

# *New Challenges for Old Laws? The Development of E-Health in Australia*

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Advances in information technology and telecommunications have fostered the development of electronic commerce. As these developments are adopted and implemented in the health sector through initiatives in telemedicine, telehealth, e-health and health informatics, the face of health care seems set for a transformation. The new electronic world of health care will facilitate the more efficient delivery of health services to rural and remote communities, will help to bring about efficiency-related cost savings in health-related business transactions, and will enable health records to be kept in an electronic form. However, developments in e-health also pose significant challenges for health consumers, health professionals, lawyers and policy makers. The new environment has the potential to change the ways that health professionals and health consumers interact, while the privacy of personal information takes on a new significance in the electronic age. Furthermore, the provision of health services by distance raises unique issues about the registration of health professionals and potential areas of liability, while the global nature of the internet will present challenges to national regulators on issues such as on-line advertising of pharmaceuticals. In this new environment, the relevance and adequacy of existing laws is of vital importance to all involved in the health sector.

This article seeks to analyse the changing face of health care in the new technological environment by providing an overview of e-health developments in Australia. Part 1 sets the scene for the article by mapping the increasing role of e-health and by providing key definitions. In Part 2 the possibilities of e-health are considered. It is through the analysis in this Part that the promises of e-health, both in terms of provider-to-consumer initiatives, and in terms of business-to-business initiatives, are considered. Finally, in Part 3, the challenges of e-health are explored in the context of existing Australian laws and recent reforms. It is in this Part that the adequacy of existing laws to meet the challenges posed by e-health is assessed.

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## 1. *From E-Commerce to E-Health*

The development of the information economy has transformed the modern corporate world. Web sites, e-mail and mobile communications are part of daily corporate life. In February 2000, 84 per cent of small businesses and 100 per cent of medium businesses owned at least one computer. Furthermore, in the year from February 1999 to February 2000, the percentage of small businesses connected to the internet increased from 48 per cent to 60 per cent.<sup>1</sup> The changes in the corporate world reflect broader social changes as the general public has adopted modern computer systems and communications. By May 2000, 54 per cent of Australian households had a personal computer and 33 per cent of households had internet access at home.<sup>2</sup>

However, while domestic use of computers has been increasing, Australia and New Zealand have lagged behind other developed countries with health information technology (IT) budgets amounting to approximately 1.5 per cent of health expenditure — compared to 2 per cent in the United Kingdom and 3.5 per cent in the United States.<sup>3</sup> Furthermore, although 73 per cent of firms responding to a 1999 survey invested in health IT research and development, half of the respondents reported spending less than \$100 000 in research and development in 1998–99.<sup>4</sup>

However, continued growth in the e-health sector can be expected. There are a number of ‘strategic drivers’ that will facilitate the uptake of telehealth initiatives, including the ageing of the population, changing models of health care, pressures to reduce the costs of health care, and improved information technology and communication.<sup>5</sup> The development of an information economy is a priority of the Federal Government. The Government has established a National Office for the Information Economy,<sup>6</sup> and has identified key priority areas.<sup>7</sup> Strategic priority 8 is to ‘Unlock the potential of the health sector.’ The key priorities in this area include: the development of a national collaborative approach; the development of sound foundations in legal, data protection, and security issues; the development of standards for health information management and information technology that

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1 National Office for the Information Economy, ‘Current State of Play – November 2000’, available from <[www.noie.gov.au/projects/information\\_economy/research&analysis/ie\\_stats/StateofPlayNov2000/index.htm](http://www.noie.gov.au/projects/information_economy/research&analysis/ie_stats/StateofPlayNov2000/index.htm)>.

2 Ibid.

3 Collaborative Health Informatics Centre, *E-Health: An Exploratory Study of Health IT in Australia and New Zealand – Executive Summary*, reporting the results of a 1999 study of health information technology in Australia and New Zealand.

4 Ibid.

5 Australian New Zealand Telehealth Committee, *Proceedings of Telehealth Think Tank Melbourne 2000, Fact Sheet 6 – Telehealth: Strategic Drivers*.

6 National Office for the Information Economy at <[www.noie.gov.au](http://www.noie.gov.au)>.

7 National Office for the Information Economy, *Second Progress Report – May 2000: Strategic Framework for the Information Economy – Action Plans* at <[www.noie.gov.au](http://www.noie.gov.au)> then click on projects/information economy/ strategic framework.

are compatible with international standards; and the building of a 'more efficient and effective health care system through a greater take-up of e-commerce, and improved availability of aggregate data for research, policy and planning purposes.'<sup>8</sup>

The developments in e-commerce and the information economy have had a dramatic impact on health care. Telemedicine, telehealth, e-health and health informatics have all developed as important components of the modern health care system. While each of these components is related to the other, there are important differences between them. *Telemedicine* has been defined as 'a system of health care delivery in which physicians examine distant patients through the use of telecommunications technology.'<sup>9</sup> It is important to realise that while telemedicine is often thought of as a development of the late 20<sup>th</sup> Century, it has in fact been around for much longer. The telegraph was used to obtain medical advice in the early 20<sup>th</sup> Century in outback Australia,<sup>10</sup> and in 1928 the first base for the Flying Doctor was established in western Queensland, and a 'significant factor in its early success was the "pedal wireless".'<sup>11</sup> Developments in technology will also have an impact on perceptions of telemedicine as 'it will be difficult to separate telemedicine from other health related activities that use information and communication technologies.'<sup>12</sup>

In contrast to telemedicine, the term *telehealth* suggests a broader application, which takes account of the activities of a range of health professionals, including nurses, psychologists and others.<sup>13</sup> Clearly the use of information technologies is an integral part of the electronic delivery of health care. The use of these technologies poses a variety of broader issues about the management and use of information. This is the field of health informatics. The Health Informatics Society of Australia defines *health informatics* as:

an evolving scientific discipline that deals with the collection, storage, retrieval, communication and optimal use of health related data, information and knowledge. The discipline utilises the methods and technologies of the information sciences for the purposes of problem solving and decision-making thus assuring quality healthcare in all basic and applied areas of biomedical sciences.<sup>14</sup>

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8 Ibid. For a discussion of health care reforms and an action plan for health information management in Australia see, National Health Information Management Advisory Council, *Health Online: A Health Information Action Plan for Australia* (1999).

