Australian Government

Department of Health and Ageing

Discussion Paper

Managing the Transition to Digital Imaging

February 2008

Deadline for stakeholder submissions: Friday 11 April 2008.

Submissions received after this date may not be considered.

Table of contents

Invitation for stakeholder submissions

You are invited to provide comments on the issues outlined in this discussion paper. Submissions must be provided by Friday 11 April 2008 and can be forwarded by:

Email to: diagnosticimaging@health.gov.au or

Writing to: The Director
Diagnostic Imaging Section
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Canberra ACT 2601

1. Introduction

This paper examines the provision of images as part of a diagnostic imaging service and questions whether, as part of a broader industry strategy to manage the transition from film to digital delivery of images more effectively, there is a need to regulate the provision of images as part of a diagnostic imaging service under Medicare. Whilst the provision and quality of diagnostic imaging services is primarily the responsibility of providers working with referring doctors, the Government has a role to play in ensuring that the requirements of the *Health Insurance Act 1973* and regulations keeps up with advances in technology, especially where there is a paradigm shift in roles or responsibilities that the legislation never envisaged or where the safety or quality of patient services is being compromised.

Regulation can also provide a 'level playing field' and certainty for businesses by establishing a standard and creating a means for its enforcement.

Whilst this paper is primarily about provision of images in the private sector, it is important to recognise that public and private hospitals also undertake diagnostic imaging services for Medicare patients and that the issues discussed here are also relevant to hospital imaging departments. The issues are also broadly applicable to screening procedures, such as screening digital mammography.

The Australian health care system is currently experiencing a fundamental change in the way diagnostic images are produced and transmitted, with a transition from diagnostic images exposed or printed onto film to images produced and transmitted digitally. This change is occurring both in the public health system in hospital imaging departments and in private imaging practices. It is being driven by the large productivity improvements that are achievable with digital imaging, as well as imaging technology advances which continue to improve and speed up diagnosis.

Digital imaging technology promises to support faster and improved diagnosis, as well as being more efficient, cost effective, and able to provide images of equivalent or better quality than film. It has been generally accepted by all professional and industry groups that digital imaging is the way of the future. Provided that its introduction can be managed carefully, it should enhance the quality of care provided to patients, reduce duplication in procedures and shorten delays in diagnostic reporting.

Although most imaging practices have the needs of their referring medical practitioners in mind when implementing digital imaging, the transition from film to digital has occurred in the field with minimal inter-professional consultation, coordination or standardisation and, in some cases, with proprietary solutions that are not interoperable with other systems.

2. Background

Diagnostic imaging services provided by both the public and private sectors are central to the Australian health care system. In 2007 the Australian Government paid $1.7 billion in Medicare rebates for 16 million diagnostic imaging services delivered to Medicare patients. Each of these services involved the generation of a number of diagnostic images and a diagnostic report transmitted to the requesting practitioner. Requests for diagnostic imaging services occur in the following clinical contexts:

- To make or confirm a diagnosis;
- To determine a prognosis;
- To monitor the progress of therapy;
- To facilitate or be performed in conjunction with a surgical procedure;
- To plan treatment;
- To determine the extent of a disease; and are also used to
- To inform and reassure the patient.

Providing both a diagnostic report and relevant images to the patient's medical practitioner is an integral component of the professional service delivered by diagnostic imaging specialists. Although some medical practitioners rely mainly on the diagnostic report without reference to the images, others use both the images and the report to make critical decisions about further treatment, including referral to specialists.

A high proportion of Medicare diagnostic imaging services (about 30%) are requested directly by specialists. For some specialists, the actual images and confidence in the accuracy and quality of them, as well as the report, are crucial for planning surgical or other interventions. In addition to medical practitioners, a small but growing proportion of a limited range of imaging services are requested by allied health practitioners. It is therefore essential that images provided as part of a diagnostic imaging service are of a high quality and take into account the various clinical contexts in which images are used.

Traditionally, in the Australian private imaging sector, prior to the advent of digital images, a copy of the (film) images produced as part of the service was delivered from the imaging practice to the requesting medical practitioner by the patient and, if needed, the requesting medical practitioner was able to view the same images, of the same quality, as those the reporting radiologist used. These images were then returned to the patient for storage. Private imaging practices have, on the whole, not stored films, while hospitals generally store images for extended periods of time in accordance with state archiving and medical records legislation.

