

Health Legal Update June 2010

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Introduction

A warm welcome to the first post-election and 2010 NHS Confederation Conference edition of our Health Legal Update.

The Government’s detailed coalition agreement [Our Programme for Government/Summary](#) is welcome evidence that the parties have been able to reach agreement on a wide range of issues, and the commitment that the health budget will increase in real terms in each year of the new Parliament is good news for the NHS.

It is clear that health services face significant changes under the new Government. The programme laid out by the coalition Government will change the way the NHS is run, funded and held accountable. The details are still being worked out but as soon as we know more we will update you.

The changes identified in the agreement such as regulation, the GP contracting out-of-hours care and the new independent board represent a considerable shift to the NHS which will have to rise to the challenge of this new agenda and work to understand its implications.

The pledge to end top-down reorganisation suggests a welcome freedom to local NHS organisations and stakeholders in transforming their community services. It is also clear that the next few years will bring significant changes across the NHS. In setting up the independent NHS board, careful thought will need to be given to the relationship between its responsibilities and those of ministers, who will remain accountable to Parliament for NHS expenditure.

We have a feast of articles for you this month – whilst there are too many to mention each one there are clear key themes of procurement, contract performance management, disclosure and successful commissioning. Please also take a look at our Supply of Medicines and Children portfolio sections.

The firm's partnership with the national health think tank, [The King's Fund](#) creates opportunities for us to share ideas and expertise on areas such as patient mobility and the EU competition policy and be involved in consideration of policy in a variety of areas. We are delighted that this month sees the publication of a paper on EU patient mobility which we co-authored with The Fund.

If you have not already done so, please have a look at our seminar programme, which can be accessed [here](#).

Our Healthcare Resource Centre (HRC) which can be accessed [here](#), may just have the answer to that simple question. Have you considered saving it on your system as one of your "favourites" for easy access?

We also have several new documents on the HRC including cross-border healthcare and patient mobility, and inquest updates.

On 17 June we are hosting a charity concert at the Birmingham Cathedral. The concert will raise funds for the Queen Elizabeth Hospital Birmingham Charity. We have joined forces with musicians and singers from Birmingham, including Birmingham Conservatoire's Brass Ensemble, Quinton Community Choir, soprano Abigail Kelly, bass/baritone Godfrun Moore and gospel singer David Copeland to present a gala evening of music. The event will be compered by TV news presenter Michael Collie. Further information can be found [here](#).

Last but certainly not least! Invitation to stand A33 at the NHS Confederation Conference. We are delighted to confirm that Mills & Reeve is again supporting the annual NHS Confederation Conference in Liverpool from 23-25 June. By the conference we will have just received the new Government's first budget so will have even more to think about! Please come and see us on stand A33 – we have a brand new game!

We look forward to seeing you there.



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NHS MANAGEMENT – MONITOR

Monitor publishes detailed guidance for the dry run of external assurance on the quality reports

Foundation trusts approaching this year's quality reports should read Monitor's updated guidance on the external assurance Monitor requires boards to obtain. The guidance can be accessed [here](#). The results of this year's dry run will inform the rules for 2010-11 and subsequent years, for which directors will be publicly certifying compliance. For 2009-10, boards will be privately certifying compliance to their auditors. Their auditors will then review the trust's compliance. Although there is no formal auditors' opinion for 2009-10, auditors will need to do much the same work, including for example walk-through tests of data systems. The auditors' report of key findings and recommendations is to be submitted to Monitor in July.

The updated assurance requirements, which trusts will need to have properly documented, include:

- clinician sign-off for data used in the report;
- training programmes on data quality and regular updates;
- monitoring of staffs' adherence to data collection guidelines, with special attention paid to agency staff; and
- evidence that clinical data is reported to the board, with appropriate level of challenge.

This last point is a further indication of Monitor's current focus on ensuring that foundation trusts' governance arrangements make a real contribution to their organisational performance.

For further information or advice please contact [Tim Winn](#) on 0121 456 8355.

NHS MANAGEMENT – PROCUREMENT

Disclosure of documents in public procurement disputes

The issue of what types of document should be made available by public sector bodies to the claimant in public procurement disputes arose in the Technology and Construction Court in April 2010 in the case of *Croft House Care Limited and Ors v Durham County Council*.

In court proceedings the parties are typically obliged to make available all documents that are relevant to the case. In cases concerning public procurement, such documents can be

especially sensitive, particularly where tenders may need to be re-run as a result of the claimant's challenge. Whilst the decision is linked to the specific facts of the case, some clarity on what the courts (and therefore the parties) may expect is welcome in this fast-developing area of law.

Here the local authority argued that certain types of document were sensitive and if disclosed would compromise their legitimate commercial and public interests and create potential difficulties for them in re-running the tender process, with other documents being confidential to the other tendering parties. The court held that these were not valid grounds to allow the authority to prevent the claimants from inspecting the documents. Certain safeguards were however put in place such that those documents could be redacted to preserve some confidentiality; could only be read in the solicitors' office; could not be copied; and notes could not even be taken during the inspection.

The court is likely to have to provide such specific direction in future cases, but it is worth bearing in mind that as a last resort, if sensitive documents ultimately do have to be disclosed, conditions to their release can be obtained which provide greater protection to the public body than might otherwise be thought to be the case.