9 J Preston, *The Telemedicine Handbook: Improving Health Care With Interactive Video* (1993) quoted in John Mitchell, *From Telehealth to E-Health: The Unstoppable Rise of E-Health* (1999) at 8.

10 Australian New Zealand Telehealth Committee, above n5, *Fact Sheet 2 – Telehealth in Australia: Major Milestones*.

11 Ibid.

12 John Mitchell, *Fragmentation to Integration: The Telemedicine Industry in Australia* (1998) at 6, quoted in Mitchell, above n9.

13 Mitchell, above n9 at 9.

14 Health Informatics Society of Australia: <[www.hisa.org.au](http://www.hisa.org.au)>.

While telemedicine and telehealth tend to be focused on the delivery of health care to remote patients, *e-health* encompasses both the remote delivery of health care and health information as well as the health sector aspects of e-commerce. E-health has been defined as ‘the use in the health sector of digital data — transmitted, stored and retrieved electronically — for clinical, educational and administrative purposes, both at the local site and at a distance.’<sup>15</sup> While the delivery of health care to remote patients is an important and highly visible aspect of the electronic dimensions in modern health care, the integration of broader developments in the information economy into the health sector promises to bring significant change, at the organisational or institutional level, as health-related business-to-business commerce realises the efficiencies of electronic business transactions.

## 2. *The Possibilities of E-Health*

### A. *Providing Health Services to Remote Communities*

One of the primary advantages of developments in telehealth is that it permits the provision of health services to rural, remote and other under-served communities.<sup>16</sup> In Australia this is particularly important. Australia has a relatively small population spread over a vast geographic region and the provision of medical and other health services to ‘the bush’ has been an on-going concern in Australia. Rural communities have been experiencing difficulties in attracting and retaining doctors and specialist services can often be located many miles away. In addition to actually providing rural and remote communities with health services, albeit at a distance, the availability of telehealth services may also help to overcome some of the concerns health care providers may have over professional isolation if they take a job in the bush.<sup>17</sup>

In Australia, the provision of mental health services by telehealth is well established. Indeed, ‘from the range of possible telehealth applications, telepsychiatry is one of the most widely developed throughout Australia.’<sup>18</sup> Other applications of telehealth in Australia include telepsychology,<sup>19</sup> teleradiology<sup>20</sup>

15 Mitchell, above n9 at 12.

16 Bruce Swanson, ‘Information Technology and Under-Served Communities’ at <[www.telehealth.org.au/discussion\\_papers/info\\_tech.html](http://www.telehealth.org.au/discussion_papers/info_tech.html)>.

17 Daniel McCarthy has argued:

Without telemedicine, a physician deciding whether to practice in a rural area is faced with potential isolation, lack of sophisticated continuing medical education, lack of contact with research facilities and the accompanying prestige and knowledge. Telemedicine has the potential to, at a minimum, offset these deterrent factors and may even negate them.

Daniel McCarthy, ‘The Virtual Health Economy: Telemedicine and the Supply of Primary Care Physicians in Rural America’ (1995) 21 *American Journal of Law and Medicine* 111 at 127.

18 Royal Australian and New Zealand College of Psychiatrists, *Position Statement #44 – Telepsychiatry*, available from <[www.ranzcp.org/statements/ps/ps44.htm](http://www.ranzcp.org/statements/ps/ps44.htm)> at 2.3.

19 Maxine Capner, ‘“Tele-Psychology”: What is the Role of Telehealth in the Provision of Psychological Services to Rural and Remote Communities?’ available at: <[www.telehealth.org.au/discussion\\_papers/Psychessay.html](http://www.telehealth.org.au/discussion_papers/Psychessay.html)>.

20 The Royal Australian and New Zealand College of Radiologists has a position statement on Teleradiology which is available from <[www.racr.edu.au/open/pol\\_teleradiology.htm](http://www.racr.edu.au/open/pol_teleradiology.htm)>.

and telemedicine ophthalmology.<sup>21</sup> The Royal Australian and New Zealand College of Psychiatrists Position Statement on Telepsychiatry notes the success of telepsychiatry services for rural and remote communities:

Early research has demonstrated that the psychiatric interview conducted over videoconferencing is reliable for diagnostic assessment and treatment recommendations. Patient and referrer satisfaction has consistently shown that this mode of clinical service delivery is widely accepted. Many thousands of psychiatric interviews have subsequently been conducted throughout Australia and New Zealand. The ongoing demand for these services and the increasing integration of telepsychiatry into mainstream services amply demonstrate that telepsychiatry is an effective means by which rural and remote communities can access specialist psychiatric services.<sup>22</sup>

The provision of telehealth services may also impact upon the medical workforce. The availability of telehealth services may increase utilisation rates for medical services in rural and remote communities where utilisation rates have tended to be much lower.<sup>23</sup> If utilisation rates in rural communities rise this may lead to an increased need for health professionals. On the other hand, telehealth-related efficiencies in health services may reduce the need for health professionals.<sup>24</sup> Other possibilities in telehealth include using secure internet sites or smart medical devices in order to monitor the health of patients while they are still at home.<sup>25</sup> Ultimately, even surgery may be carried out without direct contact with the patient.<sup>26</sup>

### **B. Electronic Health Records**

In July 2000 Australia's health ministers gave their approval to the implementation of *HealthConnect*, a national health information network.<sup>27</sup> The National Electronic Health Records Taskforce<sup>28</sup> proposed *HealthConnect* to allow

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21 Nikki AM Blackwell, Graeme J Kelly and Lee M Lenton, 'Telemedicine Ophthalmology Consultation in Remote Queensland' (1997) 167 *Medical Journal of Australia* 583.

