These notes refer to the Health and Social Care Act 2001 (c.15) which received Royal Assent on 11 May 2001

HEALTH AND SOCIAL CARE ACT 2001

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 5 : Miscellaneous and Supplementary

Patient information

Section 60: Control of patient information

291. This section enables the Secretary of State to make regulations for and in connection with requiring or regulating the processing of patient information in prescribed circumstances. This will make it possible for patients to receive more information about their clinical care and for confidential patient information to be lawfully processed without informed consent to support prescribed activities such as cancer registries. The Government places importance on the consistent use of informed consent as the basis for handling confidential patient information. The regulation–making power in this section is therefore intended to provide for exceptional situations where essential services cannot, having regard to the present NHS systems and available technology, operate on that basis.

292. In recognition of the inherent difficulties associated with using confidential information the Act builds in a number of safeguards over the use of this power to protect patients' interests. First regulations can only provide for the processing of patient information for medical purposes (defined in subsection (10)) where there is a benefit to patient care or where this is in the public interest. Secondly , regulations can only require the processing of confidential patient information, where there is no reasonably practicable alternative. The Secretary of State can only make regulations under the terms of this section following consultation with bodies representing the interests of those likely to be affected by the regulations and with the new statutory advisory group introduced by *section 61*. Finally any such regulations can only be made under the affirmative resolution procedure, requiring the consent of both Houses of Parliament (See *section 64(3)).*

293. It is envisaged that the Patient Information Advisory Group (to be established under *section 61*), will consider and advise the Secretary of State as regards each proposed use of the regulation-making power, including as regards the need to use the information and whether consent should be obtained.

294. The Data Protection Act 1998 governs, in broad terms, the processing of information relating to living individuals. This section does not amend that Act. In addition, regulations made under this section will not be capable of derogating from that Act (see note on *subsection (6)* below). Regulations made under this section may provide additional and more specific restrictions on the use of information relating to patients.

295. Information provided in confidence by patients is also subject to common law requirements which, being derived from case law, are difficult for healthcare professionals to apply with certainty in particular circumstances, especially since there has been little case law relating to healthcare settings. Regulations may provide that the

processing of patient information under the regulations is lawful despite any common law obligation of confidence (see note on *subsection (2)(c)* below).

296. *Subsection (1)* enables the Secretary of State, subject to limitations imposed by *subsections (3) – (6)*, to make regulations requiring patient information to be processed for medical purposes (as defined in *subsection (10))* and regulating such processing.

297. *Subsection (2)* specifies some of the ways in which the power conferred by *subsection (1)* may be used.

298. *Subsection (2)(a)* enables regulations to be made that require specified communications about patients to be disclosed to them by NHS bodies, in certain circumstances. Such regulations may only provide for these communications to be disclosed to those persons to whom they relate or principally relate or to a prescribed person on their behalf, for example a spouse. Such regulations are intended to support the NHS Plan commitment that clinicians will in the future be required to share information about patients with them.

299. *Subsection (2)(b)* enables regulations to be made which require the disclosure or other processing of specified patient information subject to conditions or the giving of undertakings. This will support public health work and important activities such as cancer registration where it is essential to maximise the patient information available.

300. *Subsection (2)(c*) enables regulations to be made to permit patient information to be processed lawfully where, but for the regulations, this may be prevented by an obligation of confidentiality at common law. This is subject to the limitations imposed by this section (see, for example, the note on *subsection (6))* and human rights requirements.

301. *Subsection (2)(d)* enables regulations to make provision for their enforcement by the creation of criminal offences.

302. *Subsections (3) – (5)* serve to limit the use of the power conferred by *subsection (1)* to make regulations requiring the processing of confidential patient information (as defined in *subsection (9*)).

303. *Subsection (3)* provides that regulations cannot be made under *subsection (1)* if the purpose for which confidential patient information would be used could be achieved in another reasonably practical way, having regard to cost and available technology. In practice this means, for example, that persons cannot be required to disclose confidential patient information where the purpose can be satisfied by use of anonymised information.

