the collecting agents being the doctors and suppliers who will be compelled to participate by the matters listed above, and at their cost. The costs will, in all likelihood, be passed on to the consumer.

- The secondary object of establishing a large database is evidenced by the provision for doctors and suppliers to obtain the consent of the consumer to allow the data on their record to be used for secondary purposes.
- The establishment of the record will facilitate:
 - The development of largest available data on medication use;
 - Provision of information to assist the Commonwealth Government in policy development in relation to Government pharmaceutical benefits and health policy and health budget decisions generally;
 - Tighter regulation of doctors and pharmacists by tying participation to certain medical programs and denying incentives to those who do not participate.

4. The scheme of the Bill incorporates the carrot and stick method of regulating the participation of doctors and suppliers. If participation were truly voluntary it is unlikely they would participate in the presence of:

- Limited benefit to patients of incomplete medication records;
- The high financial costs of compliance including extensive and ongoing software compliance costs (as part of a condition of participating);
- The time consuming requirement to explain the implications and obtain patient consent;
- The right to apply to participate not being matched by corresponding obligation on the Board to permit participation, and where conditions upon which permission is given can vary in respect of individual applications;
- Exposure to administrative sanctions under the Bill, including cessation of participation, in addition to the compensatory liability that might be imposed by the Privacy Commissioner;
- Exposure to criminal penalties of up to 2 years in gaol;
- The danger to patients of inevitable reliance upon the incomplete record, it being more accessible than complete patient records;
- Greater exposure to civil claims for damages in the event of over-reliance on a record that transpires to be incomplete;
- Increased security risks in relation to e-health records, with no increase in powers or resources of the Privacy Commissioner to locate and prevent on-selling or other abuse of data.

5. The sting of the bill is in the tail. The manner of selection of the Board, its powers and functions are contained towards the end of the Bill. The Board is charged with establishing and managing the record and has wide discretionary powers with respect to the total management of the BMMS. The ultimate selection of Board members from a wide range of nominees lies with the Minister.

IN SUMMARY

This is extremely complex legislation, with very high compliance costs and some far-reaching ramifications, particularly the increased risks to the security of health information, inherent dangers in the use of incomplete records, and participant

exposure to penalties that can be imposed for breaches of the Act – all this, for marginal consumer benefit.

These conclusions are reached from the analysis of the Bill below.

Analysis of the Bill

1. THE OBJECTS OF THE BILL

1.1 The stated primary object

Section 5 states that the primary object of the Bill is to improve levels of access to medication information for participating consumers, participating doctors and participating suppliers through the establishment and maintenance of an electronic record that will contain the medication histories of participating consumers. It is intended that improving levels of access to medication information will assist in reducing adverse drug reactions and interactions and hospitalisation.

1.2 Comments

1.2.1 While the AMA supports the intention of the stated Primary Object, it can't be achieved by reason of the following:

- There is acceptance that an effective medication management system is not achievable under an opt-in participation, and certainly not so long as participation with regard to every prescribing or supplying episode is voluntary.
- The Department explains that the object of “better” medication management can be achieved to the extent that when a consumer can not remember the name of a medication, the doctor or supplier can access the record to ensure consistency of prescription.
- However, there are greater dangers in the existence of an incomplete and unreliable record than in no record at all, particularly where it does not indicate the existence of suppressed entries and might appear on its face to be both accurate and complete.
- The omission of public hospital participation and aged care facilities (intended to be included at a later time) for the prescription or supply of medication in public hospitals, further diminishes the primary object of the Bill and increases the risk of error.
- The Bill does not and can not prevent “doctor shoppers” for dangerous drugs.
- While the Bill provides that doctors *may* participate, it also provides that doctors *must not* enter into the record any item that the consumer does not want entered into the record and *must* remove entries on demand, irrespective of the danger of patient “doctor shopping” for dangerous drugs.
- It is not likely to reduce adverse reactions to medication, particularly while consumer’s rights to “suppression” of medication are likely to be exercised in relation to dangerous drugs.
- Reliance on the record by doctors or suppliers as an accurate record would be negligent and exposes the patient to health risks. Yet, reliance is inevitable because of the obstacles that this and the Privacy legislation impose for doctors to quickly access complete records or other information

from previous treating doctors or suppliers. The enhanced risk of prescription error undermines the primary object.

- Also outweighing the benefits to consumers is the greater risk to the security of sensitive health information and of unlawful use of the collected data.
- Further, the doctors' and suppliers' compliance costs are likely to be passed on to the consumer.

1.2.2 A secondary, unexpressed object, can be enabled by the Bill:

- While the Bill recognises that the development of a complete and effective medication management system cannot be achieved, it is silent as to any secondary objects;
- The Bill leaves the way open for secondary objects, not expressly stated in the Bill, to be achieved at the whim of the Government of the day, for example to further regulate medical practice, or to use the database for other purposes than the primary purpose of collection (reference to the outcry in the UK);
- The spirit of the Bill is not easy to identify so as to confine the Minister or the Board as to the way in which the record should be managed or used, or any future Government as to the use to be put to the database;
- An obvious secondary object is the use to which a de-identified data developed from the record could be put in the public interest;
- The BMMS will establish a large nation wide database of medications prescribed and supplied to consumers;
- The cost of data collection will fall entirely on doctors and pharmacists;
- The electronic record, though not a complete database of the supply and use of all medications, provides a continuous survey at low cost to Government of the largest sample of consumers available from any other database of the use of any particular drug at any time;
- The information is valuable to the Federal Government's consideration of policy in relation to health policy, pharmaceutical and medical benefits;
- The information aimed to be collected, including the Medicare number, enables the Government to monitor PBS and realise savings in PBS.

