

Health legal update

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INTRODUCTION

The new Government has started with a bang. The announcement of the NHS board, abolition of SHAs, refocusing of PCTs and empowerment of GPs as commissioners are still reverberating as NHS staff try to work out what it all means for them. It is clear that Andrew Lansley is not afraid of breaking new ground, nor of revisiting old themes (eg, GP fund holding) from a fresh perspective, informed by experience. One has the sense that the Department has been told, “this is the policy, so get on with making it work”. We expect many NHS clients will be waiting for the forthcoming White Paper before committing to big decisions, anticipating that it will not only answer their questions but also propose some new organisational structures that might be even more attractive than their current plans. It promises to be a very interesting summer.

In the meantime, anyone who feels confused by the current direction of travel on targets (“surely targets are really important?”, “haven’t they served us well?” etc.) need look no further than the Conservative Party Manifesto for the philosophy underlying these changes. Written through it, like a stick of Brighton rock, is the familiar idea that if the debate is framed in the right way, the market can decide. This means even though specific targets may go, there will be contractual and other levers that are intended to achieve the same (or better) result. So, trusts should expect that the data requirements will be more, not less, and that the additional information they supply to NHS Choices (and others) will be used by GPs to assist patients in choosing their provider.

Beyond the politics, there are plenty of other interesting developments to report this month. I will delay you no further than to mention that we are delighted to be corporate partners of the [King’s Fund](#), to promote our work with Manchester Business School on their [Post Graduate Certificate in Healthcare Governance](#), to remind you of our excellent [seminar programme](#) and to encourage you to make use of our award-winning (and free) [healthcare resource centre](#).



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NHS MANAGEMENT – OPERATING FRAMEWORK

Revisions to the 2010/2011 operating framework introduced by the new Government

A Revision to the 2010/11 NHS Operating Framework (the ROF) sets out changes to key priorities for the NHS namely:

- cuts in management costs; and
- targets removed as focus shifts to outcomes.

The ROF also sets out for the first time changes to the use of targets in the NHS which include:

- removal of targets around access to primary care;
- removal of top-down performance management of the 18 weeks referral to treatment target; and
- reduction of the four hour A&E target threshold from 98 per cent to 95 per cent.

The revisions also give greater priority to two areas:

- military veterans health; and

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- o dementia (National Dementia Strategy).

The changes also reinforce recently announced plans to:

- o publish more transparent hospital infection data;
- o new rules on reconfigurations; and
- o plans to withhold payment from hospitals where patients are readmitted within 30 days of discharge.

The ROF also makes the separation of PCT commissioning from the provision of services a priority. This must be achieved by April 2011.

PCTs are encouraged to develop and review proposals for the divestment of their directly-provided community services to ensure that:

- o they have been tested with GP commissioners and local authorities;
- o final proposals are consistent with the aims of the forthcoming NHS strategy in strengthening the delivery of public health services and health services for children;
- o they consider the implications for choice and competition;
- o they consider a wide range of options, including the development and early delivery of community foundation trusts and social enterprises, providing employee leadership and ownership;
- o there has been effective engagement of staff and their representatives when considering options;
- o previous proposals for continued direct provision are reviewed and alternative options developed which secure separation; and
- o proposals should be capable of being implemented, or substantial progress made towards implementation, by April 2011.

The Department of Health will be developing proposals for a phased move towards an “any willing provider” model for community services, addressing barriers to entry to greater participation by the independent and voluntary sector.

The *Revision to the Operating Framework for the NHS for 2010/11* can be accessed [here](#) .

For further information or advice please contact [Tania Richards](#) on 01223 222476.

INFORMATION GOVERNANCE

Information Commissioner’s Office (ICO) expresses concern at NHS data security breaches

The ICO has said that there have been over a thousand breaches since 2007, with a quarter coming from the NHS. The ICO has given examples of NHS breaches including the loss of nearly 2,000 paper physiotherapy records and emailing of nearly 1,000 patients’ pathology tests from one department to another by using unsecured email. It also appears that the spreadsheet was not password protected. The chief executives of both trusts have signed undertakings agreeing to put measures in place to prevent further incidences.

These comments and incidences are a timely reminder of the need to ensure compliance of the legal requirements of patients’ data security.

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For further information or advice please contact [Jacqueline Haines](#) on 0121 456 8453.

CONTRACTS – CONTRACTUAL DISPUTES

Late payment of commercial debts: substantial remedy

In the recent case of *Yuanda (UK) Co Ltd v WW Gear Construction Ltd* [2010], the judgment of which can be accessed [here](#), the High Court has held that interest on late payments of 0.5 per cent over base rate is not a substantial remedy under the Late Payment of Commercial Debts (Interest) Act 1998 (the Act), which can be accessed [here](#).

