

Outpatient Medicines Transformation Phase Two Report:

Easing the demand on homecare - can hospital
medicines be safely supplied via alternative models?



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Acronyms

CDF – Cancer Drugs Fund

EPS – Electronic prescription service

F2F – Face to face

GP – General practitioner

HIV - Human immunodeficiency virus

ICB – Integrated Care Board

ICS – Integrated Care System

IMF – Innovative Medicines Fund

LOE – Loss of exclusivity

LPP – London Procurement Partnership

NCHA – National Clinical Homecare Association

NCL – North Central London

NHS – National Health Service

NHSBSA – National Health Service Business Services Authority

NHSE – National Health Service England

NICE – National Institute of Clinical Excellence

OPD – Outpatient department

PAS – Patient access scheme

PO – Purchase order

Rx - Prescription

UCLH – University College London Hospital

VAT – Value added tax

WDA - Wholesale distribution authorisation



Summary

Phase One of this project was centred around a deep dive into outpatient prescribing in North Central London (NCL), in which we mapped prescribing pathways, their challenges and suggested solutions. Based on the recommendations made in the Phase One report, we initiated Phase Two with a view to test the feasibility of provisioning hospital medicines, presently delivered by homecare services, via alternative methods. The focus of the project was on 'low-tech' oral medications, not requiring refrigeration, specialist monitoring or administration; medicines for which homecare had largely become an expensive 'delivery service'. The intention was to find alternative methods of provision for such medications, releasing capacity within overstretched homecare services for those more complex drugs which truly required the specialist support that homecare providers were set up to deliver.

We set out to design an alternative dispensing pathway, one that utilised the skills and expertise of community pharmacy, whilst maintaining access to medicines, care close to home for patients and the opportunity for NHS cost savings. Our intention: to reduce the growing reliance on dispense and deliver services offered by private homecare providers.

Through engagement with key stakeholders, including prescribing teams within local NHS providers, community pharmacy, pharmaceutical manufacturers, homecare companies and patients, as well as local and national NHS commissioning bodies, we discovered numerous structural barriers that compromised our ability to create the case for change. There were issues with procurement access for different types of organisations, for example, community pharmacies must procure medicines at the more expensive list price, while homecare companies can more easily access discounted rates. The deficit of robust electronic prescribing systems made sharing of prescriptions between different legal entities particularly challenging, with wet signatures being required on prescriptions. The logistics of moving medicines between hospitals and community pharmacies was complex and unfunded. Additionally, the modest operating budgets of community pharmacies (compared with large hospital trusts) often precluded their involvement due to the financial risks associated with stocking expensive medications.

Despite a clear mandate for change, outlined in detail in our Phase One project report¹, and enthusiasm from NHS partners and community pharmacy to pioneer a new service, we were unable to make change at a local level, due to the significant barriers mentioned above. This report outlines our understanding of the problem within the system, the financial, legal and logistical structures surrounding it, as well as two alternative model proposals and recommendations for change.

¹ https://s42140.pcdn.co/wp-content/uploads/Outpatient-Medicines-Phase-One-Report_final.pdf

Introduction

Background

In response to the rapid transformation of outpatient care following the COVID-19 pandemic, there is a pressing need to review the ways in which hospital medicines are provided to patients following an outpatient consultation. The rise in virtual appointments reducing footfall into hospital clinics, highlights a rationale to bring care and access to medicines closer to home. Ensuring that patients can access their medicines in a way that is safe, timely and convenient, avoiding unnecessary trips to the hospital is a key priority for the NHS and outpatient prescribers.

Under particular scrutiny are homecare medicines services, designed to deliver specialised hospital medicines to patients' homes, sometimes with a healthcare professional to support administration of medication. Homecare services, most commonly fulfilled by private providers, offer an essential service to patients and the NHS, ensuring continuity of care from the hospital to the home. They are key to facilitating care in the community for patients with long term conditions, which is often more comfortable and desirable than long term hospital stays. Homecare companies assume a high administrative burden in delivering this service, leading on patient communication around delivery, managing complex reimbursement processes and leveraging national distribution networks to bridge shortfalls in supply when required.

Despite their integral role in the system, a House of Lords Public Services Committee report², published in November 2023, outlined a number of serious concerns within the sector. The findings highlighted poor patient experience, a lack of transparency around cost and performance as well as an absence of requisite structures to enforce standards. Furthermore, it is not clear whether services have sufficiently extended their capacity to meet rapidly increasing demand.

As demand for homecare services increases, partly due to the growing number of high-cost drugs being approved for use within the NHS, so too does the number of patients receiving the service (up 150% since 2011). This increased demand on services has resulted in compromised access at times including delays, incorrect deliveries and communication challenges, the result of which can seriously impact patient experience.

UCLPartners, in collaboration with Pfizer UK & Alliance Healthcare, are working with key stakeholders nationally and across North Central London to explore and co-develop an alternative outpatient hospital medicines provision model.

This report summarises pharmacy dispensing models in use across England, reimbursement mechanisms and provides case studies of innovative approaches to dispensing outpatient medicines. This is followed by a proposal for two alternative

² House of Lords Public Services Committee: *Homecare medicines services: an opportunity lost* (Nov 2023)

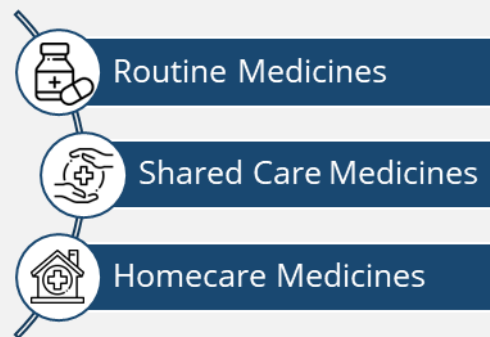
outpatient dispensing models, as well as a summary of the design process. This report builds on the findings of Phase One³ of the project, summarised below.

Prior work (Phase One)

Phase One of this project was a deep dive into outpatient prescribing pathways within North Central London Integrated Care System (NCL ICS). Eight stakeholder round tables and workshops were held to map prescribing pathways and challenges within secondary care services, as well as develop solutions and recommendations for each. The sessions were well attended by key groups (listed below), to allow for system input, co-design and sourcing of partners interested in developing alternative models of provisioning drugs as part of Phase Two.

Stakeholders Engaged

- Patient Groups
- Secondary & Tertiary Care
- Community Pharmacy
- Local Pharmaceutical Committee
- Primary Care & General Practice
- Mental Health
- NCL ICS Medicines Management Teams
- London Procurement Partnership
- NHS Digital



³ Outpatient Medicines Pathway Transformation: Phase One Report, UCLPartners (Jan 2024) accessible at: https://s42140.pcdn.co/wp-content/uploads/Outpatient-Medicines-Phase-One-Report_final.pdf

Phase One priority areas

Three priority areas were identified for each of the three medicine pathways: routine, shared care and homecare.

Routine medicines

Medicines which are prescribed in outpatients but are also more commonly prescribed and continued in primary care. Do not require additional monitoring and reimbursement processes are in place to support provision via community pharmacy.

Priority areas - Identified in Phase One for NCL ICS to lead

- a) Electronic prescription service (EPS)
- b) London Procurement Partnership (LPP) prescribing guidance
- c) NCL consensus document

Shared care medicines

Medicines considered suitable for shared care are those which should be initiated by a specialist, but where prescribing and monitoring responsibility may be transferred to primary care. Due to their potential side effects, shared care medicines usually require significant regular monitoring and/ or regular review by the specialist is needed to determine whether the medicines should be continued.⁴

Priority areas - Identified in Phase One for NCL ICS to Lead

- a) Development of shared care guidance
- b) Effective and efficient transfer of care
- c) Access to clinical information and advice

Homecare medicines

Medicines that are provided by specialist services who retain responsibility for prescribing and monitoring. They are largely provisioned by private homecare companies who provide medicines and other healthcare products and services to patients in their own homes. Homecare services have been defined as:

⁴ RMOC (North), Shared Care for Medicines Guidance - A Standard Approach (2021) Shared Care for Medicines Guidance – A Standard Approach (RMOC) – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

- **Low-tech** (self-administration of oral therapy excluding oncology products)
- **Mid-tech** (self-administration of injectable therapies which require training/ competency assessment and often have special storage requirements)
- **High-tech** (intravenous infusions or products requiring administration by a healthcare professional) and complex care (bespoke homecare solutions for individual patients⁵)

Priority areas - Identified in Phase One to take forward to Phase Two:

- a) Exploring new models of supply/ care for homecare patients, including 'low-tech' medicines (which may release capacity to manage 'mid/ high-tech' medicines)
- b) Multiple bespoke platforms have been developed to manage homecare patients
Explore potential to streamline transfers of care and communication
- c) To promote collaboration between National Homecare committee and providers

⁵ Royal Pharmaceutical Society, Handbook for Homecare Services in England. 2014.