22 Royal Australian and New Zealand College of Psychiatrists, above n18 at 2.6.

23 Swanson, above n16.

24 Ibid.

25 Carol Lewis, 'Emerging Trends in Medical Device Technology: Home is Where the Heart Monitor Is' (May-June 2001) *FDA Consumer* at <[www.fda.gov/fdac/features/2001/301\\_home.html](http://www.fda.gov/fdac/features/2001/301_home.html)>; Lisa Holewa, 'Virtual House Call' *American Medical News*, 22/29 November 1999 at <[www.ama-assn.org/sci-pubs/amnews/pick\\_99/biza1122.htm](http://www.ama-assn.org/sci-pubs/amnews/pick_99/biza1122.htm)>; Branko G Celler, Nigel H Lovell and Daniel KY Chan, 'The Potential Impact of Home Telecare on Clinical Practice' (1999) 171 *Medical Journal of Australia* 518.

26 Patrick Cregan, 'Surgery in the Information Age' (1999) 171 *Medical Journal of Australia* 514.

27 Dr Michael Wooldridge, Minister for Health and Aged Care, 'Media Release: Health Ministers Give Green Light to National Health Information Network' at <[www.health.gov.au/mediarep/yr2000/mw/mwhmc2005.htm](http://www.health.gov.au/mediarep/yr2000/mw/mwhmc2005.htm)>.

28 The Report of the National Electronic Health Records Taskforce is available from <[www.health.gov.au/healthonline/ehr\\_rep.htm](http://www.health.gov.au/healthonline/ehr_rep.htm)>.

consumers' health records to be collected, stored and exchanged in an electronic format. The proposal would mean that, with the permission of health consumers, summaries of health information about the consumer could be collected in an electronic format each time the consumer consulted a health care provider. As long as the consumer consented, the electronic record would be accessible to other health care providers via a secure network.<sup>29</sup> Participation by health consumers would be voluntary and consumers could choose to keep some aspects of their health records private.<sup>30</sup> A system of electronic health records would have a number of benefits for consumers. These include improved clinical decision-making, avoiding duplication of history taking or diagnostic testing, better management of medications and increased use of preventive health measures.<sup>31</sup>

The Better Medication Management System (BMMS) is an initiative focused on developing an electronic patient medication record to link prescription information from doctors and dispensing pharmacists. The object of the BMMS is to assist in reducing adverse drug reactions or interactions by providing a means of accessing information about medications that consumers are taking. Like the electronic health record system, the BMMS would be a voluntary system.<sup>32</sup>

The idea of introducing electronic health records has also been adopted in New South Wales. In February 2001 the New South Wales Minister for Health released a report on electronic health records.<sup>33</sup> The report recommended that 'a system of linked electronic health records across the State' be developed and that the system be governed by a new Act, the Health Records and Information Privacy Act.<sup>34</sup> The Report also recommended the introduction of a system of Unique Personal Identifiers to support the electronic health records system.<sup>35</sup>

The development of electronic health records does raise significant issues over the privacy and security of health data.<sup>36</sup> It is not the creation of an electronic record per se that creates privacy concerns — rather it is the capacity for electronic records to be linked electronically (over networks or over the internet) and to be

29 HealthConnect Fact Sheet 1 at <[www.health.gov.au/healthonline/hc\\_1.htm](http://www.health.gov.au/healthonline/hc_1.htm)>.

30 HealthConnect Fact Sheet 2 at <[www.health.gov.au/healthonline/hc\\_2.htm](http://www.health.gov.au/healthonline/hc_2.htm)>.

31 Christopher D Mount, Christopher W Kelman, Leonard R Smith and Robert M Douglas, 'An Integrated Electronic Health Record and Information System for Australia?' (2000) 172 *Medical Journal of Australia* 25.

32 Information on the Better Medication Management System (BMMS), including draft legislation is available at <[www.health.gov.au/bmms/index.htm](http://www.health.gov.au/bmms/index.htm)>.

33 Media Release, Minister for Health, 'Electronic Health Records – Better Care. Your Choice' at <[www.health.nsw.gov.au](http://www.health.nsw.gov.au)>. The report is the NSW Ministerial Advisory Committee on Privacy and Health Information, *Panacea or Placebo? Linked Electronic Health Records and Improvements in Health Outcomes* (2000) at <[www.health.nsw.gov.au/iasd/hi/privacy/papers.html](http://www.health.nsw.gov.au/iasd/hi/privacy/papers.html)>. For discussion of NSW developments see, Amanda Cornwall, 'NSW Electronic Health Records Gets Serious' (2000) 9 *Australian Health Law Bulletin* 21.

34 NSW Ministerial Advisory Committee, *ibid.* recommendations 1 and 3.

35 *Ibid.* recommendation 10.

36 Meredith Carter, 'Privacy and Public Confidence in an e-Health Era' (2000) 64 *Health Issues* 12; Meredith Carter, 'Integrated Electronic Health Records and Patient Privacy: Possible Benefits But Real Dangers' (2000) 172 *Medical Journal of Australia* 28.

accessed by multiple individuals, or for unauthorised access, that creates privacy concerns.<sup>37</sup> The New South Wales Ministerial Advisory Committee on Privacy and Health Information was unanimously of the view 'that separate and distinct legislation is required to cover the privacy of health information.'<sup>38</sup> In the Committee's view, 'Public confidence in electronic health records would be greatly enhanced by strong, robust health information privacy legislation.'<sup>39</sup>

### C. *B2B Commerce*

The application of e-commerce to the health environment creates the possibility for health-related businesses to utilise the internet in such a way as to achieve business efficiencies and cost savings in business-to-business commerce (B2B). Legal changes have already been needed to meet the new electronic commercial environment. For example, the Commonwealth government introduced the *Electronic Transactions Act 1999* (Cth) to address practical issues relating to e-commerce in Australia by permitting contracts to be made on-line. A uniform Electronic Transactions Bill 2000 has been developed by Commonwealth, State and Territory governments and has been endorsed by all jurisdictions and is being enacted and implemented at the State and Territory level.<sup>40</sup> Developments such as these are vital in providing the necessary framework for electronic commerce.

