



# **Outsourcing Hospital Pharmacy Outpatient Dispensing (OPD) Services**

## **- Challenges and Opportunities**

**“A study to compare the different models of outsourced OPD hospital pharmacy services and assess the potential strategic impact on other hospital pharmacy services and medicines procurement and distribution”**



**Commissioned by**

**The Procurement and Distribution Interest Group (PDIG)  
of the Guild of Healthcare Pharmacists (GHP)**

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<b>1. EXECUTIVE SUMMARY .....</b>	<b>4</b>
<b>2. TERMS OF REFERENCE .....</b>	<b>6</b>
2.1 BACKGROUND .....	6
2.2 SCOPE .....	6
2.3 REVIEW APPROACH .....	6
2.4 THE REPORT.....	7
<b>3. METHODOLOGY.....</b>	<b>8</b>
<b>4. OVERALL OBSERVATIONS .....</b>	<b>9</b>
4.1 DEBATE WITHIN THE PROFESSION.....	9
4.2 DRIVERS.....	10
4.3 VAT AND MEDICINES .....	11
4.4 PATIENT PERSPECTIVE .....	13
4.5 INTERFACE WITH COMMISSIONERS .....	13
4.6 STATUS OF THE PRESCRIPTION .....	14
4.7 DISPENSING FP10 PRESCRIPTIONS .....	15
4.8 MEDICINES & HEALTHCARE PRODUCTS REGULATORY AUTHORITY (MHRA) & GENERAL PHARMACEUTICAL COUNCIL (GPHC) REGULATIONS .....	15
4.9 KEY PERFORMANCE INDICATORS (KPIs) .....	16
4.10 CLINICAL CHECKING .....	17
4.11 STAFF ISSUES .....	17
4.12 DATA MANAGEMENT E.G. IMS, PHARMEX .....	18
4.13 INVOICING AND DIRECTORATE COSTING.....	18
4.14 ESTATE .....	19
4.15 TENDER PROCESS .....	20
4.16 POTENTIAL RISKS .....	20
<b>5. PHARMACEUTICAL INDUSTRY PERSPECTIVE .....</b>	<b>21</b>
5.1 GENERAL COMMENTS .....	21
5.2 PHARMACEUTICAL INDUSTRY – OUTSOURCED PROVIDER ACCOUNTS.....	21
5.3 SUPPLY CHAIN .....	22
5.4 IMPACT ON NHS CONTRACTS .....	23
5.5 MEDICINES SHORTAGES .....	24
<b>6. COMMUNITY PHARMACY PERSPECTIVE .....</b>	<b>25</b>
6.1 STRATEGIC DIMENSION .....	25
6.2 BENEFITS .....	26
6.3 ISSUES .....	26
<b>7. MODELS EXAMINED.....</b>	<b>27</b>
7.1 OUTSOURCED TO A THIRD PARTY PROVIDER E.G. COMMUNITY PHARMACY.....	27
7.2 WHOLLY OWNED SUBSIDIARY OF A TRUST.....	33
7.3 SOCIAL ENTERPRISE SCHEMES .....	38
7.4 HOMECARE .....	40
7.5 OTHER MODELS.....	42
<b>8. GOOD PRACTICE GUIDE FOR CHIEF PHARMACISTS WHEN CONSIDERING OUTSOURCING OUTPATIENT HOSPITAL PHARMACY SUPPLY.....</b>	<b>44</b>
<b>9. KEY CONCLUSIONS.....</b>	<b>47</b>

<b>10. RECOMMENDATIONS .....</b>	<b>49</b>
<b>11. ACKNOWLEDGEMENTS .....</b>	<b>51</b>
<b>APPENDIX 1 .....</b>	<b>52</b>
<b>APPENDIX 2 .....</b>	<b>53</b>
<b>APPENDIX 3 .....</b>	<b>55</b>
<b>APPENDIX 4 .....</b>	<b>60</b>

## 1. Executive Summary

- 1.1 NHS Hospital Trusts exist to meet the needs of patients. Organisations need a clear vision about what they are trying to achieve for outpatient services prior to developing options to achieve these goals, and then carefully consider the risks and benefits of each option before deciding on a course of action.
- 1.2 Outsourcing of hospital pharmacy outpatient dispensing (OPD) services has generated much debate and raised many questions and concerns across the NHS and pharmaceutical industry. However it is clear from models in operation that there are patient benefits which can arise from outsourcing. Whilst VAT savings drive the funding model there was widespread agreement that meeting patient needs must be the foremost objective.
- 1.3 To improve services to patients, a hospital may enter into a contract with a third party pharmacy company to operate a pharmacy in the hospital to dispense qualifying goods to out-patients and also to provide homecare services. In this situation the same criteria for zero-rating applies to pharmacy companies within a hospital as to normal community pharmacies.
- 1.4 Outsourcing of hospital OPD is a change in the normal patient pathway and this should be discussed in an open and transparent manner with service commissioners and patient representatives.
- 1.5 Any other charges made (e.g. management or administrative) will follow their normal VAT liability as they are not covered by the zero-rating provisions for qualifying goods.
- 1.6 Financial and activity pressures in the NHS plus demands to improve quality have caused the acceleration of schemes to outsource hospital OPD. These pressures and demands are not going to go away and are likely to increase over time.
- 1.7 Many Trusts have progressed outsourcing of outpatient dispensing at pace and are “re-inventing the wheel”. This is wasteful and most Trusts appear happy to share their experience and expertise and this opportunity should be harnessed.
- 1.8 Working with private sector providers is one way to meet increasing patient demand and to bring innovation and commercial expertise to hospital pharmacy. Community pharmacy chains and homecare providers are gaining expertise and confidence in providing aspects of some secondary care services.
- 1.9 Three models have emerged as most dominant and innovative for providing outsourced hospital pharmacy services. The most widely adopted of these to date has been to use a homecare provider. This has been subject to a Department of Health review which is currently being promulgated. The other models involve using a commercial provider e.g. community pharmacy or developing a wholly owned in house subsidiary company of a Foundation Trust. The community pharmacy model has an advantage in that it brings in external commercial expertise whilst the subsidiary company allows all ‘profits’ to be retained within the NHS.

- 1.10 The latter two models above represent a strategic shift in the relationship between hospital and community pharmacy and between the NHS and pharmaceutical manufacturers.
- 1.11 There is confusion within the pharmaceutical industry about these arrangements and concern that this may further compromise an already vulnerable supply chain. The long term implications of many of these changes do not seem to have been considered e.g. impact on hospital contracts for medicines, supply chain security and data management. This requires urgent consideration.
- 1.12 Opportunities exist for collaboration between all potential providers (community pharmacy, in house subsidiary company, homecare companies) of outsourced OPD services and such partnership working can maximise patient and NHS advantage.
- 1.13 Outsourcing OPD services is a complex process and takes a considerable amount of time and effort. Good leadership and project management skills will be necessary to achieve a successful outcome and there are impacts on staff which need to be managed. A good practice guide for Chief Pharmacists needs to be developed and we have proposed some components in this report.
- 1.14 There is a monetary value of OPD medicine costs which are issued to patients that makes such schemes viable. We believe that when staffing costs, rent administration etc. are taken into account, this will be about £1.5m per annum.
- 1.15 If regulations associated with the application of VAT to medicines provision change then outsourcing of OPD is unlikely to be viable without a new funding stream.
- 1.16 With respect to taxation issues there is variable advice from management consultancies who advise the NHS. Further clarity is needed from HMRC.
- 1.17 IT systems between outsourced service providers and the NHS need to be aligned to meet respective needs for timely and confidential data flow whilst maintaining necessary confidentiality.
- 1.18 A national group needs to be established under the auspices of the National Pharmaceutical Supplies Group to expand on some of the issues that emerge from this report. It is suggested that these could be considered and developed via workshops during a study day, possibly limited to an invited audience (including stakeholders such as NHS, community pharmacy, pharmaceutical industry, homecare companies) and where necessary specialist advisers e.g. HMRC. The outputs from this could then inform a range of guidance on outsourcing OPD (e.g. contracting, KPIs, financial and clinical governance etc) that is in the interests of patients, taxpayers and the NHS whilst maintaining the integrity of the medicines supply chain.