The provisions of the Act allow UK businesses to levy interest on late payments and debt recovery costs for clients and customers that have exceeded payment terms agreed by the parties in contracts created after 7 August 2002.

The legislation effectively allows businesses to charge 8 per cent above the Bank of England base rate. The statutory interest provisions can be superseded by the contract but only in so far as the contract provides a substantial remedy (as defined in schedule 9 of the Act) for late payment.

A remedy for late payment is substantial if either the remedy is appropriate to deter late payment and to compensate the creditor or if it is fair and reasonable to allow reliance on it, taking account of the needs of commercial certainty and the relative bargaining positions of the parties.

In the case referred to above, A entered a standard contract, subject to a substantial schedule of amendments, with B. The schedule to the contract provided that interest on late payments be paid at 0.5 per cent over base rate, as opposed to the standard contract rate of 5 per cent over base rate.

A sought a declaration from the court as to whether:

- 0.5 per cent over base rate was a substantial remedy within the meaning of the 1988 Act; and
- if 0.5 per cent was not a substantial remedy, should it be replaced with the statutory rate.

The court held that 0.5 per cent over base rate could not be regarded as a substantial remedy in the absence of special circumstances surrounding the making of the contract. Consequently, the clause in the schedule was void and replaced by the statutory rate. The court further provided useful guidance on when a contractual rate of interest should be set aside in favour of the statutory rate.

The case highlights the importance of looking at the broad circumstances in which the contractual rate was agreed between parties rather than focusing only on the difference between the statutory and contractual rates.

For further information please contact [Gill Thomas](#) on 01223 222237 or [Lara Hayward](#) on 01223 222292.

CONTRACTS – OFFICE OF GOVERNMENT COMMERCE

Office of Government Commerce (OGC) has issued new requirements

Responsibility for the OGC together with the public sector procurement agency, Buying Solutions, has moved to the cabinet office where it will form part the efficiency and reform group (ERG).

Shortly before that announcement was made, the OGC had issued the following:

- A requirement for a 30 day payment clause in new public contracts, with the aim being to assist business in managing their cash flow. Of course the requirement applies only to public supply and public services contracts.

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- A procurement policy note providing guidance and an appendix of draft model conditions to help implement Government policy on the collection and analysis of supply and management information relating to Government contracts.
- A requirement for details of all contracts awards over £20,000 to be published online, with the aim of increasing visibility of subcontracting opportunities.

For further information or advice please contact [Jacqueline Haines](#) on 0121 456 8453.

CARE QUALITY COMMISSION

Your chance to comment on CQC's enforcement policy

The CQC has now published a consultation document upon its proposed enforcement policy.

The consultation closes on the 31 August 2010 with an anticipated publication date on 1 October 2010.

Participation in the consultation is important as CQC have new powers under the Health and Social Care Act 2008 in respect of enforcement of compliance with the regulations covering health and social care. New powers include suspending registration, warning notices and penalty notices.

If you want a chance to have a say on how the CQC use their existing and new powers then please access the consultation document [here](#).

For further information or advice please contact [Katrina McCrory](#) on 0121 456 8451.

PERFORMERS LIST

List management appeals – time runs from receipt

We have been advised by the Tribunals Service (Primary Health Lists) that notices of appeal, dispatched to the respondent primary care trust in a list management case as notification of the performer's appeal, have been amended so that their wording accords correctly with the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008.

Rule 21(1) provides:

"When a respondent receives a copy of the application notice, the respondent must send or deliver to the tribunal a response so that it is received – ...

(b)...within 21 days after the date **on which the respondent received the application notice**". *[Emphasis added]*.

Formerly, notices of appeal had stated that the PCT's statement of grounds in opposition to the appeal, and any documents in support, should be delivered to the primary health lists "not later than 21 days from the date of this notice". Where documents had taken almost a week to reach the PCT from the Tribunals Service, time for liaising with solicitors, providing instructions, sourcing counsel, and getting the documentation prepared, filed and served, often proved to be painfully tight. Now, the 21 days will not begin to run until the notice of appeal has been **received** at the PCT.

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What this does mean however, is that PCTs must date stamp, on receipt, the letter from the Tribunals Service enclosing the notice of appeal and supporting documents. Moreover, if the documents are sent by recorded or special delivery, a log should be kept of receipt and, for the ultra cautious, the envelope in which the papers arrived could even be kept on the file too.