In Australia, the Health Insurance Commission has a number of e-business projects. These projects include:<sup>41</sup>

- an e-health Technology Centre;
- the use of Public Key Infrastructure (PKI) in new online business by the HIC to ensure the privacy and security of transactions;
- the establishment of the Health e-Signature Authority as an independent registration company to encourage the use of PKI in the health sector;
- electronic lodgment of patients' Medicare claims from doctors' surgeries;
- a trial of the Authority Notification System to explore the possibility of prescribers notifying the HIC of authority prescriptions via the internet.

Another example of e-commerce in the health sector is the Project Electronic Commerce and Communication for Healthcare (PeCC). The project is situated against a broad aim of using e-commerce to reduce the costs of healthcare. It has

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37 NSW Ministerial Advisory Committee, above n33 at 3.

38 Id at 24.

39 Id at 25.

40 For further information see, 'Australia's Legal Framework for Electronic Commerce' available at: <[www.law.gov.au/publications/ecommerce/](http://www.law.gov.au/publications/ecommerce/)>. For discussion of electronic commerce issues in the context of e-health see, Mark Sneddon and Paul Noonan, 'Legal and Regulatory Issues in E-Health' at <[www.claytonutz.com.au/hlth/hlth0002.htm](http://www.claytonutz.com.au/hlth/hlth0002.htm)>

41 Further information is available from the HIC website: <[www.hic.gov.au](http://www.hic.gov.au)>.

been designed to encourage the use of e-commerce and standard numbering in manufacturing and distribution and to demonstrate improvements in supply chain management.<sup>42</sup> The project has been funded by government and industry.<sup>43</sup>

PeCC works by following 'the retail industry supermarket model of barcoding and scanning.'<sup>44</sup>

In the pharmaceutical industry, distributors and manufacturers are encouraged to adopt common numbering and information exchange standards, as well as to use the Internet for e-commerce practices to distribute orders by wholesalers and to receive acknowledgments from manufacturers. Eventually the supply chain will be extended to include end-users (ie. hospitals), that will allow pharmaceuticals to be optimally scanned by the bedside on consumption.<sup>45</sup>

The adoption of standardised numbering of pharmaceuticals and other health care products using unique identifiers introduces considerable efficiencies into the supply process. The Director General of New South Wales Health has endorsed a recommendation from the New South Wales Health Peak Purchasing Council that EAN (European Article Numbering) Standards and Barcoding be adopted for products considered for use in the New South Wales health system. From 1 July 2001 EAN compliant organisations will be given preference.<sup>46</sup>

A number of demonstration projects were undertaken by PeCC as a way of demonstrating the benefits of using common numbering and e-commerce.<sup>47</sup> One of these projects was the Pharmaceutical Extranet Gateway (PEG). The PEG project linked five major pharmaceutical wholesalers with 700 manufacturers from whom they purchased.<sup>48</sup> The PEG project provides wholesalers and suppliers with an internet-based common ordering system.<sup>49</sup> There are significant cost savings attached to electronic commerce over the traditional forms:

Analysts estimate that the cost of placing an order through the normal manual process would be around \$50-\$70. With full implementation of PEG, they suggest that this transaction cost will be reduced to merely \$2-\$5 per order. Given a current purchase order transaction volume of 3.8 million per year, this equates to annual savings of the order of \$200 million.<sup>50</sup>

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42 Elizabeth More and Michael McGrath, *Health and Industry Collaboration: The PeCC Story* (May 2000) at 23, available at <[www.noie.gov.au/projects/ecommerce/ehealth/index.htm](http://www.noie.gov.au/projects/ecommerce/ehealth/index.htm)>.

43 *Id* at 25.

44 *Id* at 23.

45 *Id* at 23.

46 'Health DG Endorses PCC Recommendations on EAN/Barcoding' at <[www.health.nsw.gov.au](http://www.health.nsw.gov.au)> then click on 'Doing Business With Us'.

47 More and McGrath, above n42 at 29.

48 *Id* at 31.

49 *Ibid*.

50 *Id* at 36.



The adoption of PeCC's approach in health care will lead to substantial costs savings in the supply chain thus freeing these costs for patient care.<sup>51</sup>

### 3. *The Challenges of E-Health*

While there are enormous promises associated with e-health, its development also presents unique challenges for regulatory authorities across a wide range of areas, including provision of professional services, privacy and security of personal information, medico-legal liability and regulation of internet-based advertising. This section analyses the adequacy of Australian law in responding to those challenges.

#### A. *The Changing Health Care Relationship*

Over the past few decades the health care relationship has undergone dramatic changes. The rise of the consumer movement flowed through to health care with the concept of 'patients' rights' and the patient as consumer; the women's movement influenced perceptions of women's bodies and reproductive rights; and the rise of bioethics as a distinct area of ethical analysis, challenged narrower medical approaches by offering broader, interdisciplinary alternatives.<sup>52</sup> Modern communication and information technologies will bring about further changes in the ways that health professionals interact with each other, by 'creating a new conduit not only for communication but also in the access, sharing, and exchange of information among people and machines.'<sup>53</sup> For health professionals, liaising with a geographically remote specialist in the provision of patient care will be an increasing part of general practice. The internet also has the potential to change the way that patients and health professionals interact. It is for example, possible for patients to correspond with their health professionals by email.<sup>54</sup> The widespread availability of the internet means that patients have access to unprecedented amounts of health information. This may be a positive development, with patients more educated about health and health care. However, it may also mean that patients come to doctors and other health professionals with health-related information obtained from the internet, which may or may not be accurate.<sup>55</sup> A recent study evaluated health information that was available on the internet about

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51 Id at 47.

52 Leanna Darvall, *Medicine, Law and Social Change: The Impact of Bioethics, Feminism and Rights Movements on Medical Decision-Making* (1993).

