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Who regulates Health and Social Care?

HSE is the national independent regulator for health and safety in the workplace. This includes private or publicly owned health and social care settings in Great Britain. We work in partnership with our co-regulators in local authorities to inspect, investigate and where necessary take enforcement action. Further guidance on whether work activities are regulated by HSE or the local authority can be found on the HSE web page.

There are many other bodies responsible for regulating different aspects of these sectors, many of whom have more specific powers and legislation than HSE and may therefore be in a better position to respond to patient or service user incidents or complaints. For more detailed guidance, please refer to the A-Z guide to the Health and Safety (Enforcing Authority) Regulations 1998.

Our role in patient and service user incident investigation

Healthcare is managed and regulated differently in England, Scotland and Wales. The various regulators across GB have a range of powers to secure improvement and/or justice. Where those regulators have patient / service user safety within their remit, and have powers to secure justice, we will not - in general - investigate or take action. However we may investigate, in accordance with our selection criteria (as set out below), where other regulators do not have such powers.

In England, Scotland and Wales regulatory bodies such as the General Medical Council (GMC) and Nursing and Midwifery Council (NMC) have important roles to play in ensuring that professional standards are maintained and may be better placed than HSE to secure justice, improve standards or prevent a recurrence.

The roles of health and social care regulators, professional bodies and others are described below, where we also link to relevant agreements with them. The agreements set out our respective roles and responsibilities, clarify which regulator is likely to take action and describe information sharing arrangements. A number of agreements are currently in development.

HSE sets out its overall public safety policy and priorities for enforcement on our website. In general we will only investigate where:

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- The accident or incident is reportable under the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) and falls within our incident selection criteria. These tend to include major non-clinical accidents such as trips and falls, scalding and those arising from people handling; or
- The accident or incident is not RIDDOR reportable, but has clearly been caused by well established standards not being achieved and the failure to meet them arises principally from a systemic failure in management systems. We will only investigate such incidents where a death has occurred, or where the harm was so serious that death may have resulted; and where admissible evidence is likely to be available

The 'established standards' that HSE will consider, in deciding whether investigation is appropriate, include:

- widely recognised, followed and expected practices for dealing with a particular issue; or
- NHS, Department of Health or other 'safety alerts', or similar warnings, that are widely known across the sector; or
- duty holder's (ie healthcare providers) internal guidance, or well established external guidance from others, where this addresses issues that fall within HSE's broader selection criteria.

'Established standards' will not, in general, include those which cover:

- the standard of care or treatment, such as those dealing with the types of drugs or approach that might be appropriate; or
- 'quality of care' issues, such as those dealing with hydration or nutrition.

Systemic failures in management systems may include:

- absence of, or wholly inadequate, arrangements for assessing risks to health and safety;
- inadequate control of identified, or well recognised, health and safety risks; or
- inadequate monitoring, or maintenance, of the procedures or equipment needed to control the risk

In general, we will not investigate where:

- the incident arises from poor clinical judgement (rather than a failure to implement the actions flowing from clinical judgements);

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- the incident is associated with ‘standards of care’, such as the effectiveness of diagnostic equipment; or the numbers and experience of clinicians;
- the incident is associated with quality of care, such as hydration and nutrition; or
- the incident arose from the disease or illness for which the person was admitted, (whether or not that disease was properly diagnosed or treated) - unless the prime cause was inadequate maintenance of, or training in the use of equipment needed to treat the disease or illness; or otherwise falls within the criteria set out above, or the worked examples given below.

The policy in practice – some worked examples

The examples provided on our website illustrate how this policy works in practice in certain situations.

These will be added to over time, to help translate the overall policy and guidance into consistent decision making.

