The Licensing of Health Facilities Bill

Improving patient safety through increased legislation of healthcare providers

New legislation governing cosmetic surgery is currently being prepared by the Minister for Health, Dr. James Reilly. The Minister has indicated that the Licensing of Health Facilities Bill, which is due to be published later this year, will provide for a mandatory licensing system of public and private health service providers. The proposals are based broadly in line with recommendations made by the Madden Commission and are designed to improve patient safety by ensuring that healthcare providers do not operate below certain standards. The intention is the creation of a system which instills public confidence.

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The Licensing of Health Facilities Bill

One of the main issues of concern surrounds the regulation of medical devices. The recent problems caused by the Poly Implant Prothèse (PIP) defective breast implants, involving circa 1,500 Irish women, is at the centre of this concern. In some cases the women still haven’t been informed as to what type of implant was used during their procedure. This topic was recently the subject of an Oireachtas hearing before the Committee on Health and Children. The Committee were updated by the Irish Medicines Board (IMB), who recently met with the operators of the relevant Healthcare Service Providers where women underwent procedures and received PIP implants between 2000 and 2007.

The IMB informed the Committee that upon being notified of a potential issue in March 2010, they in turn notified the relevant clinics/hospitals. Following receipt of further information, the IMB advised each of the clinics/hospitals to notify their former patients who had received PIP implants. The committee were informed that this process was ongoing.

The IMB is the authority for ensuring standards for medical devices in Ireland. However, medical devices can be placed on the market anywhere in the EU, and the IMB has no role in authorisation before devices come into the Irish market, leaving the public potentially susceptible to injury. The PIP implants were manufactured in France and were awarded with the CE (Conformité Européane) mark based on pre-market data. There is currently legislation being discussed by the EU Commission on the reform of medical devices laws and their regulation and this is expected to be published by July/August this year.

On a national level, further legislation has been promised by the end of 2012 to ensure practitioners have adequate clinical indemnity insurance and to address current issues surrounding medical practitioners practising cosmetic surgery. Under current laws, a doctor can set themselves up as a cosmetic surgeon without the requisite qualifications. The lack of a central register or authority also means that doctors do not have to report cases involving ‘faulty’ procedures.

The Irish Association of Plastic Surgeons has been calling for regulation since 2007, and legislation is now long overdue. The Medical Defence Union, which provides indemnity cover to doctors, issued a statement in 2006 estimating that over the last ten years £8.5 million had been paid out for claims of poor cosmetic surgery between the UK and Ireland. Unless new laws are introduced this year as promised, the industry of cosmetic surgery in Ireland will be open to abuse, with little safeguards for people that opt to avail of these procedures.
What lies ahead for Primary Care Centres

As developers continue to search for new sources of income and look to Primary Care Centres those who have long been supporters of the Primary Care model continue to seek to progress their plans. However, the challenges facing these parties continue to grow while the key obstacle remains, funding.

In April Roísín Shortall, Minister of State Department of Health with responsibility for Primary Care, said that unused Garda stations may be converted into Primary Care Centres over the next number of years. Minister Shortall went on to say that “what we need to do is bring in to use, for health purposes, any empty buildings that are suitable for conversion” and that among the ideas being looked at were suitable, vacant Garda stations. Minister Shortall’s comments were not well received by all of those who have been seeking to build and develop centres of their own in recent years. One company, who will begin the construction of a €3.5m primary care project in Mayo this summer, said “we have had a strategy for ten years, and invested money on the back of that strategy. I am concerned that there are different agendas at work in the Department of Health”.

Eversheds sponsored and addressed the recent Primary Care conference entitled “Primary Care Centre Development Opportunities Conference 2012” which was held at the Royal Marine Hotel in Dun Laoghaire on 19 April 2012. The conference was attended by investors, developers and representatives of the HSE. Much debate was had on a number of key issues and Chris Wheeler, a Partner in Eversheds’ Construction and Projects Group here in Dublin, addressed the conference. He gave a presentation on the “Legal Considerations in setting up Primary Care Centres”. The overall feedback from the conference was that the key to unlocking funding was private sector finance.