53 Alejandro R Jadad, 'Promoting Partnerships: Challenges for the Internet Age' (1999) 319 *British Medical Journal* 761.

54 Kenneth D Mandl, Isaac S Kohane and Allan M Brandt, 'Electronic Patient-Physician Communication: Problems and Promise' (1998) 129 *Annals of Internal Medicine* 495; Dean F Sittig, Stephen King, Brian Hazelhurst, 'Provider Attitudes Toward Patient-Related E-mail' at <[www.informatics-review.com/thoughts/provider-email.html](http://www.informatics-review.com/thoughts/provider-email.html)>; Alissa R Spielberg, 'Online Without a Net: Physician-Patient Communication by Electronic Mail' (1999) 25 *American Journal of Law & Medicine* 267.

55 Larry Stevens, 'Net Reception' *American Medical News*, 11 October 1999 at <[www.ama-assn.org/sci-pubs/amnews/pick\\_99/biza1011.htm](http://www.ama-assn.org/sci-pubs/amnews/pick_99/biza1011.htm)>.

breast cancer, depression, obesity and childhood asthma in English or Spanish.<sup>56</sup> The study found that coverage of key information was often poor and inconsistent, although generally the accuracy of information was good. Interestingly, the study found that consumers needed high reading levels to comprehend health information on the internet: all of the English web sites and 86 per cent of the Spanish language sites required a reading level at high school level or better.<sup>57</sup>

Even the processes of consent have been transformed by the information age. Tools to assist patient decision-making and consent processes have evolved from the 'papers years' of consent forms, brochures and pamphlets, to the use of videotapes ('the video era'), to interactive CD-Rom programs, to on-line delivery of patient information.<sup>58</sup> However, the provision of patient education in this electronic era also entails difficulties in ensuring that information remains current.<sup>59</sup> Liability issues may arise if electronic patient information is outdated, wrong or misleading.<sup>60</sup>

### **B. Privacy and Personal Information**

Privacy has emerged as a major issue for e-health initiatives. In recent years, consumers have become a lot more wary about the collection and use of their personal information. Modern computing capabilities mean that huge quantities of data can be stored, sorted or accessed by large numbers of people in ways that were not possible in the days of paper-only records.

Governments have responded to these issues with privacy legislation and guidelines. However, Australian privacy laws have been characterised by their patchwork approach, with coverage varying between federal and state levels, and between the public and private sectors. In New South Wales the *Privacy and Personal Information Protection Act 1998* (NSW) covers information held by public departments and public sector agencies. The New South Wales Health Department also has an *Information Privacy Code of Practice* for the handling of personal information in the health sector. As discussed above, the New South Wales Ministerial Advisory Committee on Privacy and Health Information has recommended the introduction of new legislation in New South Wales, specifically to address the privacy issues relating to electronic health records.<sup>61</sup>

Federal privacy legislation has been in place since 1988 with the *Privacy Act 1988* (Cth). However the Act was limited in its application as it only applied to information held by federal departments and agencies. The Act contains 11

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56 Gretchen K Berland, Marc N Elliott, Leo S Morales et al, 'Health Information on the Internet: Accessibility, Quality, and Readability in English and Spanish' (2001) 285 *Journal of the American Medical Association* 2612.

57 *Ibid.*

58 Arnold J Rosoff, 'Informed Consent in the Electronic Age' (1999) 25 *American Journal of Law & Medicine* 367 at 372-378.

59 *Id* at 379-380.

60 *Id* at 381. See also, Nicholas P Terry, 'Cyber-Malpractice: Legal Exposure for Cybermedicine' (1999) 25 *American Journal of Law & Medicine* 327.

61 See above n33 and related text.

Information Privacy Principles (IPPs) that govern the collection, storage and use of personal information. However, the Act had no application to the private sector. In late 2000 substantial amendments to the Privacy Act were passed with the *Privacy Amendment (Private Sector) Act 2000* (Cth).<sup>62</sup> The Act will extend the coverage of the *Privacy Act* to the private sector, including health service providers.

The new provisions contain 10 National Privacy Principles (NPPs) which deal with the collection, storage and use of personal information by the private sector. NPP 2 imposes limits on the disclosure of health information. NPP 6 gives individuals a right of access to personal information held about them. Importantly, this will give consumers a right of access to their medical records. NPP 10 imposes limits on the collection of sensitive information, including health information. In order to provide guidance to the health sector on the new provisions and the limits they will place on the handling of personal information, the Federal Privacy Commissioner has issued *Draft Health Privacy Guidelines*.<sup>63</sup> These draft guidelines and the NPPs are intended to apply to the electronic health environment, such as electronic medical records, as well as more traditional forms of information gathering and record keeping.<sup>64</sup>

The extension of the privacy legislation to the private sector will also provide health consumers with a right to access their health records, including electronic health records, that are held in the private sector. In 1996 the High Court of Australia held that patients did not have a common law right of access to their medical records which were created and held by private medical practitioners.<sup>65</sup> Limited rights of access to medical records have been created by statute, permitting access to records held in public hospitals under freedom of information legislation,<sup>66</sup> and to private hospitals, nursing homes and day procedure centres in New South Wales.<sup>67</sup> Legislation specifically addressing health privacy and access to medical records has been introduced in the Australian Capital Territory<sup>68</sup> and in Victoria,<sup>69</sup> giving health consumers in those jurisdictions statutory rights of access to medical records. The new private sector amendments to the *Privacy Act* will be of landmark significance for they will provide health consumers with rights of access to their medical records held in the private sector.

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62 Information about the new legislation is available from the Privacy Commissioner's website: <[www.privacy.gov.au](http://www.privacy.gov.au)>.

63 *Draft Health Privacy Guidelines – A Consultation Document Issued by the Office of the Federal Privacy Commissioner* (14 May 2001).

64 *Id* at 1.8.

65 *Breen v Williams* (1996) 138 ALR 259. For an analysis of the issues raised by the case see Roger Magnusson and Hayden Opie, 'Patient Access to Medical Records: Fiduciary Duties and Other Issues – A Classroom Interactive' (1998) 17 *University of Tasmania Law Review* 99.

