Guidance ratified by the Regional Medicines Optimisation Committee (RMOC)

Principles guiding the decision making about the route of supply of medicines to outpatients

April 2019

Purpose

This document was developed to support best practice in supply of medicines. It is intended to support acute trusts when considering the benefits and disadvantages of various supply routes for high cost medicines; highlighting areas where such supply routes have been established and providing contact details for individuals who are willing to share their experiences.

The following areas are not within the scope of this document:

- Detailed decision-making support on suitability of out-sourced supply routes within a trust
- Administration of medicines

Introduction

The NHS spends approximately £18 billion on medicines annually. This represents a significant proportion of the NHS budget and an area where efficiencies can and should be delivered with minimal impact upon patient care or experience.

Simple changes to the supply routes for certain medicines may improve productivity and efficiency within acute trust providers and support the patient experience by:

- Enabling patient choice
- Ensuring patients have access to appropriate pharmaceutical advice as required
- Access to medicines at a time and site suitable to the patient
- Reduced associated costs for patients due to less travel time and parking requirements
- Reducing patient waiting times by focusing on sole or limited supply routes e.g. outpatients only rather than inpatient, outpatient and discharge routes
- Delivering new facilities e.g. by investment in new dispensaries and or retail premises
- Tying into services offered by the wider network of pharmacies offered by the outsourced provider

An additional advantage of the use of non-NHS providers of dispensing services is that NHS employed staff may be released to directly focus on more clinical aspects of their role, while allowing the non-NHS provider to have a clear focus on delivering the best possible patient experience. This may therefore enable improvement in two of the key parameters of clinical quality, in the context of patient safety and patient experience. It should also be noted that use of an outsourced supply route will provide an additional benefit of supply of medicines at zero rate VAT, however this should not be the primary reason for supply via an outsourced route.
This approach was noted in the report of Lord Carter “Operational productivity and performance in English NHS acute hospitals: Unwarranted variations”, available at: https://www.gov.uk/government/publications/productivity-in-nhs-hospitals; which included the following advice “Trusts that have not currently outsourced their outpatient dispensing services should ensure their HPTP plans include a review of these services and have a plan in place for improving productivity and efficiency, including consideration of alternative supply routes, such as homecare providers or community pharmacies.”

The Royal Pharmaceutical Society Professional (RPS) Standards for Homecare Services in England recommend that Homecare pharmacists should work collaboratively with commissioners / purchasers and primary care clinicians to ensure prescribing delivers value from the investment in medicines across the health community. The Medicines Optimisation (MO) CRG extends this recommendation to include the use of cost effective dispensing routes for all outpatient medicines.

In order to support trusts in determining the best means of achieving cost-effective dispensing the MO CRG has reviewed the current options available, while recognising that local conditions may affect the option chosen. This document is intended to support trusts when considering the benefits and disadvantages of various supply routes; highlight areas where such supply routes have been established and provide contact details for individuals who are willing to share their experiences.

### Potential supply routes

<table>
<thead>
<tr>
<th>Service type</th>
<th>Brief description</th>
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<tbody>
<tr>
<td>In-house pharmacy</td>
<td>Out-patient prescriptions are dispensed by the NHS Trust pharmacy department</td>
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<tr>
<td>Outsourced Out-Patient Dispensing (OOPD): private company</td>
<td>Out-patient prescriptions are dispensed by a separate entity (private company) contracted by the NHS trust</td>
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<tr>
<td>OOPD: wholly owned subsidiary (WOS)</td>
<td>Out-patient prescriptions are dispensed by a separate entity (private company) which is owned by the NHS Trust</td>
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<tr>
<td>Homecare Medicines Services via Homecare Provider*</td>
<td>Homecare prescriptions are dispensed by a commercial Homecare Provider and delivered direct to patients residential (or other nominated) address</td>
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<tr>
<td>Hub and spoke model (including “click and collect”*)</td>
<td>Prescriptions are dispensed by one main pharmacy and medicines are then delivered to a pharmacy nearer to the patient's home for collection</td>
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<tr>
<td>FP10 via community pharmacy</td>
<td>FP10HP prescriptions are dispensed by community pharmacies. This supply route is less often used nowadays</td>
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</tbody>
</table>

*Homecare medicines service contracts can be broadly classified into 2 types: NHS contracted homecare medicines services and Pharma funded homecare medicines services. Please refer to the table below for a brief description of these service types. Detailed information comparing the relative merits of each type of service is outside of the scope of this document. For further information please contact Chair of the National Homecare Medicines Committee (NHMC): susan.gibert@berkshire.nhs.uk.
### NHS contracted homecare medicines services vs Pharma funded homecare medicines services

<table>
<thead>
<tr>
<th>Comparison</th>
<th>NHS contracted homecare medicines services</th>
<th>Pharma funded homecare medicines services</th>
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<tbody>
<tr>
<td>Medicine prescribed and funded by NHS</td>
<td>Medicine prescribed and funded by NHS</td>
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<tr>
<td>Medicine delivery costs and associated nursing services funded by NHS</td>
<td>Medicine delivery costs and associated nursing services funded by the manufacturer of the pharmaceutical product</td>
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<tr>
<td>Subject to EU Procurement Regulations which requires a full tender process to be followed for the majority of contracts</td>
<td>Not subject to full tender process. Manufacturers assign a suitable homecare provider and the NHS must access the medicine via the chosen provider(s)</td>
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<tr>
<td>NHS funds any additional patient support</td>
<td>Many pharma funded services are accompanied by a Patient Support Programme (PSP). The benefits of PSPs to patients are outside the scope of this document</td>
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All routes of medicine supply require management and monitoring of service standards, this is especially pertinent to outsourced supply routes; these services are outside of the direct control of the NHS and therefore contracts need to be well managed, with accompanying supplier performance and careful financial monitoring. It is therefore vital to ensure that safe working systems are in place, communication channels are clear and robust, clinical pharmacy access and engagement is maintained, and that performance management incorporates a specific focus on patient safety and patient experience.