## 2. Terms of reference

### 2.1 Background

The financial pressure within the NHS has led many Trusts to consider how costs can be reduced whilst they are faced with ever increasing clinical demands. Hospital pharmacy departments have found themselves subject to these pressures and this has led to a number seeking innovative ways of dealing with this problem. Outpatient dispensing (OPD) has been one service where different models have been introduced in recent years and the rate of introduction of new services is increasing rapidly. A number of different service models are evolving and to date they include:

1. **Contracting out the OPD to a third party private provider**
2. **Creating a limited company (a wholly owned subsidiary) which is associated with the Trust**
3. **Using a social enterprise scheme**
4. **Increased use of homecare to cover the majority of OPD expenditure**

The models all have a common element which seeks to take advantage of the fact that outsourcing the provision of hospital pharmacy outpatient dispensing allows medicines dispensed by the outsourced provider to be exempt from Value Added Tax (VAT).

However, the impact on patient care, organisational benefits and any issues arising from each of the different types of service models has yet to be fully assessed. The PDIG (GHP specialist interest group) committee therefore decided to commission a study to begin this assessment.

### 2.2 Scope

The report will include a comparison of the 4 different models of outsourced hospital pharmacy OPD services.

Mental Health and Prison services were considered to be outside the scope of the project. The report is limited to services in England only.<sup>1</sup>

### 2.3 Review approach

This was agreed at a meeting of a PDIG steering group (Allan Karr, Danny Palmer and Tony West) and Martin Anderson and Ron Pate held on 19 January 2012. The brief was to examine issues from a patient and tax payer perspective and to include in the report:-

- A description and comparison of the models examined.
- Commentary on the pros/cons/complexities of the models examined.
- Identification of benefits/issues etc.

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<sup>1</sup> **Editorial note:** In the course of this review we learnt of some Trusts who are outsourcing or looking to outsource their OPD service and have included in the specification provision of medicines used in day case activity and some selective discharge medication. The limitations of this review did not allow for us to undertake any investigation of these.

- Potential operational and strategic implications and issues that may arise from the models.

#### **2.4 The report**

The report will be written by Ron Pate and Martin Anderson who have been jointly commissioned by PDIG to undertake this review. The content of the report will be both factual and, based on findings, interpretational at the author's discretion. It will include conclusions and may include recommendations for further work.

A presentation based on the report will be made to the PDIG Symposium in June 2012.

### 3. Methodology

- 3.1 The review was carried out using semi structured interviews with Trust Chief Pharmacists, other NHS pharmacy staff and key stakeholders (e.g. 3<sup>rd</sup> party outsource service providers, representatives of the pharmaceutical industry, and others). All interviewee information provided and the data gathered is anonymised in the report.
- 3.2 Semi structured interviews followed a model developed by Ron Pate and Martin Anderson to allow easy flow of dialogue. Most interviews were carried out by telephone whilst others were undertaken via face to face meetings.
- 3.3 A letter of introduction to interviewees was provided by Allan Karr and Tony West PDIG/GHP (see [Appendix 1](#)).

## 4. Overall observations

### 4.1 Debate within the profession

- 4.1.1 The outsourcing of hospital pharmacy outpatient services has generated significant debate in the Pharmaceutical Journal with many calling for a 'level playing field' with the private sector with respect to the VAT paid by hospitals on medicines. Some express concerns that this is 'privatisation by the back door'.
- 4.1.2 Others have seen the different models of service provision as an opportunity to improve the patient experience. OPD is often seen as a "Cinderella" service and so this provides an opportunity to improve the service and consequently the patient experience. Most believe this innovation should be welcomed and especially if funding is made available through VAT savings. Some see this mainly as creating an opportunity for pathway re-design but only if the overall objective is value driven and not profit driven. As such it was felt by many that it was important that models of service provision must incorporate the goals and ethos of the hospital service where care is initiated, though it was recognised that this may be different for individual hospitals and varying patient needs.
- 4.1.3 The question of competencies and training arose in a number of interviews. Some expressed the view that since the community and hospital sectors require different competencies how can community pharmacists oversee the dispensing of hospital prescriptions? On the other hand there is a view that bringing the community pharmacy culture and expertise e.g. customer focus, is an advantage. The opportunity afforded by closer working between the two sectors in a hospital environment may therefore be mutually beneficial in bringing together the skillsets from the different sectors to improve the patient experience.
- 4.1.4 It needs to be noted that community pharmacy services are becoming more "clinical" (MURs, New Medicines Service etc). Whilst many may argue that there is a long way to go before a comprehensive hospital clinical pharmacy service is available (or arguably required) in a community pharmacy, clearly good progress is being made on the journey of making better use of pharmacists clinical skills in primary care settings.
- 4.1.5 It is argued by some that OPD services are not core business to hospital pharmacy services and prescriptions for patients that attend outpatient departments should be written by the patients General Practitioner, using FP10s, since in most cases that is where ongoing prescribing responsibility will lie. Some hospitals therefore do very limited outpatient prescribing with most patients being referred back to their GP for prescriptions and on-going care.
- 4.1.6 Many other issues were raised e.g. the integrity of the supply chain and confidentiality of prices (these are dealt with elsewhere in this report).
- 4.1.7 When considering outsourcing of hospital pharmacy outpatient services all options should be considered, with service quality a high priority and not price alone. This is

consistent with the current NHS reform agenda. Whilst we are pleased to have found evidence of this we learnt this is not always the case.

- 4.1.8 The NHS needs to consider changes taking place to NHS funding via clinical commissioning groups. It is likely that these new organisations may take differing views about hospital services in future which may impact on outpatient prescribing and dispensing.
- 4.1.9 We have been made aware of a range of advice provided by management consultancies to the NHS with respect to outsourcing of OPD services. Such advice has been wide and varied and has included some consistency of view and some conflict of view. It is our view that when considering outsourcing OPD services a legal opinion may also be required.
- 4.1.10 In the course of our review we have been made aware of others who have examined issues relating to outsourcing of OPD services. Most notable for its contribution is a database in a report titled "Community Pharmacy Project" and published March 12<sup>th</sup> 2012. This is based on a survey undertaken by a Chief Pharmacist and listing current "state of play", key issues plus lessons learnt from Trusts who have or are progressing outsourcing of OPD. This is a valuable database and should be built upon.

## **4.2 Drivers**

- 4.2.1 In all almost cases examined the main driver for change was declared to be the requirement to improve the patient experience e.g. in reducing outpatient pharmacy waiting times. However, in most cases it appears that the main driver is to release cash either to meet cost improvement targets and / or to redeploy hospital pharmacy staff into more clinical roles. Consequently both in-patient and outpatient services may improve.
- 4.2.2 Therefore another key driver was to allow hospital pharmacy staff to concentrate on inpatient services by removing the 'distraction' of providing outpatient pharmacy services, much of which is seen as routine and not a clinical priority. In this way hospital pharmacy staff can be better deployed to where they can maximise their value e.g. in specialist clinical areas, patient admission and discharge.
- 4.2.3 Other drivers for change that were reported are patient surveys that have shown a desire to see a community pharmacy outlet alongside other retail outlets in hospitals.
- 4.2.4 In all cases examined Trusts utilised the opportunity arising from VAT exemption for outpatient dispensed items (see Para 4.3) to fund the new service.
- 4.2.5 It was noted that the increases in VAT from 15% through 17.5% to 20% and the QIPP initiative has increased interest in outsourcing and we were told that 30 Trusts have gone out to tender in the last 18 months.