66 See eg, *Freedom of Information Act 1982* (Cth), ss11, 41; *Freedom of Information Act 1989* (NSW) ss16, 31.

67 *Private Hospitals Regulation 1996* (NSW), schedule 1, ss42–44; *Day Procedure Centres Regulation 1996* (NSW), schedule 1, ss23–25; *Nursing Homes Regulation 1996* (NSW), schedule 1, ss49–51.

68 *Health Records (Privacy and Access) Act 1997* (ACT).

69 *Health Records Act 2001* (Vic).

While it remains to be seen how smoothly the new system will operate in practice after the new private sector provisions become operative in December 2001, the introduction of comprehensive privacy legislation at the federal level covering the private sector is a significant development in Australian privacy laws, and should go some considerable way to allaying the concerns of health consumers over the privacy of their health information in the new high-tech environment.

### C. *Registration of Health Professionals*

In Australia, professional registration is required for many health-related jobs. This means that in order to practice as a health professional, such as a doctor, a nurse, or a dentist, one must meet the requirements of the relevant registration board.<sup>70</sup> Since registration is state-based, the provision of telehealth services across state borders, or even across national borders, raises the issue of whether health professionals are practising outside the jurisdiction in which they are authorised to practice. Registration issues may also arise if a health professional is called on to provide medical assistance in an emergency. A practitioner may find that he/she is practising outside the jurisdiction in which he/she is registered if, for example, a practitioner provides emergency medical assistance while travelling on an aeroplane.

One of the difficulties for health professionals who are called on to provide assistance in emergency situations is that they may be required to assist in an area of medicine or health care that is outside their usual area of practice. Telehealth capabilities may help to deal with this situation. One company in the United States provides an Emergency Telemedicine Centre which can be contacted by commercial airlines that have in-flight emergencies.<sup>71</sup>

From a liability perspective, practising outside the jurisdiction in which the practitioner is registered will probably contravene the provisions of the relevant registration Act of the jurisdiction in which the service is provided. It will also be important for the health professional to be aware of the terms of their professional indemnity cover so that they know whether they will in fact be covered in circumstances in which they provide telehealth services in another jurisdiction.<sup>72</sup> Furthermore, where allegations of negligence arise from the provision of telehealth services across more than one jurisdiction, important questions of choice of law will arise.<sup>73</sup> This will necessitate a determination of which jurisdiction's law is to be applicable in the resolution of the dispute.

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70 See for example, *Medical Practice Act 1992* (NSW), *Nurses Act 1991* (NSW), *Dentists Act 1989* (NSW).

71 Tony Goodwin, 'In-Flight Medical Emergencies: An Overview' (2000) 321 *British Medical Journal* 1338. See also, Med-Aire Inc at <[www.medaire.com/comm\\_air.html](http://www.medaire.com/comm_air.html)>.

72 Legislative and Legal Issues Working Group of the Australian National Telehealth Committee, 'Telehealth and the Law' at <[www.telehealth.org.au/discussion\\_papers/th&law.html](http://www.telehealth.org.au/discussion_papers/th&law.html)>.

73 *Ibid.*

State-based professional registration does present a difficulty for practitioners of telehealth and for state registration authorities.<sup>74</sup> There are a number of possible responses to this situation: the medical practitioner could be required to be registered in the state where the patient is located as well as in the practitioner's own state; permitting practitioners to be registered for telehealth in the patient's state; or permitting practitioners to practice telehealth in any state provided they are registered in their home state and the practitioner is liaising with a practitioner in the patient's state who is responsible for the patient's care.<sup>75</sup>

In Australia, although separate registration requirements exist in each state or territory, a mutual recognition scheme has operated since 1993.<sup>76</sup> However, practitioners are still required to be registered in each jurisdiction in which they practice. The New South Wales Medical Board has prepared a draft model for medical registration for the Australian Council for Safety and Quality in Health Care.<sup>77</sup> A model for national portability of medical registration for practitioners who meet national standards for registration is proposed.<sup>78</sup> This approach will help to address the registration issues that arise in telehealth initiatives that are provided within Australia across state/territory borders. As the proposal notes, 'Public interest recognises no borders, and emerging technologies such as telemedicine demand a consistent approach to medical registration'.<sup>79</sup> However, where professional services are provided across international borders, from one country to another, professional registration will remain a live issue for health professionals and for registration authorities.

#### **D. Liability of Health Professionals**

Like other forms of health care, the provision of health services by telemedicine or telehealth entails risks of legal liability for health care providers. All of the traditional legal obligations of health professionals, such as the duty to exercise reasonable care, and the duty to maintain the confidentiality of patient information, remain in the world of cybermedicine. There are, however, some particular liability issues that arise in the e-health context.

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74 See Ross D Silverman, 'Regulating Medical Practice in the Cyber Age: Issues and Challenges for State Medical Boards' (2000) 26 *American Journal of Law & Medicine* 255; Alison M Sulentic, 'Crossing Borders: The Licensure of Interstate Telemedicine Practitioners' (1999) 25 *Journal of Legislation* 1.

75 Young Lawyers Division American Bar Association, *A Third Policy Alternative for Interstate Telemedicine Revisited* at <[http://tie/telemed.org/legal/pubs\\_yld\\_licensure.asp](http://tie/telemed.org/legal/pubs_yld_licensure.asp)>.

76 *Mutual Recognition Act* 1992 (Cth); *Mutual Recognition (NSW) Act* 1992 (NSW); *Mutual Recognition (Australian Capital Territory) Act* 1992 (ACT); *Mutual Recognition (Northern Territory) Act* (NT); *Mutual Recognition (Queensland) Act* 1992 (Qld); *Mutual Recognition (South Australia) Act* 1993 (SA); *Mutual Recognition (Tasmania) Act* 1993 (Tas); *Mutual Recognition (Victoria) Act* 1998 (Vic); *Mutual Recognition (Western Australia) Act* 1995 (WA).