Appendix 1 compares some of the service standards that should be taken into account when considering the most appropriate route for the supply of medicines. Attributes for each service that may be considered as advantageous are highlighted in green text.

There has been significant work undertaken in implementing a range of outsourced supply routes throughout acute trusts in England, which has provided a variety of resources to mitigate a number of the risks / disadvantages associated with the outsourced routes above; please see appendix 3.

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**Wholly Owned Subsidiaries**

The DHSC Accounting Officer System Statement (July 2018) section 9.9 states ‘The intention is that during 2018-19, the proposed creation of subsidiary companies will now become a reportable transaction to NHS Improvement under the Transactions Guidance, irrespective of size. This would ensure that transactions are visible to NHS Improvement and that assurance could be sought that NHS trusts had properly identified and reviewed associated risks.’


NHS Improvement has undertaken a consultation exercise in the context of the above statement and has published a response ‘Proposed extension to the review of subsidiaries: consultation response’ (November 2018).

[https://engage.improvement.nhs.uk/subsidiary-companies-review/extension-to-review-of-subsidiary-companies/results/consultationresponse-subsidiarycompanies.pdf](https://engage.improvement.nhs.uk/subsidiary-companies-review/extension-to-review-of-subsidiary-companies/results/consultationresponse-subsidiarycompanies.pdf)

Alongside the consultation, NHS Improvement has published an ‘Addendum to the transactions guidance – for trusts forming or changing a subsidiary’ (November 2018).

[https://improvement.nhs.uk/documents/3509/Addendum_to_transactions_guidance_FINAL_CORRECTED.pdf](https://improvement.nhs.uk/documents/3509/Addendum_to_transactions_guidance_FINAL_CORRECTED.pdf)
These documents therefore outline a new framework which clarifies the required approval process before trusts can implement plans for subsidiaries, but it is noted that it does not affect the trusts’ legal ability to develop such plans.

This area is therefore a subject of recent policy review, so any proposed commencement of a Wholly Owned Subsidiary service requires consideration of the above policy documents and dialogue with NHS Improvement at an early stage.

The September 2017 Department of Health letter ‘Tax Avoidance Issues in the NHS’ in appendix 4 should also be considered.

### Principles guiding choice of cost effective supply routes

The Royal Pharmaceutical Society (RPS) has published guidance and a framework for Medicines Optimisation. In the RPS guidance there are 3 overarching global dimensions and 4 principles. The cost effective supply routes principles below have been mapped to the 4 principles but when considering the scheme the following global dimensions should be considered first:

- The scheme must have patient centred approach
- The scheme should have the aim of improving patient outcomes
- The scheme should be measured and monitored against the 4 principles of medicines optimisation below

<table>
<thead>
<tr>
<th>Medicines Optimisation Principle:</th>
<th>Cost effective supply route principle:</th>
<th>Additional information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aim to understand the patient’s experience</td>
<td>Engagement and shared decision making:</td>
<td>Clinical outcomes and patient satisfaction are likely to be better when decisions about medicines are made jointly between the person taking the medicine and the prescriber</td>
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<tr>
<td></td>
<td>• Patients should be involved in discussions regarding the most appropriate supply route for their required medicines; this may result in a choice between a selection of available outsourced routes, for example between a homecare provider and a WOS OOPD</td>
<td>• The decision of the most suitable supply route should be made both for the patient’s benefit and to optimise the use of available cost effective supply routes</td>
</tr>
<tr>
<td>Choice:</td>
<td>• One supply route may not be appropriate for all patients; an individual’s circumstances should be considered</td>
<td>• Some patient groups / medicines may not be suitable for specific supply routes; for example, homecare supply may be less suitable for homeless people, working individuals, treatment where there is an increased risk of waste, such as hepatitis C and treatment dependent on blood results, e.g. some chemotherapy</td>
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</tbody>
</table>
### 2. Evidence based choice of medicine

- **On-going supply via a specific route should be reviewed based on patient experience and feedback**
  - Patient experience and issues encountered should be considered to ensure on-going supply by a specific route is still appropriate. A change in the patient's circumstances may require reconsideration of the most appropriate supply route; it is a requirement that all homecare patients are reviewed at least annually with the homecare service.

- **Informed consent should be documented according to local procedures for each patient who agrees to a homecare supply route**
  - Patients should be aware that a supply route may need to change based on changes in their circumstances / treatment.

- **Medicine choice is based on currently available evidence of effectiveness and safety, NICE recommendations and national policy. Selection of an appropriate supply route is made after the treatment has been agreed with the patient**
  - Choice of medicine is not normally reliant on the supply route.

