

Disability Discrimination Act (DDA) 1995; Equality Act 2010; and Multi-compartment compliance aids

Background

Prior to 2005, some pharmacies dispensed medicines in multi-compartment compliance aids (also known as Monitored Dosage Systems or MDS) either at the pharmacist's own expense or paid for by the patient or the PCT. Many were supplied free of charge to Care Homes, and some PCTs commissioned a service for supporting people with a disability or who would benefit from the convenience of provision of MDS.

In 2004, the 'New Contract Book' included a proposed Essential Service (Essential Service 7) titled 'Support for People with Disabilities'.

This service was intended to involve a pharmacist carrying out an assessment under the Disability Discrimination Act, and then if appropriate, making an adjustment of either Level 1 (e.g. large print labels, easy open containers, reminder charts etc.) or Level 2 (e.g. dispensing into an MDS). The Department of Health commissioned the development of an assessment toolkit.

Under the Essential Service 7, PCTs would pay the cost of the adjustments, and would be able to carry out their own assessments of patients. For those patients who they deemed ineligible, the pharmacist would be informed not to provide further support as part of the essential services. However, legal advice led the Department of Health to the conclusion that under the Disability Discrimination Act, the PCT would not be able to overturn the decision of the pharmacy contractor, as it is the pharmacy contractor that is responsible for making adjustments under the legislation.

This Service was not therefore transposed into the New Contract Regulations as to do so could have led PCTs and pharmacy contractors into legal difficulties.

Because PSNC and the Department of Health had already agreed that funding for supporting patients with disabilities would be made available as part of the new contract funding arrangements, the decision was taken to distribute payment as part of the Practice Payment, as it was assumed that the demand for support under the DDA would be closely related to dispensing volume.

After the new contractual arrangements came into force in 2005, those PCTs that had been supporting patients by funding the provision of MDS decided to discontinue this, believing that those patients who required MDS under the DDA would continue to receive the service under the newly funded arrangements.

The legislation

The Disability Discrimination Act 1995 which has been replaced by the Equality Act 2010 sets out a framework which requires providers of goods and services, not to discriminate against persons with a disability.

The first matter to consider is whether the patient has a disability. A person is regarded as being disabled, if they have a physical or mental impairment which has a substantial adverse effect on that person's ability to carry out day to day activities. The impairment must be either long term (that is, has lasted more than 12 months) or is expected to last more than 12 months or for the rest of the person's life (for example multiple sclerosis).

If a person is disabled, the provider of services must consider whether a feature of the way in which he provides the service means that the disabled person would not be able to access the service, whereas a non disabled person would. So for example, a patient

with severe arthritis, who is unable to open child resistant containers, would be unable to access their medicines if all medicines supplied by the pharmacy are in child resistant containers.

The provider of the service must then consider whether any adjustment could be made, which would have the result of overcoming the obstacles to accessing the service. In this example, providing an easy open container would overcome the obstacles to accessing medicines. An alternative would be to ensure that there is a care worker available to open the child resistant container every time the patient is due to take a dose.

The provider will be in breach of the legislation if there is a reasonable adjustment available which he chooses not to make, causing the person to be unable to access the service. In the above example, it would be unreasonable for the pharmacist to provide a care worker to visit the patient to help with opening the containers, but it would be reasonable to expect the pharmacist to dispense medicines in an easy open container.

The legislation does not require a provider to carry out an assessment under the Equality Act – all that is required, is that the provider makes a reasonable adjustment, if this is what is needed in order to allow the person to access the service.

Practical ways of supporting patients

The majority of patients, including patients in a care home where professional care workers are engaged to assist with medication, do not require any additional support to enable them to access medicines. Patients with a disability may be able to access their medicines without additional support but for some, the pharmacist will need to make adjustments to overcome obstacles to the use of the service.

Before assuming that the patient requires an adjustment, it is important to establish from the patient, what their personal preferences are; it should not be assumed that a patient who has a disability wants a particular adjustment. Discussing the benefits and shortcomings of particular adjustments with the patient will allow the patient to reach their own decision.

Easy open containers and large print labels are common adjustments. For patients who are forgetful, a reminder chart, showing which medicines are to be taken at particular times during the day may assist – but the pharmacist would need to ensure the patient understands how the reminder chart works, and is able to use it correctly.

For some patients, an MDS may be the only adjustment that will allow the patient to overcome the obstacles to the use of the dispensed medicine.

Whichever adjustment is made to assist patients with a disability, it is essential that the pharmacist satisfies himself that the patient is able to understand and be able to benefit from the adjustment, without introducing additional risks.