1.2.3 The meaning of "Participating" consumers, doctors and suppliers:

- It is obviously intended that consumers voluntarily "opt-in", though only those with a Medicare number will be permitted. This provision, unnecessary to ensure the primary object, (though necessary for the development of a useful database), is likely to exclude a sectors of the population;
- The voluntary "opt-in" for doctor and supplier participation is not protected by the Bill;
- The Bill leaves the way open for the Minister to compel doctors and suppliers to participate in numerous ways, for example by establishing participation in BMMS as a precondition for access to funding resources.

- If wide consumer participation is achieved, market forces will compel doctors and suppliers to apply to participate if they want to stay in business;
- Doctors and suppliers may apply to participate. There is no corresponding obligation on the part of the Board to grant approval for a doctor or supplier to participate and no stated criteria;
- The application is to be in a form approved by the Board. The Board determines the process for making the applications, and the basis on which participation is to be granted. It may determine different processes and bases in respect of application for consumer, doctors or suppliers. More comments as to this process below.

1.3 **Suggested amendments:**

- State in the objects any secondary objects of the Bill.
- Include in a Schedule to the Bill an approved application to participate rather than leaving it at the discretion of the Board.
- The criteria as to the conditions for the granting approval should be included in the legislation and apply generally to applicant doctors and suppliers, and not be at the discretion for the Board.
- The “licensing” system in relation to individual doctors and suppliers, allowing particular conditions to attach to particular participants should be abolished.
- The Board’s role in this regard should be limited to assessing whether the legislative criteria are met.
- The anti-discrimination provisions in Section 144 be extended to preclude any incentive or disincentives being tied to approval for doctors and suppliers to participate.
- Elimination of discrimination in any form on the basis of a choice not to opt-in.

1.3 **The AMA’s stand in relation to the BMMS**

- There is little in the Bill that demonstrates a commitment to its stated primary object, evidenced by the neglect of basic issues surrounding privacy concerns.
- The means by which doctor participation is to be achieved is flawed. It provides disincentives inherent in a “punitive” compliance system, with administrative sanctions, including being exclusion from participation, and criminal offences punishable by imprisonment of up to two years. It exposes doctors to time and costs of obtaining consents and explaining the purpose of patient participation. It increases risks in relation to issues of “informed” consent and access under this and the Privacy legislation, with the potential for increased indemnity costs.
- This tends to support the expectation that doctors will need to join if they are not to suffer the economic losses of patients going elsewhere.
- The delivery of incentives now available without participation, is a “stick” rather than a “carrot” if it is restricted to doctors who do participate.

- The BMMS will establish a large nation wide database of medications prescribed by doctors and supplied by pharmacists, and it will do so without encroaching on individual privacy legislation.
- The cost of data collection will fall entirely on doctors and pharmacists.
- The electronic record, though not a complete database of the supply and use of all medications, provides a continuous survey of the use of any particular drug at any time by the largest sample of consumers available.
- The information is valuable to the Federal Government's consideration of policy in relation to health, pharmaceutical and medical benefits.
- The information aimed to be collected, including the Medicare number, enables the Government to monitor PBS and realise savings in PBS.
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2. OUTLINE OF THE BILL

2.1 The content and form

Section 13 purports to outline the Bill. It states that the Bill provides for BMMS; that the participation in the System is voluntary, and open to eligible doctors, suppliers and consumers. It establishes an electronic record and then goes on to list issues such as consent and interactions with the record, and other aspects of the Bill.

2.2 Comment

2.2.1 Establishment of the Board and the record should appear at the beginning of the Bill

- As the establishment of the record is the major subject of the Bill, and only the Board can establish it – the Bill should at the outset set out provision for board appointment, and its powers.
- A Board with such wide discretionary powers in the establishment and maintenance of a national record of individual's sensitive health information must withstand scrutiny and the Bill should be able to be read in the context of the knowledge of the way in which the record is to be set up and established and by whom.

2.2.2 The Outline is misleading in its reference to administrative sanctions in the absence of any reference to criminal penalties for breaches of the provisions.

2.3 Recommendations:

- The outline of the Bill should be recast and the order of the provisions of the bill adjusted accordingly
- It should more accurately reflect the main provisions of the Bill.

3. THE BOARD

3.1 Selection

3.1.1 Section 167 establishes the BMMS Board. Sections 177 to 189 provide for Board membership. The Bill provides for the Minister to appoint the Board from a wide range of nominees. The Minister has a wide discretion as to the bodies from whom nominations are to be received and a wide discretion to appoint from the totality of nominees, or in the absence of a requisite amount of nominees, to make his or her own appointment.

3.1.2. Comments

The Board invested with the discretionary powers that it has, should be a Statutory Board independent of the Minister. According to the compromise reached between the Government and the Development Group, it must be as independent of the Minister as possible. This is not the case under the Bill:

- Section 178(2) allows the Minister to determine which national bodies he/she will approach to submit nominations. There are no parameters for this selection or restriction on the number of bodies the Minister can call on, and no requirement for peak bodies to be included.
- As each body selected is to submit 5 nominees the Minister has a wide range of nominations from which to personally select the board. This leaves open the opportunity for a Minister to manipulate membership of the Board.
- There is potential for a Minister to omit independent bodies and identify only those groups favoured by Government, as national bodies for the purposes of the BMMS Board.
- The provision incorrectly assumes that the Minister is the best placed to determine what organisations represent what groups of stakeholders.
- Sections 182 and 183 require close scrutiny. Combined with other Sections in this Part these Sections reinforce a path for selection of Board members by the Minister.