Phase Two

Overview

As agreed with North Central London stakeholders during Phase One of the project, Phase Two focussed on hospital medicines provisioned by homecare services. Our goal was to evaluate the feasibility and viability of an alternative model of provision for 'low-tech' medicines, which do not require specialist monitoring or administration by a healthcare professional. Such an intervention could potentially release capacity within homecare services for more complex medicines requiring specialist care.

During this phase, we worked with system partners to map existing dispense and deliver pathways used by homecare services, as well as the individual medicines provisioned via homecare at each trust, their patient cohorts, reimbursement models and funding schemes. We have grouped learnings into three focus areas, which were used to codevelop an alternative model of provision with a view to pilot at a secondary care trust within our geography.

Focus areas



Pharmacy dispensing models



Reimbursement mechanisms



Innovative dispensing models



Pharmacy dispensing models

In order to reimagine dispensing pathways, it is important to understand the different types of pharmacies in England, their operating models, the legal structures surrounding them and their procurement and reimbursement mechanisms. For the purpose of this report, we will refer to these as “pharmacy dispensing models”. The manner in which pharmacies are organised has various financial, logistical and legal implications, summarised below:

Financial:

- **Drug procurement and access to discounts** - the size and nature of an organisation will impact on its buying power and ability to negotiate discounts
- **VAT payment** – outsourced pharmacies are exempt from paying VAT on medicines, whereas in-house NHS pharmacies will pay VAT on most medicines dispensed within their facility
- **Reimbursement** – some reimbursement channels are only available to particular types of organisations (i.e. NHS secondary and tertiary care trusts and not community pharmacy)

Logistical

- **Communication with clinical teams** – in house pharmacies may have better communication with clinical teams and access to shared systems
- **Deliveries and homecare** – costs can usually only be reimbursed from secondary and tertiary care trusts and not community pharmacy

Legal

- **Prescription transmission** – when prescriptions are shared between different legal entities, a wet signature is usually required, unless electronic transmission through a third-party e-signature solution is used

The following table provides a high-level overview of seven pharmacy dispensing models⁶, and their organisational considerations based on the above criteria. For a more detailed summary of each, including the key advantages and disadvantages, and an overview of the ‘ideal drug’ to be dispensed under each model (in terms of cost, commissioner, complexity etc.), please see Appendix A.

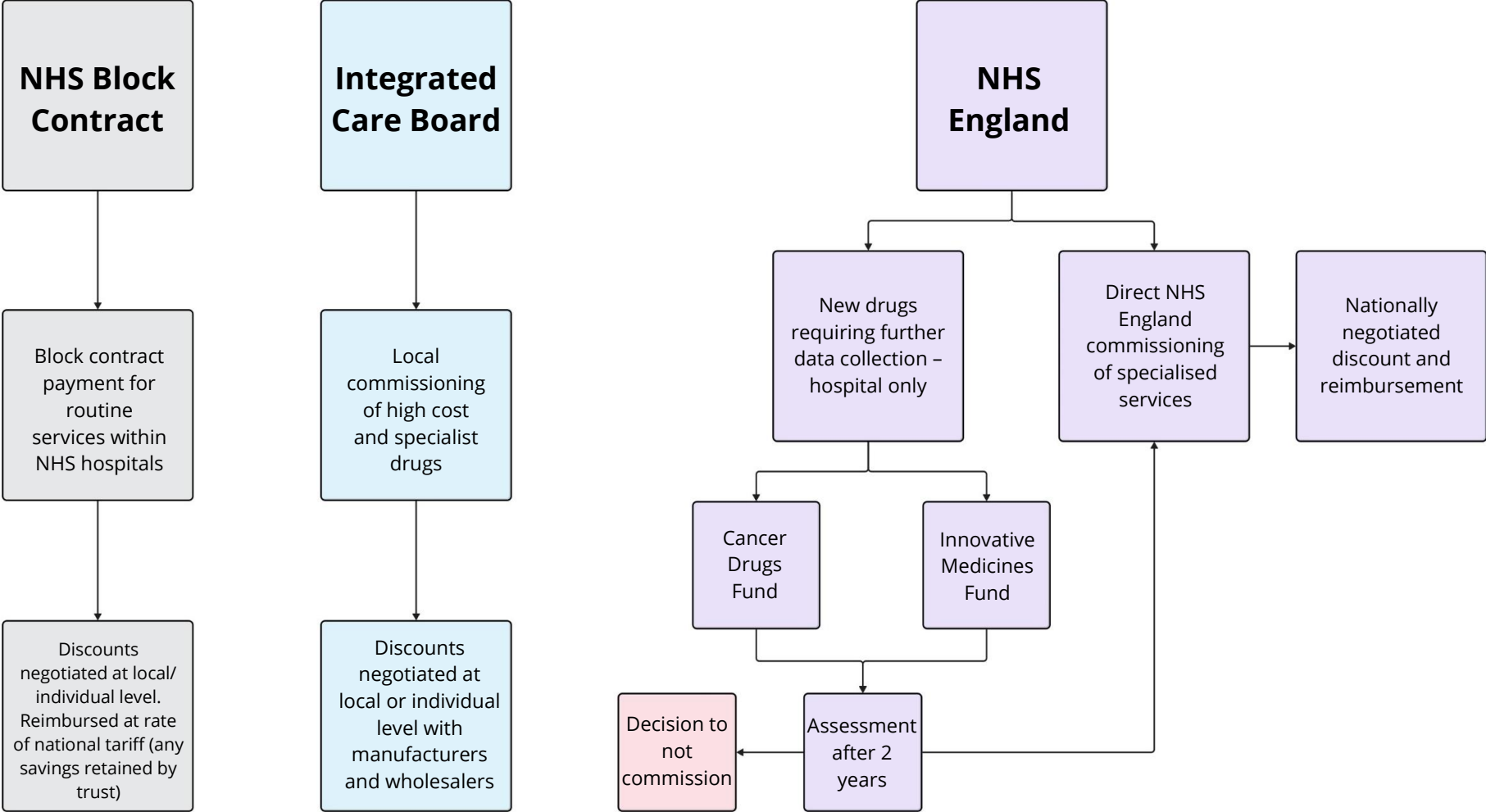
⁶ In-house NHS pharmacy, wholly owned subsidiary, outsourced outpatient pharmacy, homecare company, community pharmacy. e-pharmacy.

Model	Drug purchase	Vat paid?	Drug reimbursement	Courier/ homecare reimbursement	Prescription transmission	Limitations
In-house Pharmacy in NHS Hospital	Via hospital contract or nationally negotiated NHS price through hospital supply chain	Yes	Specialist medicines reimbursed by NHSE /CDF. Routine medicines reimbursed by ICB/ NHS block contract at national tariff	Via regional procurement framework contracts (e.g. LPP) or manufacturer funded	Electronic transmission	Hospital keep savings made by contract discounts but must pay VAT.
Wholly owned subsidiary	Via hospital contract or nationally negotiated NHS price via WDA license through hospital supply chain	No	Specialist medicines reimbursed by NHSE /CDF. Routine medicines reimbursed by ICB/ NHS block contract at national tariff	Via regional procurement framework contracts (e.g. LPP) or manufacturer funded	Different legal entity but can transmit prescriptions electronically	Only available to NHS foundation trust status. Hospital make savings by contract discounts and no VAT applicable
Outsourced OPD With/without hub/spoke model	Via hospital contract or nationally negotiated NHS price via WDA license through hospital supply chain	No	Specialist medicines reimbursed by NHSE /CDF Routine medicines reimbursed by ICB/ NHS block contract at national tariff	Via regional procurement framework contracts (e.g. LPP) (homecare is often managed by in house pharmacy team)	Different legal entity but can transmit prescriptions electronically	Pharmacy make savings by contract discounts and no VAT applicable. Profit sharing agreement with hospital
Homecare Company	NHS list price from wholesaler or manufacturer	No	Reimbursed by hospital at hospital price. Difference between nationally negotiated and NHS list price is reimbursed by drug company.	Funded by manufacturer, hospital block contract budget or regional procurement framework (e.g. LPP)	Different legal entity, need for wet signature	Lengthy process for full reimbursement (partially by NHS trust and partially by drug company)
Community Pharmacy	NHS list price from wholesaler or manufacturer	No	Highly specialist medicines not typically reimbursed. Routine medicines /shared care medicines reimbursed by NHSBSA/ ICB at national tariff	No	Different legal entity, but can prescribe through Cleo Solo® / SystemOne on FP10 without wet signature (where available)	No access to courier reimbursement or methods of drug reimbursement for specialist medicines
e-Pharmacy	NHS list price from wholesaler or manufacturer	No	Highly specialist medicines not typically reimbursed. Routine medicines /shared care medicines reimbursed by NHSBSA/ ICB at national tariff	No	Different legal entity, but can prescribe through Cleo Solo® / SystemOne on FP10, otherwise need for wet signature	No access to courier reimbursement or methods of drug reimbursement for specialist medicines

For a more detailed overview of each pharmacy dispensing model, including their advantages and disadvantages, please see Appendix A.