It is likely that requests for MDS will be made from a wider group of patients, and their carers / relatives, because of the convenience that MDS brings. As there is no funding available within the NHS to support the provision of MDS to this group of patients, the cost may have to be borne by the patient.

Deciding whether to supply MDS

Before making a supply in MDS, it is essential that the pharmacist satisfies himself that the patient will be able to use the MDS safely. There have been instances involving patients who are confused, who have taken all the morning doses sequentially, by

working horizontally across the MDS instead of taking their medicines throughout the day using the vertical compartments. MDS which are produced in a rope like sequence have also been reported to fail, where an individual dose was missed, with the result that every subsequent dose was taken at the wrong time of day. Pharmacists should ensure that whichever type of MDS is used, the patient understands the order in which the medicines should be extracted, and is physically able to do so.

It is known that some medicines start to deteriorate if removed from the manufacturer's original carton, so the impact on these medicines must be assessed before they are repackaged. If PRN (when required) medicines are supplied, these generally are unsuitable for dispensing in MDS. If the supply of an MDS plus additional containers is going to be unmanageable for the patient, then it is possible that the decision to dispense in MDS is flawed, and alternative adjustments may be required.

Under the disability legislation, an adjustment that is likely to cause harm to the patient is not going to be considered a reasonable adjustment.

The Royal Pharmaceutical Society has developed eight standards¹ for the use of MDS. The standards are based on the principle that all pharmacy activities should be undertaken in the best interests of an individual patient.

Patients who have care workers

Some patients have care workers engaged to provide support. The care worker may be engaged to assist the patient - in this case the care worker follows the directions of the patient receiving the care. For example the patient would tell the care worker "I want a blue tablet and a green tablet" the care worker would help the patient to select the blue tablet and the green tablet. This may be appropriate if for example the patient is visually impaired, or if the patient has manual dexterity problems. If a care worker is engaged to assist the patient, the extent of this assistance will be recorded in the care plan.

Or the care worker may be engaged to administer the medicines – in this case the care worker makes the decision as to whether the patient needs medicines or not. To do this they must be able to read information whether that is from a reminder chart or the labels affixed to the medicine packaging. Administration does not necessarily mean putting the individual tablets into the patient's mouth. The key criterion is that it is the care worker who makes the decision as to whether there is a particular medicine due at a particular time. The patient may still be able to take the tablets from the packs themselves. If the care worker is engaged to administer the medicines, there will be a record made by the care worker of each administration.

The Care Quality Commission, the regulator of care worker organisations has two relevant standards² linked to medicines.

Outcome 9 : Management of medicines

People using the service:

- *Will have their medicines at the times they need them, and in a safe way.*

¹ At the time of publication of this briefing, the RPS is consulting on the Standards, and once agreed and published, a link will be provided

² http://www.cqc.org.uk/db/documents/Essential_standards_of_quality_and_safety_March_2010_FINAL.pdf

- *Wherever possible will have information about the medicine being prescribed made available to them or others acting on their behalf. This is because providers who comply with the regulations will:*
 - *Handle medicines safely, securely and appropriately.*
 - *Ensure that medicines are prescribed and given by people safely.*
 - *Follow published guidance about how to use medicines safely.*

Outcome 13 : Staffing

People using the service:

Are safe and their health and welfare needs are met by sufficient numbers of appropriate staff. This is because providers who comply with the regulations will:

- *Make sure that there are sufficient staff with the right knowledge, experience, qualifications and skills to support people.*

The key point from these outcomes is that the organisation providing the care worker must make sure they have sufficient staff with the right knowledge, experience, qualifications and skills to support the people that they are caring for.

If the care plan for the patient requires the care worker to 'assist' the patient as above, then the care worker should have the necessary skills to open containers, and hand the medicines to the patient (whether they are in MDS or original manufacturer's containers). But, the care worker would not be expected to decide whether a particular medicine must be administered at the particular time.

If, however, the care worker is expected to administer medicines (as recorded in the care plan), then the care worker should have the qualifications and skills to be able to interpret instructions on the medicines container, whether that is an MDS or a manufacturer's container.

The skills that appear to be needed to administer medicines would include being able to read instructions on labels, and interpret the dosage instructions.

The employer of the care worker should specify the boundaries as to whether the care worker will assist with or administer medicines and it is the obligation of the employer to ensure that the care worker has the requisite skills and qualifications to undertake the roles.

