

22 February 2010

Ms Hilary Metcalf
Policy Implementation Section
Diagnostic Services Branch
Department of Health and Ageing
MDP 107
GPO Box 9848
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Dear Hilary

Re: Pathology Request Forms Discussion Paper

Thank you for giving the Royal College of Pathologists of Australasia (the College) the opportunity to comment on this Discussion Paper. We note that it details many of the concerns we have been raising about this initiative over recent months. It is gratifying that the Department of Health and Ageing acknowledges these concerns and recognises that this legislation could give rise to serious risks to patients, for which the Discussion Paper seeks advice on possible mitigating strategies.

It has been alarming, therefore, to learn that these risks have not given pause to the proposal, but rather the draft legislation has been presented to Parliament even before the closing date for responses to this Discussion Paper. This is considered an extraordinary move to take, and one that could alienate the very stakeholders whose engagement and cooperation will be crucial to the implementation of any subsequent change.

Furthermore, it is of great concern to the College that the Minister's second reading speech commending the Bill to the Parliament focused intently on competition based on price and convenience as being the rationale for this initiative. Whilst these factors are mentioned in the Discussion Paper, giving them primacy in this speech (to the complete exclusion of patient safety and health outcomes) represents the extent to which the specialty of pathology is being considered as a commodity rather than a specialist medical service. It completely disregards the expertise of pathologists and the pivotal role pathology has in the diagnosis and ongoing management of patients.

The proposal is described as 'removing an anomaly' between requirements for pathology and diagnostic imaging (DI), but this fails to recognise fundamental differences between these two specialties. Firstly, the patient can usually take the result of a DI consultation (for example the x-rays, CT scan or ultrasound films) with them to give to the referring practitioner, so there is no issue of trying to trace where a patient has gone for a test. Secondly, DI is rarely used to monitor chronic conditions, so continuity of test methods/assays/reference intervals is not an issue. So whilst DI and pathology have historically been subject to similar funding arrangements, they are quite different medical specialities, and there is no imperative to manage the referrals to each in the same way.

It seems somewhat disingenuous to say that this initiative will improve patient choice, and worse to imply that those who have argued against it are unsupportive of patients having such a choice. Patients are already free to choose their pathology provider at the time of consultation with their treating doctor and the College is strongly supportive of that choice being maintained. The issue is about when the patient's choice is exercised and the College's stance is based on our commitment to promoting patient safety. There is no

reason for patient choice to be foregone in the interests of patient safety, but choices must be made in a way that does not compromise safety.

As reflected in the Discussion Paper, the main concerns relate to traceability of results and the need for some serial tests to be performed using directly comparable assays, because compromise in either of these areas can result in adverse patient outcomes. The best way to facilitate patient choice while taking these factors into account is for the choice to be made during the consultation with the referring practitioner. This will enable traceability of results to be maintained and, if the patient is willing to accept the referring practitioner's recommendation, comparison of serial samples in chronic illness or use of a particular laboratory for certain tests. The choice made at the time of the consultation can take into account billing practice and convenience of collection centre locations, as well as continuity of serial results or a specific pathologist's expertise / test repertoire, and any other factors of importance to the patient (such as previous experiences with a pathology provider).

Rather than create risks by introducing an option for patients to change their minds after agreeing on a provider during the consultation, choice could be assured if the legislation included a requirement for requesters to inform patients that they have a choice. Any recommendation made should be based on objective (generally clinical) criteria and this should be documented in the health record. Clearly it would be inappropriate for a requester to recommend a particular provider on the basis, for example, that they were employed by the same parent company or derived benefit from renting space to a collection centre, and it should be mandatory to declare any potential conflicts of interest such as these.

The alternative (and in many ways safer) mechanism to prevent the risks associated with traceability of results would be to defer this initiative until a universal electronic health record is established and implemented. In this way the referring practitioner will be able to obtain results regardless of which pathologist the patient has attended.

There are inherent inconsistencies in the proposal as it stands. For example, in noting that some samples are collected in a hospital, the Discussion Paper states *"By choosing the services of a particular hospital, it could be argued that the patient has made a choice to accept the arrangements in place in that hospital for the provision of pathology services."* If this can be argued for a patient who has attended a hospital (and will often have received no information about its pathology services), why does the same argument not apply for a patient who has exercised the choice to visit a particular referring practitioner and has been given a request form after being able to discuss their options?

The application of this initiative for histopathology specimens obtained in an operating theatre creates a further complication. Currently, if a specimen arrives at a laboratory with a request form for another laboratory, it is identified as an error and the specimen is transferred. With the advent of forms stating that the specimen can be taken anywhere, there will be no way for a laboratory to know if an error has occurred or if this is what the patient wants. It would be legally acceptable, in fact, for a courier to collect a large number of specimens intended for a range of laboratories, and take them all to one laboratory for processing and diagnosis. How should this situation be addressed?

If the Government is to forge ahead with these changes in the face of contrary advice from those with expertise in pathology laboratory management and medical practice, there will be a case to answer if patients exercise their choice in a way that results in adverse events. The question is, who will be responsible? Is the Government willing to accept this liability? Or is it expected that referring practitioners and pathology laboratories will be held accountable for the problems that arise? Perhaps patients should be required to document that they accept responsibility if they change their minds, in the same way as patients must 'sign themselves out' if they leave hospital against medical advice?

In summary:

- The College regards this legislation as being introduced with haste, ahead of an appropriate and completed discussion process with stakeholders.
- Patient choice already exists in the referral process.
- Primary competition on price and convenience devalues the role of the pathologist and could lead to loss of testing and service quality, which are the current drivers of competition in the profession.
- There are substantial differences between the practice of diagnostic imaging and pathology in service delivery and transmission of reports.
- The legislation places patients at risk from potential loss of traceability of specimens and results, as acknowledged in the discussion paper.
- Some tests require serial measurement using the same assay methods.
- If the Government is determined to pass the legislation against stakeholder advice, the College would suggest deferral of the implementation of this bill until after the establishment of a functioning universal E-Health record.
- If introduced, warnings of the potential risks of changing provider and acceptance of responsibility and liability by the patient must appear on request forms.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Paul McKenzie', written in a cursive style.

A/Prof Paul McKenzie
President