Outpatient medicine reimbursement mechanisms



For a more detailed explanation of each reimbursement mechanism, please see Appendix B.

Homecare reimbursement mechanisms

Manufacturer funded

Manufacturer funded home care is paid for directly by the manufacturer at an additional cost to the medicine. In this type of contract, the manufacturer pays for the homecare as an additional fee and is separate to the medicine price agreed with NICE. A manufacturer will decide on what level of service to provide, from dispense and delivery with or without additional patient services based on market analysis, working with patient groups and/or NHS to establish requirements and support to bring the medicine to market.

While there are clear benefits to the NHS under this system, such as free homecare and a reduced administrative burden on the trust, there is also a lack of transparency and choice for prescribers. The NHS is unable to explicitly choose which homecare company delivers each contract and will usually have multiple services run by different providers.

Once a drug loses its patent, it is the responsibility of the manufacturer to decide whether they continue funding homecare services or not. The financial implications of loss of exclusivity (LOE) often means that offering homecare services for 'free' is not commercially viable. Sometimes a manufacturer will continue to provide homecare in order to retain market share, or if it is in particular interest of the patient to continue it, such as in the case of Enbrel[®] (etanercept) and Gilenya[®] (fingolimod).

Pricing homecare

When the manufacturer pays for homecare, the trust only needs to fund the cost of the drug contract, which is wholly reimbursed by the commissioning body. When the NHS trust pays for homecare directly, known as NHS funded homecare, the drug and homecare service are paid for separately, and only the cost of the drug is reimbursed by the commissioner. Under NHS funded homecare, the trust is able to specify what level of service the homecare company provides, as well as directly negotiate cost.

It is easier for trusts to demonstrate savings and identify more competitive drug contracts when the two are separated⁷. However, homecare services are often paid out of a different pot to the medicines themselves, so making comparisons and building business cases around savings can be complicated. There is not usually a holistic NHS budget to balance against.

The future of homecare

The provision of bundled homecare services has become the norm, even for 'low-tech' oral medications which do not require specialist administration, monitoring or refrigeration. Manufacturers often feel obliged to launch new drugs with 'free' homecare, even when the service is not strictly necessary. NHS Patient Access Schemes (PAS) for NHSE, CDF and IMF drugs have further increased this trend, as under the scheme homecare is often the only viable route for specialist medicines due to the

⁷ Department of Health. Homecare Medicines: Towards a Vision for the Future (2011)

medicine being classified as hospital only. Recently, there has been more impetus to encourage trusts to find alternative methods of provision for drugs which don't require homecare, due to the burden that these 'low-tech' medicines pose on already stretched homecare services.

NHS London Procurement Partnership (LPP) framework agreements

The NHS LPP framework agreements provide transport of medicines from NHS hospitals to patients in London, with similar schemes available across the UK. This is a block contract of funding provided to hospitals to be used for deliveries of medicines to patient homes, usually via courier from a set of pre agreed contractors.

LPP framework agreement for low, mid and high-tech homecare services

Directly commissioned homecare for low, mid and high-tech drugs. The 'low-tech' contract includes:

- HIV
- Hepatitis
- Immunosuppression
- Oral and inhaled antibiotic products
- Basic dispense and deliver services for licensed products including oral chemotherapy



Innovative dispensing models

The motivation for transformation within outpatient prescribing is not a new phenomenon. As such, there have been pockets of innovative work developing across England and the UK for a number of years. As part of this project, we sought to collate relevant case studies to inform our own ideas and build upon for our proposal. Outlined below are some successful examples of innovative outpatient prescribing projects from the UK.

Case study one: *London based HIV patients collect homecare medication from high street pharmacy chain*

Overview

A homecare provider is using a large high street pharmacy chain to facilitate collection of homecare medicines from community pharmacy for HIV patients.

- Drugs are dispensed by the homecare provider's pharmacy; the pharmacy chain is used as a collection point only (i.e. medications are provided in a sealed package)
- There are a number of nominated pharmacy collection points across Greater London, patients have 10 working days to collect after it has been dispensed
- Patients maintain at least one face to face appointment at the hospital per year

Benefits

- **Capacity** - Homecare providers have more capacity for home deliveries of complex medications
- **Carbon footprint** - delivering many prescriptions in bulk to each community pharmacy rather than individuals may reduce carbon emissions
- **Clinical safety net** – patients are able to speak to a pharmacist about other clinical concerns if they need to while they are collecting their prescription, however the pharmacist does not and cannot advise on the medication in collection as it has not been dispensed by their pharmacy.
- **Patient convenience** - Some patients may have difficulty accepting deliveries at home due to mobility, work commitments and privacy. This allows them or a relative to collect at a time of convenience

Challenges

- **Complex set up process** surrounding contracting with large community pharmacy chains
- **Only currently available for larger chains** who have many high street, out of town and shopping centre branches available
- **Patients must be local**, residing within the vicinity of a community pharmacy branch that is offering this service. An alternative model must be available for those who don't
- **Reimbursement challenges** of delivery to a pharmacy vs individual on LPP contract

Case study two: *eSignature solution implemented in place of wet signatures within homecare services in multiple trusts*

Overview

An eSignature solution has been implemented in place of wet signatures within homecare services across multiple trusts. Ordinarily, homecare providers would need a wet signature on each prescription, unless an individual risk sharing agreement is in place, or they are transacted through a closed IT system.

- The DocuSign solution was commissioned by the National Clinical Homecare Association (NCHA). Prescriptions are transmitted through NHSmail or equivalent secure email service.
- Homecare providers absorb the cost for document transaction via DocuSign
- Implemented at 15+ trusts

Benefits

- **Streamlined operations** with faster turnaround times
- **Improved security** and compliance
- **Improved experience** for clinicians, homecare provider & patient
- **Integration** with other software (MS office etc.)
- **Reduced paper waste** original prescription stays at NHS trust

Challenges

- **Tends to be one individual signer** which can slow the process down if they are unavailable
- **Not widely adopted** within the NHS due to the effort and time required for change
- **Cannot be used for controlled drugs and growth hormones** due to legal requirement of wet signatures.
- **There is a cost involved**, though this is usually absorbed by the homecare provider

Case study three: *London trust outpatient department (OPD) offers a hub and spoke service using its independent pharmacy chain presence and “spokes” for more convenient patient collection*

Overview

A local independent pharmacy, in charge of the hospital’s OPD, has opened an off-site pharmacy warehouse to provide ‘low-tech’ homecare services. It also hosts a ‘hub and spoke’ service, utilising its many community pharmacy branches as ‘spokes’.

- The pharmacy is a registered homecare supplier
- They run a hybrid system, where prescriptions can either be delivered to the home via homecare or collected by patients from their local community pharmacy (hub and spoke)
- The NHS trust has key personnel working within community pharmacy sites, to facilitate a streamlined pathway and improved experience for patients

Benefits

- **Potentially quicker access to medicines** for the patient as there is no third-party homecare provider
- **Electronic transmission of prescriptions** as the offsite pharmacy operates within the same legal entity as the hospital OPD
- **Prompt resolution of problems with prescriptions** due to closer working relationship of pharmacy and hospital clinicians
- **Potential cost savings** for the trust reducing the number of patients needing homecare
- **Improved capacity** for homecare companies to focus on mid/ high-tech medications

Challenges

- **Governance requirements** in relation to homecare contracts
- **Managing patient expectations of delivery**, this is usually better executed through homecare companies (e.g. 1 hour delivery window, reminders for when medication is due etc.)
- **Patients must take proactive responsibility** in ordering medicines organising monitoring etc.
- **High out of pocket expenses for the community pharmacy** to coordinate these services

Case study four – NHS Scotland outpatient prescribing

Overview

The NHS Scotland model is based on the principles of shared care, divided across individual health boards that determine local shared care need (GP takes ownership of shared care).