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

For further information or advice please contact [Paul Slinger](#) on 0121 456 8385.

NHS MANAGEMENT – LIFT

LIFT (Local Improvement Finance Trust): performance monitoring of LPAs (Lease Plus Agreements) and LRAs (Land Retained Agreements)

Following practical completion of a LIFT scheme, monitoring the performance and the payment mechanism regime in the Lease Plus Agreements (LPAs) and Land Retained Agreements (LRAs) can seem a challenging task for a PCT. Not only do systems need to be set up but the PCT needs to have enough resource to ensure that it gets full value out of these contracts. Available remedies (ensuring good performance by FundCo and its supply chain) are in danger of being overlooked or delayed.

It is really important that the PCT is able to exercise its entitlement to make deductions relating to unavailable aspects of the facilities and its extended powers to step-in and rectify matters that are lacking (and to do so within specified time periods). Please note further that in the case of complex LPAs and LRAs deductions can be made for poor performance in lieu of such extended step-in rights.

The PCT should also look to recover its reasonable costs in carrying out such rectifications.

Mills & Reeve has created a very user-friendly online performance toolkit to ease some of the concerns a PCT might have about interpreting and operating the performance monitoring system and payment mechanism contained in LPAs and LRAs.

This toolkit will save the PCT both money and time, enabling it to get more from its contracts for less.

For further information or advice on performance monitoring of LPAs and LRAs and the potential of implementing this performance monitoring toolkit please contact Bridget Archibald, partner in the projects team and Head of Health.

For further information or advice please contact [Bridget Archibald](#) on 01223 222436.

NHS MANAGEMENT – COMMISSIONING

Principles for success in Practice Based Commissioning (PBC)

The newly formed *PBC Capability Framework Providers' Network* has produced a list of 12 principles on which successful PCT/PBC relationships should be based. These include the following:

- A compact between PCTs and PBCs should be created; affirming their joint commitment to practice based commissioning. The network believes that common objectives and key performance indicators would facilitate the attainment of necessary goals.
- The network advocates the appointment of a "PBC champion" at board level, who must be able to simultaneously maintain productive relationships with GPs and influence the trust's chief executive.
- The needs of patients should be at the forefront of PBC.
- While the network acknowledges that the information available to those involved with PBC is not perfect, they call on commissioners to accept these in the short-term whilst taking action to address them.
- The network warns of a culture of fear holding back the development of PBC. They wish to see the "barriers" to enabling GPs to harness PBC skills alleviated and for PCT managers "to let go of present ways of working".
- Examples of best practice should be shared in order to "provide a culture of improving quality".

The guide dated April 2010 is available from the PBC Connection website and can be accessed [here](#).

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

NHS MANAGEMENT – CONTRACTS

OGC policy to support Government's mandate to expedite payments to subcontractors

With effect from 25 March 2010, all Government departments, agencies, non-departmental public bodies (and other bodies over which they have direct control) are now required to include in new contracts a requirement on contractors to pay their sub-contractors within 30 days.

The Office of Government Commerce (OGC) has issued a policy note that outlines the background to this development and suggests suitable wording that can be inserted by contracting authorities into new contracts in order to satisfy the new requirement. Thankfully this requirement does not have retrospective effect. However, contracting authorities are encouraged, where feasible, to seek contractors' voluntary agreement to paying within 30 days.

In addition, the OGC policy note also outlines the requirements of the new three-tier reporting system to be implemented by contracting authorities as evidence of compliance with the new payment provisions.

The practical effect for our NHS clients is that any new commercial contract permitting sub-contracting must include the expedited payment provision. Further, contracting authorities should put in place internal arrangements to comply with the corresponding monitoring requirements.

A complete copy of the OGC policy note can be found [here](#).

For further information or advice please contact [Julie Jordan](#) on 01223 222478 or [Emma Tully](#) on 01223 222485.

NHS MANAGEMENT – FIRST-TIER TRIBUNAL (PRIMARY HEALTH LISTS) CASES

In January 2010, Primary Health List cases became a jurisdiction within the Health, Education and Social Care Chamber of the First Tier Tribunal, which took over the former role of the Family Health Services Appeal Authority (FHSAA). The Tribunal has recently published decisions made in the first three months of the new process. Below are summaries of two of the tribunal's recent decisions.

Performers List Management – proposing removal on two grounds: tribunal's decision illustrates the correct approach

Dr Faghany, a dentist, appealed against the PCT's decision to remove him from its performers list on the grounds of both efficiency and suitability. The allegations against Dr

Faghany were numerous including allegations of poor clinical skills, misdiagnosis and mistreatment, poor management skills, poor communication skills, dishonesty, poor out of hours service arrangements and a failure to cooperate with the PCT.

As the case against Dr Faghany was advanced on two alternative grounds (efficiency and suitability) this decision helpfully illustrates how the tribunal will approach complex cases where the facts could, possibly, justify action on more than one ground. In this case the tribunal first considered the issue of suitability because if unsuitability was found the sanction, removal, would be automatic (contingent removal is not possible in a suitability case). The tribunal concluded that Dr Faghany was unsuitable to remain on the performers list.