The significant enhancements in computer technology and the development of computed and digital radiography systems mean that many radiologists and other specialists now report directly from images displayed on computer monitors. This is especially the case for CT, PET and MRI imaging, with diagnostic radiography (x-ray) commonly still produced on film. The digital images produced by the imaging equipment can then be exported on to a portable media device (CDs, DVDs etc), provided via internet link , accessed by embedded links in emails or printed onto film or paper for delivery to the requesting medical practitioner.

When fully introduced, digital imaging offers a 30-60% improvement in diagnostic imaging service productivity. There is therefore a strong economic driver behind implementing digital imaging. As imaging practices move to almost entirely digital systems, it is only a matter of time before film disappears as a reporting and viewing medium and the patient no longer has a role to transport and store their images.

Whilst the vast majority of services are being delivered without problem, a number of medical practitioners have complained that some imaging practices and public imaging departments are either:

- ceasing supply of film images;
- not providing images at all, or refusing to supply additional copies;
- providing a sample, not all, of images viewed by the radiologist;
- providing images not of diagnostic quality; or
- providing images in a format that is not readily suitable for use, or that cannot easily be viewed on the requesting medical practitioner's computer system.

As in pathology, electronic transmission of reports has increasingly been taken up. However, compliance with international standards is variable and conducted with proprietary, expensive and non-interoperable message transport services. The large amount of data in diagnostic quality images has meant that their transmission via email is not appropriate, except through the use of embedded links to allow retrieval on the internet. In the longer term, open standards internet - based archive and delivery of images will be commonplace.

Whilst most private imaging practices are working to ensure the needs of requesting practitioners are being met, and continue to support use of film for the time being, especially for plain x-rays, it is becoming common practice to save images to CDs because of their low cost compared to printing film, their potential to store a large quantity of images and because of an assumption that they have the capacity to be used on almost all computers.

Q1. Are problems with the provision of digital images common place? If so, what are the issues compromising the quality of diagnostic imaging services in terms of treatment of patients, costs and repetition of examinations?

3. Regulatory framework for diagnostic imaging in Australia

The legislative provisions governing the payment of Medicare benefits are contained in the *Health Insurance Act 1973* (the Act), and its associated regulations. Under the legislative provisions relating to the payment of Medicare benefits for diagnostic imaging services, there is a regulatory requirement that a diagnostic report be provided to the requesting practitioner and a requirement for the providing practitioner to keep a copy of the report and request for 18 months. It has not always been prescribed that a report needs to be given to the requesting practitioner, presumably on the understanding that the whole service consists of the provision of the image and the report. This requirement was introduced in 2001 to discourage practices who were withholding the report from the requesting practitioner.

There is currently no explicit requirement to supply images as part of a diagnostic imaging service. This legislation pre-dates digital imaging and it was never envisaged that issues might arise with the provision and storage of images. Anecdotal information provided to the Department is that some practices are relying on this "silence" in the regulations about images to not provide images to requesting practitioners. The Act stipulates that a diagnostic imaging service must be 'clinically relevant'. It could be argued that not providing images, or images that cannot be viewed and used, as part of a diagnostic imaging service, would mean a service was not 'clinically relevant' and therefore in contravention of the Act.

The provisions in the Act and regulations relevant to this paper are:

Provision(s)	**What they say**
Section 3 of the Act	A diagnostic imaging service must be 'clinically relevant', i.e. generally considered necessary for the appropriate treatment of the patient to whom it is rendered.
Subsection 3(5B) of the Act, and Subrule 2(3) of the *Diagnostic Imaging Services Table Regulations*	A diagnostic imaging service includes the procedure (image capture) and any analysis and reporting of the image.
Section 23DS of the Act	A provider must keep records prescribed in the regulations for 18 months. A provider must provide a copy to Medicare Australia when requested.
Regulation 20 of the *Health Insurance Regulations 1973*	This regulation prescribes the records that need to be kept. It requires that the report be kept.
Subrule 2(5) of the *Diagnostic Imaging Services Table Regulations*	The providing practitioner must give a report to the requesting practitioner (applies to all services except interventional and the preparation items).

4. Moving towards full interoperability

The diagnostic imaging industry is currently transitioning to full digital imaging. Once this transition is complete, providers and requesters will have the appropriate IT infrastructure to enable them to distribute and view images quickly and efficiently, and readily transfer images along the clinical pathway. In addition, images ultimately may be included in a national electronic health record. However, this is a long term outlook. The rapid technology advances being made in the imaging profession are in some cases in advance of the ability of the rest of the health care team to access and view these images. During this transition stage, it is essential that digital imaging is managed sensitively and cooperatively to ensure that patient care is not compromised. Patients should not be exposed to unnecessary radiation or non-clinically necessary repeat examinations.