### 3. Ensure medicine use is as safe as possible

- **Sufficient information is discussed with the patient to enable / support their concordance with their medication regimens**
  - Clinical outcomes and patient satisfaction are likely to be better when decisions about medicines are made jointly between the person taking the medicine and the prescriber.
  - Information may be provided at different parts of the pathway, including at initial treatment discussion, at supply / administration of the treatment and at follow up appointments.
  - Contact details on who patients should contact within the acute trust should be provided.

- **The selected supply route should deliver the required medicines at a time and venue suitable for the individual**
  - Risks of medicines being inadvertently supplied to the wrong person must be managed; this may particularly be an issue for specific patients, for example those transient patients who may change their address regularly.
  - Maintenance of cold-chain supply as required, using validated process.
Patients receiving medicines via a specific supply route should be monitored so that any adverse events or treatment failures are readily identified and managed

Providers monitor medicines-related patient safety incidents to inform their learning in the use of medicines

Effective communication channels must be in place between the patient, outsourced provider and the clinician responsible for that patient’s care

Support safety and sustainability of OOPD and homecare providers

The homecare market has experienced significant instability in past years; whilst this has improved more recently it is important to reduce the risk of recurrence in future years. This may require hub and regional collaboration regarding use of the homecare market to avoid diluting the service and ability to deliver required KPIs

4. Make medicine optimisation part of routine practice

Reduce medicine waste

Supply via an outsourced route should include steps to reduce the risk of wasted medicines, including appropriate quantities for supply, frequency of supply, and feedback on wasted medicines / doses from the outsourced provider. Patient choice and adherence for chronic treatment is key to reducing the risk of wasted medicines

Performance management of the outsourced provider

Ensure robust governance arrangements are agreed and followed; provision of Key Performance Indicators (KPIs); route for escalating issues

Key points

- Patients should be involved in discussions regarding the best supply route for them, thus supporting patient choice
- Not all outsourced routes will be suitable for all patients. In line with the Carter Report trusts should review their out-patient dispensing services with a view to providing supply of medicines by an appropriate cost-effective route; patient engagement in developing out-patient dispensing services is recommended
- The guiding principles apply to all medicines supplied to a patient, including those that are considered within tariff and those which are excluded from Payment by Results, regardless of who commissions the treatment
- Early and effective engagement with commissioners is required to discuss routes available and appropriateness of each route
- Whichever supply route is used should provide access to pharmaceutical advice as required by patients at a time and venue appropriate to the patient needs
- The originating trust always retains overall responsibility but key governance arrangements must be in place
- Usage data for all medicines supplied, regardless of supply route, should be captured for inclusion in Pharmex
- There is an opportunity to work more collaboratively across geographical areas, including at STP level, regional level and nationally, to reduce duplication of effort, share best practice and learn from others’ experiences
- Collaboration between key stakeholders nationally, such as NHS Digital, will support improved IT system compatibility
- Systems should be in place to reduce the risk of waste of medicines
- Performance metrics must be monitored on an ongoing basis to provide the assurance of the quality of the service, particularly in the context of patient safety and patient experience
- Processes must be in place to ensure that communication channels between all key stakeholders operate effectively
- Ensure clarity and ease of access for patients

**Action required**

**Acute providers** – chief pharmacists, homecare leads, out-patient contract managers

- Consider current and future outsourced arrangements within the trust and ensure HPTP plan is in place for improving productivity and efficiency, including consideration of alternative supply routes, such as homecare providers or community pharmacies
- Review current supply routes for medicines in line with above guiding principles to ensure that arrangements are fit for purpose and provide value for money
- Ensure that systems are in place to promote patient engagement such that the right route is used to supply the right medicine at the right time
- Discuss outsourced arrangements with relevant commissioners
- Contact regional leads where available for advice and support; improve collaborative working
- Access resources as required to support development of future outsourced arrangement
- Embed effective performance management systems from the outset

**Specialised commissioning hub pharmacists**

- Agree plans for outsourced arrangements with acute trusts (in support of a local service development improvement plan)
- Seek assurance that acute trusts have reviewed current and future arrangements in line with the guiding principles above
- Support collaborative working across trusts / geographies as required
Appendix 1: Service standards at supply route level

This table compares some of the service standards that should be taken into account when considering the most appropriate route for the supply of medicines. Attributes for each service that may be considered as advantageous are highlighted in green text.