In case their conclusion about suitability was incorrect, the tribunal went on to consider the alternative allegation on efficiency grounds. The tribunal also concluded that Dr Faghany's inclusion on the performers list would prejudice the efficiency of the service.

Having concluded that there would be prejudice to the efficiency of the service the tribunal went on to consider whether conditions could adequately address the inefficiency and protect the public. The tribunal concluded that it was not practicable to formulate conditions which would address the range of problems identified. Accordingly, the tribunal concluded that removal was the only appropriate sanction to address the prejudice posed by Dr Faghany's inefficiency.

In conclusion, the decision illustrates that where there is potential overlap between efficiency and suitability, the suitability test should be considered first. If it is necessary to consider the case under efficiency, if inefficiency is found, the starting point is consideration as to whether conditions would be appropriate. If contingent removal would not adequately deal with the inefficiency, removal will be appropriate.

Determining which ground to base the PCT's case on is often not a straightforward task. This decision helpfully illustrates that, for some cases, proposing removal on two alternative grounds can be the safest way forward, and demonstrates the order in which the tests should be considered.

The judgment of the case can be found on the Tribunal Service Primary Health List's website and can be accessed [here](#). Please note the judgment is subject to Crown copyright.

For further information or advice please contact [Lee Parkhill](#) on 0121 456 8420 or [Dawn Brathwaite](#) on 0121 456 8224.

Tribunal upholds appeal against refusal to grant General Ophthalmic Services Contract

In the case of *Kim Brown v North East Lincolnshire Care Trust Plus*, Kim Brown (the applicant) appealed against the refusal of North East Lincolnshire Care Trust Plus (the trust) to accept her application for a General Ophthalmic Services Contract (GOS contract).

In answer to the declaration on the application form, “Have you been subject to an investigation into **professional** or **business conduct** in respect of any current or previous employment or business where the outcome was adverse”, the applicant answered, “No” The trust was subsequently informed by the applicant’s previous employers that she had been dismissed from her role as practice manager for gross misconduct. However, the applicant had subsequently brought a claim for unfair dismissal against her former employers alleging unfair dismissal which was subsequently compromised.

On the basis of the information received from the former employers, the trust refused the application. The applicant appealed against the trust’s refusal to grant the GOS contract.

The tribunal took a strict approach to analysing the appropriateness of the appellant’s response to the question on the application form. The tribunal found that as the appellant had not been employed in either a “business” or “professional” capacity at the time of the investigation, her answer to the question was acceptable and her appeal was upheld. The tribunal determined that in the absence of a clear and specific request to provide certain information, the PCT could not conclude that there had been a deliberate intention to mislead. There must, therefore be an obvious failure to provide information that is specifically asked for before the tribunal will find dishonesty or an intention to mislead.

Although this case did not deal with an application to join the PCT’s performers list, the tribunal’s reasoning will be applicable to performers list cases. The National Health Service (Performers Lists) Directions 2010 mandate all PCTs to review their performers lists management processes, including processes for dealing with applications. The drive is to exercise greater control over entry to performers lists, but this decision confirms that PCTs will need to act with caution when attempting to conclude unsuitability based on incomplete or inaccurate application papers.

The judgment of the case can be found on the Tribunal Service Primary Health List’s website and can be accessed [here](#). Please note the judgment is subject to Crown copyright.

For further information or advice please contact [Lee Parkhill](#) on 0121 456 8420 or [Alison Fielder](#) on 0121 456 8454.

NHS MANAGEMENT – SURVEILLANCE

Regulation of Investigatory Powers Act (RIPA) – new codes of practice

Of some relevance to the NHS are the new RIPA codes of practice which came live on 6 April. The relevant sections cover covert surveillance. The changes follow on from consultations which took place last year.

The use of covert (or directed) surveillance for a particular investigation must be subject to prior authorisation under the RIPA regulations. In NHS trusts the responsibility for

authorisation (except for investigations of fraud and corruption) is with the chief executive. This responsibility cannot be delegated. The NHS Litigation Authority occasionally considers using covert surveillance in rare circumstances.

Fraud and corruption investigations will be referred through NHS Counter Fraud Service.

The changes now in effect include the appointment of a senior officer within organisations to supervise RIPA changes together with more readily available guidance on necessity and proportionality.

For further information or advice please contact [Stuart Knowles](#) on 0121 456 8461.

NHS MANAGEMENT – REGULATORY MATTERS

Clarification of test for interim order of suspension imposed by the GMC

Dr Sandler applied to the High Court for the termination of an interim order imposed by the General Medical Council, under section 41A(1) Medical Act 1983, suspending his registration. He had received a final written warning from his employer for failing properly to comply with his professional duties when completing cremation forms over a 12-month period, but his employer also referred the case to the GMC and to the police.

Dr Sandler was charged with offences under section 8(2) Cremation Act 1902 in connection with the completion of approximately 116 forms over several years, while the GMC's Interim Orders Panel (IOP) imposed an 18-month suspension of his registration. The IOP concluded that although suspension was not "necessary for the protection of members of the public", it was "in the public interest" for the doctor to be suspended so that public confidence in the profession could be maintained. The doctor argued that his suspension should be terminated because it was not justified in the public interest and was disproportionate.