The Australian Diagnostic Imaging Association (ADIA), the Royal Australian and New Zealand College of Radiologists (RANZCR) and the imaging vendor industry have a number of initiatives underway to find solutions. The ADIA and RANZCR are developing a joint Code of Practice for the provision of images and a technical specification for use of portable media. Following an industry interoperability workshop held in December 2007, organised by RANZCR, a coalition of key Australian health informatics stakeholders and imaging system vendors has been formed to work on interoperability of digital imaging systems using internationally accepted standards (e.g. HL7, DICOM) and integration profiles (e.g. IHE).

It is hoped that this work will assist software vendors to supply systems to imaging practices that are interoperable with each other and that can produce high quality digital diagnostic images on portable media that work on all requesters' systems.

5. Issues with image provision

The provision of images on digital media raises four key issues to be considered:

- the provision of the images, in conjunction with a diagnostic report;
- the quality of the images provided;
- the format of the images; and
- the storage of the images.

5.1. Provision of images

Information provided to the Department is that some digital imaging practitioners are using the 'silence' in the legislative provisions regarding providing images to only provide the report.

Question 2: Should the legislation be clarified so that a copy of the images[1], relevant to the diagnostic report, be provided to requesting (and treating) medical practitioners for a Medicare benefit to be payable?

5.2. Quality of images

When images are reported from film, the images the requesting practitioner receives are usually the same as those the radiologist has used to develop their report. This provided an assurance that the requesting medical practitioner received images identical to those viewed by the radiologist to prepare a diagnostic report. Only a light box was required to view the diagnostic images. With digital images, 'diagnostic quality' is a complex combination of the quality of the raw data out of the modality, the transmission method, and the viewing hardware and software.

The Department has received complaints that some imaging practices are providing only reference images that are of less than 'diagnostic quality' (e.g. formats such as JPEG or other formats which have undergone 'lossy'[2] compression), that the images themselves are not viewable at all because of software or system incompatibilities, or that the requesting medical practitioner is unable to view images of the 'same' quality as the radiologists because they do not have high quality monitors and software to correctly display the images received. Complaints have also been received that diagnoses are being made using images displayed on Blackberries and PDAs not capable of the resolution and calibration required to accurately view diagnostic images.

[1] Note that exceptions may be provided for, such as interventional and preparation items.
[2] Lossy compression is where the image data is compressed to make a smaller file in such a way that some data is lost, resulting in an image that may still be useful but is of lower quality than the original.

Although there are some limited clinical contexts where a non-diagnostic quality image may be acceptable (e.g. patient education, for triage or emergency care when access to a diagnostic quality image is not possible), a Medicare-funded diagnostic imaging service should involve the provision of diagnostic quality images, equivalent to that viewed by the diagnosing radiologist, whether or not lower quality images are provided as a navigation aid or to some requesting doctors who do not wish to accurately view the diagnostic features of the images.

The *Health Insurance Regulations 1973* do not generally regulate the quality of diagnostic imaging services but could do so if there was sufficient evidence that patient care was at risk. The diagnostic imaging industry can develop, in consultation with requesting doctors, a definition of 'diagnostic quality' which can be defined in an industry Code of Practice.

Question 3: Should the provision of 'diagnostic quality' images be a requirement for a Medicare benefit to be payable?

5.3. Format of images

Although it is inevitable that digital portable media will be used for some time, they are currently proving to be problematic. Problems reported to the Department include:

- Some PACS systems have not been implemented to output diagnostic quality (DICOM) images, even though they should all be capable of doing so;
- CDs arrive unlabelled, with no instructions for use and the images stored on them are in no apparent order or hard to navigate;
- The DICOM 'viewer' on CDs can lead to clinicians having to manage multiple viewers;
- Some practice computers (e.g. Apple MACs or those loaded with Vista) are incompatible with the operating system that prepared the CD;
- CDs are slow to, or sometimes won't, load onto a clinician's computer;
- The magnification of digital images is hard to ascertain; and
- Physical damage has occurred to CDs by scratching or heat, or digital data is corrupted when stored on low quality CDs.

Digital images have some drawbacks when compared to film – it is hard to compare old film images with new digital images and two digital images at one time, unless specialised viewing screens are provided; they can be slower to access and view than films and generally require higher technology and reliable systems compared to light boxes. However, multi-slice CT and MRI images are easier to view and manipulate digitally.