If you cannot prove the date of receipt, you may find yourselves caught up in unnecessary arguments about the deadline for your response, “likely” date of receipt etc – distractions you can well do without.

Those extra few days can make all the difference – don’t squander them for the sake of a date stamp!

The rules can be accessed [here](#).

For further information or advice please contact [Jane Williams](#) on 0121 456 8421.

PATIENT MATTERS - ANTISOCIAL BEHAVIOUR

‘Hospital hopper’ given an ASBO

A homeless man who faked illnesses so he could stay in hospital, has received a criminal antisocial behaviour order (ASBO).

Following an investigation by the NHS Counter Fraud and Security Management Service (NHSCFSMS), the patient, Christopher Dearlove, has been issued with a three year criminal ASBO, preventing him from attending hospital for three years. If he breaches the order, he faces a possible five year prison sentence. His fake illnesses are believed to have cost the NHS tens of thousands of pounds.

For further information or advice please contact [Jacqueline Haines](#) on 0121 456 8453.

PATIENT MATTERS – DIRECT PAYMENTS

Direct payments to patients pilot scheme is underway!

As part of the Department of Health’s pilot scheme, approved PCTs are now able to make direct payments to patients eligible for primary healthcare needs. The scheme is governed by The National Health Service (Direct Payments) Regulations 2010 (the regulations) which came into force on 1 June 2010.

It is also important to note that in the Government’s response to the direct payments consultation it is stated, at paragraph 28, that “the Government does not believe it is appropriate, except in exceptional circumstances, for family members to be paid for care as part of an employer-employee relationship”.

This will come as a blow to those individuals who would like to use direct payments in this way as payments to family member carers is a common feature of many direct payment requests received by PCTs.

A copy of the Department of Health’s response to the direct payment consultation can be accessed [here](#) and the regulations can be accessed [here](#).

The pilot period will run until 2012, but it can be extended to a maximum of five years.

For more information or advice please contact [Katrina McCrory](#) on 0121 456 8451 or [Jayne Herlihy](#) on 0121 456 8280.

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PATIENT MATTERS – DEPRIVATION OF LIBERTY

Department of Health Review of DOLS

The Mental Capacity Act Deprivation of Liberty Safeguards (MCA DOLS) were introduced in April 2009 as statutory safeguards in order to prevent deprivations of liberty of patients in hospitals and residents in care homes, other than under the Mental Health Act, without independent consideration, authorisation and review.

The Department of Health (DH) has now released a briefing, which can be accessed [here](#), following a review of the new MCA DOLS, which was undertaken after the first nine months of implementation.

Statistics

After nine months of MCA DOLS being in force, 5,500 people have had their potential deprivation of liberty independently considered by a best interests assessor.

The DH is expecting this to reach 7,000 by the end of the first year.

Activity levels are therefore a third of the level estimated before the introduction of the new safeguards.

It is likely that a number of deprivations remain unrecognised and unauthorised, as activity levels are only around one third of those estimated.

Around half of assessments undertaken have resulted in authorisations. This is double the figure predicted.

There are significant variations in activity levels in different areas of the country although regional leads continue to work to ensure that the legislation is properly applied.

Case law

There have been three significant judgments on this topic since April 2009, and these have been examined in an article entitled “Case law to clarify the Deprivation of Liberty Safeguards” which can be found in the Mental Capacity Act section on the Mills & Reeve Healthcare Resource Centre which can be accessed [here](#).

Practice issues

As part of this review the DH has identified the following five issues which have arisen in practice and have provided some guidance.

1 Choice of the relevant person’s representative (RPR)

The DH is aware of cases where family members have not been selected to act as the RPR as they are not in support of the deprivation of liberty. This alone is not a reason for the best interests assessor not to select that person.

It is noted that where a family member is not selected to act as the RPR, they may apply to the Court of Protection for permission to challenge the authorisation but will have to incur the costs of doing so.

2 Where a DOL is not authorised

Considering the situation where a deprivation is found, but where the best interests assessor would not recommend an authorisation (as a less restrictive option is available), the assessor should discuss the possibility of alternatives with the care provider during the assessment process.

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The DH recommends that managing authorities and supervisory bodies have a procedure in place in order to promote the swiftest possible response in situations where a deprivation is not authorised. This is to ensure that the least restrictive method is used and that any unauthorised deprivation of liberty does not continue.

3 **Conditions set by best interests assessors**

The briefing states that there is evidence that best interests assessors are not always following the DOLS code in relation to the setting of conditions.