3.2 The Board's Powers and Functions

The implications of a Board not independent of the Minister are seen in the context of the wide functions and powers bestowed on it:

3.2.1 The Board's Functions:

- Section 168 sets out the Functions of the Board, the primary one of which is to establish and maintain the Record.
- Sections 168 and 169 permit the Board to recommend that another person (an operator) should establish and maintain the Record under contract or agreement. The Board is empowered to delegate its functions to facilitate that arrangement.

- Its other functions are wide-ranging to enable the Board to administer the Act and include making determinations, not all of which are Under Section 168 it is a function of the board to make determinations not all of which are disallowable instruments.
- The board's functions include releasing in its discretion, de-identified BMMS data, and to deal with the release of identified and de-identified data under the Bill.
- Of note, the Board's functions include such other functions that are conferred on the Board by any other law (Section 168(n)).

3.2.2 The Board's Powers

- Under Section 170 the Board has wide powers to do all things necessary in connection with the performance of its functions.
- The Board's powers include determining the process of granting an application for a doctor or supplier to participate, and the conditions on which an individual can participate.
- The conditions can be determined by the Board from time to time, and there is nothing in the Bill to prevent conditions being attached that require doctor and supplier compliance with Government health policy or programs.
- Conditions of granting the right to participate include requirements that the doctor or supplier have specified software. These requirements might alter, particularly in the event that another (eg private) contractor wins the tender to run and maintain the database.
- The Board has power over sanctions for breaches of the Bill, including the power to cease a doctor's right to participate. This empowers the Board to interfere with the doctor/patient relationship, as the cessation of a doctor's right to participate necessitates a patient transferring to another doctor, if the patient wants continuity of a medication record.
- Under Section 79 the Board has power to determine applications for release of data. For this purpose, Section 85(1) empowers the Board to consult with any person about an application for its release. In releasing identified data the Board is constrained by the provisions of Sections 87 to 90.
- Section 91 charges the Board with the duty of determining guidelines for the release of BMMS data for research. Though it must perform this duty, the guidelines are to be approved by the Privacy Commissioner before they can be used.
- The Board is to determine complaints procedures (Section 107(1)), procedures for undertaking investigations (Section 110(1)), additional "relevant" information that can be collected through BMMS (Section 65(4)(e)) and an electronic identification system that provides for the determination by the Board of personal identifiers and authentication mechanisms (Section 51).
- Section 171(4)(a) grants wide powers to the Board to make inquiries or ask questions of any person and, in particular the doctor's or supplier's

practices in relation to the whole BMMS (“the System”). This includes the power to obtain information from the Privacy Commissioner, who has wide powers of collection under his enabling Act.

3.3 Recommendations

- The medical profession, not the Minister should decide who is to represent the medical profession.
- The provisions should reflect the process the Government described to industry stakeholders, namely that the Minister would invite national bodies representing the medical profession to jointly submit at least 5 nominees to represent the medical profession on the Board, providing the Minister with a minimum of 5 to choose from.
- The Board’s powers should be curtailed, so that, for example, it makes decisions with reference to statutory criteria or regulations, which are the subject of public consultation.

4. THE BMMS RECORD

4.1 Control of the Record and the Information on it.

4.1.1 The main feature of the BMMS is the Record.

- The Board must establish the Record (Section 15).
- It is an electronic record.
- The information in it is subject to the Board’s control under the provisions of the Bill.
- Once the information is retrieved (that is, down loaded on to a doctor or supplier’s computer or printed out in hard copy and placed on the doctor’s file), the information is no longer part of the BMMS record, and its use and disposal are subject to the *Privacy Act 1988*.

4.1.2 Comments

- Section 207 provides the power to the Minister to enter into a contract in relation to the establishment and/or maintenance of the record, or part of it. Read with Sections 168(b)(1) and 169 it is quite clearly intended that the Government will permit the operation of the Record to be contracted out. The Minister is not confined to enter into a contract only with the public sector.
- The HIC currently holds a three-year contract for the development, and possibly establishment, stages of the BMMS. Section 207(b) clearly indicates the possibility that a different contractor, not HIC, may be involved in maintenance of the record, where HIC has been able to achieve establishment under the current contract.
- The AMA has consistently expressed its view that the operation of the BMMS database should remain in the hands of the public sector, preferably the Health Insurance Commission which has experience in

establishing and maintaining the necessary security and privacy safeguards through management of PBS and MBS. Other industry stakeholders overwhelmingly agree with the AMA's view, with only one exception.

- There appears to be no prohibition on the Board or the Operator from holding paper copy of the electronic record as it may stand from time to time.

4.1.3 Recommendation

The legislation must incorporate a clear and stated intention that the operation and management of the BMMS database will be held by the public sector.

4.2 Participation Information

4.2.1 The consumer's information.

- Section 24 (1) (b) requires information of date of birth and Medicare number from the participating consumer. First, this prevents participation from members of the community that do not have a Medicare number. Secondly, the AMA has consistently questioned the intention of using the Medicare Number as a Unique Patient Identifier for the BMMS.
- The collection and use of the Medicare number is contrary to the National Privacy Principles (NPPs) incorporated in the *Privacy Amendment (Private Sector) Act 2000*. The draft guidelines under that Act¹ permit the collection of information based on the primary purpose or for a directly related purpose. It does not permit collection for a secondary purpose without separate and specific consent.
- The collection of the Medicare number is irrelevant to the stated primary purpose of the BMMS system referred to in Section 24(j), requiring the inclusion of information about a consumer's entitlement to concession card, entitlement card or concessional benefit. This is directly related to the purposes of the Improved Entitlement Monitoring Amendment to the Health Insurance Act and is unrelated to the object and purpose of BMMS.
- To enter the Medicare number in to the participation information is totally contrary to the spirit of the NPPs, and an infringement on patient privacy.
- The legislation seeks to use the Medicare number as a Unique Patient Identifier for a purpose for which it was not established contrary to the Privacy legislation.
- A further danger appears under Section 24(1)(k) that allows the BMMS Board to set out in a Determination any other information that should

¹ The NPPs come into operation in December 2001 and covers the private sector. The NPPs do not cover the public sector – the Principles in the Act prior to its amendment still apply to the public sector – these are referred to as the IPPs.

be collected from participating consumers. The only protection in this Section is that under Section 24(2) the determination will be a disallowable instrument.

