



DOMESTIC CONTROLLED DRUG LICENSING IN HEALTHCARE SETTINGS.

Care Homes

Care Homes are considered to be residential settings, providing nursing and/or personal care. This could include 'rehab' centres where personal care is provided; 'reintegration support' would not constitute personal care.

Limited exemptions to licensing for the possession and or supply of stock medicines (Schedules 2-5 inclusive) may apply (Regulations 8, 9 & 10 to the MDR 2001).

Funding/ charitable status may determine applicable exemptions- e.g. exemptions in respect of Schedule 2 'stock' will only apply to Care Homes wholly or mainly maintained (i.e. >50% funding) by a public authority out of public funds, or by a charity, or voluntary subscriptions. This provision could be applicable to Social Enterprise Organisations or Community Interest Companies.

Prisons/ Detention - including Immigration Removal Centres

Service providers require licensing to possess (and supply) stocks of any drugs in Schedules 1-4 inclusive of the MDR 2001.

Where different services- e.g. healthcare, security, substance misuse- are provided by different entities, or companies, a licence is required by each provider.

Activities are not exempt from licensing simply because they may be carried out in a 'crown' prison, the determining factor is who is providing the service. NHS bodies providing services in these environments will likely need a licence.

Custody environments- including Police Stations

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Service providers require licensing to possess (and supply) stocks of any drugs in Schedules 1-4 inclusive of the MDR 2001.

Where different services- e.g. healthcare, gaoling, property management- are provided by different entities or companies of non-police staff, a licence is required by each provider.

Activities are not exempt from licensing because they are carried out in a Police Station, the determining factor is who is providing the service. NHS bodies providing services in these environments will likely need a licence.

Hospitals

Hospitals are considered to be residential settings providing acute or chronic care or treatment. They are environments where surgery is performed under anaesthesia- either elective or non-elective, day care or longer term.

Schedule 1 licensing is required in all cases.

Funding/ charitable status may determine applicable exemptions- e.g. exemptions in respect of Schedule 2 'stock' will only apply to Hospitals wholly or mainly maintained (i.e. >50% funding) by a public authority out of public funds, or by a charity, or voluntary subscriptions. This provision could be applicable to Social Enterprise Organisations or Community Interest Companies.

All Private Hospitals require Schedule 2 licensing.

Supply of medicines in any schedule from any hospital pharmacy to location other than a ward of that hospital, or entity should be assumed to require licensing. NHS trusts should contact us to discuss their situation.

Other 'Healthcare' Services

Whilst limited licensing exemptions may apply, the following services should assume licensing is required by the company or individual delivering the service to possess and/or supply stocks of drugs :

- Fertility Clinics
- Cosmetic Surgery Clinics, including Laser Eye Surgery
- Out of Hours (doctors) Services
- Privately run or contracted 'clinic' services- e.g Fracture Clinic- even when undertaken in an NHS building
- Private Paramedic Services
- Air Ambulance Services
- NHS Ambulance Trust
- Some Toxicology/ Biochemistry Services- including those in NHS hospitals
- Substance Misuse Services

NOTE: MDR 2001- Misuse of Drugs Regulations 2001. **Does not constitute legal advice, and is not exhaustive.** Relates to stocks of medicines-dispensed named patient medicines are not covered by this document and can be lawfully possessed by another person for the purposes of administration without a licence. Relates solely to Home Office Controlled Drug Licensing- other types of licensing may be required.