<table>
<thead>
<tr>
<th>Service Standards</th>
<th>Contract management information</th>
<th>Contract management costs</th>
<th>Access to CMU contract and PAS prices</th>
<th>Effect on hospital stock holding-medicines spend</th>
<th>Care closer to home for patients</th>
<th>Patient access to specialist clinical pharmacists</th>
<th>Clinical pharmacy teams released from dispensing activities</th>
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<tbody>
<tr>
<td>In-house pharmacy</td>
<td>Direct control</td>
<td>Overhead costs managed in-house</td>
<td>Readily accessible</td>
<td>No reduction in stock holding</td>
<td>Patients must travel in order to collect medicines</td>
<td>Patients have access to experienced NHS pharmacy staff</td>
<td>Potential for highly qualified NHS pharmacy staff to be pulled away from delivering more clinically focussed roles</td>
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<td></td>
<td>No recommended national Key Performance Indicator (KPI) data or supply data</td>
<td>No constraints / restrictions on making off contract claims</td>
<td>Formulary management possible</td>
<td>Usage data supplied to CMU and included in Pharmex data for contracting purposes</td>
<td>Training opportunities for NHS staff in patient counselling and pharmacy management</td>
<td>NHS pharmacy staff may be used to support the service at times of pressure</td>
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<td></td>
<td></td>
<td>Usage data supplied to CMU and included in Pharmex data for contracting purposes</td>
<td>Standard rate VAT on all transactions</td>
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<td>OOPD: private company</td>
<td>Indirect control KPI and regional sales data templates clearly defined and can be adapted for local use</td>
<td>Wide variation but it is difficult to share information</td>
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<td>Contract management workload is significant</td>
<td>Off-contract claims will not necessarily be met. This is solely at the discretion of the contract holder</td>
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<td>Commercial provider may support capital expenditure on the pharmacy – however such costs will be recouped over the duration of the contract</td>
<td>Usage data is not consistently supplied to CMU and included in Pharmex data for contracting purposes</td>
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<td>Contract will be of a limited duration. Generally between 5-10 years. Any significant changes in service provision will need to be managed through a change control process</td>
<td>VAT zero rated</td>
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<td>At the end of the contract period a re-tendering process will need to be undertaken</td>
<td>One off reduction in stock holding on initiation of service</td>
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<td>Avoidance of increased stock holding as new medicines are launched</td>
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<td>Formulary management possible</td>
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<td></td>
<td></td>
<td>Patients must usually travel in order to collect medicines</td>
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<td>Sometimes able to deliver prescriptions to local patients’ homes or their nearest community pharmacy for collection at their convenience via their existing transport infrastructure</td>
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<td>Patients have access to a pharmacist at the time of receiving their medicines</td>
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<td>Training opportunities for NHS staff in patient counselling and pharmacy management</td>
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<td>Release of capacity of dispensary staff to clinical roles</td>
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<td>OOPD: wholly owned subsidiary (WOS)</td>
<td>Direct control</td>
<td>Recommended KPI and regional sales data templates clearly defined and can be adapted for local use</td>
<td>Contract should be appropriately structured to ensure no conflict of interests between the WOS and members of the trust</td>
<td>Contract management workload is significant</td>
<td>Wide variation but it is difficult to share information</td>
<td>Establishment costs of the WOS need to be borne by the host organisation. These may well include detailed legal and tax advice. Profits made by the WOS are retained within the NHS and therefore potentially can be re-invested in service development. Trust has closer / tighter control of strategy, process and business. Trust and WOS aims and objectives can be very closely aligned. Expertise is developing in this area as more and more trusts go down this route. Such information can be shared thus reducing overall costs of establishing these vehicles.</td>
<td>Accessible but may require a separate agreement from Manufacturers. Ability to make off contract claims when NHSE CMU contracted medicine is not available provided that there is an agreement from Manufacturers and this often requires an extra step in the process.</td>
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<tr>
<td><strong>Homecare Medicines Services via Homecare Provider</strong></td>
<td><strong>Contract management workload is significant</strong></td>
<td><strong>Contract management workload is significant</strong></td>
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<td>Regional funding models exist. National</td>
<td>Acceptable but requires a separate agreement</td>
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<td>documentation and support available</td>
<td>from Manufacturers</td>
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<td>Management costs have been quantified</td>
<td>Ability to make off contract claims when</td>
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<td>National documentation and support available</td>
<td>NHSE CMU contracted medicine is not available</td>
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<td>National, Regional and local strategic</td>
<td>requires negotiation on a case by case basis.</td>
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<td>oversight and support available</td>
<td>Potential for one 'stock out' to cause financial pressure to the NHS</td>
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<td>Considerable Pharmacy resource required</td>
<td>Usage data is not consistently supplied to CMU and included in Pharmex data for contracting purposes</td>
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<td>VAT zero rated if medicines are delivered to the patients home</td>
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<td>Formulary management possible</td>
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<td></td>
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<td>Delivery charges often funded by Manufacturers (70% homecare market)</td>
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<td>Care is provided closer to home</td>
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<td>Nurse training, patient education and home administration of medicines is possible</td>
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<td>Not all patients / patient cohorts will be suitable</td>
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<td>Patients may have access to experienced NHS pharmacy staff on attendance at outpatient appointments but not at the time of receiving their medicines</td>
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<td>Telephone support often available</td>
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<td>Release of capacity of dispensary staff to clinical roles</td>
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<td><strong>Hub and spoke model</strong></td>
<td><strong>Indirect control</strong></td>
<td><strong>No current national KPI dataset</strong></td>
<td><strong>Contract management workload is significant</strong></td>
<td><strong>Accessible but requires a separate agreement from Manufacturers</strong></td>
<td><strong>One off reduction in stock holding on initiation of service</strong></td>
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<td>Ability to make off contract claims when NHSE CMU contracted medicine is not available provided that there is an agreement from Manufacturers and this often requires an extra step in the process</td>
<td>Avoidance of increased stock holding as new medicines are launched</td>
<td>Formulary management difficult unless all prescriptions are validated by the Trust prior to dispensing</td>
<td>Patients have access to a non-specialist pharmacist at the time of receiving their medicines</td>
</tr>
<tr>
<td>FP10HP via Community pharmacy</td>
<td>No control</td>
<td>No national KPI dataset</td>
<td>ePACT data is available but no patient specific information available to the NHS</td>
<td>Billing to commissioners is delayed</td>
<td>NA</td>
<td>Unable to access Patient Access Scheme (PAS) / contract prices</td>
<td>One off reduction in stock holding on initiation of service</td>
</tr>
</tbody>
</table>
Please note that individual trusts should make decisions around the suitability of each drug category as listed below taking into account local population variation and the ability to support the cost effective dispensing route under consideration. The availability of pharma funded schemes and local, regional and national NHS contracted homecare medicines services as well as the use of the national Homecare Risk Assessment toolkit will also help to inform these decisions.

