Monitored dosage systems: FAQs

The information contained within this document is in line with the current Data Protection Act (DPA) requirements. This information may be subject to change upon implementation of the General Data Protection Regulations (GDPR) on 25th May 2018.

FAQ	Answer
1) Am I obliged to provide a patient's dispensed medicine(s) in a monitored dosage system (MDS) if the patient or their carer requests this?	This will depend on whether the pharmacist is satisfied that the patient has a disability, the supply of the MDS best meets the patient's clinical needs and that the patient will be able to use the MDS safely. Under the Equality Act 2010, the patient is regarded as having a disability if they have a physical or mental impairment that substantially adversely affects their ability to carry out day-to-day activities. The impairment must have lasted for at least 12 months or is expected to last at least 12 months or for the rest of the patient's life. If the pharmacist decides that the patient has a disability, they must consider whether any reasonable adjustments can be made to overcome obstacles preventing the patient from receiving any pharmacy goods and services compared to someone without a disability. The adjustment provided does not necessarily need to be the provision of an MDS; it may be a compliance chart, non-child resistant containers or large print labels (this list is not exhaustive). Supply of an MDS should only be made when the pharmacist has assessed the patient and concluded that the supply of an MDS best meets the patient's pharmaceutical care needs.
2) The doctor is requesting that a patient's medicines are dispensed in an MDS; am I obliged to provide an MDS?	No. It is the responsibility of the pharmacist to comply with their obligations under the Equality Act 2010. The legislation does not necessarily require the pharmacist to carry out an assessment of the patient; the pharmacist is required to ensure that adjustments are made for the patient if they have a disability. If the patient has a disability, an MDS is only required if it is deemed the most appropriate adjustment to be made. The pharmacist will need to decide whether an MDS is appropriate for an individual patient by taking into account the patient's medicine compliance, their medicine regime and any existing health conditions that may make an MDS unsuitable. The provision of an MDS may not be the most suitable adjustment for the patient; the patient may require large print labels on their medicines or memory aids for taking their medicines. Provision of an MDS should not be regarded as the only way to assist the patient with their healthcare needs.

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3) A carer will only administer a patient's medicines if they are in an MDS; am I obliged to provide an MDS?	The Care Quality Commission (CQC) fundamental standards require service providers to ensure that staff are appropriately trained to administer medicines. This could include administering medicines supplied in an MDS; however it does **not** require all medicines to be in an MDS for carers to administer. Where carers refuse to administer medicines unless they are in an MDS, pharmacists will need to establish what service the carers have been commissioned to provide. If the service contract expressly states that medicines can only be administered if they are supplied in an MDS, whilst this is not ideal, the CQC would not intervene. The Local NHS Organisation may be approached for advice in these circumstances: • England: NHS England regional team • Wales: NHS Wales Local Health Board • Scotland: NHS Scotland Health Board • Northern Ireland: Health and Social Care Trust If the contract does not specify that medicines can only be administered from an MDS, and there are concerns that the care agency is not providing support and training their employees, this should be reported to the CQC. Pharmacists should not enter into an agreement with the carer to dispense a patient's medicine(s) into a MDS to make administration of the medicine(s) to the patient more convenient for the carer; appropriate assessment of the patient and medicine stability should be used to determine whether an MDS should be provided.
4) Am I required to carry out an assessment to determine whether a patient is eligible for a MDS?	The Equality Act 2010 does not require a pharmacist to carry out an assessment to determine whether the patient has a disability. However, it does impose a requirement on the pharmacist to make a reasonable adjustment, if this is what is needed in order to allow the patient to access pharmacy goods and services. The Department of Health has commissioned a non-official, Disability Discrimination Act (DDA) resource kit with assessment forms that can be used by pharmacists; completion of these may help in determining whether, and what type of, adjustment is needed, but is not mandatory. Before making a supply of an MDS, it is essential that the pharmacist is satisfied that the patient will be able to use the MDS safely and that it will not introduce additional risks for the patient.