Primary Care Centres and more specifically their direction was also a topic of conversation at the recent IMO conference in Killarney. IMO Chief Executive George McNeice said that he endorsed Minister Shortall’s plan and said that there was a “yawning gap” between what had been delivered and what had been promised. At the same conference, Minister Reilly announced that the management of chronic illness is to be transferred from hospitals to Primary Care Centres under a new initiative. Between 15 and 20 Primary Care Centres will be chosen to act as demonstrator models in a new approach. The Minister said that the goal was to improve quality and outcomes while allowing greater self-management by patients of their own conditions.
Irish Dental Association welcomes regulation of tooth whitening

On the 26th of September 2011, The Irish Dental Association welcomed the passing of a new European Directive which regulates the use of hydrogen peroxide in tooth whitening products. The Directive was introduced in line with advice from the European Scientific Committee on Consumer Safety. Member States will have 12 months to transpose the Directive after its publication.

The new regulation ensures that properly qualified dentists are carrying out tooth whitening, which is a dental procedure, that safe products are being used, and that the treatment is restricted to those over eighteen. Furthermore, the new Directive prohibits the use of tooth whitening products containing over 6% of the chemical hydrogen peroxide.

For products containing between 0.1% and 6% of the chemical, a consultation and first treatment by a dentist will be required, after this, the patient will be able to continue the treatment by themselves.

VAT on Medico-Legal Reports

Healthcare service providers, specifically independent medical experts, should be aware of the recent change in the VAT rules and the application of VAT to certain medico-legal reports.

Particular attention should be paid to the decision in the Unterpirtinger Case C-212/01 before the European Court of Justice and the VAT rate, if applicable, in Appendix B of the below link to the revenue leaflet:
Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) (Amendment) Regulations 2012

The Principal Regulations have been amended to the effect that where a designated centre provides care only to those who have been assessed as not requiring full time nursing care, the person in charge is not required to be a nurse with the minimum of three years experience in the area of geriatric nursing within the previous six years, provided that the management arrangements of the designated centre ensure that the assessed care needs of the residents are at all times met.

In addition the designated centre is not required to have an appropriately qualified nurse to be on duty and in charge of the designated centre at all times, provided the management arrangements of the designated centre ensure that the assessed care needs of the residents are at all times met.

In both situations a designated centre must notify the Chief Inspector when it proposes to make management arrangements pursuant to the regulation.

Recent cases

**OK v Hospital**

In January 2012 this “symphysiotomy” test case came before Mr Justice Ryan for its second High Court hearing. Instructed by the insurers we represented the interests of the Defendant. Previously the Supreme Court had overturned a High Court decision which had struck out the Plaintiff’s case on the basis that the Defendant was prejudiced by the delay in bringing the proceedings. The Supreme Court however afforded the Plaintiff/Applicant the opportunity to “reformulate” her pleadings in respect of a precise and net clinical negligence aspect of her claim. Mr Justice Ryan found in favour of the Plaintiff in terms of her (reformulated claim). A Notice of Appeal has been lodged in the Supreme Court. They have given the matter priority and they have confirmed that the Appeal will in fact proceed on 23 May 2012.

**Plaintiff v Private Hospital**

In a recent case handled by our healthcare team, the hospital sought to defend the Plaintiff’s claim on the basis that the Plaintiff had failed to institute proceedings within the statutory time period and as such it was argued that the matter was statute barred. We ran the Statute of Limitations as a preliminary issue before the President of the High Court.

