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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made under the Care Standards Act 2000 (“the Act”) and apply to independent hospitals, independent clinics and independent medical agencies in Wales. The Act provides in relation to Wales for the registration and inspection of establishments and agencies, including independent health care establishments, by the Welsh Ministers and empowers the Welsh Ministers to make regulations governing their conduct.

Section 2 of the Act defines a number of “listed services” which (if they are provided in an establishment) bring an establishment within the definition of an independent hospital. Regulation 3 provides that “listed services” include treatment using the prescribed techniques and technology set out in regulation 3(1). Regulation 3(2) then excepts certain techniques and technology from being “listed services”, namely certain infra-red heat treatments, certain laser treatments and the use of ultra violet lamps for acquiring an artificial sun tan. Regulation 3(3) excludes certain establishments from the definition of an independent hospital under section 2 of the Act. The exceptions include establishments providing medical or psychiatric treatment or palliative care but which have no overnight beds for patients, establishments which are service hospitals under the Armed Forces Act 2006, or which are establishments catering for offenders under the Prison Act 1952. In addition, establishments where general practitioners provide NHS services, but where there may be a small minority of private patients who also receive treatment are excluded. The private residence of a patient is also excluded provided that treatment is provided there only to that patient. There are also excluded surgeries and consulting rooms (which are separate from a hospital) which provide medical services under arrangements made on behalf of patients by their employers or others, and sports grounds and gymnasias where treatment is given to those taking part in sporting activities and events. Establishments which carry out podiatric procedures or minor skin procedures under local anaesthetic are excluded from registration as independent hospitals.

Regulation 3(4) provides a definition of local anaesthetic. Regulation 3(5) modifies section 2(7) of the Act so that the effect is as if the words “intravenously administered” were inserted after “or” in section 2(7)(a).

Regulation 4 defines the meaning of the term “independent clinic”.

Regulation 5 excepts certain undertakings from the definition of an independent medical agency.

Each establishment and agency must have a statement of purpose consisting of the matters set out in Schedule 1 and a patients' guide to the establishment or agency which must be kept under review (regulations 6 to 8). By virtue of regulation 6(3) the establishment or agency must be carried on in a manner which is consistent with the statement of purpose.

Regulation 9 sets out the policies and procedures which must be prepared and implemented in relation to an establishment or agency.

Regulations 10 to 14 make provision about the fitness of the persons carrying on and managing an establishment or agency and require full and satisfactory information to be available in relation to the matters prescribed in Schedule 2. Where the provider is an organisation, it must nominate a responsible individual in respect of whom this information must be available (regulation 10). Regulations 11 and 12 prescribe the circumstances where a manager must be appointed for the establishment or agency and for the fitness requirements of a manager. Regulation 13 imposes general requirements in relation to the proper conduct of an establishment or agency and the need

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

for appropriate training. Regulation 14 requires offences and being charged for certain offences to be notified to the appropriate office of the registration authority.

Part III of the Regulations makes provision about the conduct of establishments and agencies, in particular about the quality of the services to be provided in an establishment or for the purposes of an agency, including matters relating to the quality of treatment, privacy, dignity and religious observance of patients, the staffing of the establishment or agency, the suitability of workers, safeguarding patients and about complaints, annual returns and record keeping. Provision is also made about the suitability of premises and the fire precautions to be taken and the management of establishments and agencies. Specific provision is made with regard to independent hospitals accommodating patients with learning disabilities (regulation 27). The registered provider is required to visit an establishment as prescribed (regulation 28) and regulation 29 imposes requirements relating to the financial viability of the establishment or agency. Regulations 30 to 35 deal with the giving of notices to the registration authority when certain events occur such as the death or serious injury of a patient; the unauthorised absence of a patient who is detained or liable to be detained under the Mental Health Act 1983; in the case of a manager's absence from the establishment or agency; where certain changes occur, for example, a change in the registered person and other personnel or significant changes to the premises; where liquidators and others are appointed and where the registered person dies.

Part IV and Schedule 4 sets out additional requirements that apply to independent hospitals in relation to pathology services, resuscitation, the treatment of children, certain surgical procedures, dental treatment, obstetric services, terminations of pregnancy, the use of certain techniques and technologies and independent hospitals providing mental health services.

Part V (regulation 50) contains additional requirements where antenatal care is provided by an independent clinic.

Part VI deals with miscellaneous matters. In particular, regulation 52 provides for offences. A breach of regulations 6 to 17, 18(1), 19 to 35, 37 to 45 and 47 to 50 may found an offence on the part of the registered person. Regulation 53 provides transitional provisions relating to the application of regulation 27 and certain persons registered prior to 1 April 2011. Regulation 54 revokes the Private and Voluntary Health Care (Wales) Regulations 2002 but saves regulation 3(4) of those regulations. This retains the modification to section 2(7)(e) of the Act (reference to cosmetic surgery).