4.2.2 The doctor and supplier participation information.

- Section 25 (1)(i) allows for a determination to be made on additional information required to be provided by participating doctors and suppliers. Section 25(2) establishes that such a determination is a disallowable instrument.
- This allows the potential for information to be required about a doctor's billing policy, participation in Government initiatives and so forth as part of an application to participation.

4.3 Medication Information

- Section 27(2)(e) and (f) sets out what comprises medication information.
- It is not clear which of this information must be provided by a participator and which is only to be provided with the consent of the consumer. In particular the field in Section 27(2)(f) provides a definition of *medication background information*, which does not appear anywhere else in the legislation as a “required” field in the record. It appears that Section 28 may be the optional field.
- Other areas of the legislation that address patient rights in relation to therecord imply that the doctor is obliged to fill these fields if the patient requests. However, Section 102(3) would indicate that it is optional for a doctor to enter a reason for treatment.
- Details described in Section 27(2)(e) and (f) are unacceptable as compulsory fields – they must be optional fields for the doctor.
- Throughout all consultations the AMA opposed the inclusion of the “reason for treatment” field, or argued that at the very least it must be optional for the doctor.
- The “other comments” field is possibly where allergies etc or reactions are identified. This also must be optional. That they are optional fields must be indicated in the legislation.
- At the very least the above indicates that there is a problem with clarity.

4.4. Suppressed Medication Information

Sections 32 to 35 deal with information that may be suppressed, who may suppress it and lift it. Issues surrounding suppression of medical information are discussed in more detail below.

4.5 Comments

The legislation seeks to set up personal identifiers, rules for release of identifiable and de-identified data, data links and access to an individual's personal health information to more people and bodies than ever before. It cannot be in the interests of Australians to have such information

exposed to the undue additional risks that potentially arise with a private contractor. Besides security issues there are also general operational risks, particularly in relation to contract disputes, where a company could withhold the database to exact some outcome.

It is not in the best interests of patient privacy to permit such a huge database of personal health information to be contracted to the private sector, particularly when the BMMS system will be integrated into the broader HealthConnect. The integration of BMMS with HealthConnect will necessarily be based on data linkage. Data linkage of personal health information that goes beyond medications through a private contractor is unacceptable to the AMA and will be unacceptable to the broader community.

5. THE PARTICIPANTS

The draft legislation purports to provide for an “opt-in” system for all participants.

5.1 Participation is not open to all consumers, doctors and suppliers

- Provision is made for participants to apply to participate.
- As to consumers, to be eligible they must have a Medicare number. This eliminates some disadvantaged members of the community in particular, and around 15-25% of the Aboriginal and Torres Strait Islander population that do not have a Medicare card.
- As to doctors and suppliers, participation is conditional upon terms and conditions not necessarily known at the time of application, and that can be altered from time to time.
- There are costly compliance costs.

5.2 Compulsion to participate

- As the Board has discretion over the conditions from time to time of participation, and can tailor those conditions to specific doctors and suppliers, the Bill is akin to a commercial licensing arrangement.
- The anti-discrimination provisions in Section 144 do not protect the doctor or supplier from only qualifying for Government incentive programs if they are participants in the BMMS and do not prevent the Government from introducing specific discrimination measures through a range of mechanisms, not covered by other discrimination laws.
- Once a participant, harsh penalties apply for breaches of conditions, or of the provisions of the Bill.
- Compliance is costly as participating doctors and suppliers are required to possess the specified soft-ware, ensure consumer understanding of the BMMS, obtain necessary consents, and otherwise comply with both this enactment and the Privacy legislation with respect to BMMS information.
- Should there be wide consumer participation doctors and suppliers will be commercially severely disadvantaged if they fail to participate.

- This ensures that doctors and suppliers who feel compelled to participate will be forced to adhere to the conditions of participating.

5.3 The flaws in the anti-discrimination provision

- Section 144 makes it an offence for any person to make a condition of *the insurance, employment or membership of any body* that a person becomes a participant.
- In explaining the Bill the Government advised that this Section protected doctors from discrimination arising from a decision not to participate in the BMMS. It does not.
- The Section does not address the concerns of doctors that their participation might be required so as to take advantage of incentive schemes or gain access to new resources. For example, the manner in which the incentives are delivered in PIP could potentially discriminate against doctors. The After Hours components of PIP for example have just been changed so that a GP/practice has to fulfil all three tiers of the PIP After Hours requirement or they receive no PIP payment. It is not hard to envisage that the IT related requirements under PIP could be altered so that BMMS participation was a precondition of PIP payments against all the IT tiers.
- This opportunity exists for the Government in order to ensure that doctors will have little option but to participate, on the dictated terms and conditions.
- In the context of wide participation facilitating Government monitoring of the use of medications for the purpose of making PBS savings, the lack of protection given to doctors by Section 144 is of concern.