304. *Subsection (4)* requires the Secretary of State to carry out an annual review of whether regulations made under *subsection (1)* and requiring the processing of confidential patient information would contravene *subsection (3).* The review must be conducted within one month of each anniversary of the making of the regulations (*paragraph (a)*) and, if he determines that they would contravene *subsection (3),* he must vary or revoke them (*paragraph (b)*).

305. *Subsection (5)* provides that regulations may not be made under *subsection (1)* solely or principally for the purpose of determining the care and treatment that is to be provided to individual patients. The care and treatment of individuals should be determined by appropriate professional staff that work with, and are responsive to the preferences of, those in their care.

306. *Subsection (6)* provides that regulations made under this section cannot make provisions for the processing of information which are inconsistent with the provisions of, or the provisions in instruments made under, the Data Protection Act 1998.

307. *Subsection (7)* provides that before the Secretary of State may make regulations under this section, he must consult such bodies as appear to him to represent the interests

of those likely to be affected by the regulations as he considers appropriate in the light of the requirements of section 61. The consultation is intended to ensure that the regulations are fair and non-discriminatory.

308. *Subsection (8)* defines patient information as any information that is, or is derived from, information concerning a patient's physical or mental health or condition, the diagnosis of his condition or his care or treatment. In addition to information which directly identifies individuals, this would include information which is either anonymised (e.g. any information that cannot be tracked back to the individual) or coded (e.g. information that can be tracked back to an individual by persons in possession of the key to the code). It includes information recorded in any manner, whether electronically or manually.

309. *Subsection (9)* provides that "confidential patient information" for the purposes of the section is patient information that has been obtained by a person who owes an obligation of confidence to an individual where the identity of that individual is ascertainable from that information or from that information and other information which is in, or is likely to come into, the possession of the person processing the information .

Section 61: Patient Information Advisory Group

310. This section requires the Secretary of State to establish, by regulations, a committee to be known as the Patient Information Advisory Group. The Secretary of State is required to seek and have regard to the views of this Advisory Group prior to laying draft regulations before Parliament under section 60(1) or making regulations under section 60(4)(b).

311. The work of the Advisory Group is intended to provide an additional safeguard for patients as regards use of the power provided by section 60, complementing the safeguards included within that section. Before draft regulations under section 60(1) are laid before Parliament or regulations under section 60(4)(b) are made, the advice of the Advisory Group must be sought. The Secretary of State is required to publish the views of the Advisory Group.

312. In recognition that there may be other issues arising in relation to the processing of patient information, or other information obtained or generated through health service provision, the section also allows the Secretary of State to seek the views of the Advisory Group on these wider matters. It is envisaged that the Advisory Group's views will be sought on a range of issues pertaining to the confidentiality of patient information and standards of processing such information.

313. It is intended that professional and patient groups will be consulted on appointments to the Advisory Group and its proceedings.

314. A detailed commentary on the subsections of section 61 is set out below.

315. *Subsection (1)* requires the Secretary of State to establish by regulations the Patient Information Advisory Group as soon as reasonably practicable after Royal Assent.

316. *Subsection (2)* requires the Secretary of State to seek and have regard to the views of the Advisory Group prior to laying draft regulations before Parliament under section 60(1) or making regulations under section 60(4)(b).

317. *Subsection (3)* gives the Advisory Group the function of providing advice on wider patient and health service information issues at the request of the Secretary of State.

318. *Subsection (4)* specifies particular matters that may be contained in the regulations that establish the Advisory Group.

319. *Subsection (5)* places a duty on the Secretary of State to publish, in an appropriate manner, the advice provided to him by the Advisory Group on proposed regulations.