In finding that the Plaintiff’s claim was not statute barred, the Court appears to have altered the interpretation of the Statute of Limitations as it previously applied to medical negligence claims and, in particular, MRSA claims. As such, the matter is now under Appeal to the Supreme Court as the ruling may have a serious impact for future defences of claims of this nature.
Boy awarded €11.5m following catastrophic injuries

The High Court has recently approved a landmark settlement of €11.5m for the benefit of a ten year old boy who suffered catastrophic injuries when he was involved in a road traffic accident in County Clare in 2008. The child is quadriplegic and will require 24 hour nursing care for the rest of his life. While approving the settlement and referring to it as “excellent” Judge Mary Irvine, who chairs the Medical Negligence Working Group, said that “the reality is we don’t know when people are going to die” and that “we are gambling every day”.

In October 2010 the Medical Negligence Working Group unanimously reported that legislation was required to allow cases be settled using Periodic Payment Orders (PPOs). This method has now been adopted in an interim manner by the State Claims Agency however the legislation is still awaited. Private insurers have not shown the same appetite for the method. Awards of this size will likely cause a stir in the insurance market and they may now reconsider their position. A difficulty arises because no insurance product, we understand, is currently available to make this system possible for private insurers. Clearly if there are further awards at this level a solution will simply have to be found as PPO’s will be the norm, in the absence of a functioning long-term illness card system.
Appointments:

Government appoints new Secretary General in the Department of Health

The Government has appointed Dr Ambrose McLoughlin as the new Secretary General in the Department of Health. He will replace Mr Michael Scanlan who retired this month having been Secretary General for the past seven years. Prior to his appointment Dr McLoughlin was Registrar and CEO of the Pharmaceutical Society of Ireland. He has also worked on various health boards and was at the forefront of the implementation of the 2007 Pharmacy Act.

Judicial appointments

Twelve new judges have been appointed to the Circuit Court and District Court.

Sarah Berkeley, BL; Mary Ellen Ring, SC; and Carmel Stewart, SC; have been nominated for appointment to the Dublin Circuit.

Pauline Codd, BL; Barry Hickson, SC; and Keenan Johnson, solicitor, will serve as unassigned judges of the Circuit Court and Judge David Riordan has been assigned to the Cork Circuit.

Alan J. Mitchell, solicitor; Eugene O’Kelly, solicitor; Marie Quirke, solicitor; Kevin Staunton, solicitor and Michael Walsh, solicitor have been nominated for appointment to the District Court.

The appointments arise mainly from judicial retirements between September 2011 and February 2012, as well as the death last summer of Judge Con Murphy and the promotion of Judge Michael White to the High Court in October 2011.

Court fees

The Courts Service has introduced increases in certain fees, following a demand from the Department of Finance for an increase in its fee income. The increases are across the board and range from 8.3% to 455%. The most relevant increases from a Litigation perspective are the following:

- Notice of Motion in the High Court from €40 to €60 (plus 50%);
- Setting down an action for trial increased from €120 to €130 (plus 8.3%); and
- Notice of Motion in the Supreme Court increased from €40 to €62 (plus 55%).
Bills expected to be published during 2012:

A number of Bills are expected to be published from the start of the current Dáil session to the beginning of the next session, these include:

**Health**

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<tr>
<th>Bill</th>
<th>Description</th>
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<tr>
<td>Health (Pricing and Supply of Medical Goods) Bill</td>
<td>To empower the Minister to introduce a system of Reference Pricing and Generic Substitution for drugs prescribed under the GMS and community drug schemes</td>
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<tr>
<td>Health and Social Care Professionals (Amendment) Bill</td>
<td>To amend the 2005 Act in relation to the membership of the Council and other technical matters</td>
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<tr>
<td>HSE Governance Bill</td>
<td>To provide for the abolition of the HSE Board and to provide for replacement governance structures</td>
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The Group regularly produces and circulates client e-zines and alerts. We also host breakfast briefings on current topical matters which are of relevance to both our own healthcare clients and the greater healthcare community. Please contact healthcare@eversheds.ie if you wish to receive updates.