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5) Do I get a fee for providing a patient's medicines in an MDS?	Currently in Wales, Practice Payments payable to pharmacists include a contribution towards the provision of auxiliary aids for people eligible under the Equality Act 2010. This means that these eligible patients should not be charged for the provision of auxiliary aids. In England, a Single Activity Fee includes a contribution towards the provision of auxiliary aids for patients that meet the Equality Act 2010 criteria.
6) Can I charge a patient for supplying their dispensed medicines in an MDS?	This depends on whether the patient is eligible to have their medicines dispensed in an MDS under the Equality Act 2010. If the patient satisfies the Equality Act 2010 criteria and the provision of an MDS is the most appropriate adjustment to be made, the pharmacist must not charge for providing an MDS. If the patient is not eligible to have an MDS under the Equality Act 2010 but prefers to have one, then the pharmacist would need to decide whether or not to apply a charge, and what the charge levied should be. This would be a business decision and should be agreed by the superintendent pharmacist/pharmacy owner.
7) Am I required to have a standard operating procedure (SOP) in place if I am providing medicines in an MDS?	Yes. Regulation 4 of The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 requires the Responsible Pharmacist to establish, maintain and keep under review (at least every two years) a SOP that covers each stage in the assembly and supply of medicines to a patient including those dispensed in an MDS. The SOP should also include assessing: • The patient to determine that they have a disability as defined under the Equality Act 2010 • That the supply of the MDS best meets the patient's clinical needs • That the patient will be able to use the MDS safely
8) Can cytotoxic medicines be put into an MDS?	No. Cytotoxic medicines should not be put in an MDS because of the increased risks to pharmacy staff and/or patients/carers when handling these medicines.
9) Are Controlled Drugs allowed to be placed in an MDS?	There is no legal restriction on the supply of Controlled Drugs (CDs) in a MDS – this would be at the pharmacist's professional discretion. Before supplying, the pharmacist would need to: • Ensure the supply satisfies all the CD legal requirements as stipulated in The Misuse of Drugs Regulations 2001 • Be satisfied that the CD remains stable and pharmaceutically

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	active outside of its original container • Ensure that the supply is appropriate, for example, a supply to a patient whose dosing changes frequently or require titration If the MDS contained a CD which requires safe custody, the entire MDS would need to be stored in the CD cabinet until collection. The pharmacist should establish if storage in the CD cabinet is feasible, bearing in mind the size of the CD cabinet. If the MDS contained a CD which requires entry into the CD register, the entry for supplying the CD to the patient should only be made when the MDS is supplied to the patient/carer or when it leaves the premises for delivery.
10) What are the labelling requirements for medicines supplied in an MDS and can I put all of the labels on one backing sheet for multiple boxes or does each box need to be individually labelled?	Medicines dispensed in an MDS are subject to the same labelling requirements as other dispensed medicines. Therefore they need to be labelled in accordance with Regulation 258 and Schedule 25 Part 1 of The Human Medicines Regulations 2012. Separate labels must be printed for each item dispensed into the MDS and these labels must be attached directly to the MDS. The MDS should have sufficient space for affixing all the dispensing labels and the font and labelling must be clear, legible and of an appropriate size for the patient. If there is insufficient space for labels (for example, if a patient is taking a large amount of medicines), the labels can be attached to a separate sheet and attached securely to the MDS.
11) Do I have to include the description of the tablet/capsule on the backing sheet or label(s) of the MDS?	The pharmacist should consider including the description of the tablet/capsule on the backing sheet, although it is not a legal requirement to do so. A description can help clinical and accuracy checks to be conducted effectively, especially if the MDS is being transferred open in the dispensary. Also it is important for the patient or their carer to be able to identify the medicines in the MDS.
12) Can I cut a tablet from a blister strip and place this into the MDS so that the tablet remains in its original blister packaging?	It is not recommended that a tablet/capsule is placed in an MDS within its original blister strip. This is because there is a risk of serious harm to the patient if they swallow both the tablet and the packaging. Should a pharmacist consider dispensing a tablet/capsule within an MDS in their blister strip, they must be satisfied that the patient understands that the original blister packaging must be removed prior to administration. A medicine stored in this way would become unlicensed because it is no longer stored in accordance with the Summary of Product Characteristics.

