These notes refer to the Health Act 2006 (c.28) which received Royal Assent on 19 July 2006

HEALTH ACT 2006

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 3Chapter 1

Supervision of Management and Use of Controlled Drugs

110. Part 3 of the Act contains provisions intended to strengthen the arrangements for the safe management of controlled drugs in health and social care settings. It provides the legislative underpinning to the programme of action set out in *Safer management of controlled drugs*, the government's response to the Fourth Report of the Shipman Inquiry. The key elements are:

- all NHS healthcare organisations, and larger private healthcare organisations such as independent hospitals, will be required to nominate an officer of sufficient seniority – an "accountable officer" – to ensure that the organisation has robust arrangements for the safe and effective handling of controlled drugs. In NHS primary care, primary care organisations will exercise this responsibility on behalf of all the contractors with which they have contracted to provide services;
- a duty of collaboration will be placed on healthcare organisations, and on other local and national agencies such as professional regulatory bodies, police forces, the Healthcare Commission and the Commission for Social Care Inspection, requiring them to share intelligence on controlled drugs issues and to coordinate the action they take to protect patients and the public
- police officers, accountable officers and their staff and other authorised persons will have a right of entry and inspection into the premises of relevant healthcare providers to enable them to discharge these responsibilities. The power of entry will not necessarily be exercisable by all accountable officers.

111. The relevant authority regarding the regulation making powers within this Chapter are the Secretary of State in respect of England and Scotland, the National Assembly for Wales in respect of Wales and the Department of Health, Social Services and Public Safety in respect of Northern Ireland.

Section 17: Accountable officers and their responsibilities as to controlled drugs

112. Section 17 allows the relevant authority by regulations to determine the organisations which are to be required to appoint an accountable officer, the functions of the accountable officer, and the criteria to be satisfied in making appointments. The intention is that all NHS hospital trusts and primary care trusts, and the larger private sector healthcare organisations such as independent hospitals, should appoint accountable officers.

113. *Subsection (1)* sets out the general power to make regulations under which certain organisations ("designated bodies") are required to appoint accountable officers with specified responsibilities. The responsibilities are to relate to the management and use of controlled drugs in connection with activities carried on by or on behalf of

the organisation (eg a hospital trust) or by third parties under arrangements with the organisation (eg a primary care trust). *Subsection (2)* introduces the term "accountable officer". *Subsections (3) and (4)* define more closely the types of organisations which may be required to appoint an accountable officer, ie those which are directly or indirectly involved in providing healthcare or other activities which may involve the supply or administration of a controlled drug. *Subsections (5) and (6)* give examples of the detailed requirements which may be laid down in regulations, including criteria for appointment, funding, the requirement to follow best practice guidance, and responsibilities of the accountable officer. The regulations may also create offences or other procedures for enforcing any provisions of the regulations. *Subsections (7) and (8)* ensure that requirements set out in regulations can have application to a wide variety of settings in which controlled drugs may be supplied or administered, including care provided by third parties under contract to a designated body (eg a primary care trust). *Subsection (10)* allows regulations to cover issues not listed in (5) or (6).

Section 18: Co-operation between health bodies and other organisations

114. Section 18 allows the relevant authority to make regulations to require organisations ("responsible bodies") described in the regulations to co-operate, by sharing intelligence and coordinating action, in order to ensure the safe management of controlled drugs and to safeguard patients from harm. The intention is that the duty to co-operate would be applied to all bodies required to appoint an accountable officer under section 17, to police forces, to local authorities, and to regulatory bodies with inspection rights such as the Royal Pharmaceutical Society of Great Britain, the Healthcare Commission and the Commission for Social Care Inspection.