5.3 Comments

- Doctors may apply to participate. It is a privilege, not a requirement. There is no corresponding obligation on the board to allow all doctors to participate.
- For this privilege doctors have access to an unreliable record, significant additional compliance costs, the burden of responsibility and risks associated with gaining consumer consent, increased insurance costs, the risk of incurring a range of offences under the Criminal Code with penalties of up to two years imprisonment, additional workload and privacy requirements that are more complex and onerous than the Privacy legislation under which doctors will also be operating.
- Further, the severe and punitive nature of the sanctions are inconsistent with an “opt-in” system. The fact is that the sanctions alone will create a significant deterrent to GPs participating.
- Should the Government develop financial incentives for participation say through the PIP the opportunity exists for discrimination.
- The fact is that for BMMS to work, as many doctors and suppliers as possible must participate. The question then is why then does this legislation provide so many deterrents to a doctor or pharmacist participating? The capacity for coercion must exist.
- An unknown factor is the extent to which the BMMS will influence the market share of non-participating doctors. Will consumer loyalty to their GP override

a patient's desire to participate in the BMMS? This, of course, is related to the perceived value of BMMS to consumers. Given the strong element of trust in a doctor patient relationship it is reasonable to assume that a decision by the GP not to participate is likely to influence the patient's confidence in the system and thus their decision to participate.

- The very fact that the Government will be relying on GPs overwhelmingly to gain informed consent from patients to participate is based a recognition of the influence GPs will have with their patients in their decision to participate or not.
- On the other hand, participation by doctors allows them to continue to see all their current patients. Those that don't participate are not able to continue to treat patients who wish to participate.
- A doctor who breaches this Act is also subject to a penalty of being excluded from participation in the BMMS for a period of time. In order that this does not prejudice the comprehensiveness of a patient record, the Board can arrange for the patient's record to be transferred to another participating doctor, rather than allowing the patients record to be destroyed. The patient is then obliged to change doctors. This is a loss to both doctor and patient, and damages doctor/patient relationships.

5.4 Recommendations

- Section 144 should be amended to prevent any form of Government coercion or incentive scheme to compel doctors or suppliers to participate.
- The sanction of removing a doctor as a participant should be eliminated, and breaches dealt with in a more appropriate manner.

6. THE OBLIGATIONS OF PARTICIPATION

The following details the obligations of participation to enter information on the record; duties to comply with consumer suppression requests, Interactions with the record, access to the record, and consent issues.

6.1 Entering information

- Section 102 (3) makes it an offence for a participating doctor to enter a reason for treatment without the consent of the participating consumer concerned. This Section appears to be inconsistent with other areas of the Bill.
- The Bill can regard as an offence and impose sanctions in relation to a BMMS event that has yet to be determined as compulsory or optional.
- Section 59(4) provides the power to the Board to determine optional fields in the medication information, including "reason for treatment" yet before the Board even exists to make such a Determination the Act establishes the non completion of this field as an offence.

6.2 Suppression Requests

- Section 103 relates to obligations to suppress medication information in a participating consumer's record. The comments made in discussion of Sections 34 and 35 in Part 4 on suppression about the rights of the doctor to refuse to prescribe on the basis of a suppression request are relevant here.
- Section 12 states that suppressed medication information ceases to be available to any person except the Board, the consumer and the doctor or supplier or a supplier intending to supply a medication. As to the latter, does this permit all suppliers supplying a medication not on the record to view the suppressed medication record?
- The issue remains then as to who has the right to unsuppress the medication – it would seem that only the prescriber or supplier of that particular medication or the Board could re-instate the suppressed medication record at the patient's request. This needs to be clarified.
- Another prescribing doctor is unable to access the suppression record to ensure the further prescription of a drug is appropriate. Thus, there is no control over "doctor shopping".

6.3 Interactions with the Record

- Section 104 is linked to Section 70. The AMA's concern in relation to both Sections is that they do not appear to provide any limits on the Board's capacity to ask anyone who has interacted with the Record about an interaction. It would appear that the Board's powers in relation to Section 70(1) and Section 103 must be modified to ensure they are clearly linked, to and limit, its powers in accordance with Part 10- - Investigations and Complaints.

6.4 Access to the Record

- Section 105 prohibits a doctor or supplier from charging for a copy of the medication record if it is undertaken during a consultation. However, it requires that the copy be provided from the doctor's own records. The record held by the doctor is not a BMMS record but a record subject to the *Privacy Amendment (Private Sector) Act 2000* under which, in some States and Territories, it is specifically permitted for a doctor to charge an administration fee for the provision of records whether or not the request is made during or outside of a consultation. The note to Section 165 makes reference to the *Privacy Act 1988* (Cth), but does not clear up the inconsistency.
- This gives rise to the absurd situation that when a patient arrives at a surgery and requests a copy of their record they may be asked under which legislation they are seeking the record – BMMS or Privacy. If BMMS the patient will need to make a consultation and not be charged a fee for the copy of the record. If under the Privacy legislation they may have a copy on the spot but be charged a fee.
- In the context of other Sections in the Bill which provide that the Government will charge a fee for providing a copy of a their record to the consumer, this imposes an undue burden on the doctor and supplier.

6.5 Consent Issues.

The Bill commences from the point of a person putting in an application to participate in the BMMS. In this context the absence of the complex informed consent process which must be undertaken prior to a person submitting an application is glaring.

- The informed consent process as the basis for consumers participating in the BMMS was a strong focus of both consumer and AMA concern during development of the BMMS.
- From both the consumer and GP perspective this aspect of the process covered such things as adequate written information, opportunities to take information away to consider, alternative information sources and a signed consent form.
- Both consumers and the AMA shared strong concerns about this process and the absolute necessity for “informed consent”. Its absence from the Act is of serious concern.
- From the GP perspective there was considerable concern as to the requirements for GPs to ensure an “informed consent” process. Issues relate to the GP being the central source of information on the system for patients, regardless of what other sources may exist. Issues. The include the need for GPs to establish a system of evidentiary proof that informed consent from the patient was obtained and for the GPs to have an extensive knowledge of all aspects of the system.
- Given the pre application “informed consent” process is where patients make such critical decisions, such as release of their identifiable data for research, provision of information that provides the capacity for data linking, the omission of this highly significant step in the process is unacceptable.