### 4.3 VAT and Medicines

4.3.1 Medicines purchased by NHS Trusts are subject to VAT as their issue to patients is considered by Her Majesty's Revenue and Customs (HMRC) to be part and parcel of a Trust's statutory (i.e. non business) function.

4.3.2 The issue of VAT and its application to outpatient medicines provision from various providers has been subject to wide ranging discussion in the Pharmaceutical Journal over the last 12 months or so. With feelings running high this is clearly a contentious issue. A range of relevant guidance on VAT is available on the HMRC website<sup>2</sup>. This includes "VATHLT6120 Dispensing by a pharmacist: Scope of the zero rate" to help clarify regulations applicable to community pharmacies, hospital pharmacies and external pharmacy companies in NHS hospitals (see Appendix 2 for full guidance note). This is key guidance – in summary:

#### 4.3.3 VATHLT6120 - Dispensing by a pharmacist: Scope of the zero rate

##### a. Community pharmacies

Most dispensing in a traditional high street retail pharmacy is zero rated under item 1 or one of the concessions outlined in VATHLT6070 and VATHLT6080. When dealing with hospitals and nursing homes) pharmacists may only zero-rate the dispensing of prescribed qualifying goods if the goods are for an individual named patient and they are satisfied that either:

- the goods will not (our italics) be used while the patient is within the institution; or
- one of the concessions outlined in VATHLT6070 & VATHLT6080 applies."

##### b. Hospital pharmacies

Where an NHS hospital pharmacy supplies qualifying goods to out- or discharged patients as part of the NHS's statutory obligation of care, this is not a business supply for VAT purposes. Other than this, hospital pharmacies may zero rate dispensing of qualifying goods to out- or discharged patients for their personal use, including dispensing by:

- pharmacies in private hospitals;
- independent pharmacies situated in NHS hospitals (e.g. where the pharmacy is run by a private company) ( see c below) ; or
- NHS hospital pharmacies dispensing to private patients.

##### c. External pharmacy companies in NHS hospitals

To improve services to patients, a hospital may enter into a contract with a third party pharmacy company to operate a pharmacy in the hospital to dispense qualifying goods to out-patients. In this situation the same criteria for zero-rating applies to pharmacy companies within a hospital as to normal community pharmacies.

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<sup>2</sup> <http://www.hmrc.gov.uk/vat/index.htm> (VATHLT 6120, VATHLT 6020, VATHLT 6040, VATHLT 6050, VATHLT 6060, VATHLT 6065, VATHLT 6070, and VATHLT 6080).

Any other charges made (e.g. management or administrative) will follow their normal VAT liability as they are not covered by the zero-rating provisions for qualifying goods.

- 4.3.4 It would appear from the above that outsourcing the provision of hospital OPD should allow medicines dispensed by the outsourced provider to be exempt from VAT. However, to avoid this being considered as ‘tax avoidance’ and therefore subject to challenge by HMRC it needs to be demonstrated that the potential VAT savings are not the sole reason for outsourcing the provision of medicines to outpatients and that there are operational benefits (including direct patient benefits) of any new arrangements.
- 4.3.5 When considering outsourcing outpatient pharmacy services it is important to model the potential VAT savings carefully since a number of products are zero rated for VAT or homecare services are already used.
- 4.3.6 The NHS is funded for the VAT it pays on the medicines it purchases. If the majority (or all) hospitals spend less on medicines dispensed by using an outsourced provider (through VAT avoidance) then the Exchequer may intervene and top slice NHS budgets. (See also Para 4.16.1)
- 4.3.7 Some hospitals are looking to explore VAT recovery on medicines in areas of hospital activity other than outpatients. Such further development may be covered by other VAT guidance as follows. Guidance VATHLT6070 – “The zero rate for dispensed drugs: background: concession for NHS prescriptions” makes reference to a range of other regulations and as such is not simple to interpret. However, we believe, this may allow medicines to be dispensed by a community pharmacy for use by an individual patient during an inpatient attendance provided and only if the medicines are prescribed using a FP10 prescription form and the community pharmacy is reimbursed by the Prescription Pricing Authority. For a wide range of reasons this would appear to rule out outsourcing inpatient NHS hospital medicines provision.
- 4.3.8 Guidance VATHLT6080 relates to medicines dispensed by a retail pharmacist to an individual patient on the private prescription of a GP for personal use when the medicines do not form part of the care provided by the hospital e.g. insulin for a diabetic admitted for a respiratory complaint. This would appear to support the use of patients own (VAT free) medicines during an inpatient stay.
- 4.3.9 There is a wide range of other relevant guidance (VATHLT6020, VATHLT6040, VATHLT6050, VATHLT6060, VATHLT6065)<sup>3</sup> which may impact on provision of medicines to inpatients including scope to recover VAT on private outpatient medicines spend as this is seen as a business activity. This is likely to impact on those patients who have their cancer medicines supplied via a “top-up” payment

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<sup>3</sup> <http://www.hmrc.gov.uk/vat/index.htm> (VATHLT 6120, VATHLT 6020, VATHLT 6040, VATHLT 6050, VATHLT 6060, VATHLT 6065, VATHLT 6070, and VATHLT 6080).

arrangement. Supply here is essentially private, VAT free and probably consistent with published VAT guidance. In addition we are aware of some hospitals who issue FP10 (NC) prescriptions for patients to obtain (often high cost) medicines via a community pharmacy and have these medicines administered during their hospital attendance. The cost of such medicines is VAT free and this may not be consistent with published VAT guidance.

#### **4.4 Patient perspective**

- 4.4.1 In a number of instances where trusts have progressed outsourcing of their pharmacy OPD services there has been no patient involvement or consultation whilst in others there has. This may be achieved more easily in Foundation Trusts (FT) as they often have a patient panel or patient governor with whom they can consult. A view was expressed that patients should be informed that the service provider for dispensing their outpatient prescriptions is an outsourced service though the prescription they receive is still a hospital (NHS) prescription.
- 4.4.2 Given that in the large majority of services we examined there was a noticeable service improvement for patients e.g. reduced waiting time, overall we believe patients welcome the advent of outsourced OPD pharmacy services in hospitals. This was also evidenced by patient satisfaction surveys we were made aware of.
- 4.4.3 In most instances the outsourced pharmacy OPD service is in a geographical location on the hospital campus quite distinct from that of the inpatient pharmacy. Whilst this is helpful, signage and guidance for patients about which pharmacy to take their prescriptions to must be made clear so as not to cause confusion or have adverse impact on patient flow. We were told of some instances where patients take their prescriptions to the inpatient pharmacy and then have to be re-directed to the outsourced service. It appears this problem can arise when a hospital has locum doctors or new nurses unfamiliar with arrangements. In other cases confusion may occur if some prescriptions are to be dispensed in-house whilst others are via the outsourced service.
- 4.4.4 Where a 3<sup>rd</sup> party provider is used for OPD services, patients are often aware that the service is outsourced since the commercial provider uses their own corporate branding. This may not be as clear to patients when an in-house subsidiary company is used.

#### **4.5 Interface with commissioners**

- 4.5.1 Most people interviewed were of the view that the Trusts host commissioner needs to be informed of service outsourcing and some were of the view that they should be involved in the process to outsource. The main reason for this is that Trusts are still accountable to commissioners for standards of service provision (e.g. methotrexate dispensing) and they should be transparent in their dealings and highlight service quality improvements which are being pursued. The main discussion point was how, or if any, savings should be shared.
- 4.5.2 The interface between Trusts and commissioners is complex, and possibly more so for tertiary care centres, where a high number of commissioners might be involved.

Within the NHS, some Trusts and commissioners have close and collaborative relationships, but this is not true in all cases. Examples of Trusts wanting to involve commissioners from the outset and to share any savings equally with them were found. Other Trusts take the view that the service development ‘risk’ is theirs and so they should retain any savings which accrue.