Nicol J concluded that, whilst suspension on public protection grounds could only be imposed if it was "necessary", there was no such qualification on the public interest limb. The court said that although the panel had to consider carefully the proportionality of the measure, weighing the significance of any harm to the public interest in not suspending the doctor against the damage to him by preventing him from practising, the court had to be cautious about superimposing additional tests over and above those which Parliament had set. In all the circumstances, the court was entitled to give considerable weight to the views of the panel that the balance came down in favour of suspension.

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

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

PATIENT MATTERS – SUPPLY OF MEDICINES

NHS permitted under EU law to incentivise money saving prescribing practices

The European Court of Justice (ECJ) ruled in April in *Association of the British pharmaceutical industry (ABPI) v Medicines and Healthcare Products Regulatory Agency (MHRA)* case c-62/09) that an incentive scheme operated by certain NHS bodies in England and Wales in a bid to reduce costs relating to prescription medicines did not breach European Union (EU) law.

The NHS bodies encouraged health professionals, by use of financial incentives, to prescribe either specific named or generic treatments based on a different cheaper active substance, which had been verified for equivalence using National Institute for Health and Clinical Excellence guidelines.

The MHRA claimed that such schemes breached the EU Directive dealing with the Community code on medicinal products for human use (the Directive), Article 94 of which states:

“1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.”

“3 Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1.”

The MHRA's argument was that Article 94 limited “commercial” influence over doctors’ prescribing practices, it was not meant to impinge on Member States’ health authorities’ powers to manage pricing in order to keep down costs. ABPI, claiming that Article 94 did apply to national authorities, disagreed and sought judicial review of MHRA’s interpretation. In order to give a judgment in the judicial review proceedings, the High Court sought a ruling on the Directive from the ECJ.

In its ruling the ECJ referred to the “broad logic” of the Directive which aimed, by curtailing “promotional” activities of commercial entities, to avoid the inducement of health professionals to act in accordance with their economic interests instead of adhering to professional conduct rules.

The ECJ ruled that, although Article 94(1) could also apply to those not acting for profit-making purposes, it could not apply to Member States’ public health bodies whose responsibilities include “(i) ensuring that the existing rules, of which [Article 94(1)] form[s] part, are applied and (ii) defining the priorities for action in relation to public health policy, in particular so far as concerns the rationalisation of the public expenditure allocated to the policy which is precisely what they are responsible for”.

The ECJ concluded that a Member State's health policy and the corresponding expenditure did not constitute a commercial venture. These incentive schemes were part of that health policy and could not be linked to the commercial promotion of medicinal products.

The case can be found [here](#) (© European Union, <http://eur-lex.europa.eu/>).

For further information or advice please contact [Rona McPherson](#) on 01223 222299 or [Gill Thomas](#) on 01223 222237.

Department of Health asks NICE to look into the possibility of appraising (Avastin) for the treatment of wet AMD

Two years after the initial pre-TAG wave of litigation and campaigning to try to compel PCTs to commission ranibizumab (Lucentis) for the treatment of wet age-related macular degeneration (wet AMD), the National Institute for Health and Clinical Excellence (NICE) has finally been asked by the Department of Health (DH) to look into the possibility of appraising the clinical and cost effectiveness of bevacizumab (Avastin) to treat wet AMD, the leading cause of blindness in the UK, and other eye conditions.

Although Lucentis and Avastin are closely related to one another chemically, the manufacturer has apparently refused to apply for the licensing of Avastin for the treatment of wet AMD – hardly surprising given the relative costs of the two drugs, with the licensed Lucentis tipping the scales at approximately £10,000 per patient and Avastin being substantially cheaper.

NICE does not usually appraise drugs outside of their licensed indications but will do so when the DH requests it, as has happened previously in the case of drugs for use in paediatric medicine, where off-label prescribing is customary. Anecdotally, there have been favourable reports on the intra-ocular use of Avastin for wet AMD. Two clinical trials comparing the use of Avastin against the current treatment, Lucentis, however, are not expected to report until the end of 2011 and the beginning of 2012 respectively.

Lest we get too excited, it must be noted that the department has not yet taken the decision to refer Avastin in this off-label indication to NICE. NICE's current remit is merely to explore with stakeholders whether undertaking an appraisal would be possible. The Institute is expected to report back to the DH later this year.

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

Guidance issued to ensure more uniform provision of newly licensed drugs north of the border

Guidance on the introduction of newly licensed medicines has been issued to Health Board Chief Executives by the Healthcare Policy and Strategy Directorate of the Scottish Government. The guidance covers all medicines which have either not been approved or not

yet considered by the Scottish Medicines Consortium, Scotland's equivalent of NICE. The guidance will apply whenever a clinician makes an individual funding request for a drug to be used for a patient and is aimed at securing a more uniform and consistent approach to NHS drug funding across the country, so eliminating current allegations of "postcode prescribing".

The guidance seeks to:

- provide an overview of the "end to end" process from licensing of medicines through to individual patient treatment (exceptional prescribing) requests;
- set out the framework under which local NHS board policies about access to newly licensed medicines are expected to be developed;
- remind NHS boards about their responsibilities about providing information for patients describing the arrangements and informing them of decisions;
- identify specific key features for NHS boards to address when considering individual patient treatment requests; and
- consolidate previously issued guidance on the role of the Scottish Medicines Consortium under HDL(2003)60 and the status of Single Technology Appraisals (STAs) from the National Institute for Health and Clinical Excellence under HDL(2006)29.