Other regulators

Health and social care are devolved matters and there are different regulators in England, Scotland and Wales. The powers, roles, remits and ways of working of each of these regulators are all different. A brief summary of their roles and responsibilities follows. Further information can be found on their websites:

Regulators in England

Care Quality Commission (CQC) - In England, the CQC is the independent regulator for the quality and safety of care. This includes the care provided by the NHS, local authorities, independent providers and voluntary organisations in registered settings. CQC register most but not all types of care. They regulate:

- Providers of healthcare services to people of all ages, including hospitals, ambulance services, clinics, community services, mental health services and other registered locations, including dental and GP practices.
- Providers of social care services for adults in care homes (where nursing or personal care is provided), in the community and in people’s own homes.
- Providers of services for people whose rights are restricted under the Mental Health Act.

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CQC register care services under the Health and Social Care Act 2008 and associated regulations. CQC focuses on outcomes for people who use services and assess these using information from a wide range of sources. This includes reports of incidents, as well as information from both people who use services, through inspections carried out by expert teams. CQC publishes information on its judgements including a rating to help people choose care; and taking action when services need to improve. CQC have a wide range of enforcement powers that they can use, if they find care services are not meeting fundamental standards. In particular they can prosecute, impose penalties, and otherwise secure improvements under the Health and Social Care Act 2008 (Regulated Activities Regulations) 2014.

Details of HSE's agreement with the CQC is contained within the Memorandum of Understanding. In general CQC, rather than HSE, will deal with the majority of patient and service user serious health and safety incidents.

Regulators in Scotland

Healthcare Improvement Scotland (HIS) - Healthcare Improvement Scotland (HIS) was formed on 1 April 2011. The Healthcare Environment Inspectorate (HEI), which was set up in April 2009, is now part of HIS. HIS' focus is to reduce healthcare associated infection risk to hospital patients, to improve the care of elderly patients, and to regulate independent healthcare services through an inspection framework. HIS inspectors do this by carrying out announced and unannounced inspections in acute NHS hospitals in Scotland to check that the NHS QIS standards for older people in acute care and standards for prevention and control of healthcare associated infection are being met.

A Memorandum of Understanding has been agreed between HSE and HIS - has been produced on working arrangements between the two organisations.

Care Inspectorate - In April 2011 the Social Care and Social Work Improvement Scotland (SCSWIS) was created to scrutinise social care, social work and child protection services. In September 2011, their everyday name became the "Care Inspectorate" although the formal name (SCSWIS) as set out in legislation was not changed. As with HIS, the role of the Care Inspectorate is to inspect, regulate and support improvement of services and provide public assurance on service quality.

HSE has a liaison agreement with Scottish Local Authorities and the Care Inspectorate. The aim of the agreement is to describe and promote effective working arrangements between the respective organisations.

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Mental Welfare Commission for Scotland (MWC) - The Mental Welfare Commission for Scotland (MWC) promotes the welfare of individuals with mental illness, learning disability or related conditions. It investigates cases where it appears that there may be ill-treatment, deficiency in care and treatment or improper detention of any such person. Following investigations, it can make and follow up recommendations.

A Liaison Agreement between the MWC and HSE has been agreed to promote effective working arrangements and information sharing on areas of mutual interest.

Regulators in Wales

Care Inspectorate Wales (CIW) - In Wales, CIW regulates social care, early years services and Local Authority care support services. Regulation includes registration, inspection, responding to concerns about regulated services, compliance support and enforcement.

HSE has agreed a Memorandum of Understanding with CIW and Local Authorities in Wales (gael yn Cymraeg) which outlines our respective roles and responsibilities to enable effective, co-ordinated and comprehensive regulation of care, safety and health in Wales.

Healthcare Inspectorate Wales (HIW) - In Wales, HIW's role is to review and inspect NHS and independent healthcare organisations. Services are reviewed against a range of published standards, policies, guidance and regulations. They also register independent services and have powers to take enforcement action in these matters. HIW is the Local Supervisory Authority (LSA) for the statutory supervision of midwives. It also has inspection and enforcement powers for the Ionising Radiation (Medical Exposure) Regulations, which stem from the Health and Safety at Work etc Act 1974.