- A more holistic approach to care that is able to better utilise community pharmacy, due to its particular funding and reimbursement models
- Drugs are procured centrally, and dispensed by the community pharmacy for patient collection
- National NHS Scotland portal used to manage reimbursement

Benefits

- **More flexible provision of care** as the cost of medications are reimbursed to the individual health board in Scotland through the national NHS Scotland portal allowing more flexible provision of care across hospitals and community pharmacies
- **Fewer hospital visits**, as blood testing and drug monitoring services are set up within community pharmacy

Challenges

- **Complex rebate system** as community pharmacy cannot access manufacturer discounts – therefore community pharmacies must buy at list price, but receive reimbursement at the discounted price, and then claim the additional rebate from pharmaceutical company or wholesaler. This can be time consuming.
- **Credit limits of the community pharmacies may not be sufficient** to sustain the pathway, particularly for high-cost medicines
- **Requires particular reimbursement infrastructure**, not available in England, and for community pharmacies set up to deliver these services. (This cannot be scaled to England).

Case study five: NHS Wales outpatient prescribing

Overview

NHS Wales operates two distinct models, one for high-cost medicines and one for non-high-cost medicines.

- High-cost drugs are prescribed by secondary care and have BlueTEC completed there, in order to secure funding against set criteria. Patient can then access the drug via their local community pharmacy (prescribed from hospital).
- National rebate schemes established with manufacturers for each medicine
- Clinical ownership and distribution of high-cost drugs are managed entirely by secondary care. This is not a shared care system, though medicines are dispensed via community pharmacy

Benefits

- **Innovative reimbursement management model** for high-cost drugs
- **One central financial model** - coordination of which is outsourced to a third-party company
- **Holistic funding and procurement model**, whereas NHS England has multiple add-ons and complexities which makes it harder to streamline and innovate
- **Improved patient experience**

Challenges

Not scalable to the volume of medicines reimbursed by NHS England due to the number of patients and medicines dispensed.

Designing a New Model

Pilot Site: UCLH

After engaging with hospitals across NCL, we selected UCLH as our partner site for the pilot project. This decision was based on their broad selection of homecare medicines, ranging from high to low-tech as well as their appetite for transformation and ability to allocate resources and time to the project.

Shortlisting and selection of drug

The criteria used to select a suitable drug for a pilot within a community pharmacy model are as follows:

- Large patient cohort
- Low cost of the drug
- Reimbursement of the drug is through a hospital block contract
- Cost of homecare is funded by the hospital
- Dispensing and monitoring frequency is greater than every three months
- A large percentage of patients are local to the pilot hospital
- Patients are mobile and able to visit a community pharmacy to collect their medication
- No requirement for refrigeration or cold chain
- Patient acceptability
- Workforce acceptability in new model

Selected drug

Out of the medicines provisioned through homecare at UCLH, only 10 are in oral form, and most of these are high-cost drugs centrally reimbursed by NHSE, precluding them from this project.

Given this, we expanded our assessment of suitable drugs and were able to identify methotrexate which, although classified as a 'mid-tech' drug, is self-administered by the patient and is already being dispensed within the community elsewhere in England, under shared care agreements.

Methotrexate injection (monotherapy) is an antimetabolite with anti-inflammatory properties administered by subcutaneous injection. It is licensed for the treatment of active rheumatoid arthritis (the focus for this pilot), but is also used in gastroenterology, dermatology, and cancer.

Methotrexate for the treatment of rheumatoid arthritis at UCLH

Patient age: Typically, aged 30-70

Disability: While most patients can walk, it may be difficult, particularly during flares

Patient cohort: 334 existing patients (UCLH)

Dose: 7-25 mg subcutaneously, once a week

Frequency of supply: Every 3 months

Frequency of blood tests and monitoring: Every 3-6 months

Percentage of patients local to NCL: Mostly local

Reimbursement: Red list, hospital-only drug (block contract) / delivery paid by UCLH

Advantages:

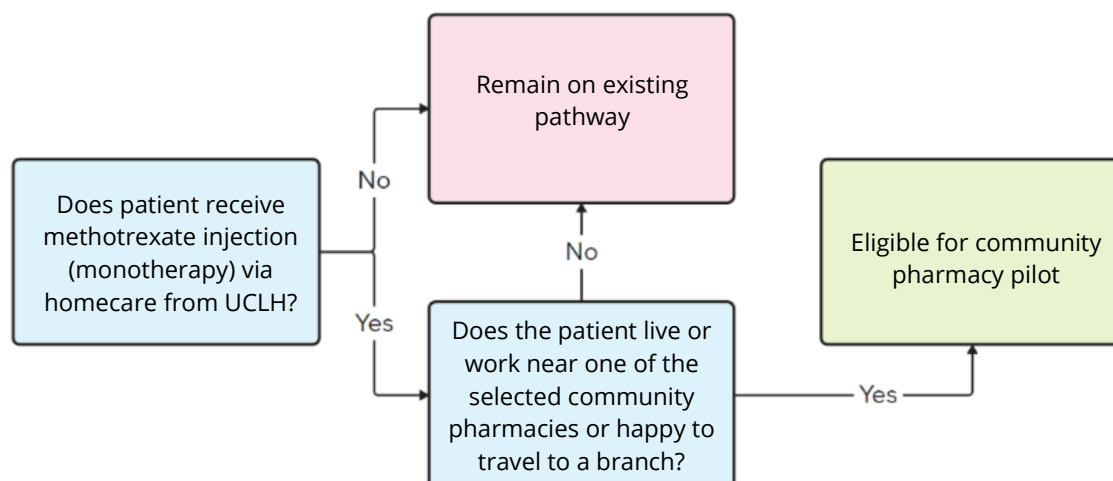
- Self-injected by the patient (via needle-guarded injectable pen)
- Relatively inexpensive for community pharmacies to purchase (£13/pen or £54/month per patient)
- Methotrexate is funded by the trust, not part of any reimbursement tariff (through block contract)
- Homecare cost is funded by UCLH, with opportunity for cost savings
- Already offered as shared care through schemes elsewhere in the country, demonstrating that community pharmacies have the expertise to manage this
- Patients are mostly local to NCL

Disadvantages:

- There are different strengths of methotrexate available, adding complexity to ordering and stock management/ dose change processes within the community
- Cytotoxic sharps waste disposal will need to be arranged via the local authority, GP or hospital

Patient selection

Patient selection for the pilot is according to the following diagram:



Patient engagement and feedback

As part of designing the new delivery model we spoke with patients currently receiving methotrexate for rheumatoid arthritis via homecare at UCLH, a list of key themes raised can be summarised as follows:

Communication and transparency

- Patients often do not know who to contact when they have issues with their delivery, because of the number of parties involved in the homecare pathway
- Automated systems used by homecare companies reduce the ability for human interaction, which some patients prefer
- The opportunity to interact with a community pharmacist while collecting their medication could support both of these issues

Travel

- Patients have nominated pharmacies where they receive other routine prescriptions. A new model may require them to collect their homecare medication from a different pharmacy. Patients were generally happy to use a different community pharmacy, so long as it was within a 1 mile distance of their home.
- Patients generally do not mind travelling to another pharmacy as long as it has convenient transport links or parking