OTHER CONCERNS

1. CONSENT ISSUES

PART 5 - Consent

Division 1 – Outline

Section 36(1) pre-judges a determination yet to be made under Section 18(1) which establishes that the Board has to determine the process for making of applications and may also be inconsistent with Section 18(4)(a) which says the Board “may” specify that applications can be made electronically.

Division 2 – Consent for Application for Participation as a Participating Consumer to be made.

Section 37 pre-judges a determination to be made by the Board on forms of application.

Division 3 – Consent to Interactions with a Participating Consumer’s Record During Consultations or Dispensing Events.

This Division raises consent types and processes that were not ever, in the AMA’s knowledge, discussed during BMMS consultative forums. There is the potential that in one consultation the GP could have to request consent for about four separate interactions (consent to interact plus see Note on Page 45 under Section 39(6)).

Specific or Standing Consent is dealt with under Sections 39(2), (3) and (4). This does not reflect the intent of the industry stakeholders position. Standing Consent was determined as the capacity to give the GP or pharmacist consent to interact with the record from that point on an ongoing basis without having to seek consent at each consultation (with the right to terminate that consent). Section 39(4) limits this concept of standing consent in that “a standing consent must specify the consultations or dispensing events in relation to which the consent is given”. Further 39(4) will potentially create confusion about what the patient may be consenting to – interaction on only this consultation or the next four or forty.

Division 6 – Withdrawal of Consent

Sections 43 and 44 apply to the capacity to withdraw consent on issues that are related to “interaction with the record”. The capacity to revoke consent (given under 41(d)) to allow the Board to release data that is identified or may be identified for research purposes is provided under Section 44(3). The process is

unclear. The wording of Section 44(3) represents an unusual “vagueness” on process and sets no time frame for the Board to act upon a notification to revoke of consent. Issues of consent related to Section 41(d) and the capacity to revoke consent Section 44(3) are not transparent. Given the implications of providing consent under Section 41(d) this is not acceptable.

Division 7 – BMMS Agent

Section 42 (1)(c) establishes that for a patient under 15 the parent or the guardian appointed by a parent can consent and revoke consent. This applies to application to participate and provides access to the parent or guardian to a young person’s record. It would, necessarily follow that it would be a breach of the legislation for the GP or pharmacist to allow a person under 15 to participate in BMMS without an agent. This is inconsistent with National Privacy Principles incorporated in the *Privacy Amendment (Private Sector) Act 2000*.

The draft legislation must address the means of a prescriber or supplier being able to verify both the identity of the agent and the fact that the person is the agent appointed by the patient and is recorded as such in the record.

2. BMMS RELATIONSHIP WITH THE PRIVACY LEGISLATION

Doctors and suppliers are exposed to paying both compensation under the Privacy legislation and to sanctions under the BMMS legislation for the same breaches.

At the same time, the increased exposure to abuse of e-health information by on-selling of data created by the BMMS, is not matched by bestowing any additional powers or resources on the Privacy Commissioner.

The collection of unnecessary information under the BMMS legislation such as Medicare Number represents an increased threat to consumer privacy.

The Government has consistently stated that the BMMS legislation will “lift the bar” in relation to privacy. It has not. It has, however, introduced unjustifiably punitive sanctions into what it calls breaches of BMMS privacy. In fact the Act sets aside most of the critical privacy issues for Board determination. Key privacy issues such as guidelines for release of identifiable or potentially re-identifiable data, informed consent mechanisms, complaints procedures and an undisclosed consequential amendment to the *Privacy Act 1988* (as amended by the *Privacy Amendment (Private Sector) Act 2000*), are not outlined in this Bill. The Bill provides no reason for either consumers or GPs to have confidence in the maintenance of health information privacy. That the Bill leaves the way clear for the open tender of the operation and management of the database to the private sector is hardly a step forward in raising the bar in relation to health privacy. Further we remain unconvinced that the BMMS legislation has been

developed in close consideration of developments going on elsewhere in relation to the *Privacy Amendment (Public Sector) Act 2000* and its National Privacy Principles.

It must be noted that the development of the BMMS has been undertaken by the Department of Health and Aged Care in isolation from other significant Government e-health initiatives. It is also not an initiative that has come under the responsibilities of the National Health Information Management Advisory Council (NHIMAC) as has HealthConnect and other initiatives. This does not augur well for consistency in e-health and provides further support for the development of specific health information privacy legislation.

3. SUPPRESSION

Sections 32 to 35 address the issue of suppression of specific medication events from the record. The issues that might need to be considered relate to the possibility of a GP refusing to prescribe a medication on the basis that the patient wishes to suppress the information – this may particularly be the case for a person who is not a regular patient of the GP. The medication may be of a type that could cause interactions and/or adverse events making suppression a health risk, or the person could be clearly doctor shopping in relation to this medication.

The legislation must reflect the fact that the decision to prescribe is the doctor's and that part of that decision making may include consideration of the patient's wishes in relation to suppression. The Bill establishes that a request to suppress by a patient creates an obligation for the doctor to oblige that request with administrative sanctions should they fail to accede to such a request.

This has implications for independent clinical decision-making, patient risk assessment etc that is a responsibility of the doctor. In this scenario, refusing to prescribe because a patient wants the item suppressed the doctor may be defined as "discriminating" against the patient in prescribing.

Further, liability risk for GPs in terms of an obligation to fulfil the patients wishes in this regard need to be considered. Would there be an onus, in terms of liability, on the GP to counsel patients who request suppression. Alternatively, given the legislation makes it obligatory for the GP to suppress at the patient's request does this remove any requirement (and thus liability) for the GP to counsel the patient against suppression.