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13) Does a patient information leaflet have to be provided with each medicine supplied in an MDS?	Regulation 260 of The Human Medicines Regulations 2012 requires a patient information leaflet (PIL) to be provided on each occasion a medicine is supplied. Pharmacists must ensure that a PIL is provided on each occasion a licensed medicine is supplied to a patient in an MDS. This does not apply to unlicensed medicines.
14) Is it a legal requirement to provide a medicines administration record (MAR) chart with an MDS?	No. It is not mandatory to provide a MAR chart with an MDS although the National Institute for Health and Care Excellence (NICE) recommends in its guidance "*Managing medicines in care homes*" that pharmacists should supply one wherever possible.
15) For medicines returned by a patient, should I remove the medicines from the MDS before they are placed in the waste container?	No. The medicines should not be removed from a single use MDS; the MDS together with the medicines should be placed in the waste container for collection by the waste contractor. This does not apply to Schedule 2, 3 and 4 (Part 1) Controlled Drugs because they must be denatured before they are placed in the waste container.
16) I have dispensed a prescription for 28 days treatment in an MDS for a patient. During this treatment period, the prescriber has changed one of the patient's medicines. Am I obliged to amend the MDS that has already been dispensed?	Pharmacists are not contractually obliged under their NHS Terms of Service to make changes to medicines or to re-package an existing MDS once it has been dispensed. If a patient has their medicines dispensed in an MDS and the prescriber changes or adds a medicine part way during the use of the MDS, it is up to the prescriber to issue a new prescription for all of the items. Where it is likely that a patient will need changes to their medicines or doses, the prescriber should be contacted to discuss whether they can provide prescriptions with a short prescribing interval, such as seven days.
17) A patient has brought in a prescription for dispensing and requested that I add the medicine to their MDS containing medicines that were dispensed elsewhere; should I do this?	Re-dispensing of medicines supplied by another pharmacy into an MDS is not recommended. This is because the pharmacist re-dispensing the medicines would not be able to confirm the identity, source or the storage condition of the medicines. They would also not have had sight of the prescription that the medicines were dispensed against. Pharmacists seeking to offer this type of secondary dispensing would need to consult their indemnity insurance provider; an assessment of the level of risk and the cover required would need to be determined. The pharmacist must have considered other possible options to support patient adherence and have evidence that this practice is essential for the patient's compliance and care. In order to minimise any potential risks, there must be robust SOPs in place and these SOPs must clearly identify the responsibilities of each party involved.

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18) I have received an FP10 prescription for 28 days treatment from a GP for a patient who is eligible under the Equality Act 2010 to have their medicines supplied to them in an MDS. The GP is requesting that I supply the medicines in an MDS to the patient on a weekly basis for four weeks; am I obliged to do that?	Prescriptions ordering 28 days treatment should be dispensed on one occasion (except for instalment prescriptions) and this applies to medicines provided in an MDS. The pharmacist should supply 1 x 28 days MDS or 4 x 7 days MDS on one occasion. Occasionally, a patient may benefit from having their medicines dispensed at shorter intervals, for example, weekly. This may be because of the following: • The stability of the medicines may only be guaranteed for short periods of time outside of the manufacturer's original packaging • There may be risk to the patient or others (for example, young children or animals) from having a large quantity of medicines in the home • The patient's medicines may be changed at short notice so dispensed medicines would need be returned to the pharmacy and new MDS packs • The patient is at risk of deliberate or accidental self-harm by taking all their medicines in one go In these circumstances, where it is in the patient's best interests to do so, the prescriber should be contacted to arrange prescriptions with a shorter prescribing interval.
19) I have received a request from a nursing home for a MAR chart for one of their MDS patient who has had their medicines dispensed at another pharmacy; am I able to do this?	MAR charts should be produced at the point of dispensing using the original prescription. Pharmacists should not routinely provide MAR charts for medicines that have been dispensed by another pharmacy because they have not had sight of the original prescription. The pharmacist should signpost the nursing home to the pharmacy where the medicines were dispensed. If a pharmacist decides to provide a MAR chart in these circumstances they must ensure that clinical and information governance procedures are in place to cover this practice. The pharmacist must also be satisfied that this practice is essential for the patient's compliance and care. Advice should also be sought from the pharmacist's professional indemnity provider.

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References and further reading

- Equality Act 2010: http://www.legislation.gov.uk/ukpga/2010/15/contents
- National Institute for Health and Care Excellence "*Managing medicines in care homes*": https://www.nice.org.uk/guidance/sc1/resources/managing-medicines-in-care-homes-61677133765
- Primary Care Commissioning "*Disability Discrimination Act – a resource kit*": http://www.pcc-cic.org.uk/article/disability-discrimination-act-resource-kit
- The Care Quality Commission: http://www.cqc.org.uk/
- The Human Medicines Regulations 2012: http://www.legislation.gov.uk/uksi/2012/1916/contents/made
- The General Pharmaceutical Council "*Standards of conduct, ethics and performance*" https://www.pharmacyregulation.org/standards/conduct-ethics-and-performance
- The General Pharmaceutical Council "*Standards for registered pharmacies*" https://www.pharmacyregulation.org/standards/standards-registered-pharmacies
- The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008: http://www.legislation.gov.uk/uksi/2008/2789/contents/made
- The Misuse of Drugs Regulations 2001 and amendments: http://www.legislation.gov.uk/uksi/2001/3998/contents/made
- The Misuse of Drugs (Safe Custody) Regulations 1973 and amendments: http://www.legislation.gov.uk/uksi/1973/798/contents/made
- The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 http://www.legislation.gov.uk/uksi/2013/349/contents/made