Reference is made to paragraph 4.74 of the DOLS code, "... it is not the best interests assessor's role to specify conditions that do not directly relate to the issue of deprivation of liberty".

The briefing states that the assessor should also discuss any proposed conditions with the relevant personnel at the care home or hospital before finalising the assessment. Conditions should not be recommended which could otherwise be achieved through the use of an effective care plan.

4 **Proposal for "no contact" with named individuals**

Paragraph 4.74 of the DOLS Code recognises that a best interests assessor may recommend conditions in respect of contact issues. These could include conditions encouraging contact or limiting contact.

The briefing, however, draws attention to paragraph 8.28 of the MCA code which suggests that the court should ultimately decide matters where contact is to be prevented. Therefore DOLS conditions relating to contact in a safeguarding case should only be seen as a short-term measure.

5 **Where authorisation fails to resolve disputes**

The briefing states that completion of the DOLS process should not necessarily be regarded as a final resolution in all cases.

If, despite authorisation and the use of appropriate conditions, there is a continuing dispute with the person's family, then the matter will require the last resort determination of the Court of Protection.

For further information or advice please contact [Charlotte Mawdesley](#) on 0121 456 8402.

PATIENT MATTERS – UNLAWFUL DETENTION

Mental Health Act patient fails to win damages for unlawful detention

This recent case considered a patient's claim for damages in respect of his unlawful detention on the basis that the approved mental health professional (AMHP) had wrongly concluded that the nearest relative did not object to the patient's admission for treatment under the Mental Health Act.

T was admitted to hospital under section 2 of the Mental Health Act 1983 (MHA 1983) for assessment after being arrested for "bothering" women. He was later assessed for admission under section 3 MHA 1983. In the absence of a consensus, the hospital obtained the opinions of two independent practitioners who agreed that T should be detained under section 3 MHA 1983.

The AMHP spoke to T's brother, who was acting as T's nearest relative. His brother expressed to the AMHP that he did not agree to the application for admission for treatment, however the AMHP mistakenly believed that T's brother had changed his mind since that conversation. Such an objection prevents an AMHP from making an application for admission under section 3 and can only be overcome by an application to the county court to displace the nearest relative.

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T was subsequently granted a writ of habeas corpus by the court.

T sought a declaration that his admission to hospital under section 3 MHA 1983 was unlawful and damages under the European Convention on Human Rights (ECHR).

- 1 T submitted that there was a failure to appreciate that his brother, as nearest relative, continued to object to his admission under section 3 MHA 1983.
- 2 He also argued that there was a breach of section 12(2) MHA 1983 as neither of the independent practitioners who recommended his detention had any previous knowledge of him.
- 3 T argued that if the hospital managers had exercised their duty to scrutinise the application to admit him, then they would not have been satisfied that the application was duly made.
- 4 Finally, T claimed that the court should declare section 139(1) and section 6(3) MHA 1983 incompatible with the ECHR. Section 139(1) provides that no person shall be liable for action taken in pursuance of the MHA 1983, “unless the act was done in bad faith or without reasonable care”. Section 6(3) provides that an application for admission which appears to be duly made may be acted upon without further proof of signature or qualification of the person making the application.

Judgment

In his judgment, Mr Justice Collins found that:

- 1 The AMHP had made an honest mistake in failing to realise T’s brother’s continuing objections. Section 139 MHA 1983 recognises that a lack of care in respect of any act purporting to be done in pursuance of the MHA 1983 could result in civil proceedings. Whilst an honest mistake can still be negligent, the judge did not find negligence in this case. Examining the case law, the judge concluded that compensation for unlawful detention should only follow if there was negligence or bad faith.
- 2 On the facts it was found that the decision to use two professionals “who came afresh” and who had full access to hospital notes was a reasonable and proper exercise of judgment in T’s best interests. Therefore there was no breach of section 12(2) MHA 1983. The judge stated that “only if it is considered on reasonable grounds to be appropriate in the given circumstances for doctors who have not had previous acquaintance to decide whether to recommend admission should such a course be adopted”.
- 3 The judge found that “there can be no doubt that the managers were entitled to rely on the AMHP’s confirmation that there had been no objection from the nearest relative”.
- 4 The judge also found that there is no incompatibility in section 139 or section 6(3). He concluded that, provided there is no fault by anyone involved in the decision making process which could lead to civil proceedings (negligence or bad faith), the detention is to be regarded as lawful until (once a defect is identified) the court declares that the patient must be released.

A link to the full text of the judgment in this case, *TTM v Hackney London Borough Council and East London NHS Foundation Trust* can be found [here](#).