It remains to be seen, however, how successful the guidance will be in the endeavour to introduce uniformity and consistency. Scottish Health Secretary Nicola Sturgeon said that "all boards will be expected to follow the same guidance, which will be adapted to meet local circumstances". It is in that local adaptation that the whole scheme could come undone.

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

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

PATIENT MATTERS – FERTILITY

NICE seeks views on scope for updating fertility guideline

The National Institute for Health and Clinical Excellence (NICE) has been asked by the Department of Health to develop a clinical practice guideline to update its Fertility Guideline (2004) CG11, for use in the NHS in England, Wales and Northern Ireland. The typical PCT/health board/SHA can expect to see around 230 new consultant referrals per 250,000 population each year, although only approximately 1.5 per cent of babies born in the UK are conceived using assisted reproduction techniques.

NICE has issued a draft scope, defining what aspects of care the guideline will cover, and has invited registered stakeholders to submit comments and propose clinical questions which the guideline could address. Only registered stakeholders may submit comments and registration can be effected via the NICE website at Stakeholder Registration which can be accessed [here](#).

Key clinical issues to be covered in the updating guideline will be:

- tests for ovarian reserve;
- effectiveness and safety of ovulation induction agents;
- effectiveness of intrauterine insemination for unexplained infertility;
- clinical effectiveness, cost effectiveness and referral for IVF treatment; and
- effectiveness of different embryo/blastocyst transfer strategies (number of embryos and timing of transfer).

The recommendations on these topics will be revised in the light of new evidence.

The consultation also asks whether the scope could be changed to better promote equality of opportunity relating to age, disability, gender, gender identity, ethnicity, religion and belief, sexual orientation or socio-economic status. However, issues which were excluded from CG11 and which undoubtedly impinge on equality of access (such as criteria for access to fertility treatment by people seeking assisted reproduction for a reason other than infertility problems – which could be interpreted as including gay and lesbian couples – and surrogacy in the absence of reproductive pathology) will remain excluded from the update. What NICE purports to ask in terms of equality impact assessment, therefore, seems to sit slightly uneasily with the issues excluded from the draft scope.

The consultation will close on 15 June 2010 and the development of the guideline recommendations will begin in July 2010. The draft scope can be accessed [here](#).

For further information or advice please contact [Helen Burnell](#) on 020 7648 9237 or [Jane Williams](#) on 0121 456 8421.

HFEA sets fees for single embryo IVF treatment

The Human Fertilisation and Embryology Authority (HFEA) has announced it will redefine the fee it charges clinics for IVF following a single embryo transfer. The move recognises that patients who transfer only one embryo per round of treatment should not be penalised within the existing scheme.

From 1 October 2010, the new arrangement will see clinics pay the HFEA fee of £104.50 for a patient's initial treatment cycle using single embryo transfer. If the first cycle is unsuccessful, each additional frozen embryo transfer will not be charged. Currently, clinics pay the HFEA for each cycle of IVF they carry out. Many clinics pass this fee onto patients. The extra cost can influence patients to have multiple embryos transferred in a single cycle, increasing the risk of a multiple pregnancy.

The move is seen as sending a positive message to patients and clinics that HFEA is doing everything it can to promote low risk single embryo transfer fertility treatment.

For further information or advice please contact [Lucy Johnston](#) on 01223 222366.

PATIENT MATTERS – END OF LIFE

GMC publishes revised guidance on end of life care

After extensive consultation, the General Medical Council has launched its updated guidance *Treatment and care towards the end of life: good practice in decision making*, including advice on how to decide whether to attempt cardiopulmonary resuscitation (CPR) and when to withhold or withdraw artificial nutrition and hydration.

The guidance, which comes into force on 1 July 2010, covers the whole of the United Kingdom and replaces the GMC's 2002 document *Withholding and withdrawing life-prolonging treatments*. The newly launched guidance takes into account recent case law, the Mental Capacity Act 2005, the GMC's 2008 consent guidance, and Government strategies on end-of-life care in England and Scotland.

The GMC said it also wanted to use the guidance to deal with requests from doctors for clarification about CPR and "ongoing public concerns about the standard of end-of-life care provided to some patients such as people with disabilities or dementia." The GMC has urged GPs to take on a more prominent role in end-of-life care by helping to set up advanced care plans for terminally ill patients at an earlier stage of their illness.

The guidance, whose publication is supported by a package of learning materials and case studies, can be accessed [here](#).

For further information or advice please contact [Helen Burnell](#) on 020 7648 9237 or [Jane Williams](#) on 0121 456 8421.

PATIENT MATTERS – RIGHTS OF OVERSTAYERS

Court of Appeal rules that local authority should provide support to overstayers with an outstanding application for leave to remain

The Court of Appeal has ruled, in the case of *Birmingham City Council v Clue & Others* [2010] EWCA Civ 460 on the approach that a local authority should adopt when an individual who is unlawfully in the UK seeks social services support from it. Ms Clue was a Jamaican national and her eldest daughter was born in Jamaica. Her other three children, born in the UK to a British father, were British. Ms Clue and her eldest daughter were granted leave to enter as visitors for six months. They remained, illegally, in the UK after their visa expired. Several years later Ms Clue applied to the UK Border Agency (UKBA), for indefinite leave to remain on the basis that her eldest child had been living in the UK for more than seven years. The UKBA then had a policy of, generally, not removing families where a child had been in the UK for seven years.