- 4.5.3 How savings are to be shared with commissioners may be dependent upon the outsourcing model pursued and/or any start up costs incurred. However, most, but not all, reported that an open and sharing approach had wider benefits when dealing with commissioners. The principle of “gain sharing” to drive longer-term strategic partnerships with commissioners is also supported by DH guidance<sup>4</sup>.
- 4.5.4 Sharing of savings becomes complex for medicines excluded from NHS Tariff pricing (PbR). These medicines often have the highest acquisition price. Some Trusts take the view that they should charge commissioners the cost that they are invoiced for the medicine (normally NHS contract price) plus a sum equivalent to VAT (as if they had paid it). This would be at worst cost neutral to commissioners and in some health economies may even represent a saving since some Trusts also add a service charge for the transaction. Since most financial savings will arise from non-PbR medicines it is important to get early engagement and agreement with commissioners on this issue.

## **4.6 Status of the prescription**

- 4.6.1 The status of prescriptions issued by hospital outpatient clinics and dispensed in an outsourced pharmacy service is not clear since the in-house service is part of the business of the hospital and the outsourced service is not. However, in all cases examined the outpatient prescription could only be dispensed via the onsite 3<sup>rd</sup> party hospital outpatient pharmacy. Some (3<sup>rd</sup> party providers and hospital pharmacists) take the view that such prescriptions must be seen as private prescriptions since they are written on hospital “business” stationary and not approved stationary for NHS dispensing in a community pharmacy. We share this view though a General Pharmaceutical Council (GPhC) opinion would be helpful.
- 4.6.2 If prescriptions issued by hospital outpatient clinics are dispensed in an outsourced pharmacy service and are technically a private prescription there is a requirement for the outsourced pharmacy to keep records of supplies made. We understand that outsourced pharmacy service providers do keep such records electronically and an audit trail can be established.
- 4.6.3 In some instances Trusts have designed specific prescriptions for use only when a product is to be dispensed by the outsourced outpatient pharmacy service. This may be helpful to patients in directing them to the correct pharmacy in the hospital for their medicines to be dispensed.

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<sup>4</sup> Procurement guide for commissioners of NHS-funded services. DH Gateway Reference 14611, p21

4.6.4 Some hold the view that if the legal status of prescriptions issued by hospital outpatient clinics is that they are NHS prescriptions then the direction of a patient to a 3<sup>rd</sup> party pharmacy provider (i.e. commercial pharmacy) on the hospital site raises a range of issues e.g. patient choice. We do not share this view since we understand that regulations relating to “direction of a patient?” only applies to FP10 prescriptions.

#### **4.7 Dispensing FP10 prescriptions**

4.7.1 For an outsourced OPD service to be able to dispense FP10 prescriptions it will be necessary for them to obtain an NHS dispensing contract via the host PCT. This will not be granted automatically and is likely to be subject to challenge from the Local Pharmaceutical Committee.

4.7.2 For a range of reasons it is unlikely that a hospital based FP10 dispensing service will generate much activity either from staff or passing visitors to the hospital. However, as an additional service to the hospital outpatient dispensing service this can improve viability and offer an added value service to visitors and staff.

4.7.3 Many hospitals have General Practitioner (GP) led urgent care or out of hours services on site. An outsourced hospital pharmacy service with an NHS dispensing contract to dispense FP10 prescriptions may therefore be an advantage or even expected. However, given that by definition “out of hours GP led services” are occurring outside normal hours demand to warrant opening during such hours will need to be demonstrated for the service to be cost effective.

4.7.4 In any event, where an outsourced OPD service has an NHS dispensing contract to dispense FP10 prescriptions it will be necessary for the pharmacy to ensure separation of stock between that used for the hospital service and that used for dispensing of FP10 prescriptions. In addition, Trusts and the pharmaceutical industry will want verifiable assurance that such separation of stock actually exists and that NHS contract stock is not used when FP10s are dispensed.

#### **4.8 Medicines & Healthcare Products Regulatory Authority (MHRA) & General Pharmaceutical Council (GPhC) Regulations**

4.8.1 Wherever an outsourced service provider receives its medicines from it will be necessary that regulations relating to sale and supply plus wholesaling are complied with. Changes resulting from repeal of Section 10(7) of the Medicines Act 1968 will necessitate outsourced OPD services to only receive medicines direct from manufacturers or from locations that have a Wholesale Dealer’s Licence. This latter point is important since if supplies are made from a hospital pharmacy the location (e.g. store or dispensary or both) from which the supply is made must be covered by the Wholesale Dealer’s Licence. We were told of instances when an outsourced service provider requested supplies of medicines they had run out of from the hospital main pharmacy or store.

4.8.2 All outsourced service providers examined sold over the counter medicines to the public (but not to patients) and were registered with the GPhC.

- 4.8.3 GPhC standards relating to registered premises will need to be applied to outsourced service provider premises. These may be subject to change and ensuring compliance with standards for premises must form part of the contract with outsourced service providers.
- 4.8.4 All registered pharmacies (or corporate groups of pharmacies) must employ a Superintendent Pharmacist who has the overarching responsibility to ensure that appropriate systems are in place to ensure that the pharmacy operates safely and effectively. Wholly owned subsidiaries providing outsourced OPD services will need to appoint a Superintendent Pharmacist.

#### **4.9 Key Performance Indicators (KPIs)**

- 4.9.1 It is important that NHS Trusts give due consideration to key performance indicators (KPIs) prior to establishing a contract with a 3<sup>rd</sup> party service provider for the dispensing of medicines to hospital outpatients. Ideally these KPIs should be identified and agreed by both parties prior to contract completion as they can be difficult, and expensive to build into contracts once underway.
- 4.9.2 Given that it needs to be demonstrated that savings accruing from the non-payment of VAT on medicines provided through outsourced OPD services is not the sole reason for outsourcing, then direct patient benefits must be identified in KPIs. We were pleased to see that this point had been considered in all the models examined. However in some cases we viewed the service improvement to be somewhat marginal or tenuous and were concerned that a challenge from the HMRC might occur at some time in the future.
- 4.9.3 The most common KPI used was waiting time for patients to have their medicines dispensed. In many instances we learnt of highly significant waiting time improvement (reduced from almost one hour to 10 or 12 minutes) whilst in others no real significant change was reported.
- 4.9.4 Formulary compliance rate has potential as a KPI as Trusts and commissioners will want prescribers to follow agreed prescribing policies and procedures.
- 4.9.5 A range of KPIs that were fairly common to most services examined included, stock outs, dispensing error rates and patient satisfaction surveys. Others which were less common included costing reports and invoice accuracy. Whilst measures associated with these varied, there was a widely held view that they should be no worse than the former hospital service. Some contracts included escalating year on year improvements in KPIs in order to demonstrate step change improvements in service provision.
- 4.9.6 KPIs should be looked at more broadly in how they benefit the hospital as a whole and not just pharmacy services e.g. increasing patient throughput.
- 4.9.7 Most problems in failing to meet KPIs occurred early in the contract life and many were related to unfamiliarity with the medicines dispensed and the hospital systems.

In one instance it was reported that hospital staff had to train 3<sup>rd</sup> party provider staff to correct failings.

- 4.9.8 Some providers of outsourced services subcontract components of their service delivery to other providers e.g. homecare companies. In such circumstances NHS Trusts should ensure that arrangements are transparent and agreed as part of the contract prior to commencement. Agreed KPIs should be adhered to by whichever 3<sup>rd</sup> party provider is involved in the service provision. Care will be needed to ensure an accountability framework for agreed KPIs and that subcontracting is not at the expense of transparency.

#### **4.10 Clinical checking**

- 4.10.1 In all outsourced service provision it needs to be clear which party is undertaking and responsible for clinical checking of prescriptions and associated standards.