For further information or advice please contact [Charlotte Mawdesley](#) on 0121 456 8402.

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PATIENT MATTERS TRAVEL COSTS

Healthcare Travel Costs Scheme (HTCS) revised

The Department of Health has recently updated its *Healthcare Travel Costs Scheme: Instructions and Guidance for the NHS*, to incorporate amendments made to the regulations governing the scheme – the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003.

The *Instructions and Guidance* document is divided into two parts, providing the NHS with information on:

- the legal requirements in relation to the administration of the Healthcare Travel Costs Scheme (HTCS); and
- good practice guidance on how the scheme may be delivered, including details on eligibility criteria and best practice resources.

The document (which is addressed to both NHS bodies and independent sector providers contracted by the NHS to provide services) provides a clear framework for local decision making that takes into account variations in geography and circumstances which can affect individuals' need for help with travel costs. The unit providing the treatment is responsible for verifying the patient's eligibility for payment of expenses, calculating the amount payable and making the payment.

HTCS is part of the NHS Low Income Scheme and was established to provide financial assistance to those NHS patients who do not have a medical need for ambulance transport, but who require assistance with their travel costs. Under the scheme, patients on low incomes or receiving certain qualifying benefits or allowances are reimbursed, in part or in full, for costs incurred in travelling to receive certain NHS services, where their journey meets certain criteria.

The scheme deals with NHS travel expenses, ie, the travel expenses which a person necessarily incurs:

- in **attending any place in the UK** for the provision of any services under the NHS Act 2006 (except primary medical/dental services) which are provided pursuant to a referral by a doctor/dentist (but not provided at the same visit or on the same premises as the primary medical/dental services which led to the referral); or
- in **travelling to a port in Great Britain** for the purpose of travelling abroad in order to receive services provided pursuant to arrangements made under section 12 of, or paragraph 18 of Schedule 4 to, the 2006 Act. Where a patient is travelling abroad for treatment under the NHS, a claim may be made for travel costs incurred in travelling to a port (including an airport, ferry port or international train station) in Great Britain from which an international journey begins. However, the costs of the patient's **travel from the port to the place of treatment fall within NHS foreign travel expenses and cannot be claimed through HTCS**. A person will only be entitled to the payment of NHS foreign travel expenses where the health service body which has made the arrangements for services to be provided overseas agrees the mode and cost of travel and the necessity or otherwise for a companion **before the costs are incurred**.

The *Instructions and Guidance* can be accessed [here](#).

For further information or advice please contact [Jane Williams](#) on 0121 456 8421.

Judicial review of PCT decision not to provide exceptional funding for breast augmentation surgery for transsexual refused

AC, who was born male, was diagnosed as suffering from gender identity disorder in his mid-forties. He began to undergo hormone therapy and adopted a female name but had not, some fifteen years later, undergone genital gender

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reassignment surgery (GRS). AC was dissatisfied with the degree of breast development following hormone treatment, suffering, as a result, what her psychiatrist described as “chronic mild to moderate distress”, and therefore applied to West Berkshire Primary Care Trust (the PCT) for funding for breast augmentation surgery. Funding was refused. AC sought judicial review of the decision not to fund the procedure and a declaration that the PCT’s policy of classifying breast augmentation as a low priority or non-core procedure was unlawful. The Equality and Human Rights Commission intervened in the proceedings.

The application for judicial review was refused.

The PCT had a gender dysphoria (GD) policy which drew a distinction between “core” surgical procedures, which it would fund, and “non-core”, which it would not. It provided that “cosmetic surgery and other non-core procedures such as breast surgery ... should not be considered as a core part of GRS. Patients who wish to be considered for those treatments should be considered in accordance with the existing ... policies on cosmetic breast surgery (No.7) and cosmetic procedures (No.9). The GD policy also permitted evidence of exceptional circumstances to be adduced “where there is evidence of significant health impairment and there is also evidence of the intervention improving health status”.

While the judge in the case deplored the use of the word “cosmetic” in this context – because applicants for funding were not seeking the treatment simply to look more attractive, but as treatment for psychological illness – he determined that, with NHS budgets under severe pressure from the increasing longevity of the population and the development of expensive new drugs and procedures, it was lawful for the PCT to have policies about which treatments would, and which would not, be routinely funded.

The PCT **had** funded breast augmentation surgery in the past for a natal woman (X) who, at the age of 18, was diagnosed as suffering from a congenital absence of breast tissue. The PCT’s case review committee had decided that the extent of mental illness documented [in X] was substantially different to the chronic mild to moderate distress ... in AC’s case”. The PCT decided that it was rational to draw a distinction between the two cases and Mr Justice Bean agreed. He also dismissed the argument of the Equality and Human Rights Commission that it was wrong to use a natal woman as the comparator in this case.