In the legislation information session on 6 June the AMA queried these points with the Department. The response was that a GP was not obliged to enter any information in the record. There was a right of patients to not have items entered and there was an equal right for doctors. We have been unable to find this point in the legislation.

Cross-reference Sections on suppression to Part 1 Section 12 that outlines the meaning of suppressed medication information. Section 12(e) appears to be completely inconsistent with the purpose of the suppression capacity in that it makes the suppressed medication information available to “a supplier or employed pharmacist intending to supply a drug mentioned in the suppressed medication information” – this may simply be a problem of clarity in the wording – what the legislation may intend to say is that a GP may suppress a prescribed medication (and always has access to that record) and then the pharmacist who supplies that medication does not need to suppress separately but always has access to that record.

The BMMS Board has access to the patient record including the suppressed record and at the same time has the power to delegate a significant number of its functions and powers to a potential private contractor and a Departmental Secretariat. This may include access to the patient record including suppressed records.

The capacity to suppress will impact on the quality of the record and thus GP confidence in the system. The Bill must provide that:

- the existence of suppressed records that might be unavailable to the GP creates no liability for a GP who does not have access to them and;
- there is no onus on the GP to question and counsel the patient to “own up” if they have suppressed records.

A key omission in draft Bill is agreement that the record itself will not indicate that a suppressed record exists (except to the prescriber and supplier related to that specific medication event).

4. INTERACTIONS WITH THE RECORD

Division 2 – Preliminary Matters Required for Interactions

Section 51 provides the Board with the responsibility for determining an electronic identification system for doctors and suppliers that also provides for the determination of personal identifiers and authentication mechanisms. It also provides for determinations on an electronic identification for consumers to view their record independently and that such an identification system should also provide for determination of personal identifiers and authentication mechanisms.

The concern in relation to Section 51 is that the issue of electronic identification and personal identifiers, will be determined by the Board, and thus removes the issue from debate in the public arena. In addition the Determinations made under Section 51 by the Board will not be disallowable instruments. This is unacceptable.

Electronic identification and personal identifiers go to the heart of security, privacy and confidentiality issues and as such they must be put out for public debate.

Division 4 – Interactions with a Participating Consumer’s Record by Participating Doctor, Participating Supplier, Employed Pharmacist or Board.

Section 59(4) provides the power to the Board to determine optional fields in the medication information, including “reason for treatment”. The consensus of industry stakeholders was acceptance of this field as optional although the AMA opposed the existence of this field at all.

Under Section 59(4) the determination is not a disallowable instrument. This is unacceptable. Section 59(4) is critical in terms of the type and amount of information that the Board (and thus the Government) will be permitted to collect under the heading of medication information.

Section 61 establishes that the Board may interact with the record on the basis of consent from the patient or for the purposes of carrying out the Board’s functions. It is not clear as to where the Board obtains consent for interaction of the Board with the Record. It would appear logical that this occurs on application but this specific consent is not mentioned in the section on consent, types of consent and events to which the patient consents to. The question is then whether the general capacity for the Board to interact with the record provided under Section 61 is based on implied consent either through the application process or through consent as in Section 41(d). Is a reliance on implied consent in this context consistent with the *Privacy Amendment (Private Sector) Act 2000* (given it is the doctor who is “collecting” the information)?

Combined with the Board being able to determine what information will be collected under Section 59(4) the lack of specific consent to Board interaction is of significance. Further, whatever form the application to participate takes the capacity of the Board to interact with the record and the basis on which it may interact must be part of an “informed consent” process prior to application to participate.

Section 61(2) is too broad and the circumstances in which the Board may interact with the consumer’s record are not limited in the Bill. Section 168(n) establishes that other functions not currently in the Bill may be established under the Act and these may relate to many of the determinations as yet to be undertaken by the Board. The circumstances under which the Board may interact with the consumer’s record must be specified in the Bill. However, it is difficult to see how any interaction by the Board with the consumer record, including release of data, is related to the primary purpose of the Bill. Board interaction may be inconsistent with the *Privacy Act*.

Sections 65(4)(e) and 65(5) provide for the Board to make determinations on any other category of “relevant information” that the HIC may enter into the Record outlined in (65(1)(a) and (b). There are questions about 65(4)(c) and (d) as to what purposes these serve. It is possible that a combination of issues under Section 65 and elsewhere in the Bill serve to permit the linking of BMMS information with a range of other information, prescriber information for example. Section 65(4) allows the linking of any information held by the HIC to the BMMS, based on a Board determination as to what is contained in 65(4)(a) to (d).

The only protection is that the determination relating to 65(4)(e) is a disallowable instrument.

Division 7 – During What Timeframe May Interactions By Participating Doctor, Participating Supplier or Employed Pharmacist Occur?

Section 69 does not provide a specific time frame in which the Board must interact at the patient’s request except “when it is reasonably practicable to do so”. A time frame for Board response must be established in the Bill.

Division 8 – Board May Seek Information or Give Out Information About Interactions.

Section 70 sets no limits on the Board’s capacity to ask anyone who has interacted with the Record about an interaction. The Board’s powers in relation to Section 70 (1) must be modified to ensure they are clearly linked and limited to its powers set out in Part 10- - Investigations and Complaints.

5. RELEASE OF IDENTIFIED AND POTENTIALLY RE-IDENTIFIABLE DATA

Part 8 Section 88(1) (a) to (c) reflects the work of the BMMS Privacy Working Group and its desire to develop a limited set of conditions for the release of identifiable data. Section 88(1)(d) provides what is a somewhat broad criterion but further protections are provided in Section 90.