<table>
<thead>
<tr>
<th>Drug Categories</th>
<th>Examples</th>
<th>Homecare</th>
<th>OOPD</th>
<th>Notes</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Oral/Inhaled</td>
<td>IV/SC</td>
<td>Oral/Inhaled</td>
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<tr>
<td>AIDS / HIV antiretrovirals</td>
<td>Emtricitabine, tenofovir</td>
<td>✔ ✔ ✔</td>
<td>✔ ✔ ✔</td>
<td>✔ ✔ ✔</td>
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<tr>
<td>Allergic emergencies</td>
<td>Icatibant</td>
<td>✔ ✔ ✔</td>
<td></td>
<td>✔ ✔ ✔</td>
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<tr>
<td>Antibacterial drugs (inhaled)</td>
<td>Colistimethate sodium, tobramycin</td>
<td>✔ ✔ ✔</td>
<td>✔ ✔ ✔</td>
<td>✔ ✔ ✔</td>
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<tr>
<td>Antifungals</td>
<td>Voriconazole, posaconazole</td>
<td>✔ ✔ ✔</td>
<td>✔ ✔ ✔</td>
<td>✔ ✔ ✔</td>
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<tr>
<td>Antituberculosis drugs</td>
<td>Bedaquiline, delamanid</td>
<td>✔</td>
<td>✔ ✔ ✔</td>
<td>✔ ✔ ✔</td>
</tr>
<tr>
<td>Blood-related products (factors)</td>
<td>Factor VIII, factor VIII inhibitor bypassing Factor</td>
<td>✔ ✔ ✔</td>
<td></td>
<td>✔ ✔ ✔</td>
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</tbody>
</table>
| Chemotherapy                                         | Capecitabine, temozolomide           | ✔ ✔ ✔     | ✔ ✔ ✔ | ✔ ✔ ✔ | This may change over time as new services join the market
| Cytokine modulators                                  | Adalimumab, etanercept               | ✔ ✔ ✔     |       | ✔ ✔ ✔ |
| Cytomegalovirus infection                            | Valganciclovir                       | ✔         | ✔ ✔ ✔ | ✔ ✔ ✔ | × |
| Drugs used in hypoplastic, haemolytic, and renal anaemias - iron overload | Deferasirox, deferiprone              | ✔ ✔ ✔     | ✔ ✔ ✔ | ✔ ✔ ✔ |
| Drugs used in metabolic disorders                    | Carnitine, nitisinone                | ✔ ✔ ✔     | ✔ ✔ ✔ | ✔ ✔ ✔ |
| Drugs used in neutropenia                            | Filgrastim                           | ✔ ✔       |       | ✔ ✔   |
### Erythropoietin stimulating agents
- Darbepoetin, epoetin

### Growth hormone & growth hormone receptor antagonist
- Pegvisomant, somatropin

### Hormone antagonists
- Abiraterone, enzalutamide

### Hypnotics and anxiolytics
- Sodium oxybate

### Immunomodulating drugs (MS)
- Dimethyl fumarate, glatiramer acetate, beta interferon

### Immunomodulating drugs (haematological oncology)
- Lenalidomide, thalidomide

### Lysosomal storage disorder drugs
- Agalsidase alpha and beta, migalastat

### Mucolytics
- Dornase alpha, ivacaftor

### Multiple sclerosis (MS)
- Daclizumab

### Neuromuscular disorders
- Ataluren

### Other anti-cancer therapies
- Trastuzumab

### Parenteral nutrition (home)
- Parenteral Nutrition

### Phosphate binding agents
- Sevelamer, lanthanum

### Protein kinase inhibitors
- Imatinib, dabrafenib, pazopanib

### Pulmonary fibrosis
- Nintedanib, pirfenidone

### Somatostatin analogues (except inpatient use)
- Octreotide, lanreotide

### Human normal immunoglobulins
- Gamunex, Subcuvia, Subgam

### Transplant immunosuppression
- Mycophenolate, tacrolimus

Sub cut ok but IV products are usually delivered as day case.
### Vasodilator antihypertensive drugs / Pulmonary arterial hypertension

<table>
<thead>
<tr>
<th>Drug</th>
<th>Rating</th>
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<td>Sildenafil, bosentan</td>
<td>✔ ✔ ✔</td>
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</table>

### Viral hepatitis (B&C)

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<th>Drug</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir</td>
<td>✔ ✔ ✔</td>
</tr>
</tbody>
</table>

**OOPD**

- Outsourced out-patient department
- ✔ May be suitable for some patients
- ✔ ✔ Suitable, although some additional work may be required
- ✔ ✔ ✔ Suitable
- ✗ Not appropriate

### Notes:

This document is primarily focused on the acute sector. However, it is noted that mental health drugs such as clozapine and long acting atypical antipsychotic injections may be outsourced.