- 4.10.2 In most trusts a risk based approach is adopted for clinical checking of prescriptions. Some trusts identify areas of clinical activity where the clinical check must be undertaken only by in house hospital pharmacy staff (a pharmacist either in the dispensary or a specialist pharmacist working in the clinic or specialty). Examples of such clinical activity include HIV, oncology and paediatrics.

- 4.10.3 In a number of trusts all outpatient pharmacy activity (except clinical trials but including unlicensed medicine provision) has been outsourced.

#### **4.11 Staff issues**

- 4.11.1 When the issue of outsourcing has been raised in Trusts the initial response of staff has been of concern about loss of NHS jobs and job security. In some instances job losses have occurred whilst in others staff time released has been re-invested in inpatient services. Another concern raised was that standards of service delivered by the outsourced service provider should be no less than that provided by the in-house team.

- 4.11.2 Whether an in-house subsidiary or a commercial 3<sup>rd</sup> party provider, staff involved in a permanent role for an outsourced pharmacy services are employed on non-NHS terms and conditions. Some NHS staff are utilised on a rotational scheme through the outsourced service and have remained on NHS terms and conditions.

- 4.11.3 We were told of a variety of schemes for contracting with staff for in-house subsidiary outsourced services. Some were a variation of NHS terms e.g. mid-band 7 for pharmacists, ATO rates for dispensing staff, variable/flexible hours, no holiday/sick pay or pension contribution etc. Where the service was a 3<sup>rd</sup> party provider we understand that staff are paid on the same terms as other staff in the 3<sup>rd</sup> party provider.

- 4.11.4 Staff rotational schemes through an outsourced service provider can be mutually beneficial e.g. in supporting familiarity of outsourced service provider staff with hospital prescribing and supporting hospital staff with customer service skill development.

4.11.5 In some Trusts there is good collaboration between the Trust in-house pharmacy service and outsourced service provider. The NHS providing clinical training, information about new medicines etc and the outsourced service provider delivering customer service training. In some this is on a “quid pro quo” basis and seen to be of mutual interest, whilst in others it has been proposed that the clinical training is charged for since this is felt to be more of an ongoing requirement.

4.11.6 All outsourced service providers are responsible for their own staff Occupational Health and staff CRB checks (some in house subsidiary companies buy this service from the host Trust) and cover for staff absences.

#### **4.12 Data management e.g. IMS, Pharmex**

4.12.1 We learnt of a number of instances where there is no data capture from outsourced service providers to support the NHS for contracting purposes e.g. via Pharmex or analysis of medicine use e.g. benchmarking using IMS health data. Both of these have significant potential for adverse impact on NHS medicines procurement and optimisation. If data is supplied to IMS from an outsourced service provider, care must be taken to ensure it is on the same basis as for the NHS i.e. anonymised for prescriber and hospital and that all data (Pharmex or IMS) is provided in a timely manner.

4.12.2 We were told of problems experienced by NHS medicines procurement contracting teams having to examine data manually from many Trusts because each one was obtaining data using different IT systems from 3<sup>rd</sup> party providers. This problem could be solved by outsourced service providers using the same IT system as the pharmacy in the NHS hospital for which they are providing the service.

4.12.3 The problems in paras 4.12.1 and 4.12.2 above do not occur where the outsourced provider sources its medicines exclusively via the hospital in house pharmacy store.

#### **4.13 Invoicing and Directorate costing**

4.13.1 Frequency of invoicing may be dependent upon the needs of the outsourced service provider cash flow and Trust needs for directorate expenditure reporting. It appears most outsourced service providers invoice monthly for medicines supplied and services provided and this would fit with the needs of most NHS finance departments for directorate re-charging. Checking of invoices can cause delay and an electronic system should be used where possible.

4.13.2 Directorate and ex PbR reporting is seen as a critical issue for Trusts. This can be addressed by the outsourced service provider using the same medicines dictionary and cost codes as the in-house pharmacy service and compatible or identical IT systems. However, problems may arise when system upgrades are required and this may need to feature in contract agreements with outsourced service providers.

4.13.3 We were informed of examples where the outsourced service provider uses the same IT system as the hospital and costs issues to directorates using codes provided by the hospital. Where there is an IT interface with the hospital finance system this

seems to work well e.g. in house subsidiary company, but where there is no IT interface, a printed report is sent directly to the Trust. The latter example will then need to be checked manually for accuracy.

- 4.13.4 Medicines issued by outsourced OPD services need to be recorded to ensure medicines excluded from PbR can be identified and cross charged to appropriate commissioners. Additional information is therefore needed about patients for whom these products have been dispensed e.g. patient address, hospital number.

#### **4.14 Estate**

- 4.14.1 In the course of this review we learnt of numerous arrangements for occupancy of NHS estate from which outsourced OPD services were provided. These may become complicated where the estate occupied is provided via a Private Finance Initiative (PFI) i.e. the hospital doesn't own the building. In this instance it needs to be clear as to arrangements for making alterations to the occupied area, who pays whom (hospital or PFI provider) and for what (e.g. rent, utilities etc). Additional aspects need to be considered and may be further complicated dependent upon the emphasis that a 3<sup>rd</sup> party outsourced service provider or Trust wishes to put on retail sales e.g. size of footprint required and associated utilities.
- 4.14.2 Trusts need to ensure the size of "footprint" to be occupied by an outsourced service provider is sufficient for the dispensing and associated professional service to be undertaken.
- 4.14.3 Given that it will be normal for an outsourced OPD service to have premises distinct from and separate to the inpatient service (e.g. for separation of stock and staff), space may be freed up in the inpatient pharmacy service. This is likely to be limited since some pharmaceutical stock will be duplicated in both environments though any staff congestion that exists should be reduced.
- 4.14.4 There needs to be clarity of ownership of, and payment for, fixtures and fittings in any outsourced outpatient pharmacy service. This may be straight forward for a Trust wholly owned in-house subsidiary company but not so clear with a 3<sup>rd</sup> party provider where we found a number of arrangements existed. In all cases where a 3<sup>rd</sup> party provider was involved the 3<sup>rd</sup> party provider wanted to "brand" the external frontage of the pharmacy.
- 4.14.5 The capital investment required to establish an outsourced outpatient pharmacy service is not insignificant. This is not just fixtures and fitting but pharmaceutical stock, staff training and overall project management. We found various arrangements for funding these and this needs to be made clear in contracts at an early stage in service consideration.
- 4.14.6 In the cases we examined the outsourced OPD service was provided on NHS (or NHS PFI) estate. Any tax liability associated with such provision requires clarity e.g. Stamp Duty Land Tax on the property occupied, assets and liabilities transferred that can be offset against tax and VAT recovery or liability on equipment utilised/ leased/ purchased etc.

## **4.15 Tender process**

- 4.15.1 When a decision is taken by a hospital to outsource its outpatient pharmacy service provision this should be subject to competitive tender. Given the scale of such a contract it will be necessary for such tenders to be advertised in the Official Journal of the European Union (OJEU). We do not believe this has occurred in all cases. Whether this is necessary for an in-house subsidiary of a Trust is a moot point.
- 4.15.2 When advertising in the OJEU it is usual for expressions of interest to be invited and responses assessed against criteria developed by individual Trusts. Whilst we recognise this report may be helpful to both the NHS and potential outsourced service providers in the tender process, we believe there is merit in the NHS collaborating to develop an example of a standard service specification which can become a useful template for Trusts to use. This will avoid unnecessary duplication of effort and potential omission of some key issues.