There is the issue, however, of the impact of the potential release of identified data as a factor in consumers’ decisions to participate. While the Bill seeks to provide protection to consumers in this regard, community concerns about privacy, particularly in the context of information technology, will ensure that potential use of personal data, even based on consent, will act as a deterrent to participation. The AMA would insist that given the significant sensitivities related to release of personal health information the informed consent process and consent options in the initial application must list consent to the release of identifiable data separate to other consents related to data release.

The legislation is not clear as to what criteria will apply to decision making on the release of data that **may** identify the consumer (that is potentially re-identifiable data). That is that data which is the also the subject of consumer consent under Section 41(d). The Bill fails to specifically address criteria relating to release of data that "...**may** identify, the consumer". It appears that Section 91 may relate to potentially identifiable data. It directs the Board to establish guidelines for the release of BMMS data for research. While these guidelines must be approved by the Privacy Commissioner, Section 91(3) establishes that the Determination will not be a disallowable instrument. It is unacceptable that the guidelines for release of BMMS data for research are not a disallowable instrument. In terms of transparency the draft is lacking in clearly separating out the two critical types of data (identifiable and potentially identifiable) and associated criteria for release (even where these are yet to be developed by the Board).

The informed consent process should be reflected in an application form that sets out separate consents for use of identifiable data and potentially identifiable data given it appears that different criteria will apply to their release.

6. COMPLAINTS AND INVESTIGATIONS

Part 10 – Complaints And Investigation

The industry stakeholders and, in particular, those involved in the Privacy Group, committed a significant amount of time to development of a BMMS Complaints mechanism. In May the AMA wrote to DHAC querying how the Government proposed to resolve the issue of two separate complaint mechanisms (a BMMS and Privacy Act) being relevant to a doctor-patient consultation that may involve interaction with the BMMS record. We noted that confusion as to where coverage of each piece of legislation, and therefore the complaints mechanisms, began and ended would not make the BMMS complaints mechanism easy for either doctors or patients.

The upshot is that there is no real BMMS complaints mechanism in the Bill. While consumers can put a complaint to the Board the legislation notes that the Privacy Commissioner has the primary role in handling privacy complaints that arise under this Act.

This section of the legislation, while giving the Board the right to take complaints and investigate complaints and initiate its own investigations, provides no indication of exactly what type of complaints or incidents it may investigate. The definition of a BMMS Record as data in the HIC database must limit the powers and functions of the Board to the BMMS.

There is the potential for confusion over which legislation, the Privacy or the BMMS, will cover exactly what "actions" in the context of a doctor-patient consultation that involves interaction with the BMMS record. Identifying in the Bill

exactly what the Board is able to do is therefore essential. The capacity to receive and act on complaints or investigate must be limited to those processes that relate to BMMS data (as defined) and must be detailed in the legislation.

Section 107(1) states that a person may complain to the Board about any matter arising under the System. However, there is no definition anywhere of exactly what the BMMS “System” encompasses. In that context this legislation may give the Board the power to take up complaints about processes that do not relate to the BMMS Record as defined for the purposes of the Bill.

107(2) provides the Board with the power to make a determination on procedures for dealing with complaints, Section 110(1) allows the Board to make a determination on procedures for the conduct of investigations and Section 111(2) allows the Board to determine procedures and practices for the referral of matters to appropriate persons, bodies or organisations. None of these determinations are disallowable instruments. This places the complaints process and mechanism out of the public arena and no consultation is required. This is unacceptable.

7. SANCTIONS AND OFFENCES

PARTS 11 AND 12 – ADMINISTRATIVE SANCTIONS AND OFFENCES

In the Overview to the Bill, “administrative sanctions” are referred to without reference to the penalties that can apply, of up to two years in gaol for offences under the Bill.

Further, there is a link with the Privacy legislation, providing sanctions for breaches of the Privacy Act found to have occurred by a participating doctor in relation to a participating consumer. Thus, more severe sanctions than are given to the Privacy Commissioner under his Act, apply under the BMMS legislation. A doctor can thus find him or herself subject both to a compensatory payment under the Privacy legislation and a sanction under the BMMS legislation for the same breach.

8. EXPOSURE TO CIVIL CLAIMS FOR DAMAGES

PART 7 – Protection From Civil Liabilities Arising Under The System

While the Bill specifically declares that no civil liability will arise from a person’s failure to participate in the BMMS scheme, this does not prevent a doctor or pharmacist from being immune to allegations of negligence in a civil suit for not availing him/herself of the possible advantages of participating generally or in a particular event, if such participation might have avoided an adverse outcome, or for a participant to fail to have regard to the Record, or, to have regard to the record which transpired to be incomplete.

Given the difficulties under this and the Privacy legislation to accessing past full clinical records from other or previous treating doctors, undue reliance is likely to be placed on the Record where a doctor requires information about previous medication.

9. CEASING TO BE A PARTICIPANT

Part 14 – How A Participant Ceases To Be A Participant In The System

Industry stakeholders' concerns (particularly consumer concerns) in this area were that the capacity to "opt-out" of BMMS should be as simple as possible and that a request can be dealt with in a timely manner.

10. ANNUAL REPORT

Section 200 sets out the specific matters to be included in the Annual Report. Under Section 200(a) the Board is required to advise the number of times it has released BMMS data under Part 8 (possibly on identifiable or re-identifiable data). This is inadequate in terms of transparency of what is a major privacy issue. The Board should be required to advise to whom and/or for what project or what purposes data was released and whether specific consent was gained or consent was accepted as implied (if getting consent is problematic) as is indicated elsewhere in the Act.

The requirement to report on complaints, Section 200(b) and (c) should also provide more detailed information. This is particularly important as complaints under this Act may potentially bounce between the BMMS Board, the Privacy Commissioner and the two pieces of legislation that they operate under.