Homecare is suitable for regular supplies of medication where dose changes are infrequent and a delay in the supply of a dose adjustment will not compromise patient safety or outcome. Mid- and high-tech Homecare medicines services may be available but will require additional work. The originating trust always maintains responsibility and will be held to account for medicines supplied via Homecare companies; an SLA will be required with each provider.
Appendix 3: Toolkit to support trusts when considering options for an Outsourced Out-Patient Dispensary service

Homecare:

There are national documents available to assist national, regional and local trusts when contracting homecare services which include Service Specification Template, KPIs, patient registration and consent forms and a new services risk assessment document. There is comprehensive guidance and a training programme for the NHS on the management of complaints and incidents in homecare services. If you require assistance or would like advice and / or access to any of the additional resources that are available, please contact your Regional Outsourced Service Manager or your Regional Homecare Specialist in the first instance.

If your Regional Homecare Specialist is unable to help, please contact your National Homecare Specialist. Contact details of the homecare national and regional specialists are available at https://www.sps.nhs.uk/articles/nhmc-homecare-regional-contacts/.

Homecare Waste – London Initiative

Introduction

Across London, we have a large cohort of patients on immune altering biologic medicines for rheumatology, gastroenterology and dermatology indications. The cost of providing these medicines and homecare services by Healthcare at Home (HAH) each month to patients within London is £8,555,318.09. Audits in other areas of the UK have shown that approximately 5% of medicines supplied through the Homecare route are wasted. All homecare biological medicines in London are dispensed and delivered by a commercial provider, with the main partner being Healthcare at Home which supplies in excess of 90% of these medicines via this route across London. NHS LPP has worked in collaboration with HAH to carry out this project. We have analysed the data that is already collected by HAH to determine:

1. Does supply of medicines via Homecare increase the risk of waste?
2. If medicines are wasted, what are the reasons for this waste?
3. Does the waste relate to any particular group of patients?
4. Are there any trends or patterns in where and how this waste occurs?
5. Can we do anything about this waste?

Methods

Healthcare at Home collected data for Humira, Cimzia and Enbrel over 12 months for each London Trust that uses HAH for these products. The data collected included name of Trust, clinical speciality, name of medicine, amount returned, and reason for return, if it was destroyed, any credits and the cost of the returned medicine. The cost of waste as a percentage of total invoiced cost of all those medicines supplied was also considered.
Results
During this 12-month period, HAH dispensed £63,726,633 on biological medicines shown above. The amount of returned biologic medicines during this time however was 0.4% of this cost, a value of £227,688. There were differences between the Trusts in the number of incidents of return and the cost of these returns.

There were a number of reasons recorded for medicines to be returned to HAH. The most common reason was that the patient was off treatment. With this data, we do not have a further breakdown of why the patient was off treatment, whether this was temporary or permanent. The incorrect storage temperature of medicines in the patients home was the third most common reason for returns.

The cost of waste as percentage of cost of all medicine returned was analysed by patent group. In this we saw that the returns from gastroenterology speciality were significantly higher than dermatology and rheumatology. This may be flawed however as there was a significant return from one Trust for this speciality.

Of the returned medicines described above, 100% had to be destroyed and with the cost of the waste being borne by the NHS.

Conclusion
The initial data above shows a lower level of waste than previously reported for homecare supply of these medicines. However the data was incomplete as this is only data from one homecare provider, and took no account of possible differences in wastage between different patient groups or due to other variables. There were differences in the number of returns per Trust which did not appear to be directly related to the number of patients being treated at each.

The reasons for the returns seemed to vary but the predominated reason was the patient off treatment; however this is unclear whether it was a short term or permanent discontinuation of therapy. Providers and commissioners should review the patient pathway to try to avoid deliveries if there is a likelihood of stopping treatment or changing dose. Our data also suggests that we need to improve patient education about the importance of storing these medicines appropriately, in particular if they require refrigeration.

Future Plans
- Healthcare at home are continuing to work to give LPP data on returns from other areas
- A Pilot project is planned to take place with two London Trusts, looking at current returns for subcutaneous biological medicines, and to see if intervention with patients can reduce this
- Work with all homecare companies to include wastage in their monthly reporting to the regional lead so this can be monitored
- To write up the above findings as a detailed report to enable healthcare professionals (HCPs) working in this area to make informed decisions on how to improve practice reduce waste
- The above results indicate that the majority of this waste was avoidable. Review of care pathways and improved communication between the prescribing organisation and homecare suppliers will be pursued to reduce waste

For further information contact: Jacqueline.eastwood@lpp.nhs.uk
Outsourced Outpatient Pharmacy Model:

In London, East of England and Thames Valley & Wessex areas an outsourced contract management group has been set up to focus:

- On issues that they have encountered in setting up an outsourced supply route
- Learnings from setting up such supply routes
- Support for trusts looking at developing an outsourced supply route

This group does liaise with the regional procurement pharmacists in Yorkshire and North West England to ensure that any documents are shared. To date a standard set of service KPIs have been designed with the aim that these are used for all services going forward as the minimum data set. This will allow the NHS to benchmark the services being provided.