## **4.16 Potential Risks**

- 4.16.1 Since the funding of outsourced outpatient pharmacy services is predicated on VAT savings, any change to VAT rates will impact on outsourcing models. If VAT increases this improves the opportunity for savings and if it decreases it reduces the savings which could impact on the viability of some schemes. This could then have cost consequences for the NHS as some may need to return to NHS provision.
- 4.16.2 If calls for a 'level playing field' with respect to the application of VAT to medicines in community and hospital settings are accepted then either all medicines will be VAT exempt or all medicines will be subject to VAT. In either of these scenarios the funding model that underpins outsourcing is removed and therefore the associated services will not be financially viable without utilising existing NHS funds. We do not believe that reverting services to their previous provision or utilising scarce NHS resources to maintain the new level of provision is in the best interests of patients.
- 4.16.3 Under existing schemes for outsourcing of hospital medicines provision the NHS and therefore patient services benefit from VAT avoidance, potentially to a sum of around £100m per annum (excluding homecare). However, NHS funding could subsequently be adjusted based on an estimate of VAT being saved through outsourcing and homecare medicines provision. This would then create a significant and additional cost pressure for NHS hospitals.
- 4.16.4 Few Trusts appear to have considered an exit strategy from their outsourced service contracts and most appear to have assumed this would be gradual using a termination date or notice period specified in contracts. We are not aware of any that have robust plans for a scenario where an outsourced service provider may suddenly withdraw from a contract e.g. due to insolvency. The NHS needs to ensure this issue forms part of contracts with outsourced providers along with other areas of potential risk and liability.

## 5. Pharmaceutical Industry perspective

### 5.1 General comments

- 5.1.1 The pharmaceutical industry would welcome an understanding (from Trusts) about the aims of outsourcing initiatives and to better understand the associated commercial drivers and the NHS logic for outsourcing OPD. The industry would also welcome a better understanding from 3<sup>rd</sup> party service providers about how they want the pharmaceutical industry to work with them.
- 5.1.2 With regards to outsourcing, pharmaceutical companies are seeking to avoid the 'law of unintended consequences' and feel there is an urgent need for proper discussion and engagement between all parties. They wish to re-assure the NHS of their desire to work with them and to assist with problems where they exist, but this requires genuine dialogue from all parties.
- 5.1.3 Trusts and the DH Commercial Medicines Unit (CMU) could help to reduce problems by increasing the visibility of real time usage data (e.g. volumes, clinical demands). For example, could pharmaceutical companies have visibility when an outsourced 3<sup>rd</sup> party service provider invoices the hospital? This would allow pharmaceutical companies to coordinate distribution and plan production and to reassure them that medicines are retained in the authenticated and agreed supply chain.
- 5.1.4 The pharmaceutical industry recognises that outsourcing is a rapidly growing trend. The industry has informed us that they are working hard to deal with the 'here and now' as well as understand the longer term implications. Some speculated as to whether community pharmacies were looking to take over hospital pharmacies and that in the absence of any explicit strategy there is considerable uncertainty and concern.

### 5.2 Pharmaceutical Industry – Outsourced Provider accounts

- 5.2.1 Many pharmaceutical companies have separate business accounts for community and hospital pharmacies. It was clear to us that there is uncertainty about which category 3<sup>rd</sup> party service providers should sit. At the outset, most would have treated them as a new 'community' account but there is consideration by some about moving newer outsourced accounts to the 'hospital' category.
- 5.2.2 Some pharmaceutical companies have adopted the not unreasonable view that if it 'looks like a community pharmacy' then they should set up a community pharmacy account. However, the hospital still claims to be the customer. This makes it difficult to understand whose needs to meet. Some companies said that the biggest problem is understanding how to set up outsourced pharmacy services as an account as it is often unclear about who the commercial relationship is with and who is responsible for any debts should they occur.
- 5.2.3 Pharmaceutical companies have standard operating procedures (SOPs) about whom they will do business with and trading partners need a good trading history before an account is opened. Some outsourced OPD service providers do not have trading

histories e.g. wholly owned subsidiaries and some pharmaceutical company lawyers are struggling to understand this model.

- 5.2.4 Similarly, some community pharmacy providers of hospital based OPD services have very little knowledge of working with pharmaceutical companies directly as most of their previous transactions in primary care will have been via wholesalers. In such instances, pharmaceutical companies have organised workshops to explain to them how hospital contracting /pricing works from a supplier perspective. This not only adds time and cost to pharmaceutical companies but invites them to question the expertise of the new providers.

### **5.3 Supply chain**

- 5.3.1 Although the review is not about the pharmaceutical supply chain, readers of this report need to understand a little about the relationships between the various players involved and issues raised about the outsourcing of hospital OPD services. The pharmaceutical supply chain is complex, with literally hundreds of different manufacturers selling or supplying medicines to numerous wholesalers and then on to thousands of pharmacies (both within hospitals and in the community setting).
- 5.3.2 Supplies of medicines from pharmaceutical companies to community pharmacy groups for outsourced OPD services are becoming easier for some, but not necessarily for all as this new business model becomes more established and levels of trust increase. Some pharmaceutical companies are known to have concerns about supplying these new models.
- 5.3.3 Pharmaceutical industry interviewees expressed varying levels of understanding of the outsourcing initiatives and all had concerns about weakening the integrity of the supply chain as a consequence of new models of supply. They see the drivers to be financial benefits to Trusts, plus gains in efficiency, capacity and improving the clinical service.
- 5.3.4 The pharmaceutical industry does not see outsourcing of OPD as offering any benefits to the pharmaceutical industry, only extra cost. They are of the view that such costs should be factored in when tendering as they will come through the supply chain in some shape or form.
- 5.3.5 Some of the new models offer more comfort to the pharmaceutical industry than others. They appear least comfortable with 100 hour hospital out-patient pharmacies set up to dispense FP10s. These arrangements are understood to have separate community pharmacy and hospital pharmacy work stations with separate IT systems. However, the lack of transparency from a pharmaceutical industry perspective raises questions about stock ordering and the separation of stock.
- 5.3.6 Concerns were frequently expressed about the 'law of unintended consequences'. For example, pharmaceutical companies that have Direct to Pharmacy (DTP) models are concerned about losing visibility in transaction data. This threatens the continuity of supply, particularly for low volume specialised medicines.

- 5.3.7 Concerns were expressed about hospital specialist medicines being delivered to the same address as the outsourced OPD service provided by a community pharmacy. Some companies would prefer to deliver hospital specialist medicines to the hospital rather than to a community pharmacy.
- 5.3.8 A number of pharmaceutical companies reported that some 3<sup>rd</sup> party service providers were very commercially aggressive and that others were also litigious in nature. They expressed concerns about this and were suspicious that such groups were actively looking for weaknesses in the supply chain. As a result pharmaceutical companies have developed consistent and clear trading rules regarding medicines supply. Some community pharmacy groups have a known track record of trading in medicines thus creating extra work and costs in the supply chain to the potential detriment of UK patients. This is, of course, legal but increases the risk of shortages. As a consequence some pharmaceutical companies are dealing with community pharmacies 'at the lowest common denominator' resulting in poorer service to 'higher quality' community pharmacy providers.
- 5.3.9 A concern was expressed to us about the long duration of outsourced service contracts. Pharmaceutical supply chain models are likely to evolve rapidly in the coming years due to financial constraints, with centralisation ever more likely. Whilst the quoted reasons were that long duration contracts are necessary due to the investment required this can lock the NHS into a model for too long a period thereby blocking future competition and new ways of working. We remain unclear as to the investment required that necessitates such long duration contracts with outsourced providers.
- 5.3.10 Other areas of supply chain concern reported to us was where 3<sup>rd</sup> party service providers sub-contract components of supply to homecare companies. This leads to a further loss of transparency and visibility.

## **5.4 Impact on NHS Contracts**

- 5.4.1 NHS Trusts work collaboratively and obtain competitive prices from manufacturers (NHS contract prices), whilst community pharmacy chains and groups also seek best prices. All of these prices are commercially sensitive and regularly reviewed, resulting in a very dynamic and competitive procurement environment. Relationships between the various supply chain players are often tense, as all are charged with getting the 'best deal' for their employers.
- 5.4.2 With regards to products and prices the view is that in 99% of cases CMU contract prices are better than can be obtained in primary care. When out-patient services are commissioned the contracts should stipulate that 3<sup>rd</sup> party service providers should buy products from CMU contracts.
- 5.4.3 A concern expressed amongst a number in the pharmaceutical industry was that companies suspect some community pharmacy chains are bidding (very competitively) to win outsourced contracts in order to get access to CMU contract prices and products.