She also sought accommodation and financial support from the council which refused support on the ground that Ms Clue and her children could return to live safely in Jamaica.

The Court of Appeal held that where an individual has an outstanding application for leave to remain (and that application is not totally without merit), the local authority should not refuse to provide support if the consequence of not providing support would be that the individual would have to leave the UK, and so forfeit their application for leave to remain.

Health and social care duties towards people subject to immigration control can be complex, with eligibility to some services being heavily restricted. This decision potentially widens the scope of local authorities' duties. This decision will directly affect local authority social services, but NHS bodies will also need to be aware of how this decision will change the scope of social care support which is available to people who are often supported by packages of care from both health and social care bodies.

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

For further information or advice please contact [Sonal Lala](#) on 0121 456 8248, [Lee Parkhill](#) on 0121 456 8420 or [Dawn Brathwaite](#) on 0121 456 8224.

PATIENT MATTERS – BEST INTERESTS

Court of Protection rules that patient should have surgery against her wishes

The President of the Court of Protection has continued the approach outlined in previous decisions of the court in relation to compelling a patient who lacks capacity to undergo surgery, in their best interests, in the case of *DH NHS Foundation Trust v PS* [2010] EWHC 1217 (Fam).

PS is a 55-year-old woman who has significant impairment in her intellectual functioning. She lacks capacity to make decisions about her care. She is suffering from cancer of the uterus and the medical opinion is that she should undergo surgery.

Attempts had been made to explain surgery to PS. She had agreed on a previous occasion to undergo an operation in relation to her cancer but she had then refused to attend hospital. She also suffers from a needle phobia. The treating team are of the view that she may require special arrangements (including sedation) in relation to her pre and post-operative care.

The President held that it was in PS's best interests to undergo surgery and confirmed that sedation could be used to convey her to hospital, if required. The President also agreed that she may need to be detained at hospital for post-operative care. The court did not believe that it was necessary to invoke the Deprivation of Liberty Provisions under Schedule 1 of the Mental Capacity Act 2005 and this was dealt with within the declarations available to the court.

Mills & Reeve has acted in several cases of a similar nature both historically under the inherent jurisdiction of the High Court and more recently under the Mental Health Act and would be happy to discuss issues relating to this type of application with readers.

For further information or advice please contact [Helen Burnell](#) on 020 7648 9237 or [Jill Mason](#) on 0121 456 8367.

PATIENT MATTERS – RIGHT TO LIFE

Claim for damages allowed under the Human Rights Act following suicide of a detained inpatient

The family of a patient detained under Section 3 Mental Health Act 2007 (MHA) who committed suicide whilst under the care of South Essex Partnership NHS Foundation Trust (the trust) has been awarded damages of £10,000 and costs against the trust under Article 2 of the Human Rights Act 1998 (Article 2), which protects a person's "right to life".

The patient had a 30-year history of mental illness and had most recently been diagnosed with paranoid schizophrenia. Prior to her death, she had absconded from hospital on several occasions and had threatened to harm herself.

The court found that the trust had breached Article 2 because the patient was at a "real and immediate risk of suicide or self-harm" and therefore the trust should have done everything that could reasonably be expected of it to prevent the patient's suicide. In particular, the trust was criticised because:

- the doctors employed by the trust had not read the patient's medical history and did not therefore realise that she had absconded several times and threatened to harm herself;
- it failed to follow its own policies;
- there was no documented risk assessment or care plan; and
- higher levels of observations were never engaged.

The damages award confirms a distinct cause of action for cases such as this which is separate from a claim in negligence. For further information please see our client briefing which can be accessed [here](#).

At the time of writing the case, *Savage v South Essex Partnership NHS Foundation Trust*, has not yet been formally reported and so we are unable to provide you with a link to the judgment.

For further information or advice please contact [Lucy Johnston](#) on 01223 222366 or [Alison Fielder](#) on 0121 456 8454.

PATIENT MATTERS – HEALTH AND SAFETY

NHS trust ordered to pay £100,000 following patient death

Great Western Hospitals NHS Trust have been fined £75,000 this week and ordered to pay £25,000 costs for putting patient safety at risk through negligent storage and mismanagement of drugs.

In May 2004 a female patient who had just given birth, Mayra Cabrera, was mistakenly given an epidural drug by intravenous drip instead of saline solution, causing her immediate death. The two drugs had almost identical packaging and were stored in the same cupboard.

Following an inquest verdict of unlawful killing, the Health and Safety Executive (HSE) prosecuted the trust for breach of section 3(1) of the Health and Safety at Work Act 1974.

This is a stark reminder to all health bodies of the broad application of the Health and Safety at Work Act 1974. Whilst HSE policy excludes purely clinical decision making, they continue to investigate the policies and procedures that surround clinical incidents. Several prosecutions have taken place in recent years, including the 2006 prosecution of Southampton University Hospitals NHS Trust for deficiencies in the supervision arrangements for junior doctors.