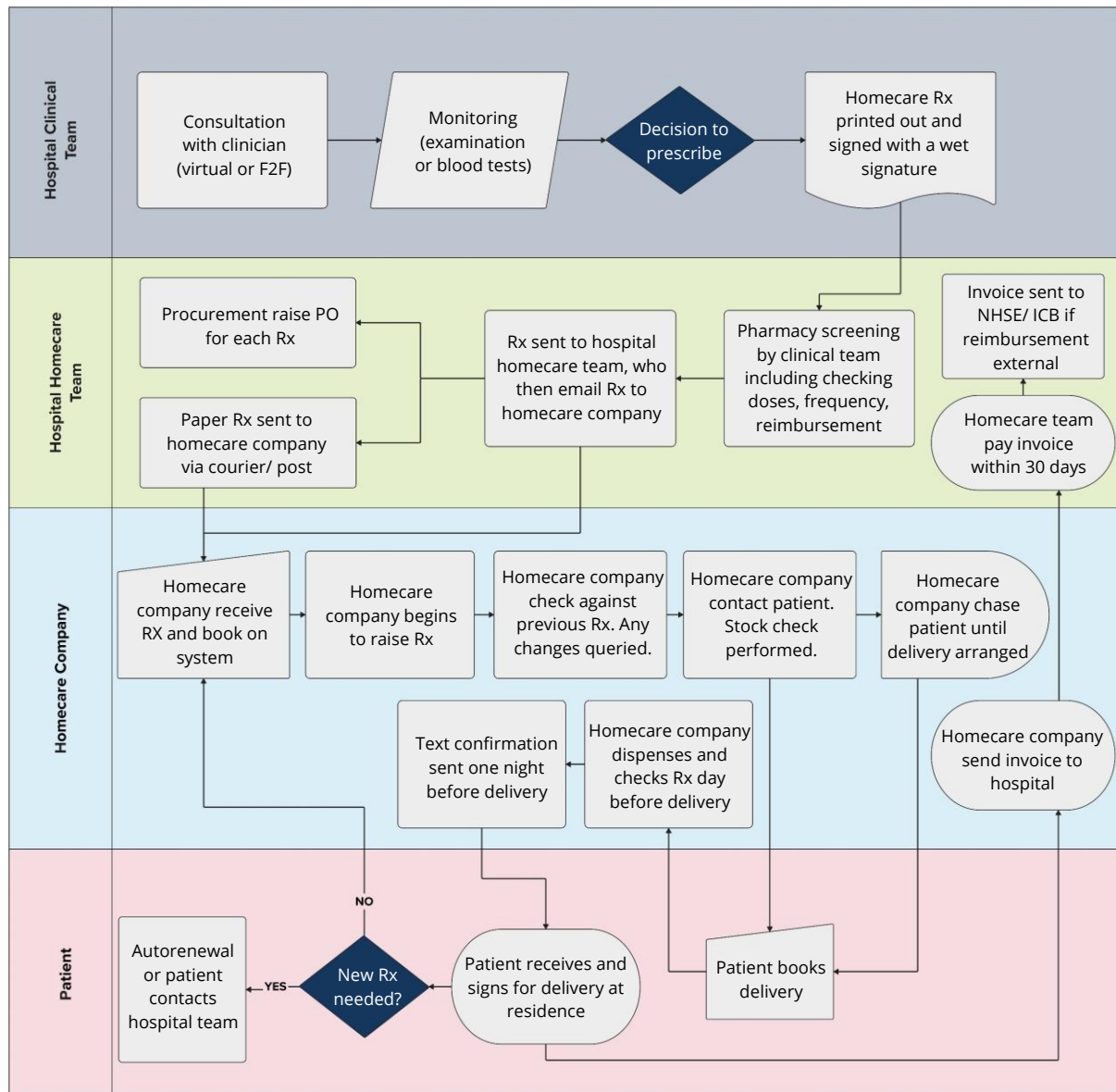
Logistics and supply

- Patients commented that they do not completely rely on homecare services to remind them about their prescriptions. Many mentioned that they take ownership of their medication supply and chase when necessary
- Patients do not mind collecting their homecare medicines from community pharmacy as long as the correct quantity is there and provided in a timely manner

Cost savings for the NHS

- Patients were generally happy to support moderate changes to their service, if they believed it would save money/ resources for the NHS

Current UCLH homecare pathway

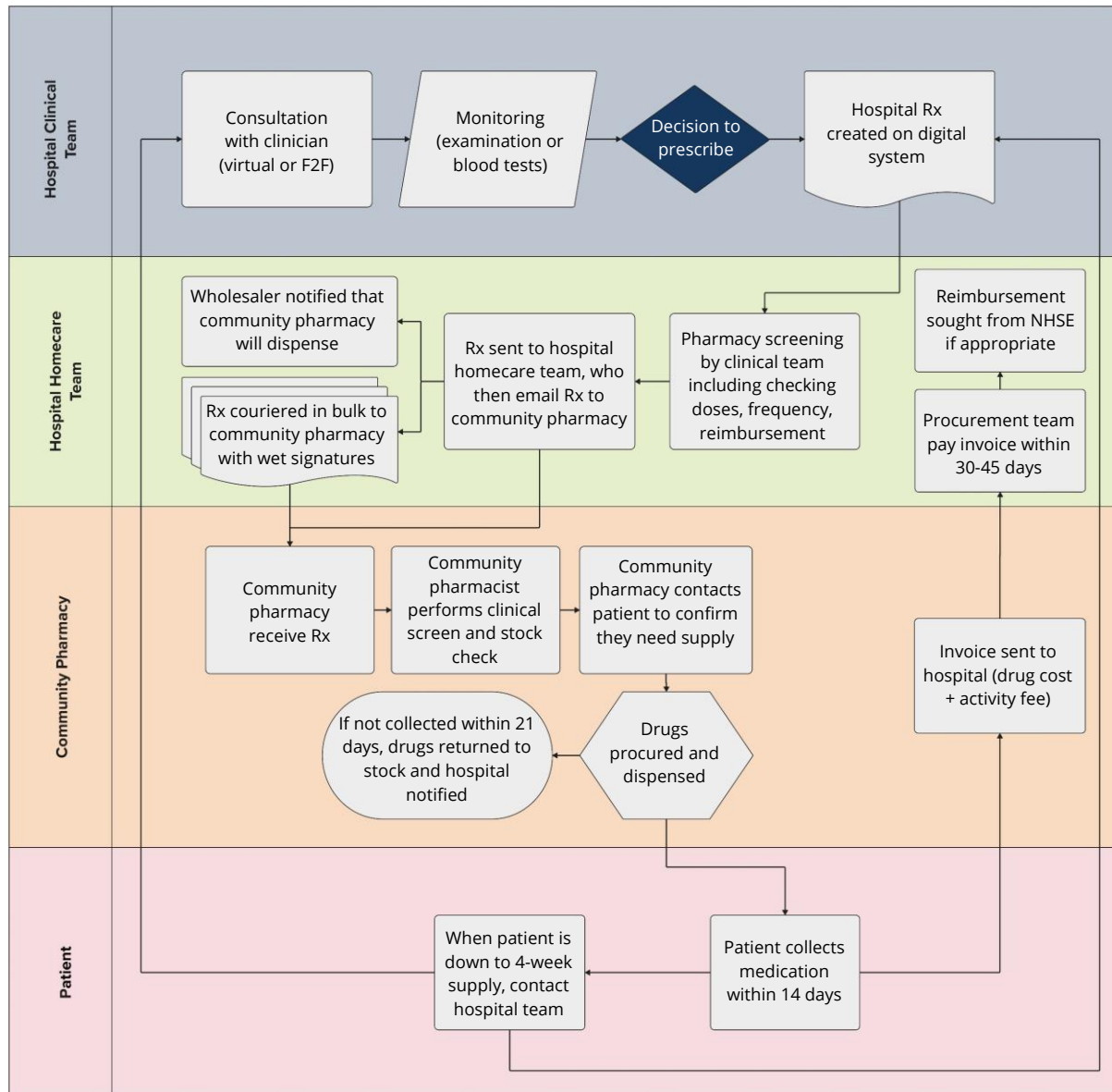


Homecare reimbursement pathway

- Homecare companies will purchase the drugs in two different ways:
 - **At list price:** Most medication (inc. high-cost drugs/ NHSE-funded drugs)
 - **At hospital discount rate:** This is primarily for cheaper drugs or those funded through block contracts
- Upon confirmation of delivery, the homecare company raises an invoice to the hospital at the hospital discount price, which is to be paid within 30 days
- The homecare company will claim reimbursement (from manufacturer, on proof of supply), on the difference between their purchase price and the hospital reimbursement price, if different

Proposed alternative pathways

Pathway One: Community Pharmacy Model



Community pharmacy reimbursement pathway

- The community pharmacy purchases drugs at list price
- Upon the patient collecting the medicines, the community pharmacy raises an invoice to the hospital for the drug plus any applicable activity fee, to be paid within 30 days
- The hospital pays the invoice