- 5.4.4 Access to contract prices was a major concern expressed by the pharmaceutical industry. We were given an example where a pharmaceutical company might already be trading with a community pharmacy chain and then receive a letter from them asking for NHS contract prices to supply a hospital. In some circumstances, the same individual (working for the community pharmacy chain) is dealing with the outsourced site (and supplies to it using NHS contract prices) and is also negotiating with the pharmaceutical company about discounts for products for use in primary care. The term 'Commercial in Confidence' used by the hospital sector therefore loses credibility.
- 5.4.5 There was a view from the pharmaceutical industry that in some situations, community pharmacy chains are competing with pharmaceutical companies in the hospital contracting process to supply NHS contract lines whilst knowing the pharmaceutical companies 'Commercial in Confidence' NHS contract price.
- 5.4.6 We were told that the pharmaceutical industry has little faith about 'firewalls' within the community pharmacy group setting and needs transparency where required and confidentiality where necessary. Since neither of these are met as yet, they were of the view that as a consequence, and in the longer term, hospital prices might increase.
- 5.4.7 Allegations were made that some 3<sup>rd</sup> party service providers supply cheaper generic products or parallel imports in place of the hospital contracted branded product and were still charging the hospital for the contracted branded product. This is primarily an issue for the Trusts concerned as they are being over charged and patients are being denied the product chosen for them by the Trust. However this also threatens the long term credibility of the contracting process as if contract lines are not purchased then it is likely that advantageous prices will not be forthcoming in future.
- 5.4.8 It is clear that the National Pharmaceutical Supplies Group (NPSG) brief for Chief Pharmacists dated 30<sup>th</sup> September 2011 (see Appendix 3) is the reference document that all NHS Trusts should be working to. However pharmaceutical companies cite many instances of hospitals either ignoring or misusing the advice. Where pharmaceutical companies have legitimate concerns they should refer Trusts to the NPSG paper and if issues are unresolved then these should be referred to CMU formally.

## **5.5 Medicines shortages**

- 5.5.1 It was reported that the pharmaceutical industry already invests a lot of time and money in trying to manage shortages. Their fear is that 3<sup>rd</sup> party OPD community pharmacies with access to medicines at NHS contract prices will further increase shortage problem as some groups are already known to trade and export medicines.
- 5.5.2 Outsourcing of OPD pharmacy services makes it more difficult for the pharmaceutical industry to track medicines through the supply chain. Some companies have noticed unusual demands for certain products from 3<sup>rd</sup> party service providers and suspect trading is going on.

## 6. Community pharmacy perspective

### 6.1 Strategic dimension

- 6.1.1 The increasing involvement of community pharmacy groups in the provision of outsourced OPD service provision needs to be seen as part of a wider strategic shift in the business model of community pharmacy. Community pharmacy is a business and, as for all businesses, will be looking for business development opportunities and increasing revenue and profit.
- 6.1.2 Over recent years, community pharmacy has moved towards a 'paid for service' business model rather than simply generating income from dispensing. It is becoming more clinical as demonstrated by services such as Medicine use Reviews and the New Medicines Service. Most prisons and a number of Mental Health Trusts are now serviced by community pharmacy providers and this has reportedly increased confidence within the sector to look at secondary care pharmacy services. Expertise in this sector is increasing rapidly as more outsourced contracts are awarded.
- 6.1.3 The increase in VAT from 15% through to 20% and the demands of QIPP has increased secondary care interest in outsourcing. Community pharmacy chains recognise that although VAT savings are important they should not be the only factor in deciding to outsource OPD services. Community pharmacy chains interviewed recognise that outsourcing will not be right for every hospital as needs are different in different centres.
- 6.1.4 Trusts need to recognise that outsourcing OPD is a strategic decision. Community pharmacy chains can provide a wide range of outsourced service models and advise Trusts to determine the type of service they wish to provide, and to whom, prior to engaging with potential providers. For example, for some Trusts the retail element is an important consideration, whilst others will be more interested in reducing pressure on the hospital dispensary in order to redeploy staff to more clinical roles. Some may wish to do both.
- 6.1.5 Some community pharmacy groups express the desire to work in partnership with Trusts when providing OPD services, whilst others will undoubtedly prefer more of a transactional relationship. Regardless, it is important for the outsourced provider to establish a good working relationship with the Chief Pharmacist in order for the service to be delivered effectively and according to specification. The view was that outsourcing needs NHS commitment and trust to make it work well and that all should think about patients first when developing and delivering outsourced OPD services.
- 6.1.6 The community pharmacy chains interviewed were comfortable that their professional staff are competent to dispense hospital prescriptions, perhaps after some awareness training from hospital clinical pharmacy staff. The view expressed was that although the skill sets are different in hospital and community pharmacy, all pharmacists have the same basic training and expertise comes with experience and post basic training.

## **6.2 Benefits**

- 6.2.1 All the Trusts interviewed reported a significant drop in patient waiting times following the appointment of an outsourced community pharmacy chain. For most patients, the outpatient dispensary or collection of a discharge prescription is their last experience in the hospital and any further delay is dispiriting and can be a cause of complaint.
- 6.2.2 Community pharmacy groups are commercial organisations and will bring new investment and expertise to secondary care (e.g. systems, premises, patient experience and physical environment). Some expressed the view that it makes sense to use hospital clinical expertise in clinical areas and community pharmacy expertise in the dispensary.

## **6.3 Issues**

- 6.3.1 Some community pharmacy chains confirmed that access to products at NHS contract prices from pharmaceutical companies was a problem in the early days of outsourcing. As both parties begin to establish a new business model, medicine supplies are reportedly becoming easier as the practice becomes more common place and levels of trust increase, although this is not necessarily true for all.
- 6.3.2 IT systems are an issue as community and hospital systems do not interface but this is reportedly evolving. Some community pharmacy chains allow the hospitals to have open access to all of their dispensing data (although processing this requires manual input from both parties).
- 6.3.3 In some outsourced Trusts it is important that some staff (pre-regs for example) still gain OP experience and this can be provided if specified and agreed at the outset. (Some expressed the view that in an outsourced service there should be no barrier between OP (community pharmacy) staff and (hospital) clinical staff and both should work to provide good quality patient care).
- 6.3.4 Cash flow can be a problem for community pharmacy chains when large quantities of high cost medicines need to be purchased. Trusts were asked to ensure that finance departments are managed so that, for example, large invoices are not 'stopped' for small sums due to a minor discrepancy caused by an IT or timing issue. Some Trusts reportedly pay an agreed fee one month in advance (for the medicines) and then this is reconciled when actual usage data is available. A few community pharmacy chains reported difficulties caused when pharmaceutical companies provide Trusts with rebates rather than allowing access to NHS contract prices as this increases work load for both parties.

## 7. Models examined<sup>5</sup>

### 7.1 Outsourced to a third party provider e.g. community pharmacy

#### 7.1.1 General comments

- 7.1.1.1 This was the most widely adopted model we were able to examine and all were provided by large community pharmacy chains and in some instances in collaboration with homecare providers.
- 7.1.1.2 In most cases the service had been introduced following a thorough consideration of the potential issues by the Chief Pharmacist and the pharmacy team. However a number of schemes had progressed following a direct approach by the community pharmacy chain to the Trust Finance Director thus bypassing the hospital pharmacy team and resulting in difficulties in progressing the proposed model.
- 7.1.1.3 In some instances Trusts had moved relatively quickly into pilot scheme arrangements and “learnt along the way”. All such pilots were subsequently tendered and we are not aware of any instance where the community pharmacy involved in the pilot was not awarded the contract.
- 7.1.1.4 Given the complexities inherent in progressing outsourcing of OPD services to a 3<sup>rd</sup> party, project management support is seen as critical.
- 7.1.1.5 It was apparent that outsourcing to a 3<sup>rd</sup> party provider can bring new investment (systems, premises, patient experience and physical environment) to meet increasing patient needs. Commercial organisations can bring business acumen and commercial skills to work alongside the NHS to improve the patient experience.