115. *Subsection (1)* sets out the power to make regulations for requiring organisations described in the regulations to co-operate and describes in broad terms the areas to be covered by the duty of co-operation. *Subsections (2) to (4)* specify the types of body to which the duty would apply ie. bodies that are concerned with the provision of healthcare, or carry on activities that involve the supply or administration of controlled drugs. *Subsections (5) to (7)* give examples of the requirements as to co-operation that may be included in the regulations, including the circumstances in which the duty to disclose information to other organisations could be triggered (subsection (5)(a)) and the duties which may be imposed on the accountable officer of the bodies concerned to make recommendations for action (subsection (6)) including recommendations relating to disciplinary action (subsection (7)).

Section 19: Meaning of "relevant person in section 18

116. Section 19 defines the term "relevant person" referred to in subsection (1) of section 18. This would allow any information that comes to the attention of responsible bodies, in relation to the use or management of controlled drugs by people who have no connection or contract with a designated or responsible body, to be shared by them under section 18. Examples of such people might be private doctors, individuals working for independent care homes which are not providing services to a Primary Care Trust or local authority and private dentists (and their staff).

Section 20: Controlled drugs: power to enter and inspect

117. Section 20 creates a power for police constables or other authorised persons to enter the premises of healthcare providers and to inspect the arrangements for the safe management of controlled drugs. This power would go beyond the existing provision in section 23 of the Misuse of Drugs Act 1971 (the "1971 Act"), which is limited to entering the premises of a person carrying on business as a producer or supplier of any controlled drugs. The intention is that the inspections would generally be carried out by police constables or by accountable officers appointed under section 17 and their staff, or by the regulatory bodies with inspection rights such as the Royal Pharmaceutical Society of Great Britain, the Healthcare Commission and the Commission for Social

Care Inspection although the section allows for other persons to be authorised by the relevant authority.

118. *Subsection (1)* sets out the general power. *Subsection (3)* prevents an authorised person from entering relevant premises which are or form part of a private dwelling unless they are accompanied by a police constable. However, it also creates regulation making powers which can prescribe circumstances in which this regulation does not apply, for example, in the regular inspection of care homes which are legally defined as private dwellings.

119. *Subsection (4)* allows the authorised person to take copies of relevant records and retain them. *Subsection (5)* defines the persons who would be authorised to carry out inspections, including accountable officers and staff of designated bodies and allows the relevant authority to authorise other persons in addition to accountable officers and their staff, while *subsection (6)* enables the relevant authority to exclude particular categories of designated bodies from the general authorisations under subsection (5). *Subsection (7)* allows the relevant authority to define more closely the categories of premises which are subject to inspection, subject to the general constraints of *subsection (8).*

Section 21: Offences in connection with power to enter and inspect

120. Section 21 creates an offence of obstructing a person making an inspection or deliberately concealing material or information relevant to the inspection. The offence is similar to that in section 23 of the 1971 Act. *Subsection (1)* defines the circumstances in which an offence is committed and *subsections (2) and (3)* the maximum penalties on conviction.

Section 22 Guidance

121. Section 22 allows the relevant authority to give guidance to designated bodies and responsible bodies about the appointment of the accountable officer, the accountable officer's functions and the duty to co-operate. Designated bodies and responsible bodies must have regard to guidance in exercising their functions *(subsection (4)).* The intention is that regulations will set out the essential requirements relating to accountable officers.

Section 23: Crown application

122. Section 23 extends the provision in this Chapter to the Crown and to people in the public service of the Crown. *Subsection (2)* provides that the Crown will not be criminally liable for contravention of any provision in this Chapter but any such contravention maybe declared unlawful by the relevant court.

Section 24 Relevant authorities

123. Section 24 sets out which authorities (the relevant authorities) have responsibility for the powers set out in this Chapter. The Secretary of State will exercise the functions to cover England and (after consulting the Scottish Ministers) Scotland. The National Assembly for Wales will exercise the functions for Wales and the Department of Health, Social Services and Public Safety will exercise the functions for Northern Ireland. Under *subsection (4)* any of the powers of a relevant authority to make regulations under this Chapter are exercisable, in relation to cross-border bodies (as defined under *subsection (5)*), by the Secretary of State (after consultation with the Assembly).

Section 25 Interpretation

124. Section 25 defines the terms used in this Chapter.