Carer organisations may benefit from seeking the assistance of a pharmacist to provide training to the care workers on interpreting dispensing labels, particularly for those care workers that are engaged to administer medicines. It should not be the case, that carer organisations simply rely on pharmacists to provide medicines in MDS as a matter of routine to lower the skills required of care workers.

If pharmacists believe that a patient has been provided with a carer who is not sufficiently skilled and qualified to provide the required level of support to the patient, then consideration ought to be given to using the raising concerns procedures (as required in the clinical governance section of the terms of service) to alert the Care Quality Commission.

Considerations, when providing medicines in MDS

Whenever a decision is made to provide medicines in an MDS, it must:

- Be appropriate for the patient
- Preserve the integrity of the medicine

As indicated above, some patients who have a disability may need their medicines dispensed in an MDS to allow the patient to access their medicines. But, there should be no general assumptions that patients who have a disability, or who receive multiple medicines would benefit from, or need MDS.

Patients must, if they have mental capacity, be involved in all aspects of their care, and it would be wrong to assume they want their medicines to be repackaged into MDS. A patient in a care home is entitled to manage their own medicines, if they want to, and pharmacists providing medicines to care homes should be prepared to discuss individual patient's requirements, where the patient has exercised the right to deal with their own medicines arrangements.

In some cases, the families or care workers of patients who suffer from a degree of confusion may suggest that the patient will benefit from having their medicines provided in an MDS. Sometimes, the provision of medicines in an MDS may be a substitute for other more appropriate arrangements, and there is a danger of patients being left alone, with an MDS, by family and care workers who believe that the patient will be able to manage their medicines when presented in that way. These assumptions could be dangerous for the patient – and as the decision to remove medicines from a manufacturer's pack and place them in an MDS is that of the pharmacist, it is the pharmacist who should satisfy himself that the patient can understand and be able to use the MDS trays. Therefore before providing medicines in an MDS, pharmacists should ensure that this will not lead to a false sense of security for others involved with the care of the patient.

If an assessment under the disability legislation determines that the patient would not be able to handle their medicines if they were not in an MDS, then this poses problems if there are any medicines that cannot be placed in the MDS for example, hygroscopic medicines, PRN medication and liquids. If they are not in the MDS, then the use of the MDS to overcome confusion may not be effective, as the patient will need to identify the medicines to take, from two containers, the MDS and the other medicine containers – in other words, it would be no different to the dispensing in two manufacturer's containers – an outcome that the MDS is trying to avoid. There is a risk that the patient might not remember to take the products dispensed separately to the MDS.

All medicines that have been manufactured and supplied in manufacturer's cartons have been tested for stability in those cartons. Removing medicines from the manufacturer's carton poses a risk to the quality of the medicine.

As stated above, the Royal Pharmaceutical Society has developed standards for the use of MDS, and once these have been published, pharmacists will need to consider these when making the professional decision whether or not to supply an MDS.

Links to prescriptions and period of treatment

There is no fundamental link between dispensing in an MDS and the period of treatment covered by a prescription. A prescription for 28 days supply might be supplied in an MDS, and a prescription for seven days might be supplied in the original manufacturer's carton.

Once medicines have been dispensed by a pharmacist, whether in an MDS or in manufacturer's cartons, then no further changes to what has been dispensed should be made by a pharmacist. If a prescribed medicine is no longer required, the prescriber

should inform the patient of that clinical decision, and ensure that the patient understands that previously dispensed medicine should not be administered. If the medicine has been provided alongside other medicines in an MDS, it might be acceptable for the prescriber to advise the patient not to take the particular product if it is readily identifiable visually by the patient. But if the MDS was provided because of a disability and the patient does not have the ability to identify and discard the medicine, when opening each compartment, then the whole MDS would need to be replaced. This is potentially very wasteful, because all the medicines contained in the MDS will need to be re-prescribed. The NHS terms of service for pharmacies does not require pharmacists to modify previously provided MDS trays.

For patients requiring medicines in MDS as an adjustment under disability legislation, the prescriber may decide to prescribe in 7 day quantities, to minimise the amounts of waste that would occur on medication changes. This would be a clinical decision of the prescriber, just as the decision to dispense in MDS is a decision solely for the pharmacist.

Funding Issues

When an NHS prescription is presented in a pharmacy, any medicines prescribed must be dispensed 'with reasonable promptness'. If the patient requires an MDS because of a disability, then the pharmacist must make that adjustment. It is not permitted under the terms of service, for a pharmacist to turn away a prescription, simply because the pharmacist does not want to dispense the medicines in MDS because of the cost of the equipment and the time commitment. Occasionally, pharmacists contact PSNC to express concern about the number of patients who attend their pharmacy, having tried to have it dispensed elsewhere, only to be refused. This should be notified to the PCT.