Benefits of the proposed community pharmacy model

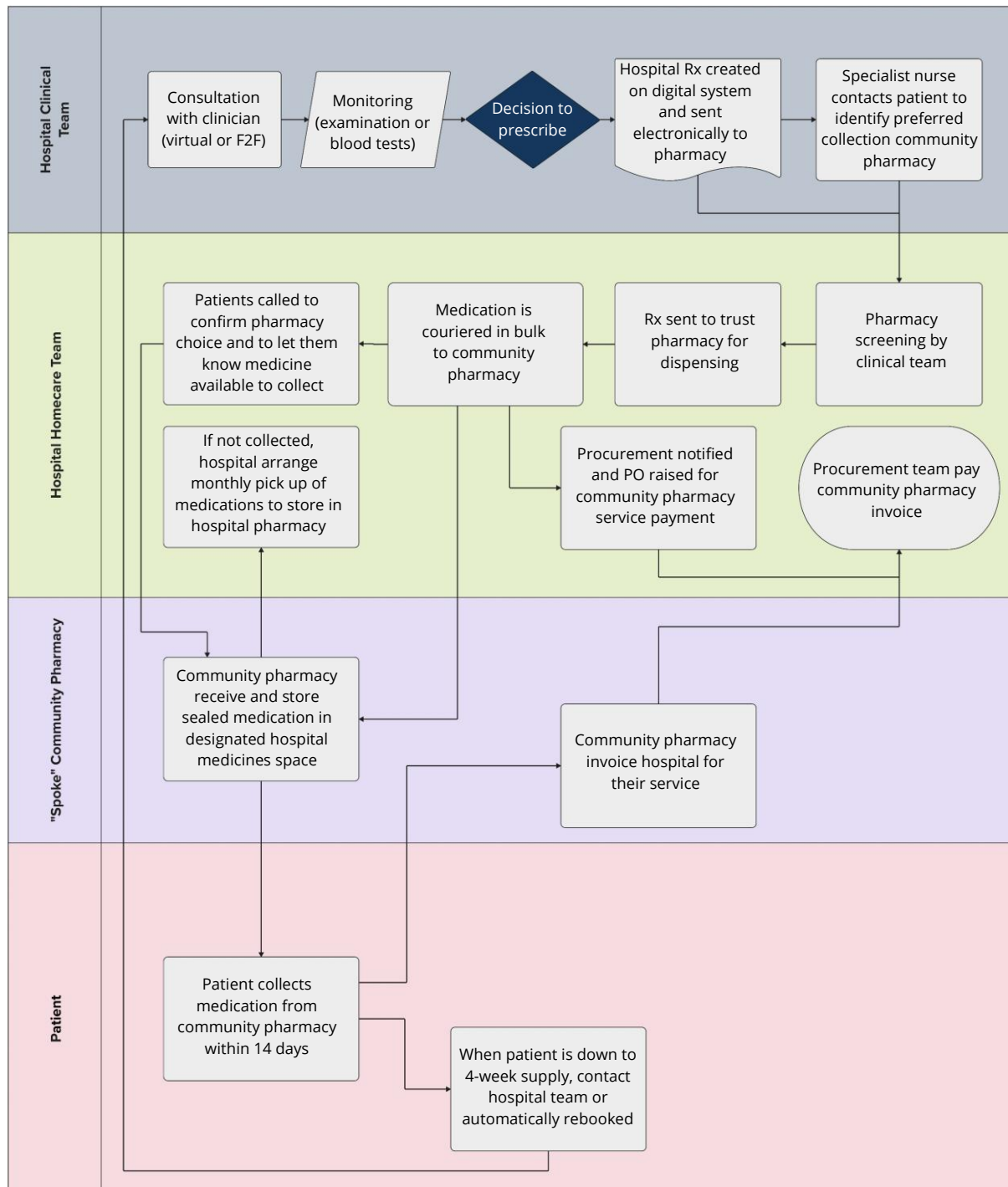
- **Patient access to medication & care closer to home**
- **Promotes patient responsibility for their care:** By engaging patients directly in the collection process, the model encourages them to take an active role in managing their health, fostering a sense of ownership and accountability
- **Potential for cost-effectiveness:** The activity fee charged by community pharmacies is often lower than homecare costs
- **Optimal resource utilisation:** Leveraging the resources available in community pharmacies enhances overall cost-effectiveness for the NHS, maximizing the use of existing infrastructure and personnel
- **Financial sustainability of community pharmacies:** Implementing this model can potentially increase revenue streams for community pharmacies, contributing to their financial sustainability and viability
- **Appropriate service utilisation:** By directing suitable patients to community pharmacies, homecare services can be reserved for those with greater needs such as home administration, home blood tests or home delivery for housebound patients ensuring efficient resource allocation and improving overall service quality
- **Safety net of pharmacist intervention:** Patients have the option to speak to a pharmacist upon collection, providing a safety net for medication-related inquiries or interventions, thereby enhancing medication safety and adherence

Barriers to the community pharmacy model

- **Prescription transmission challenges:** Prescription transmission to community pharmacies currently requires a wet signature or secure transmission, which is suboptimal. An electronic solution, such as Cleo Solo® EPS or a similar system, would be preferable for streamlining this process in the future
- **Purchasing at list price:** Community pharmacies are obligated to purchase medications at list price rather than benefiting from hospital discounts. This may pose financial challenges, particularly for expensive drugs, due to the price disparity with hospitals
- **Logistical challenges for injectable drugs:** Sharps bin collections for injectable drugs would need to be coordinated with the local authority, GP or hospital
- **Patient preference for home delivery:** Some patients may prefer home delivery and opt to remain on the existing homecare pathway, presenting a potential barrier to the community pharmacy model
- **Financial constraints for community pharmacies:** Community pharmacies may face financial strain if required to purchase higher-cost drugs beyond their credit limits, rendering them unsuitable for a community pharmacy model

- **Bureaucratic processes:** The community pharmacy encounters bureaucratic processes in manually documenting prescription collection and sending invoices to the hospital for payment, which may be time-consuming and resource intensive
- **Lack of direct reimbursement process:** There is no direct reimbursement process within community pharmacies for red list drugs. All prescriptions must be manually reimbursed via the hospital, paid out from block contract funding
- **Patient access:** Patients may need to be directed to community pharmacies which are not their regular pharmacy

Pathway Two: Hub and Spoke Pharmacy Model



Hub and spoke reimbursement pathway

- The in-house pharmacy or outsourced OPD pharmacy purchases drugs at a hospital discount rate through the hospital supply chain via their WDA license
- No additional steps for reimbursement for the drug are required as it is purchased within the hospital
- Upon the patient collecting the medicines, the community pharmacy raises an invoice to the hospital for any applicable activity fee, to be paid within 30 days
- The hospital pays the invoice
- Although the cost of delivery to the community pharmacy and the pharmacy activity fee is a cost pressure, this is offset by not having to pay homecare fees

Benefits of the hub and spoke model

- **Potential efficiency savings** over homecare model, for dispensing medicines at the hospital's OPD or 'hub', especially for low -tech medicines
- **There is no need for paper prescriptions or wet signatures**, streamlining the process
- **Financial risk diminished for community pharmacy** as the hospital pays upfront for stock through direct procurement
- **Fewer financial transactions** and less transmission of documents/ prescriptions
- This method works well if the hospital has an outsourced OPD with community pharmacy presence that can be utilised as 'spokes'

Barriers to hub and spoke model

- **Only suitable for trusts with OPDs that have access to 'spoke' pharmacies.** As such, this model is not suitable for UCLH (whose OPD is run by Lloyds Pharmacy), as Lloyds lacks a community retail presence. A third-party contractor would need to be utilised as a 'spoke', which until now has not been allowed. The consultation process to allow this mechanism is ongoing, see comments below.

Department of Health and Social Care consultation on hub and spoke dispensing

A consultation on hub and spoke has been conducted by the Government's Department of Health and Social Care, published on May 13th 2024⁸. The outcome of the

⁸ Government response to the consultation on hub and spoke dispensing, Department of Health and Social Care. Available at: <https://www.gov.uk/government/consultations/hub-and-spoke-dispensing/outcome/government-response-to-the-consultation-on-hub-and-spoke-dispensing>

consultation will trigger legislation to allow hub and spoke models to exist between different legal entities. It is anticipated that this will be amended by January 1st, 2025.