77 New South Wales Medical Board for the Australian Council for Safety and Quality in Health Care, *A Draft Model for Medical Registration – For Consultation* (August 2001).

78 *Ibid.*

79 *Id* at 13.

It is clear that health professionals owe their patients a duty to exercise reasonable care in diagnosing and treating the patient. In Australia, this duty has been held to be a 'single comprehensive duty' which covers 'the examination, diagnosis and treatment of the patient and the provision of information in an appropriate case.'<sup>80</sup> The standard of care to be exercised by health professionals 'is that of the ordinary skilled person exercising and professing to have that special skill.'<sup>81</sup> However, it is unclear how these standards will be applied in the context of provision of health services to geographically remote patients. For example, the ease of accessing information in the electronic age could mean that health professionals could face increased pressures in terms of the quantity of medical information they need to keep up to date with.<sup>82</sup> At what point will health information become part of the body of knowledge of which health professionals are supposed to be aware? In the event of an allegation of negligence, a determination of this issue will turn on whether the health information had become part of the body of knowledge of which a reasonable health professional would have been aware. However, modern information technologies have the potential for the boundaries of the body of knowledge to be expanding constantly.

Where the provision of health services by telehealth means that the service may not be as effective as health services provided by traditional means, a duty of care may arise to advise the patient of this. Health professionals have a duty to advise their patients of 'material risks' of proposed treatment.<sup>83</sup> This means that a duty of care will arise not only to advise the patient of material risks in relation to the particular form of treatment proposed, but also about the material risks associated with the provision of treatment by distance.<sup>84</sup>

Other important areas of potential liability that may arise in the telehealth context include possible missed diagnoses in circumstances where the practitioner advising by distance does not have the opportunity to examine the patient, or where the quality of the images is not as good as that provided by traditional means. It will be important for providers of telehealth services to ensure that their equipment and practice meet technical specifications recommended by professional organisations or government departments.<sup>85</sup> Indeed, equipment issues may ultimately prove to be an extremely complex dimension of the telehealth debate and to issues of potential liability. The obligations of health professionals to upgrade their telehealth equipment and their skills in the face of improving technology, the liability of equipment manufacturers or

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80 *Rogers v Whitaker* (1992) 175 CLR 479 at 483.

81 *Ibid.*

82 Ken Ramsay, 'Legal Ramifications and Controls in Telemedicine: What Are They?' (1998) *HealthCover* 53.

83 *Rogers v Whitaker* (1992) 175 CLR 479.

84 Julianne Fitzsimon, 'Telemedicine: Negligence Revisited' (1998) 7 *Australian Institute for Health, Law and Ethics: Topics for Attention* at 5.

85 See for example, the Royal Australian and New Zealand College of Psychiatrists Position Statement on Telepsychiatry which includes Quality Practice Guidelines for Telepsychiatry (appendix 1) and Guidelines for Technology and Telepsychiatry (appendix 2).

telecommunications companies in the event of equipment failure, and the determination of appropriate technical specifications for equipment, are all complex matters that are yet to be addressed by the courts or by legislation.<sup>86</sup>

The requirement to maintain the confidentiality of patient information is just as important in the telehealth context as it is in traditional health care settings. The duty of a medical practitioner to respect patient confidentiality has been recognised both in professional codes of ethics and in case law.<sup>87</sup> It is vital that practitioners are aware of the privacy and confidentiality issues that arise in the use of e-mail, fax and even the telephone in the discussion of sensitive health information. The use of videoconferencing facilities for health care also potentially presents confidentiality issues. It is important that health professionals ensure that each person who is in the room during a videoconference for a consultation with a patient is identified to the patient.

As discussed above, the electronic age is altering the context of the relationship between health professionals and their patients.<sup>88</sup> E-mail communication between health professionals and patients may open up new areas of liability. One of the difficulties with e-mail communication in the context of sensitive medical information is that there is a need to ensure the protection of patient privacy. Encryption programs may be required in order to ensure that the privacy of sensitive health information is maintained.<sup>89</sup> Furthermore, health professionals need to be aware that there is no reason for advice given by e-mail to be treated any differently from advice given in a face-to-face consultation with a patient.<sup>90</sup> In many respects, e-mail communication is analogous to telephone communication between health professionals and patients, and should be treated just as cautiously.<sup>91</sup>

### ***E. On-Line Advertising***

One of the great challenges posed by the internet is the regulation of on-line content. One of the health areas in which this issue becomes relevant is that of advertising of pharmaceutical products. The internet is likely to pose particular challenges in the regulation of direct-to-consumer advertising of prescription pharmaceuticals. Both the United States and New Zealand permit direct-to-consumer advertising of prescription medicines.<sup>92</sup> In the United States advertising on direct-to-consumer advertising had reached an estimated \$US1.8 billion in

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86 Ramsay, above n82 at 54.

87 See eg, Australian Medical Association *Code of Ethics*; *Duncan v Medical Practitioners Disciplinary Committee* [1986] 1 NZLR 513.

88 See Part 3 (A) above.

89 Spielberg, above n54 at 293.

90 *Id* at 292–93.

91 *Ibid*.

92 For a history of direct-to-consumer advertising in the United States see Wayne L Pines, 'A History and Perspective on Direct-to-Consumer Promotion' (1999) 54 *Food and Drug Law Journal* 489.