Many of the queries that PSNC receives about support for patients who have a disability concern instructions given by prescribers on the prescription, to dispense weekly into compliance aids. The NHS Pharmacy Terms of Service do not impose a requirement to dispense into compliance aids or to dispense in instalments (other than instalment prescriptions for the treatment of substance misusers). Therefore a prescription ordering 28 days treatment should be dispensed on one occasion as the NHS requires the medicine to be dispensed on the one occasion, for one dispensing fee. It is for the pharmacy contractor to decide whether it is appropriate to dispense into MDS and this decision is not influenced by the period of treatment.

If a prescription for 28 days treatment is issued for a patient who satisfies the DDA criteria, and the pharmacy contractor decides that the adjustment required is an MDS, then 4 x 7 day MDS containers or 1 x 28 day MDS container should be prepared and supplied to the patient on one occasion.

As stated above, there is no obligation on pharmacy contractors to amend what has already been dispensed, so if changes are made to a patient's medicines midway through the period of treatment, the prescriber would be obliged to make his own DDA adjustment, by issuing a prescription for all the current medicines, so that they can all be dispensed into a new MDS. For this reason, prescribers could be advised to issue 7 day prescriptions, if the patient is likely to have changes made to prescribed medicines.

Convenience / Concordance MDS

There are some patients who GPs (or care workers) believe would benefit from MDS, but who are not disabled, or whose disability does not justify the use of MDS. In these cases, MDS may be provided at the patient's expense, or the pharmacist might be willing to provide MDS free of charge. But, the cost of the equipment and the resources necessary to dispense into MDS are much higher than dispensing the manufacturer's

original carton, particularly if the activity is being carried out on a monthly basis (since four separate weekly MDS containers must be dispensed). In these circumstances, the pharmacist may be willing to provide an MDS only if the GP is supportive of the use of the MDS. Consider the position above, where a medicine is changed mid-way through a period of treatment – in the event of a change of medicines for a patient receiving the medicines in MDS due to DDA obligations, the GP would need to make an adjustment by issuing a replacement prescription. If the patient was supplied the MDS for another reason, the GP's willingness to issue another prescription, to replace wasted medicines may not be so forthcoming. Therefore, GPs have demonstrated their support for MDS by prescribing in weekly quantities, to make the workload manageable for the pharmacist, and to minimise the waste should the patient's treatment be changed.

If the GP is not supportive of MDS (and would not welcome the extra demands on his time or prescribing budgets, if replacement prescriptions had to be issued), then he ought to make this known to the patient and pharmacist so that the patient is not suddenly left with a part used MDS and no replacement prescription.

Questions

Q. Must I always carry out an assessment under the Equality Act, if a patient asks me to make an adjustment to the way in which I normally dispense, because of a disability?

A. No. The legislation does not require a formal assessment to be carried out, only that a reasonable adjustment is made to help a disabled person overcome the obstacles to the use of the service. A pharmacy could provide compliance aids (such as easy open containers, reminder charts) if they decide with the patient, that this will assist the patient to use the service.

BUT – if an adjustment is made, the pharmacist is responsible for the decision. If the adjustment causes harm, the pharmacist could be liable – for example, providing a reminder chart that the patient is not able to understand, or an MDS which results in incompatibilities or deterioration of the medicines.

Q. Where can I find an assessment toolkit?

A. The Department of Health commissioned an assessment toolkit which is available at <http://www.pcc.nhs.uk/98.php>, but the use of this toolkit is not mandatory.

Q. A patient in a care home has requested that we dispense medicines in easy open rather than child resistant containers. If the home has staff able to assist, is this necessary?

A. If the patient wishes to manage their own medicines, and the arrangements have been made for the patient to retain their own medicines, then this adjustment may be appropriate, because it allows the patient to maintain their own independence.

Q. A patient has severe visual impairment, and has successfully used an MDS tray to be able to take their three medicines which are all similar sizes and shapes, so cannot be identified by touch. The latest prescription includes two additional drugs - one is hygroscopic and must be dispensed in its original container, and the other is a PRN analgesic, so neither can be put into the MDS tray. Is it still appropriate to use MDS, if the patient's medicines are supplied in this plus two other containers.