What emerges from this case is the importance of procedure, both in the development of commissioning policies in the first place (they must be grounded in demonstrable evidence of clinical and cost effectiveness and, where appropriate, have been put out to consultation) and in the taking of decisions within the remit of those policies. Minutes of panel meetings must make it absolutely clear which policies are considered to be applicable to a case and why and, in considering evidence of exceptionality, which factors were weighed in the balance, which accepted and which rejected and the reasons for that. Although discussions at panels seldom progress in a clear, linear fashion, it is imperative that the facts and issues at hand are set out and analysed with forensic rationality. Should your minutes and correspondence come before a High Court judge, they will be dissected with a scalpel and pored over by a razor-sharp mind, leaving any imprecise or muddled thinking brutally exposed. You need to be clear what you are doing – and clear as to why you are doing it.

The judgment can be accessed [here](#).

For further information or advice please contact [Jane Williams](#) on 0121 456 8421.

briefing continued

PATIENT MATTERS – DRUGS APPRAISALS

NICE says no to Nexavar

The National Institute for Health and Clinical Excellence (NICE) has issued technology appraisal guidance 189 in respect of sorafenib (Nexavar) for the treatment of advanced hepatocellular carcinoma (HCC), the most common form of primary liver cancer. NICE has concluded that sorafenib is not recommended for the treatment of advanced and metastatic liver cancer in patients for whom surgical or locoregional therapies have failed or are not suitable.

The appraisal committee concluded that the drug was clinically effective within this subset of patients but not cost-effective, despite considering that it fell within the group of life-extending end-of-life treatments and despite the existence of a patient access scheme for the drug, under which the cost of every fourth pack of the drug would be rebated by the manufacturer to the NHS.

The guidance, which will be considered for review in November 2012, can be accessed [here](#).

For further information or advice please contact [Jane Williams](#) on 0121 456 8421.

Breast cancer patients denied Lapatinib

The National Institute for Health and Clinical Excellence (NICE) has announced that it will not be licensing Lapatinib for use by breast cancer patients.

NICE has said that there is not enough evidence of the drug's benefits to justify its £27,000 a year, which it is claimed can allow patients to live for an average of ten weeks. This decision comes despite the fact that GlaxoSmithKline had offered to give Lapatinib free to NHS patients for the first three months of the treatment.

The drug is designed for patients whose breast cancer has metastasised and for whom Herceptin has stopped working.

It is thought that around 2,000 women a year would be able to benefit from the drug which is used in conjunction with chemotherapy.

Final guidance from NICE is expected later in the summer.

For further information or advice please contact [Jacqueline Haines](#) on 0121 456 8453.

PATIENT MATTERS – ORGAN TRANSPLANTS

New EU laws on organ transplants

Our *May Health Legal Update*, which can be accessed [here](#), included information on the new Department of Health guidance for transplant teams. Following on from that there have been further updates in the world of organ transplantation.

The European Parliament has approved a draft directive (the directive) which requires Member States to adopt minimum standards on quality and safety in relation to human transplant organs. The directive will enter into force later in 2010 and national governments will have two years to implement its requirements into national legislation.

Whilst exchange of human organs between Member States does currently take place, there are significant differences between Member States when it comes to rules concerning quality and safety aspects of human transplantation. This

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is a significant issue as the risk of transmission of infectious or cancerous diseases to the recipient presents a real safety concern for patients.

The practical effect of the directive is that in the next two years we will see the establishment of a national authority set up in each EU Member State to ensure compliance with EU quality and safety standards. Standardised measures will include:

- establishing a traceability system of human organs;
- setting up a reporting system of serious adverse events and reactions;
- standardising data collection on specific organ characteristics; and
- conducting national quality programmes to ensure continuous monitoring of performance.

In summary, the goal of establishing common minimum standards between Member States is to minimise risks to the organ recipient, improve and optimise the allocation of organs across the EU and to provide critical information to the transplant surgeon to ensure that he/she can make an informed decision.

For further information or advice please contact [Gill Thomas](#) on 01223 222237 or [Emma Tully](#) on 01223 222485.

PATIENT MATTERS – HEALTH AND SAFETY EXECUTIVE

Hospital trust fined £50,000 following death of a patient who got his head stuck between bed bars

Basildon University Hospitals NHS Foundation Trust has been fined £50,000 following a prosecution brought by the Health and Safety Executive. Kyle Flack was aged 20 and a quadriplegic with cerebral palsy when he died in 2006 after getting his head trapped in bed bars whilst in hospital.