Services for disabled people

Section 62: Reports to Parliament on services for disabled people

320. *Section 62* amends section 11 of the Disabled Persons (Services, Consultation and Representation) Act 1986 ("the 1986 Act") so that, for England and Wales, the Secretary of State is required to produce annually separate reports on the development of health and social services for people with mental illness and people with learning disability . The reports can include other appropriate information, for example information from other Government Departments about services for which they are responsible. There will is no longer be a statutory requirement to include information on the number of people receiving treatment for mental illness/learning disability as in-patients in hospitals. This section changes the terminology from "mental handicap" to "learning disability" and includes a definition of learning disability for the purposes of Section 11 of the 1986 Act. The law in Scotland remains unchanged.

Prescribing rights

Section 63: Extension of prescribing rights

321. *Section 63* introduces new arrangements for the prescribing of medicines. Currently doctors, dentists and certain specified nurses, health visitors and midwives are authorised to prescribe prescription only medicines for human use. The Review of Prescribing, Supply and Administration of Medicines recommended the extension of prescribing rights to other health professionals.

322. *Section 63* amends section 58 of the Medicines Act 1968 which governs the sale, supply and administration of prescription only medicinal products both privately and within the NHS. New subsection (1)(e) enables new registered professional groups to be designated by order for the purpose of prescribing such medicines for human use. For example, physiotherapists may be given prescribing rights for certain drugs e.g. anti- inflammatories. One of the effects of this policy might be to remove the need for routine visits to the GP for continuing care.

323. *Subsection (3)* provides that the categories of persons who may be granted prescribing rights must be registered health professionals. It includes provision to ensure that health professionals regulated by statute under separate Scottish and Northern Irish legislation will have the same potential right to prescribe.

324. *Subsection (5)* allows Ministers to provide by order that specified descriptions of appropriate practitioner designated under *subsection (1)(e)* of section 58 of the Medicines Act 1968 (or nurses, midwives or health visitors designated under *subsection (1)(d)*) must comply with specified conditions relating to the circumstances of prescribing which may apply to appropriate practitioners .

325. *Subsection (7)* makes it an offence for a person to prescribe a medicinal product in contravention of a condition imposed under *subsection (4A)* of section 58 or to prescribe a medicinal product for which he is not an appropriate practitioner.

326. *Subsection (8)* enables the Secretary of State to establish an advisory body under section 4 of the Medicines Act 1968 , to consider whether prescribing rights should be granted to any additional group of health professionals and to advise on any conditions or limitations that should be applied to their prescribing, prior to the Section coming into force.

Section 64: Regulations and orders

327. *Section 64* makes provision about orders and regulations, in particular when they are exercisable by statutory instrument; the parliamentary procedures relating to statutory instruments; and how the powers in question may be exercised.

Section 65: Supplementary and consequential provision etc

328. *Section 65(1)* and *(2)* enable the Secretary of State by regulations to make such supplementary, incidental or consequential provision, or such transitory, transitional or saving provision, as he considers necessary to give full effect to the Act. This includes power to amend or repeal any enactment, instrument or document.

329. *Subsection (3)* provides that such regulations may also be made by the National Assembly for Wales, Scottish Ministers and the First Minister and Deputy First Minister in Northern Ireland in respect of devolved matters.

Section 66: Interpretation

330. This section contains definitions of certain terms used in the Act. In particular, it provides that "regulations" means regulations made by the relevant authority and defines "the relevant authority".

Section 67: Minor and Consequential amendments and repeals

331. *Section 67* gives effect to *Schedule 5* and the repeals specified in *Schedule 6*. *Schedule 5* makes minor and consequential amendments resulting from provisions in the Act. *Schedule 6* repeals provisions of enactments listed in that Schedule.

Section 68: Powers of National Assembly for Wales for Wales under amended Acts

332. *Section 68* provides that in the National Assembly for Wales (Transfer of Functions) Order 1999 any reference to an Act amended by this Act is to be treated as a reference to that Act as amended (except as regards the amendments made by section 27 of this Act).

Section 69: Financial provisions

333. *Section 69* provides for expenditure relating to the Act to be paid out of money provided by Parliament.

Section 70: Short title, commencement and extent

334. *Section 70* gives the short title of the Act and makes provisions for commencement and extent.