A. Where the reason for dispensing in MDS is not because of confusion, and alternative methods can be used to allow the patient to identify their medicines correctly, then the MDS remains appropriate. But, if the purpose of the MDS is because

they need the 'reminder' of which medicines to take at particular times of day, then supplying other medicines (in this case, the hygroscopic medicine) may be inappropriate, since that may be missed by the patient. The dispensing of a separate container for PRN medicines may be appropriate alongside the MDS, if the level of confusion is not so great that the patient understands the when required medication is in another containers. If the medicines (one hygroscopic to be taken regularly and one to be taken PRN) are excluded from the MDS and the patient has confusion such that MDS is the adjustment necessary to overcome the obstacles to taking the medicines, then there may be confusion over which is the regular medicine and which is the analgesic. The pharmacist should discuss with the patient, what their needs are, and determine whether the patient's treatment or safety will be compromised.

Q. A housebound patient's care worker has asked me to dispense the patient's medicines in an MDS, because the care worker finds this easier and quicker to use than individual manufacturer's containers. Do I need to comply with that request?

A. It is the patient's needs that must be addressed. If the care worker is engaged to administer medicines, then they must have sufficient knowledge, experience, qualifications and skills to be able to undertake that activity. The convenience of the care worker could be a valid consideration, but this would not be funded under the NHS arrangements. If care workers make frequent requests for MDS, try to ascertain why, and if appropriate, consider contacting the care worker's employer and / or CQC if you believe that the level of experience, knowledge, qualifications and skills appear inadequate.

Q. I have decided to dispense a patient's medicines in an MDS because the patient has a disability, and between us we have determined that the MDS provides the best way of allow the patient to access their medicines. Unfortunately, due to intolerance of one of the medicines, the GP has prescribed an alternative and has asked that I replace this in the previously dispensed medicines. Can I do this.

A. Once a medicine has been dispensed, the NHS pharmacy terms of service do not require any further adjustments. Therefore, unless the GP has instructed the patient to ignore any of the discontinued medicines from the MDS, and is confident that the patient will do this and be able to take the separately dispensed replacements, the whole MDS container should be discarded, and a new one produced. As the decision to dispense in an MDS was on disability grounds, it is possible that the patient will not be able to handle a separately dispensed item, and if this is the case, there is no alternative but for the GP to issue a new prescription for all current medicines, so that they can be dispensed together in a replacement MDS.

This is wasteful of the medicines already dispensed, and is the reason why GPs may prefer to prescribe on a weekly basis if the patient is likely to have changes made to the medication.

Q. In the Drug Tariff, the practice payment is stated to include 6.6 pence 'contribution for DDA'. What is this payment for?

A. In 2005, the funding agreed for the pharmacy contractual framework included a sum towards the pharmacist's compliance with the Disability Discrimination Act. This sum is not distributed specifically for any adjustments made, but is distributed on a flat rate basis, towards any adjustments that the pharmacy makes. It is therefore towards the funding for easy open containers, large print labels, reminder charts, MDS etc.

Q. In that case, would it be right to say that I am funded for providing MDS on request?

A. No. The funding is towards compliance with the DDA. If a patient requires an MDS because they have a disability, and the MDS is the only reasonable means of overcoming the obstacles to using the dispensed medicines, then that will be funded by the DDA element of the practice payment. It will not cover MDS provided as a convenience, or where the MDS is being used for a purpose other than DDA support.

Q. Can the GP insist that I dispense a medicine in an MDS?

A. No. The compliance with the obligations in the Equality Act are for the pharmacist and the Courts. The final decision whether or not to use MDS for a DDA patient would rest with the pharmacist. However, if a GP is supportive of MDS to provide greater convenience for the patient, or to improve concordance, then the GP could ask if the pharmacist is willing to dispense in an MDS. Because of the additional costs of equipment and time dispensing in an MDS, particularly on a monthly basis, and the risks of wastage if medicines are changed, the agreement of the pharmacist may be dependent on the GP prescribing on a weekly basis.

Q. The GP has agreed to provide prescriptions on a weekly basis so that I can supply MDS. He has provided four weekly prescriptions at once – can I dispense all four weekly MDS together?

A. No. The purpose of the weekly prescriptions is to support the supply of MDS containers on a weekly basis, and to minimise waste if there were to be a change to the patient's treatment. Dispensing all four MDS containers at once would defeat the purpose, and create unnecessary waste.

Further support on the Equality Act

If the further questions arise that are not covered by the above, pharmacy contractors can obtain support on the implications of the Equality Act by contacting Steve Lutener, Head of Regulation (steve.lutener@psnc.org.uk)