Trusts should take steps to carefully consider their arrangements for identifying and managing all the risks that arise out of their services and check that they are complying with the Health and Safety at Work Act and not just NHS policy.

For further information or advice please contact [Duncan Astill](#) on 0121 456 8318.

PATIENT MATTERS – MENTAL HEALTH ACT

Court rules that disclosure of medical reports should be ordered even if this could lead to a deterioration in a patient's medical condition

The background to the case of *RM v St Andrew's Healthcare* [2010] UKUT 119 (AAC) (which can be accessed [here](#)) is that the applicant, who had been detained under section 3 of the Mental Health Act had learnt, during previous proceedings, through the disclosure of documentation, that he had been covertly medicated. This knowledge led to the patient refusing medication and becoming suspicious of food and drink and a subsequent deterioration in his condition.

In the current proceedings the patient had applied for discharge and the treating trust was objecting to the disclosure of reports that showed that once again the patient was being covertly medicated. The Upper Tribunal decided the legal consequences of non-disclosure could not be justified by the short-term adverse effects of disclosure on the patient's health. It set aside the non-disclosure direction made by the First-tier Tribunal in respect of two reports which revealed the patient was being medicated covertly.

Rule 14(2) of the Tribunal Procedure (First-tier Tribunal) (Health, Education and Social Care Chamber) Rules 2008 empowers the First-tier Tribunal to prohibit disclosure if it is satisfied that:

- disclosure is likely to cause serious harm to the patient (or any other person); and
- having regard to the interests of justice, non-disclosure is proportionate.

The First-tier Tribunal found disclosure was not in the patient's medical best interests because his health had deteriorated following similar disclosure on a previous occasion. Furthermore, non-disclosure did not prevent the patient from making representations on the reports because they had been seen by his legal representatives. Non-disclosure was therefore proportionate.

The Upper Tribunal however permitted disclosure. The overriding objective requires that cases are dealt with fairly and justly and this includes ensuring full participation in the process, as far as practicable. Further, rule 14(2) expressly requires consideration of the interests of justice and the correct test is whether non-disclosure would prevent the patient from effectively challenging his detention.

Without information about his covert medication, the patient would be excluded from the "real process", and his legal team severely hampered from participating effectively in that process. Non-disclosure would therefore sacrifice the patient's right to effectively challenge his detention and such legal implications could not be justified by the risk of any adverse impact on his health.

For further information or advice please contact [Ami Patyal](#) on 020 7648 9257.

PATIENT MATTERS – INQUESTS

Coroner's open verdict quashed because investigation too narrow

David Jones suffered from Asperger's Syndrome and Crohn's disease. He was prescribed fentanyl (a strong opioid painkiller) by his GP but had already been prescribed fentanyl and morphine by out of hours doctors' services three times during the preceding week. He was found dead in bed as a result of fentanyl toxicity. An inquest was held and the coroner adopted a narrow view as to its scope. He referred to the unexplained question of how the deceased came into possession of sufficient fentanyl to achieve such a high blood level but assumed it was from an unknown source. He therefore delivered an open verdict.

The deceased's mother instigated further investigations and, as a result decided to seek a judicial review of the coroner's verdict. The divisional court quashed the inquisition and a fresh inquest was ordered (with a jury) on the basis that:

- The coroner had failed to investigate how the deceased came into possession of such a large amount of fentanyl. A full and proper investigation into the means by which the

deceased died would have involved investigating, in particular, whether the quantity of the fentanyl prescribed (and apparently used) could have been fatal in certain circumstances and, if so, whether such circumstances were present. If that quantity could have been fatal, it would be necessary to inquire into how and why the deceased was repeatedly prescribed fentanyl. There was a possibility of a conclusion of accidental death if a further inquest was held.

- There was a wider public interest in a full inquiry into the means by which the deceased had died given that there had been a number of deaths both in this country and the US linked to unintended overdoses of fentanyl. Such an inquiry would address a number of issues including the degree to which the medical profession was alive to the possible danger to life presented by the prescription of fentanyl.
- The circumstances in which the deceased came to be given repeat prescriptions over a short period of time, apparently on demand, and, in the case of the out of hours services, without reference to the deceased's medical records, were of obvious public concern.

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

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

PATIENT MATTERS – COURT OF PROTECTION

Court of Protection case heard in open court

Traditionally all Court of Protection cases have been heard in secret, it being the sole remaining court where all proceedings have been held in private, until now. The Court of Protection was established by the provisions of the Mental Capacity Act 2005 to deal with the affairs of those who lack capacity.

This case relates to Derek Paravacini, a well known 30-year-old man who is totally blind and suffers from learning difficulties associated with an Autism Spectrum Disorder. He is incapable of leading an independent life. However, despite his severe disabilities, he is a man of remarkable accomplishment, a musical prodigy. His life story was described as being of “compelling human interest” which had attracted public attention in the media.

The recent Court of Protection hearing appointed Mr Paravacini's parents and sister as “deputies” to enable them to handle his affairs on his behalf and for the first time selected members of the press were allowed into the hearing.