There is a plan to set up a national group with a similar remit as the National Homecare Medicines Committee, but for outsourced outpatient pharmacy services, so a national plan of standardisation can be implemented to ensure that the governance for these services is aligned across England.

NHS London Procurement Partnership Framework agreement for the provision of outpatient pharmacy dispensing services

With an increasing number of NHS organisations looking to generate efficiencies and service improvements in Outpatient Pharmacy Dispensing (OPD), NHS London Procurement Partnership (LPP) took the decision to procure a framework agreement for the provision of outpatient pharmacy dispensing services LPP. The framework agreement which was awarded for a four year period from 1st January 2017 encompasses the following services within the provision of OPD:

- Outpatient Pharmacy Dispensing services
- Emergency Department Dispensing services
- Provision of Retail Pharmacy services
- Outpatients Pharmacy Dispensing Home Delivery Service
- Discharge to take out or take away (TTO/TTA) Medicines Dispensing
The suppliers who have been awarded to the framework agreement are as follows:

- Fairview Health Partnerships Ltd
- Lloyds Pharmacy
- Rowlands Pharmacy

Further information and an access agreement can be found on the LPP website (http://www.lpp.nhs.uk/categories/medicines-optimisation-pharmacy-procurement/secondary-care/outpatient-pharmacy-dispensing-services-framework-agreement/). The award of a trust contract for these services is via a further competition process with provision all the documents required within a further competition toolkit put together by LPP.

For further information contact: Jacqueline.eastwood@lpp.nhs.uk

**Case study: Set up of Pharm@Sea, a private limited company and wholly owned subsidiary of Brighton & Sussex University Hospitals NHS Trust (BSUH)**

BSUH set itself a highly ambitious plan in 2013 to transform its pharmacy operations to help drive improvements in patient experience and efficiency. It was recognised that the quality of service could be improved through the separation of inpatient and outpatient pharmacy services, thus ensuring each dispensary team could focus on one core activity. In order to do this, an options appraisal was carried out to explore whether the outpatient service should remain in-house; be outsourced to a third party provider or a new wholly owned subsidiary company be set up to run the service.

To decide on the best model for the outpatient pharmacy service, the options appraisal evaluated:

- Patient benefits of each option
- Costs of each option
- Which option best fitted BSUH’s strategic objectives

Whilst benefits were seen for all options, the leading option for BSUH was to set up a wholly owned subsidiary company to run its outpatient pharmacy service. There were many reasons for taking this option but a key one was that this model of employing staff from hospital and the community to run the service took the best from the NHS in terms of high quality clinical skills, practices and a deep knowledge base, and combined this with the opportunity to learn from the commercial sector. This joint model was felt to be best placed to focus on outstanding care for the customer, to drive efficiency savings, seek new revenue opportunities, and exploit innovative ideas.
There were additional qualitative benefits to the pharmacy department by choosing this option. It allowed training opportunities across hospital and community pharmacy areas and enabled a joint working environment with support for each other.

The wholly Trust owned subsidiary company (called Pharm@Sea©) also allowed the Trust to gain experience of developing a new business with a dedicated Board of Directors that would oversee the running and development of the business to provide services in addition to dispensing (e.g. Homecare, flu vaccinations, clinics).

A number of patient benefits have been realised with this model:

- 9 minute average turnaround times for prescriptions, reduced from an average of 40 minutes before the establishment of Pharm@Sea
- Over 90% of all outpatient prescriptions are dispensed and returned to the patient within 15 minutes
- 93% of service users rate the pharmacy as ‘excellent’ or ‘very good’ overall
- Further value is also added to our patients, provided through ancillary services such as providing flu vaccines, Pertussis vaccines and a smoking cessation service

Benefits to the Trust can also be demonstrated:

- Quality improvements:
  - Turnaround times for discharge medicines (TTO’s) halved from an average of 2 hours to 59 minutes
  - Supporting improvements in patient flow, e.g. Paediatric Day Case dispensing by Pharm@Sea, where improved dispensing efficiency means 25% more patients are seen per month
- Financial benefits:
  - Charitable donation or dividend distribution is provided to the Trust at the end of each financial year
- Capacity benefits:
  - Increased ward presence of clinical pharmacy staff, and rollout of 7-day pharmacy service

For further information contact: Jatinder.Harchowal@rmh.nhs.uk
Sheffield Teaching Hospitals NHSFT: Benefits from the establishment of an outsourced OPD model

Patient waiting times for OPD prescriptions halved

![Mean OPD prescription turnaround (mins)](image)

High levels of patient satisfaction

![Patient experience](image)
Redeployment of Trust pharmacy staff from outpatient to inpatient services helped to drive Trust-wide discharge prescription turnaround times down

Other benefits:
- Reduced Trust stockholding of pharmaceuticals
- Lease income to Trust Estates
- Retail sales offering for patients, visitors and staff
- Medicines budget savings (Trust and commissioners)