HSE has a Memorandum of Understanding (gael yn Cymraeg) with HIW which has been agreed to promote effective working arrangements and information sharing on areas of mutual interest.

UK-wide regulators

Medicines and Healthcare Products Regulatory Agency (MHRA) - The MHRA is a government agency that is responsible for ensuring that medicines and medical devices work, and are acceptably safe. It is an executive agency of the Department of Health. The MHRA is responsible for the regulation of medicines and medical devices and equipment used in healthcare and the investigation of harmful incidents. The MHRA also looks after blood and blood products, working with UK blood services, healthcare providers, and other relevant organisations to improve blood quality and safety.

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As the UK Competent Authority, the MHRA is responsible for the regulation of devices throughout the UK and for issuing Medical Devices Alerts (MDAs). In Scotland, Health Facilities Scotland (HFS), which is part of NHS Scotland, works closely with the MHRA, and will notify MHRA of each adverse incident report in Scotland and the results of any investigation. For example, HFS may identify a need for a MDA and will liaise with MHRA on the need for and drafting of the alert.

HFS, receives adverse incident reports from NHS Boards and Local Authorities. It is responsible for coordinating investigations so that, as far as possible, root causes can be established and remedial action taken to prevent or reduce any identified risks.

HSE has an agreement with the MHRA which formalises current working arrangements on matters concerning medical devices, such as: co-operating on non-fatal accident investigations; investigating fatal accidents; sharing information and awareness-raising.

Professional bodies

In addition to these regulators, there are also professional regulatory bodies who aim to ensure that proper standards are maintained by health and social care professionals and act when they are not. In order to practice in the UK, professionals are required to register with the appropriate body.

These bodies fulfil similar functions for different professions across the UK. Their main duties are to:

- maintain an up-to-date register of professionals;
- set and maintain standards for education, training and conduct; and,
- investigate when these standards are not met or when a professional's fitness to practise is in doubt.

A summary of the professions covered by each body follows. For further information on their role, please check their websites:

Healthcare Professional bodies

- **General Medical Council (GMC)** - The GMC regulates doctors. HSE has a Memorandum of Understanding with the GMC which is an agreed framework for co-operation and

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collaboration between the two organisations. The Memorandum sets out the respective roles and responsibilities and outlines mechanisms in place for effective liaison relationships

- **Nursing and Midwifery Council (NMC)** - The NMC regulates nurses and midwives
- **General Dental Council (GDC)** - The GDC regulates dental professionals in the UK. This includes dentists, dental nurses, dental technicians, clinical dental technicians, dental hygienists, dental therapists and orthodontic therapists.
- **General Optical Council (GOC)** - The GOC regulates optometrists, dispensing opticians, student opticians and optical businesses.
- **General Chiropractic Council (GCC)** -The GCC regulates chiropractors.
- **General Osteopathic Council (GOsC)** -The GOsC regulates osteopaths.
- **General Pharmaceutical Council (GPC)** - The GPC is the regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain.
- **Health and Care Professions Council (HCPC)** – The HCPC regulates 15 healthcare professionals: arts therapists, biomedical scientists, chiropodists / podiatrists, clinical scientists, dieticians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists / orthotists, radiographers, and speech and language therapists. From 1st August 2012, the HCPC also assumed responsibility for regulating social workers in England.

The work of these professional bodies is regulated by the Professional Standards Authority (previously known as the Council for Healthcare Regulatory Excellence). This authority aims to protect the health and well-being of patients and the public by scrutinising and overseeing the work of regulatory bodies that set standards for training and conduct of health and care professionals.

Social Care Professional bodies

- **Health and Care Professions Council (HCPC)** - The HCPC is the regulator of the social work profession and social work education in England.
- **Social Care Wales (SCW)** - The SCW is the social care workforce regulator in Wales.
- **Scottish Social Services Council (SSSC)** - The SSSC is the regulator of the social work profession and social work education in Scotland.

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