The prosecutor said that the hospital had failed to properly supervise Mr Flack, to properly pass on information, train staff, assess risk and had not heeded warnings. He said the offences amounted to a "serious" breach of duty and the hospital had fallen "markedly short" of the required standard. The trust accepted that its breach of health and safety legislation was a significant cause of the death and has since taken action including improving the management of equipment and the care of patients with special needs.

The hospital was also ordered to pay £40,000 costs.

For further information or advice please contact [Alison Maw](#) on 0121 456 8454.

PATIENT MATTERS – ARTICLE 2

Court decides relevance of Article 2 for non-detained mental health patients

You may recall the case of *Savage* where the court looked at the scope of a trust's obligation under Article 2 of the European Convention on Human Rights in respect of the right to life. It was established that the trust had an "operational obligation" towards mental health patients with suicidal tendencies who are detained. Earlier this year it was also established that a breach of these obligations could attract an award for damages to the "victims" of the breach.

In the case of *Rabone*, the Court of Appeal has now considered the extent of a trust's obligation under Article 2 for informal mental health patients, which was not fully explored in the case of *Savage*. Lord Justice Jackson summarised the case law and stated that:

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“I do not believe that health trusts have the Article 2 operational obligations to voluntary patients in hospital, who are suffering from physical or mental illness, even where there is a real ‘real and immediate’ risk of death.”

He also confirmed that it was important for NHS trusts and their legal advisers to be clear about their legal obligations and liabilities and that it was not and should not, be the law that voluntary mental health patients should fall into a different category of patients who can claim under Article 2 against other non-mental health patients, who cannot. For example, a patient undergoing a major heart surgery could be just as greater risk of death as a schizophrenic patient.

The *Rabone* case has also confirmed that there was no breach on the facts of the case, of the trust’s investigatory obligations under Article 2 as there had been an inquest and there had been an SUI investigation and civil litigation. Lord Justice Jackson was satisfied that the investigatory obligation had been satisfied.

Lord Justice Jackson finally considered if the parents in this case would have “victim” status if he had found that the trust had an Article 2 obligation and it had been breached. The proposition that Lord Justice Jackson put forward was as follows:

“If an applicant brings a claim and succeeds this ‘may’ deprive him of the status of victim.

It is then necessary to consider a) if liability has been accepted or proved b) the adequacy of any compensation awarded. If the compensation awarded falls short of the losses suffered by the applicant this factor points against the applicant having ‘victim’ status.”

This judgment is good news for the NHS as it clearly restricts the use of the *Savage* judgment in persuading courts that trusts have Article 2 obligations in respect of informal mental health patients.

The judgment can be accessed [here](#).

For further information or advice please contact [Katrina McCrory](#) on 0121 456 8451.

CHILDREN – CHILD PROTECTION REVIEW

Munro review of child protection practice

Professor Eileen Munro has been invited by the Secretary of State for Education to undertake an independent review of frontline child protection practice in the UK.

The review will consider ways in which current barriers and bureaucracy can be removed in order to enable social workers to spend more time with vulnerable children.

The Government seeks to strengthen the profession by placing social workers in a better position to make well informed decisions, based on up to date evidence. The aim is for the decision making process to be free from unnecessary bureaucracy and regulation.

Professor Munro has been asked to set out the obstacles which would prevent these improvements taking place. She has also been asked to consider how effectively professionals, from the various agencies involved with children, are able to work together.

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It is anticipated that the review will also consider the systems of child protection operating in other countries and whether there are elements of these that can be incorporated into UK practice.

For further information or advice please contact [Charlotte Mawdesley](#) on 0121 456 8402.

GMC – FITNESS TO PRACTISE

GMC finds that acts of dishonesty by a doctor which do not affect his clinical competency and performance can still undermine public confidence

In the case of *Steven Bradshaw v General Medical Council*, the judgment of which can be accessed [here](#), a doctor (B) applied to terminate a GMC interim order suspending his registration.

B had been suspended by his employer pending an investigation into several allegations made against him, which arose following claims of harassment made by B against a colleague with whom he was alleged to have had an affair. B resigned during the investigation. The investigation concluded that B had made false allegations of misconduct, had lied to the investigator numerous times with the intention of perverting the course of the investigation and had fabricated and altered original documents in order to discredit his colleague and undermine the testimony against himself.