The decision to allow the public into the hearing had originally been opposed by the official solicitor acting for Mr Paravacini and the issue went to the Court of Appeal to be resolved. The Court of Appeal observed that the public interest may, in exceptional cases, outweigh the privacy which those with a disability can normally expect in relation to a hearing in the Court of Protection. The court emphasised the need for any judge making a decision such as this to consider whether any article 8 (right to respect for private and family life) under the European Convention on Human Rights may be intruded upon if such an order was made.

In this case, the media were granted access as allowed by the High Court. It should be noted that, as stated above, this type of ruling would be exceptional and the usual approach of hearings in private can be expected to be followed by the Court of Protection.

For further information or advice please contact [Helen Burnell](#) on 020 7648 9237.

PATIENT MATTERS – CHILDREN

ECHR ruling on removal of child from parents in suspected abuse case

The case of *M.A.K. and R.K. v the United Kingdom* related to incidents from 1997-98.

A child had injured herself in the genital area whilst riding her bike, there had also been previous unexplained bruising of which the GP was aware. The father took the child to hospital and left her with the doctor to go to work, with the mother expected to arrive soon thereafter. He asked that there be no examinations until the mother was there. The doctor undertook an examination anyway. When the mother arrived she was informed of this and that the local authority had been notified. A social worker informed her that the doctor thought the child had been abused. With the mother's consent, a police surgeon examined the child's legs and genitalia.

That night the parents were refused access to the child on the request of the local authority. The wife asked for a second opinion but the social workers refused. The child remained in hospital for tests. Ten days after her admission (and separation from her parents) the child was discharged with a supporting letter from the doctor saying that there was insufficient evidence to say she had been abused.

The applicants then made a complaint to the NHS and it escalated through the court system. They argued that the separation was in breach of respect for their private and family life under Article 8 of the European Convention on Human Rights (the ECHR) and that the examinations without consent were an interference with the child's physical and moral integrity.

The court found that there had been an unjustified breach of Article 8, given the delay in carrying out tests on the child. The separation was not considered proportionate by the court.

Practitioners are reminded by the court's findings that there must be lawful authority to remove a child from their parent's care/prevent contact and that where there are allegations of abuse, these must be investigated as promptly as possible.

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

For further information or advice please contact [Helen Burnell](#) on 020 7648 9237 or [Ruth Creed](#) on 0121 456 8323.

NICE publishes draft guidance on strategies to prevent unintentional injuries among under 15s

The above draft guidance was published on 17 May 2010. One of the provisions is that all children under 5 should have an inspection of their house carried out to ensure they are safe. Parents would be expected to allow health inspectors into the family home to check heaters, stairs, taps etc.

The guidance outlines that health visitors, school nurses and GPs should be told if children are repeatedly admitted to A&E departments for accidental injuries as well. Practitioners will be aware of the recommendation for increased communication between agencies in the Lord Laming reports and these appear to be following that trend.

Only registered stakeholders can comment on the provisional recommendations made, via the NICE website, which can be found [here](#). Individuals and organisation not registered as stakeholders are not able to comment but can speak to a registered stakeholder or register themselves.

The consultation closes on 15 June 2010.

For further information or advice please contact [Helen Burnell](#) on 020 7648 9237 or [Lucy Johnston](#) on 01223 222366.

Court of Appeal overturns GMC decision to strike off doctor who allegedly accused woman of murdering her son

The Court of Appeal has ruled that Dr Southall is to be placed back on the medical register following a ruling that the GMC had not given adequate reasons for striking him off following his involvement in a case involving Mrs M. Mrs M claims that Dr Southall accused her of killing her son, who apparently hanged himself aged 10.

The case is to be remitted back to the original panel and the GMC has said it will take immediate action to resolve the case. The GMC has also said that it will review the guidance it gives to paediatricians involved in child protection cases. We do not have a timeframe for the anticipated guidance as yet but expect that it will be keenly anticipated by all NHS professionals working in the child protection arena.

For further information or advice please contact [Helen Burnell](#) on 020 7648 9237 or [Ruth Creed](#) on 0121 456 8323.

Guidance on the discharge from hospital of children and young people with high support needs

Guidance has been produced by the Council for Disabled Children that provides a framework to assist staff in hospitals, as well as the commissioners and providers in primary care trusts, when negotiating and planning the discharge of children and young people with high support needs. The guidance is available to download [here](#).

The guidance relates to children and young people who normally require an extensive package of care, 24 hours a day. The council sets out the key basic principles that should be applied to discharge cases.

The guidance should be read in conjunction with the *National Framework for Children's Continuing Care* which was issued by the Department of Health and came into force on 1 April 2010. A summary of the National Framework can be found in the May edition of the *Health Legal Update* and can be accessed [here](#). Reference should be made to the *Children's Continuing Care* guidance when considering the assessment, decision making and funding process, in relation to the discharge plan.

The guidance suggests that the planning process should start as early as possible and as soon as it is likely that a child will require a home care package. However, the guidance warns against hospital staff discussing the level of support and creating unrealistic expectations for the parents.

When undertaking an assessment of the child's needs, the council suggests that this should be based on an individual assessment. The assessment should include the input of other agencies, such as housing and social services, who may be involved with the child or the family.

For further information or advice please contact [Sonal Lala](#) on 0121 456 8248 or [Jill Mason](#) on 0121 456 8367.

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