Additional Guidance issued by the Home Office on the use of the mandatory requisition form for Schedule 2 and 3 controlled drugs.

On 30 November 2015 legislative provisions came into effect which made it mandatory for specified health and veterinary care professionals, and organisations listed at regulation 14(4) of the Misuse of Drugs Regulations 2001, to use an approved form for the requisitioning of Schedule 2 and 3 controlled drugs. This change, which the Home Office consulted on in 2011, implemented a final recommendation of the Shipman Inquiry on requisitions.

Following the introduction of the form, the Home Office has been made aware that activities within the hospital sector which would normally be governed by provisions under regulation 14(6), and which were not expected to come within the scope of the new requirement, is now captured as a result of changes in the NHS structures in recent years. This is an unintended consequence of the changes to NHS structures and healthcare delivery since 2011 rather than a result of a regulatory change.

The Home Office circular which introduced the change made it clear that the requirement to use the mandatory form was to be limited to activities undertaken by health and veterinary care practitioners in the community to enable their requisition activities to be monitored. The requirement to use a mandatory form was not expected to extend to the hospital environment, where traditionally supplies of controlled drugs were undertaken by an onsite pharmacy owned by the hospital and under the regulation 14(6) provisions.

This additional guidance is therefore being issued to further explain how the provisions governing the use of the new mandatory form may be interpreted. This guidance does not impact on the need for a Home Office licence. The Guidance should also not be interpreted as a change in Home Office licensing requirements, which these regulatory and procedural requirements relate to but are not necessarily interdependent on.

1. The use of the form is mandatory when individual health and veterinary care professionals requisition the relevant controlled drugs in the community, including when such drugs are ordered from pharmaceutical wholesalers and community pharmacies;

2. It is not the intention of the policy on requisitions forms to capture requisition activities for hospital wards etc. However, as a number of hospitals wards now obtain the relevant controlled drugs from other trusts or organisations, and therefore across legal entities, these activities do fall within the scope of regulation 14(2) and therefore the use of the form is mandatory, unless an exemption applies (e.g. registered pharmacies are completely excluded from the requirement to use a requisition when obtaining the relevant controlled drugs). In order to ensure that the regulatory provisions are complied with, it is the view of the Home Office that the person in charge or acting person in charge of a hospital or care home (excluding hospices) can issue a ‘bulk’ or ‘global’ requisition based on previous year’s orders to a separate legal entity which supplies its wards. Hospital or Trust wards can then draw on this ‘bulk’ requisition throughout the year using the duplicate order forms as happens presently. Hospital or Trust wards therefore do not need to use the mandatory form when obtaining the relevant controlled drugs from another trust or legal entity. Similarly, the person in charge or acting person in charge of an Ambulance Trust, as defined under the 2001 regulations, can issue a ‘bulk’ requisition when obtaining the relevant controlled drugs to be supplied directly to employees of the Trust by a

separate legal entity. However, those employees when individually drawing on the 'bulk' requisition must use the mandatory form.

3. Additionally, pharmaceutical wholesale suppliers (excluding community pharmacies) are exempt under current regulatory provisions from submitting requisitions received for Schedule 2 and 3 controlled drugs to the NHS Business Services Authority (NHSBSA). The only requisition forms that must be submitted to the NHSBSA following the introduction of the mandatory form are those provided by individual healthcare professionals when obtaining the relevant controlled drugs in the community.

The table below provides some examples of how the regulations apply in specific circumstances with reference to regulations 14(2) and (4). This is only a Home Office view and does not constitute legal advice. Organisations are advised to seek their own independent legal advice where appropriate. This guidance has been developed with the Department of Health and the Care Quality Commission.

Supplier	Recipient	Do I need to use the new FP10CDF?	Do I need to submit the FP10 CDF to the NHSBSA
Wholesaler	Practitioners Paramedics and the other professionals and organisations listed in Regulation 14(4).	Yes, all practitioners and the list of healthcare professionals must use the form when they requisition for stocks.	No, the regulation exempts the submission of requisitions received by wholesalers from being sent to the NHSBSA
Wholesaler	Registered Pharmacy (including a hospital registered pharmacy)	NO	N/A
Wholesaler	Hospital, care home or ambulance trust without a registered pharmacy **Excludes Hospices	Yes, in line with Regulation 14.	No, the regulation exempts the submission of requisitions received by wholesalers from being sent to the NHSBSA
Legal entity A	Legal entity B's hospital wards	Yes, person in charge of legal entity B must issue a yearly global requisition to legal entity A. Wards in legal entity B can then draw on this requisition through the year using duplicate order books.	NO
Legal entity A	Legal entity B's registered pharmacy	NO	N/A
Legal entity A	Legal entity B	Yes if organisation is listed at Regulation 14(4)	NO