While the guidance seeks to remove the legal barriers to outsourcing a 'spoke' pharmacy to a third party, the consultation did not address the financial and logistical barriers to applying this model in practice. We have outlined some comments in relation to the consultation below:

Financial

- There will be a cost attached to delivering medicines between the hub and spoke, as well as activity fees for the community pharmacy's time. How this will be funded was not addressed in the consultation
- In the case of an OPD with a community pharmacy presence, they may be able to utilise existing procurement channels to deliver medications, and an activity fee at the 'spoke' may not be required if they are part of the same legal and financial entity
- However, if a third-party community pharmacy is contracted as a spoke, courier costs to and from the spoke and spoke activity fees/ financial incentive will need to be accounted for

Logistical

- In the case of a third-party 'spoke' pharmacy, the community pharmacy will likely encounter a highly bureaucratic process in documenting prescription collection and sending invoices to the hospital for payment
- The lack of efficient electronic prescribing systems may lead to issues in prescription transmission. For example, there may be confusion regarding which spoke pharmacy a prescription has been sent to
- For injectable drugs, arrangements for sharps bin collections would need to be organised with the local authority/ GP/ hospital

Patient Experience

- It is possible that some patients may need to be directed to community pharmacies which are not their usual nominated pharmacy
- Some patients may prefer home delivery and opt to remain on the existing homecare pathway

Conclusion

Pharmacy dispensing models in England are varied and do not operate on an equitable landscape, making interchangeability between them very challenging. To reimagine and redesign dispensing pathways in England, it is crucial to understand their operating models, legal structures, procurement processes, and reimbursement mechanisms. Each model has a unique set of advantages and challenges which makes each of them best suited for specific use cases.

Through our review of innovative case studies and available dispensing models, along with stakeholder engagement with pharmaceutical companies, homecare providers, procurement leads, clinical leads, community pharmacies and patients, we concluded that the community model would be the most suitable for our chosen partner hospital, UCLH. This decision is based on the existing infrastructure at the trust, who operate an outsourced OPD without hub and spoke capabilities and would apply to other trusts operating a similar pharmacy dispensing model.

Our work has shown that an alternative model is agreeable by hospital and community pharmacy. However, despite clear desire from system partners to change the way hospital medicines are supplied to patients, we were unable to design a model that was financially and logistically viable under current frameworks. Financial, legal and logistical issues were highlighted as significant barriers and are summarised below:

Financial

- Community pharmacies can only procure medicines at list price, while homecare companies can charge the hospital contract discounted rate.
- Community pharmacies cannot be directly reimbursed by NHS England, as most homecare drugs are hospital-only drugs, and prescriptions are treated as private prescriptions for legal purposes. Therefore, reimbursement must happen through the NHS trust.
- Community pharmacies operate with much smaller budgets than hospitals, so purchasing expensive drugs upfront may put financial strain on them while waiting for reimbursement.
- The delivery of prescriptions between the hospital and community pharmacy is unfunded.

Legal

- Due to being different legal entities, a wet signature is required on the prescription. Therefore, prescriptions must be printed from the electronic prescribing system and signed. These are treated as private prescriptions from a legal standpoint.

Logistical

- For injectable methotrexate, there are logistical challenges around sharps bin disposal. This would need to be arranged by the patient with the local authority (collected from the patient's home free of charge).

Our report demonstrates the complexity of the outpatient prescribing landscape, detailing the many financial, legal and logistical levers involved in transformation. While we were unable to design a financially viable model for our local system partner, we hope our findings and research may benefit future projects, should there be a change in legislation or reimbursement structures. We continue to engage with national and local stakeholders in improving services for patients, NHS providers and staff.

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Appendices

Appendix A: Pharmacy Dispensing Models

1. In-house NHS Hospital Pharmacy

The hospital pharmacy is managed by the trust with staffing provided in-house, making communication with clinical teams more straightforward. Procurement contracts and discounts are negotiated directly by the hospital with wholesalers, though VAT is payable at 20% on medicines purchased within the NHS. For this reason, outsourcing to homecare and other private sector services is incentivised due to the 20% VAT savings which can be obtained. Greater visibility and ownership over procurement and contracting brings more opportunities to innovate and optimise services.

Drug procurement	Via hospital contract (may include discounts) or nationally negotiated NHS price through hospital supply chain.
VAT paid?	Yes, must pay VAT at 20%.
Specialist medicines	Reimbursed by NHS England, Cancer Drugs Fund or Innovative Medicines Fund. Routine medicines reimbursed by ICB/ NHS block contract at national tariff.
Deliveries & homecare	Via London Procurement Partnership (LPP) contracts or manufacturer funded homecare.
Same legal entity?	Yes. Transmission of prescriptions can be electronic through existing IT infrastructure.
Key advantages	The hospital keeps savings made by contract discounts and there is usually better communication with clinical teams.
Key disadvantages	Must pay VAT.
Ideal drug to be dispensed under this model	Any drug, any cost, any reimbursement. However, trusts incentivised to push high-cost medication out to homecare services in order to make VAT savings.

2. Wholly Owned Subsidiary

The hospital pharmacy is outsourced to a separate company that is 100% owned by the trust, ensuring that profits are reinvested. A dispensing fee is payable by the trust to the wholly owned subsidiary per item dispensed. VAT is not payable.

Drug procurement	Via hospital contract (may include discounts) or nationally negotiated NHS price via a wholesaler distributor authorisation (WDA) license through hospital supply chain.
VAT paid?	No, VAT is not applicable.
Specialist medicines	Reimbursed by NHS England, Cancer Drugs Fund or Innovative Medicines Fund. Routine medicines reimbursed by ICB/ NHS block contract at national tariff.
Deliveries & homecare	Via London Procurement Partnership (LPP) contracts, or alternative regional mechanism.
Same legal entity?	No, but can transmit prescriptions electronically through existing IT infrastructure.
Key advantages	The hospital can make savings through contract discounts, and they do not have to pay VAT. Hospitals are incentivised to make savings, as they are kept by the trust and can be reinvested in research, workforce etc.
Key disadvantages	Only available to NHS foundation trust status organisations.

Ideal drug to be dispensed under this model	Any drug, any cost, any reimbursement. Incentivised to retain block contract drugs purchased in bulk with discounts, as the pharmacy can keep the difference between this and the set Drug Tariff price.
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3. Outsourced Outpatient Pharmacy Dispensary (OPD) – Dispense & Collect

The hospital pharmacy is outsourced to a private third-party company, for example Lloyds or Boots, who are entitled to any profit made, though 'gains share agreements' can be put in place for profit sharing. A dispensing fee is payable by the trust to the OPD per item dispensed. VAT is not payable.

Drug procurement	Via hospital contract (may include discounts) or nationally negotiated NHS price via a wholesaler distributor authorisation (WDA) license through hospital supply chain.
VAT paid?	No, VAT is not applicable.
Specialist medicines	Reimbursed by NHS England, Cancer Drugs Fund or Innovative Medicines Fund. Routine medicines reimbursed by ICB/ NHS block contract at national tariff.

Deliveries & homecare	Via LPP contracts (or alternative regional mechanism) or manufacturer funded homecare, although homecare is often managed by the in-house homecare team
Same legal entity?	No, but prescriptions can be transmitted electronically through existing IT infrastructure
Key advantages	Often gainshare agreements are built into contracts so that trust benefits from profits. They do not have to pay VAT.
Key disadvantages	Pharmacy make savings by contract discounts but pay back to hospital through gains share agreement. No VAT applicable.

Ideal drug to be dispensed under this model	Any drug, any cost, any reimbursement. Incentivised to retain block contract drugs purchased in bulk with discounts, as the OPD can keep the difference between this and the drug tariff price.
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4. Outsourced Outpatient Pharmacy Dispensary (OPD) – Hub & Spoke Model

The hospital pharmacy is outsourced to a private third-party company, for example Lloyds or Boots, who may utilise community sites as part of a hub and spoke model. The OPD are entitled to any profit made, though ‘gains share agreements’ can be put in place for profit sharing with the trust. A dispensing fee is payable by the trust to the OPD per item dispensed, but VAT is not payable. This may enable the OPD to make cost savings on more efficient dispensing and deliveries to local community pharmacies acting as “spokes” from which patients can then collect. Often an offsite “hub” can also be utilised.

Drug procurement	Via hospital contract (may include discounts) or nationally negotiated NHS price via a wholesaler distributor authorisation (WDA) license through hospital supply chain.
VAT paid?	No, VAT is not applicable.
Specialist medicines	Reimbursed by NHS England, Cancer Drugs Fund or Innovative Medicines Fund. Routine medicines reimbursed by ICB/ NHS block contract at national tariff.
Deliveries & homecare	Delivery to local pharmacy not reimbursed.
Same legal entity?	No, but prescriptions can be transmitted electronically for dispensing at hub (hospital or off-site pharmacy) and delivered to spoke (community pharmacy).
Key advantages	Often gainshare agreements are built into contracts so that the trust benefits from profits. They do not have to pay VAT.