1999. While the figures are smaller in New Zealand, spending on direct-to-consumer advertising of prescription medicines was approximately \$17.9 million in 2000.<sup>93</sup> In New Zealand the Ministry of Health is currently reviewing New Zealand's laws on direct-to-consumer advertising of medicines.<sup>94</sup>

One of the difficulties for consumers in purchasing pharmaceutical products over the internet is that it is not easy for consumers to assess the quality of the site they are visiting.<sup>95</sup> In the United States, the federal Food and Drug Administration provides an on-line safety guide for consumers who wish to purchase pharmaceutical products on-line.<sup>96</sup> In addition, the National Association of Boards of Pharmacy (NABP) in the United States has a Verified Internet Pharmacy Practice Sites program (VIPPS) which provides voluntary certification to on-line pharmacies. Information on the VIPPS program from the National Association of Boards of Pharmacy website states:

To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.<sup>97</sup>

Restrictions on promotion of therapeutic drugs means that companies must be aware of the potential liability issues that may arise from the use of the internet as a promotional tool. These liability issues include over-promotion of therapeutic products, the promotion of off-label use, and choice of law issues arising from internet-related litigation.<sup>98</sup>

In Australia, advertising of prescription medicines directly to consumers is prohibited.<sup>99</sup> The Australian Pharmaceutical Manufacturers Association (APMA)

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93 Ministry of Health, New Zealand, *Direct-to-Consumer Advertising of Prescription Medicines in New Zealand: A Discussion Paper* (November 2000), available from <[www.moh.govt.nz](http://www.moh.govt.nz)>.

94 Ibid.

95 For discussion of this point see Patricia Stolfi, 'Caveat Emptor: Regulating the On-Line Medicine Man in the New Frontier' (2000) 17 *Journal of Contemporary Health Law and Policy* 377; John Henkel, 'Buying Drugs Online: It's Convenient and Private, but Beware of "Rogue Sites"' (Jan-Feb 2000) *FDA Consumer* available at <[www.fda.gov/fdac/features/2000/100\\_online.html](http://www.fda.gov/fdac/features/2000/100_online.html)>; Jane E Henney, Jeffrey E Shuren et al, 'Internet Purchase of Prescription Drugs: Buyers Beware' (1999) 131 *Annals of Internal Medicine* 861.

96 Food and Drug Administration, 'Buying Medicines and Medical Products Online' at <[www.fda.gov/oc/buyonline/default.htm](http://www.fda.gov/oc/buyonline/default.htm)>.

97 National Association of Boards of Pharmacy (US), *Internet Pharmacy and Online Pharmacies Verification* available at <[www.nabp.net/vipps](http://www.nabp.net/vipps)>.

98 Marilyn A Moberg, James W Wood and Howard L Dorfman, 'Surfing the Net in Shallow Waters: Product Liability Concerns and Advertising on the Internet' (1998) 53 *Food and Drug Law Journal* 213.

99 *Therapeutic Goods Act* 1989 (Cth) ss42C, 42D.



Code of Conduct also prohibits advertising of prescription medicines.<sup>100</sup> Recognising the role of the internet in providing pharmaceutical information, the APMA Code states that 'APMA supports the right of its Members to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner for the benefit of both patients and health care professionals.'<sup>101</sup> However the Code would be breached by promotion of prescription pharmaceuticals to the general public via the internet.<sup>102</sup> Advertising of therapeutic goods to the public is governed by a code of practice overseen by the Therapeutic Goods Advertising Code Council.<sup>103</sup> A recent review of Australian laws dealing with drugs, poisons and controlled substances has recommended against any major changes to Australia's restrictive laws on advertising of prescription drugs to consumers.<sup>104</sup> However, in the world of global access to information over the internet it remains to be seen whether national limits on information can be sustained.

#### 4. Conclusion

The development of e-health in Australia promises exciting new opportunities in the provision of health care to consumers, in the management of health-related information, and in the organisation of health-related supply chains. Each one of these developments promises to deliver real benefits to health consumers, health professionals and governments. However, as has been pointed out in this article, the development of e-health does pose regulatory challenges that will need to be met if e-health is to function effectively. The need for the provision of appropriate regulatory frameworks for protection of personal information, for the registration of health professionals and for the promotion of pharmaceutical products takes on new significance in the e-health era. To some degree, Australia is meeting these challenges, with new privacy legislation to cover the private sector and a proposal for a national registration system for medical practitioners.

While many existing laws are able to meet the demands of the new era to some degree, there are nonetheless gaps and areas of uncertainty. The legal liability of health professionals engaged in the provision of health services to remote patients is still unexplored terrain leaving health professionals to operate in uncertain

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100 Paragraph 9.4 of the APMA Code of Conduct states:

It is the intention of the Code that prescription products be promoted only to healthcare professionals. Non-promotional material used in patient education must not contain material which could be regarded as advertising to the general public.

Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only product is unacceptable.

Australian Pharmaceutical Manufacturers Association, *Code of Conduct – Edition 13*, para 9.4, available at: <[www.apma.com.au](http://www.apma.com.au)>

101 APMA, *Code of Conduct*, *ibid* at para 3.9.

102 *Ibid*.

103 Therapeutic Goods Advertising Code Council: <[www.tgacc.com.au](http://www.tgacc.com.au)>.

104 Rhonda Galbally, *National Competition Review of Drugs, Poisons and Controlled Substances Legislation – Final Report Part A* (2001) at 49–56. The report is available at <[www.tga.health.gov.au/docs/html/rdpdf.htm](http://www.tga.health.gov.au/docs/html/rdpdf.htm)>.

territory. Perhaps the greatest challenge of e-health is that posed by modern IT generally: that the internet is largely a world without borders. The internet exists both within and outside national borders, raising questions about the relevance and efficacy of national laws to an international phenomenon.<sup>105</sup> The regulation of on-line content in areas such as the advertising of pharmaceuticals, and the accuracy, or otherwise, of internet-based health information accessed by patients are but two examples of the challenges that the internet will pose for the modern health sector.

The challenges posed by the internet and the electronic world generally are, of course, not unique to the health sector. However, as the e-world continues to grow, and to impact upon the health sector, it will continue to present new possibilities, new opportunities and new challenges. The development of a sound regulatory framework is essential if we are to make the most of these possibilities.

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105 Indeed it has been argued that a distinct system of laws is required for cyberspace: David R Johnson and David Post, 'Law and Borders – The Rise of Law in Cyberspace' (1996) 48 *Stanford Law Review* 1367. As Johnson and Post have argued: 'Cyberspace radically undermines the relationship between legally significant (online) phenomena and physical location.' *Id* at 1370.