For further information contact: damian.child@sth.nhs.uk
Hub and Spoke model:

Thames Valley and Wessex Hub and Spoke Model

In Thames Valley and Wessex one specific out patient service is provided by a dedicated community pharmacy company ‘hub’ which is situated adjacent to one of the community pharmacy chain’s stores. The dedicated unit provides the dispensing for one particular patient cohort. The community pharmacy ‘hub’ is permitted access to the hospital only medication at prices equivalent to CMU contract prices. Hospital / homecare prescriptions are dispensed by this hub and then sealed packages are delivered to each patient’s local branch of the community pharmacy chain for collection. Patients are made aware of when their medication is ready for collection following their outpatient appointment. If patients fail to collect their medicines the clinical teams are alerted. If the packages are not collected within an agreed timeframe, they are returned to the ‘hub’ and provided that there is evidence that the package has remained within the approved supply chain, the Trust is not charged for the medication.

For further information contact: susan.gibert@berkshire.nhs.uk

Reducing waste where medicines are supplied by an out-patient pharmacy:

A technician led service to manage the supply of high-cost oral medicines

In 2014 The Christie NHS Foundation Trust realised that there was potential for there to be significant wastage of high cost oral cancer medicines. Over the preceding years the management of cancer had changed and in a number of tumour sites, treatment practice had changed and there was a greater usage of high cost oral therapies, with treatment continuing until disease progression. In particular the Trust was treating large numbers of patients with renal cell carcinoma and metastatic prostate cancer with novel oral agents. Monthly treatment costs were in excess of £1500. Often these patients were given 3 month prescriptions when seen in clinic, as they were judged to be relatively stable, and did not warrant closer follow-up. However if between appointments their condition changed, or disease progressed, then treatment would be stopped, resulting in significant wastage of the medicines. To address this situation the Trust introduced a technician led follow-up service whereby patients were only ever given one month’s supply of the high cost oral medicine. Every 3 weeks patients are contacted by a technician – and on confirming that the patient is still on their medicine they will initiate a further supply. This service means that patients will never have more than one month’s supply of their medicines, and in the 3 years the service has been operational over £1m has been saved through the tight control of out-patient medicine supply.

For further information contact: Robert.duncombe@christie.nhs.uk, Natasha.scarry@christie.nhs.uk
Available resources:

Appendix 4: Tax avoidance issues in the UK – letter from the Department of Health

Christopher Young
Finance Director
Department of Health
Quarry House
Quarry Hill
LEEDS
LS2 7UE
Christopher.young@dh.gov.uk

28 September 2017

NHS Provider Finance Director

Dear Colleagues

Tax Avoidance Issues in the NHS

Whilst the challenge facing NHS organisations in delivering efficiency savings remains a clear priority, within that context this letter seeks to clarify the Departmental of Health (and Government) view on the use of tax advisors, with particular reference to tax avoidance.

You will be aware that an element of VAT incurred on the supply of any applicable services “contracted-out” of the public sector is genuinely reclaimable and this is accepted practice worth in the region of £2 billion per annum across the NHS.

However, the Department has been made aware of a number of tax advisors offering tax solutions to health bodies which, although legal, avoid the payment of tax for which that body has been funded. The fees chargeable to the tax advisors represent a direct leakage out of the health system and while at a local level there may be an immediate financial benefit, there is an overall net loss to the exchequer as a result.

The only tax advice the Department deems acceptable is that necessary for the fullfilment of statutory functions or to assist in compliance with tax rules beyond in-house expertise. Tax avoidance schemes should not be entered into under any circumstances: for the avoidance of doubt, HMRC’s definition of tax avoidance is:

‘...bending the rules of the tax system to gain a tax advantage that parliament never intended...it often involves contrived, artificial transactions that serve little or no purpose other than to produce this advantage. It involves operating within the letter, but not the spirit, of the law.”

HMRC are actively investigating the health sector in relation to tax avoidance schemes and the level of scrutiny is likely to increase in the future. Any findings indicating systemic issues will likely have significant implications, both locally for those organisations directly involved and nationally for the future use of the contracting out regime by the NHS.
I seek that careful consideration be given by NHS organisations when looking into contractual arrangements which give rise to a tax advantage. If there are genuine commercial reasons for entering into contracts which, as a by-product, have a tax benefit this is considered acceptable. However, arrangements considered solely to gain a tax advantage is clearly tax-avoidance and should not be entered into for the reasons set out above.

For further information and any advice on this matter, please do not hesitate to get in touch.

Yours sincerely,

Chris Young
Finance Director

Document control

Document location
If you are looking at a hard copy of this document, check the Specialist Pharmacy Services website https://www.sps.nhs.uk/ to make sure you are using the most recent version.

Revision History

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<td>Ratification by RMOC with minor clarifications</td>
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Approvals

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Consultation
The production of guidance involved MO CRG T & F members and consultation with RMOC members,

MO CRG T&F members:
Nicola Berns, The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
Damian Child, Sheffield Teaching Hospitals NHS Foundation Trust
Rob Duncombe, The Christie NHS Foundation Trust
Jacqueline Eastwood, NHS London Procurement Partnership
Susan Gibert, National Homecare Medicines Committee
Charlotte Skitterall, University Hospital of South Manchester NHS Foundation Trust
Further information

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