The GMC were notified and its Interim Orders Committee suspended B's registration for 18 months, noting that the allegations related to his honesty and probity. The committee were satisfied that there could be impairment of his fitness to practise that posed a real risk to members of the public or could adversely affect the public interest.

B applied under section 41A(10) Medical Act 1983, which can be accessed [here](#), to terminate the suspension. B denied the alleged relationship and submitted that none of the allegations concerned his clinical competency or performance.

The application was refused and it was held that the panel had been correct to order B's suspension. Although an interim suspension would usually be viewed as disproportionate in circumstances not involving any criticism of clinical performance or abuse of patient care, the matters alleged were serious and had serious implications as to B's probity and integrity.

In addition, the initial and disciplinary investigations appeared to have been very careful and thorough. Although the allegations involved a colleague and not a patient, a member of the public might legitimately question B's honesty and probity. Such factors would be likely to undermine public confidence in a doctor's core duties and responsibilities of honesty and integrity.

For further information or advice please contact: [Kevin Duce](#) on 0121 456 8263.

EMPLOYMENT – VETTING AND BARRING SCHEME

Government calls a halt to vulnerable groups registration scheme

The Coalition Government has announced a review of one of the key components of the Safeguarding Vulnerable Groups Act, (the provisions of which are referred to as the Vetting and Barring Scheme) which would have eventually required all workers performing regulated activities to be registered with the Independent Safeguarding Authority (ISA). The news comes just weeks before ISA was due to open its doors to registration on a voluntary basis, and less than five months before registration would have become compulsory for new staff. This decision is on top of a review started

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by the outgoing Labour Government last year, which is looking at whether the additional category of controlled activities is needed at all.

The provisions of the Act which have already been brought into force will not be affected. So employers must continue to check whether recruits to regulated or controlled activities are on the relevant barred list maintained by ISA. The obligations to make referrals where staff are removed from these activities also continues. Unfortunately the announcement came too late to forestall the introduction of new forms by the Criminal Records Bureau, which it had planned to use in the registration process from 26 July. Instead the new forms will be phased in as planned, but users have been advised to ignore the fields that contain information that would only have been relevant for registration purposes.

For further information or advice please contact [Charles Pigott](#) on 01223 222411.

Vetting and barring scheme challenge

The Royal College of Nursing (RCN) has made a judicial review application in relation to the scheme. They allege that the scheme, which extended the right to ask for an enhanced CRB disclosure to all those who employ or use volunteers in "regulated activity" from October 2009 may breach the European Convention on Human Rights as they feel that it denies the right to a fair hearing and appeal.

We understand that the RCN plans to continue with its application regardless of the halt put on the next phase of the introduction of the scheme (voluntary registration). We will update readers in relation to any further announcements that may be made by the Government and of course in relation to the RCN's legal challenge.

For further information or advice please contact [Lee Parkhill](#) on 0121 456 8420 or [Helen Burnell](#) on 020 7648 9237.

CONSTRUCTION – ADJUDICATION

The seven golden rules of adjudication

Adjudication is favoured by many in the construction industry as a way of resolving disputes because it is quick and relatively cheap. However, adjudicators' decisions are frequently challenged by the losing party. Thankfully, during a talk he gave to the Society of Construction Law recently, Mr Justice Coulson has provided seven key pointers for adjudicators to maximise the chances of their decisions being upheld.

- First, the adjudicator should be bold. Mr Justice Coulson reminds us that the adjudicator's decision can be incorrect (in terms of fact and law) and still be upheld. The important thing is that payment is made to the correct person.
- Second, the adjudicator should not shy from dealing with challenges relating to his jurisdiction. Better to exercise caution and withdraw at an early stage than have the decision overturned.
- Third, the adjudicator should make sure he identifies the issues in dispute and deals with each one giving only concise reasons for his decision.
- Fourth, the adjudicator must act fairly but remember that the need to arrive at an answer quickly is greater than the need to arrive at the correct answer.
- The adjudicator should ensure that his decision is clear and free from ambiguities.

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- Mr Justice Coulson's sixth rule is that the adjudicator should deal with the adjudication "in time" not allowing deadlines to slip.
- Finally, the adjudicator should avoid silly mistakes such as arithmetical errors.

Mr Justice Coulson is a High Court judge who frequently deals with challenges to adjudicators' decisions. Whilst he makes no promises that his rules will prevent successful challenges, adjudicators and those who find themselves party to an adjudication should try to follow his rules in order to increase their chances of the decision being upheld.

For further information or advice please contact [Susannah Wilson](#) on 0121 456 8276.



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