To help manage this period of transition the Health Insurance legislation could be amended to require that digital images are provided in a format accessible and viewable by the requesting medical practitioner. The legislation could refer to an industry Code of Practice for guidance on how this can be done.

Question 4: Should digital images be provided in a format accessible and viewable by the requesting (or treating) medical practitioner? Should this be a requirement for a Medicare benefit to be payable?

It is also important to acknowledge the on-referral of patients to third parties including specialists and the need for diagnostic images to be transmitted along the clinical pathway. On referral can occur a number of months after the images have been captured and it cannot always be predicted that referral is necessary. In addition, it is normal for there to be a review of any prior studies available.

Cooperative arrangements need to be made as required to ensure appropriate images are transmitted on referral and prior studies made available if the patient does not transmit their own digital images. Such cooperative arrangements could be detailed in an industry Code of Practice developed in collaboration with requesters and referrers.

Question 5: Should a Medicare benefit be payable contingent on the provision of additional copies of digital images to treating practitioners on referral within a reasonable time period?

5.4. Storage of images

The advent of digital imaging sees a paradigm shift from the role of the patient storing their images and transporting them on film to the requesting practitioner to direct transmission to the requester by physical media or other electronic means. Although damage and loss of films has always been an issue, the increased susceptibility of digital media and digital images to damage or loss is an important issue. The need to keep patient exposure to harmful doses of radiation and to avoid wasteful re-imaging is paramount. This makes it essential that the imaging practice archives digital images. The time required for a requesting practitioner to access the images and for the patient to progress through the clinical pathway, including on-referral to specialists, then becomes an important consideration.

Question 6: What role, if any, should requesting and treating medical practitioners have in storage and transmission of copies of digital images?

Recent reductions in the cost of storage have made it more cost effective for image capture sites to store digital images and these costs are far lower than those for films. Images stored can readily be made available to patients, requesters and other treating practitioners. Access to the images would, of course, be subject to appropriate privacy and security requirements for the collection and storage of personal health information in accordance with the Privacy Act and medical records legislation.

Anecdotal evidence is that practices have variable approaches to storage of images (from no storage, archiving on CD, storage for limited or extended periods of time, only certain images or selections of images, e.g. thick slices, to indefinite permanent storage). Because of this, it seems reasonable to establish an agreed standard for the archiving of images. A minimum requirement could be established in the legislation, for example, copies of digital images should be kept for 18 months, in line with Medicare requirements to keep diagnostic reports and requests. Images may need to be stored for longer periods if clinically indicated. Recommendations about the archive periods required for various studies and/or diagnostic outcomes in excess of the minimum standard could be included in an industry Code of Practice.

Question 7: Do you agree that storage of digital images by the diagnostic imaging service provider be a requirement for payment of a Medicare benefit[3]? If so, for how long?

Question 8: Under what clinical contexts should digital images be retained for longer than the proposed 18 months?

[3] A suitable transition period/s could be defined to ease the compliance burden

5.5 Equipment requirements

Given the clinical contexts outlined in the background to this paper, digital images need to be accessible and viewable in a variety of locations from imaging practices, GP rooms, specialist rooms or hospitals (including operating theatres). At this stage, not all medical practitioners in all the clinical settings where images are used are equipped and trained to use digital images. It should be noted that specialised, more costly viewing platforms are not required for ALL medical practitioners since digital diagnostic images may be viewed adequately for most clinical purposes (e.g. in GP surgeries) by normal practice computers, providing the images on the CDs are accessible.

It is the joint responsibility of medical practitioners, imaging practices, public and private hospitals, and government to ensure diagnostic quality images are able to be viewed where medical practitioners need them. It will not be possible for the diagnostic imaging industry to indefinitely support film production, although plain radiographs in limited circumstances may need to be provided for some time. Requesting medical practitioners will need to equip, adapt their workflow and computer systems and become comfortable with manipulating images electronically. Further work is required to determine what needs to be done to improve the access to, and use of, digital diagnostic images in the health system.

Question 9: What actions (and by whom) do you consider need to be taken to improve the ability of medical practitioners to view and use digital images?

5. What Next?

After receipt of all comments, the Department will analyse and compile all views received and consider what, if any, recommendations should be made to the Government. These recommendations will also consider what progress has been made by the diagnostic imaging industry on a Code of Practice. If a Code of Practice can be agreed by all relevant professional groups and businesses and implemented by the diagnostic imaging industry, there may be no need for regulation.