<p>Key disadvantages</p>	<p>Can make savings on home delivery if hub & spoke model used to deliver medicines to community pharmacy.</p> <p>Patients must live locally to the 'spoke' (community pharmacy) to be able to access medicines.</p> <p>'Spoke' community pharmacies must be part of the same legal entity under current legislation although a consultation on hub and spoke dispensing is underway to help alleviate the legal challenges when operating across legal entities.</p>
<p>Ideal drug to be dispensed under this model</p>	<p>Any reimbursement model. Will likely want to avoid higher cost drugs in case they go missing or are not collected. They would likely avoid medication for patients with physical disabilities if there were no home courier service.</p>

5. Homecare Company

Dispense and deliver service for particular drugs is outsourced to a third-party company. Homecare services provide high-cost complex hospital drugs to patients at their homes, sometimes with a healthcare professional to support administration and monitoring. Hospitals will often have contracts with a number of different homecare companies, each providing services for different drugs/pathways.

<p>Drug procurement</p>	<p>The homecare company usually procure at NHS list price but sometimes at a discounted contract price. It is at the manufacturers discretion as to whether the homecare company purchase at list price and claim the difference as a rebate or buy directly at discounted price. Usually, when there is a patient access scheme (PAS) in place for the drug, they must purchase at list price and claim a rebate. The hospital is charged at their own contract price with the homecare company, seeking alternative reimbursement from the wholesaler or manufacturer for the difference.</p>
<p>VAT paid?</p>	<p>VAT is not usually applicable, however if the drug is delivered to, and administered in, an NHS entity (e.g. because the homecare patient is in hospital) it then must be paid.</p>
<p>Specialist medicines</p>	<p>Reimbursed by hospital at hospital contract price. High-cost drugs reimbursed to hospital by NHSE at a nationally negotiated discount price. The difference between nationally negotiated and purchase price is reimbursed by manufacturer/ wholesaler.</p>
<p>Deliveries & homecare</p>	<p>Either funded by manufacturer or by hospital block contract budget/ LPP contract.</p>

Same legal entity?	No, a wet signature or certified electronic signature through a third party is needed for each prescription.
Key advantages	<p>Homecare service is often funded by the manufacturer.</p> <p>Alleviates the administrative burden of providing repeat prescriptions for patients with long term conditions where the drug must be supplied from the hospital.</p> <p>Reduces the burden on hospital services where patients require specialist administration.</p> <p>May be more convenient and comfortable for patients to access care within their home.</p>
Key disadvantages	<p>Many homecare services are operating at capacity, with limited funding and should be utilised with discretion.</p> <p>High cost to NHS trusts if the NHS is paying for these services directly (i.e. they are not funded by the manufacturer).</p> <p>Slower process to get patients set up and receive their first delivery compared with in house or outsourced pharmacy dispensing. Patients will often receive initial supplies from a hospital pharmacy and subsequent deliveries from homecare once appropriately enrolled.</p> <p>From a homecare company perspective, lengthy and complex process for full reimbursement (paid in part by the NHS trust and part by the manufacturer).</p>

Ideal drug to be dispensed under this model	Any reimbursement model. Preferable for drugs that have the homecare service funded by the manufacturer, as the trust would have to pay for homecare if the drug is funded under hospital LPP or block contracts/ payment by results.
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6. Community Pharmacy

Drug procurement	NHS list price through primary care supply chain.
VAT paid?	No, VAT is not applicable.
Specialist medicines	Specialist and Highly Specialist commissioning medicines and drugs on the Cancer Drugs Fund and Innovative Medicines Fund are not typically reimbursed (these are often hospital only drugs).

Routine & shared care medicines	Reimbursed by NHS business authority/ ICB at drug tariff price. Where this is higher than the purchase price the savings are kept by the pharmacy; where this is lower than the purchase price, the pharmacy makes a loss.
Deliveries & homecare	Not reimbursed. Typically, patients collect their medicines from the community pharmacy, or a member of staff will make pro-bono deliveries to the immediate local area.
Same legal entity?	No, different legal entity. Prescriptions can be sent through EPS, or System1 from primary care on an FP10 (without a wet signature). From Secondary Care, Cleo Solo® EPS can be used to transmit an FP10 prescription, though this can only be used for routine medicines (reimbursed by the ICS), otherwise a wet signature would be required.
Key advantages	Care closer to home, may save money on couriers. The majority of prescribing is from primary care.
Key disadvantages	No access to courier/ delivery reimbursement or reimbursement for specialist medicines, typically are not able to purchase at a discount due to low buying power, which results in a higher cost to the NHS.
Ideal drug to be dispensed under this model	Not NHSE, ICB, Cancer Drug Fund or Innovative Medicines Fund reimbursement drugs. Only suitable for 'routine' or 'shared care' medicines. Cheaper medicines preferable due to stock holding at the community pharmacy. Not suitable for medicines that would otherwise benefit from significant discounts when purchased in bulk by the hospital, as these savings would not be obtainable by the community pharmacy.

7. e-Pharmacy

Drug procurement	NHS list price through primary care supply chain. Can obtain a discount if buying in bulk
VAT paid?	No, VAT is not applicable.
Specialist medicines	Specialist and highly specialist commissioning medicines and drugs on the Cancer Drugs Fund and Innovative Medicines Fund are not typically reimbursed (these are often hospital only drugs).
Routine & shared care medicines	Reimbursed by NHS business authority.

Deliveries & homecare	Not reimbursed. These are funded by the e-pharmacy company in order to win business.
Same legal entity?	No, different legal entity. Prescriptions can be sent through EPS, or System1 from Primary Care on an FP10 (without a wet signature). From Secondary Care, Cleo Solo® EPS can be used to transmit an FP10 prescription, though this can only be used for routine medicines (reimbursed by the ICS), otherwise a wet signature would be required.
Key advantages	Usually operate as central hub out of a warehouse - medicines can be delivered nationwide.
Key disadvantages	No access to courier reimbursement or methods of drug reimbursement for specialist medicines. Unclear what the risk and cost of loss of medicines is to ePharmacies.
Ideal drug to be dispensed under this model	Only 'routine' medicines via FP10. Not NHSE, ICB, Cancer Drug Fund or Innovative Medicine Fund reimbursement drugs. Nor drugs which receive a significant discount when purchased by the hospital, as this would not be attainable via an e-Pharmacy.

Appendix B: Outpatient Medicine Reimbursement Mechanisms

NHS Block Contract

NHS block contracts are annual payments made to an NHS hospital to deliver a particular service. As block contracts are drawn up and agreed in advance of a service being delivered, unexpected pressures such as increased patient demand or cost of care are not considered. Block contracts are usually used for routine medicines and specialist services within secondary and tertiary care.

Payment By Results

This reimbursement model pays NHS healthcare providers a standard tariff for each patient based on their diagnosis, reflecting the complexity of their healthcare needs.

NHS England Direct Commissioning

NHS England directly commission specialised and highly specialised drugs, once they have completed a NICE (National Institute of Clinical Excellence) appraisal. These specialised services are planned nationally and regionally by NHS England.

Funding decisions are based on considerations such as clinical efficacy, cost-effectiveness, estimated number of patients and the impact on the overall NHS budget. These services are delivered by specialist teams who have the necessary skills and experience. They are typically delivered within NHS secondary and tertiary care trusts.

Often, a nationally agreed discount is applied after negotiations between the manufacturer and NHS England. This is often referred to as the patient access scheme (PAS) price. Medicines within secondary and tertiary care are purchased and reimbursed at this price. If these drugs are dispensed within the homecare setting, the homecare company will often have to purchase at the list price and seek reimbursement from the manufacturer for the difference, while charging the hospital customer the PAS price.

The value of the NHS England specialised commissioning budget for 2022/23 was £22.9bn.

Cancer Drugs Fund (CDF)

The Cancer Drugs Fund provides reimbursement for promising new treatments via managed access arrangements while further evidence is collected to address clinical uncertainty. It provides interim funding for newly recommended cancer drugs, giving patients access to treatments many months earlier than they would via routine NHS England commissioning.

The value of the CDF budget for 2022/23 was £340m.

Innovative Medicines Fund (IMF)

The Innovative Medicines Fund is similar to the CDF, but for non-cancer medicines.

The value of the IMF budget for 2022/23 was £340m.

ICB (Integrated Care Board)

These drugs are reimbursed directly by the ICB based on local formulary decisions. Such decisions are taken by the individual ICB and can differ from area to area, based on population need.

The advantage of this is it gives power to each ICB to make decisions based on the needs of their population, specific patient demographics and clinical requirement. In practice this means that a drug may be reimbursed at one hospital or GP practice and not in another.