#### 7.1.2 Medicines procurement

- 7.1.2.1 It was clear from interviews held with NHS and Pharmaceutical Industry employees that there were concerns about maintaining the integrity of NHS contract prices and that no physical movement of products bought off NHS contracts should occur into the community pharmacy supply chain (as these are subject to separate legally binding contractual arrangements). Such movement of stock could have Pharmaceutical Price Regulation Scheme (PPRS) implications for pharmaceutical manufacturers and possibly for the community pharmacy NHS contract.
- 7.1.2.2 Given that wholesalers already have access to NHS contract prices it is possible for community pharmacies to get agreement with wholesalers to source products at NHS contract price only for, and direct delivery to, the hospital outsourced

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<sup>5</sup> **Editorial Note:** In the models examined below we have included a section titled “Strengths and Weaknesses” for each. Readers of this report should note we do not consider these lists to be exhaustive.

service. It should be possible to verify that physical movement of NHS contract stock into the community pharmacy supply chain has not occurred. This can be via a number of routes including either the Trust (or wholesaler or other direct supplier) reconciling stock purchased by the hospital outsourced service with that charged to the Trust. This will require a mutual understanding and transparent audit arrangements working between all parties.

- 7.1.2.3 At the outset of any contract with an outsourced service provider it may be necessary for Trusts to check all purchases against all items dispensed. However, when it can be demonstrated that supply chain integrity is maintained it should be possible to reduce checks to a random proportion of transactions to verify that the system is working properly.
- 7.1.2.4 Consideration may also be given by hospitals to the provision of anonymised transaction data to pharmaceutical manufacturers. This can then be checked by the manufacturers to establish if any leakage of stock has occurred.
- 7.1.2.5 Another model described to us is that all supplies from pharmaceutical manufacturers to outsourced pharmacy outpatient service providers are sold at NHS list prices and (for products subject to NHS contract prices) the manufacturers of these products provide rebates to individual Trusts. Whilst this addresses the issue of confidentiality of NHS contract prices it adds to the administrative burden of NHS Trusts and pharmaceutical manufacturers.
- 7.1.2.6 It was also suggested that an outsourced service provider could obtain the medicines it needs for dispensing hospital outpatient prescriptions from the hospital pharmacy store. This would ensure that only NHS contract medicines were used though the 3<sup>rd</sup> party provider would need to reclaim the VAT and have an agreement with the Trust on how this is shared.
- 7.1.2.7 Whatever approach is adopted it should be noted that NHS contracts for the procurement of medicines are between the NHS and individual pharmaceutical companies (i.e. not between the 3<sup>rd</sup> party provider and the pharmaceutical company). NHS Trusts therefore need to recognise their responsibilities with NHS contracts in order to ensure the integrity of the supply chain and in notifying the pharmaceutical manufacturers of 3<sup>rd</sup> party involvement.
- 7.1.2.8 Bearing in mind options described above it should be possible to get agreement across all parties (NHS Trusts, pharmaceutical companies, wholesalers and community pharmacy chains) on an agreed approach such that the necessary assurances are provided around integrity of the supply chain. This need not be unduly burdensome but will require some investment in time and IT development. Failure to reach an agreement that provides the necessary assurances may result in increasing tension and a less efficient and more expensive supply chain. Ultimately, pharmaceutical manufacturers might see little value in contracting with the NHS for medicines used in outpatients.

- 7.1.2.9 We were informed by one Trust that the outsourced service provider tends to purchase whatever brand of a generic medicine they can obtain, presumably to reduce costs to the outsourced service provider. Other Trusts were not able to tell us if similar instances occurred since they did not perform any checks to audit 3<sup>rd</sup> party provider compliance with NHS contracts. This is likely to have adverse impact on CMU framework agreements and weakening of future contracting for all NHS hospital services through higher tender prices. It is also important to note that national generic contracted products are always assessed by NHS regional Quality Assurance pharmacists. This may not be the case for products purchased outside of NHS contracts and so the quality of them cannot be similarly assured.
- 7.1.2.10 It was reported that on rare occasions an outsourced pharmacy service provider may want to buy a product outside of an NHS contract because of what is seen as excessive delivery charges from the NHS contracted supplier. Such instances should be reported to and agreed with the hospital Trust before implementation and care taken that these do not destabilise NHS contracts.
- 7.1.2.11 Whatever system is in place it will be financially prudent for Trusts to ensure they are being charged in accordance with the agreement reached and invoices for supplies made will need to be checked line by line. This is particularly important when contract prices change and to provide an assurance that the outsourced provider is not purchasing non -contract lines even when these may be cheaper. Such an action can adversely impact upon and undermine NHS contracts with the pharmaceutical industry.
- 7.1.2.12 Trust contracts with outsourced service providers should specify which pharmaceutical suppliers should be used when purchasing medicines for hospital outpatients. Where the NHS contract offers options around this the outsourced service provider should agree with the Trust which manufacturer they will purchase from.
- 7.1.2.13 Given medicines shortages and the Chief Pharmaceutical Officer's directive to NHS hospitals, contracts should be explicit in stating that outsourced service providers must only use medicines purchased for hospital outpatient use in these settings and not move hospital stock into primary care or elsewhere. (See Appendix 4)
- 7.1.2.14 Medicines procured by an outsourced service provider must be delivered directly to the outsourced service provider or arrangements put in place to ensure that it is not possible for stock to become mixed with NHS hospital stock.

### **7.1.3 Contract management and charging**

- 7.1.3.1 Contracts with 3<sup>rd</sup> party providers should be subject to OJEU tender and be time limited. We learnt that the duration of contracts varied. Some were for 3 years and as such allowed for re-tendering to NHS budgetary advantage and standards review. Others were X years plus an option for a further X years and some were proposed as long as 15 years which seems unduly long. Other than Private Finance Initiative (PFI) schemes we are not aware of any contracts for outsourced services that are for long time periods such as 15 years.
- 7.1.3.2 Typically, an outsourced OPD contract will be over a 5–10 year period as the 3<sup>rd</sup> party (and possibly NHS Trust) investment is reported to be high at the outset. Shorter contracts may be agreed if the investment required is lower. It is our view that in all instances there is a need to ensure contracts are of sufficient duration to be commercially viable yet still allow timely change to maximise NHS patient and budgetary opportunity. The need for long term contracts needs to be justified and validated.
- 7.1.3.3 In one Trust the estate occupied by the 3<sup>rd</sup> party provider was built via the Trust's PFI partner and the 3<sup>rd</sup> party provider has a 7 year contract to provide the service but a 10 year lease on the premises. There is a need to align service and estate contracts to the same time period.
- 7.1.3.4 The Trust Chief Pharmacist and medicines procurement lead should be closely involved in the tender process. This will help ensure specialist knowledge with respect to professional standards and medicines procurement are in place and that robust arrangements exist for oversight and governance of contract prices and payments including the monitoring of adherence to the use of NHS contracts and prices paid and recharged by providers.
- 7.1.3.5 With respect to medicines procurement this will need careful management to ensure that Trusts are not being over charged for products e.g. those products not in CMU contracts but which feature in local NHS contracts. This should be overseen by the Trust lead for medicines procurement and not by the Trust finance department.
- 7.1.3.6 There are costs incurred by hospitals in overseeing and auditing pharmacy services outsourced to a third party provider. These relate not just to standards of professional service and meeting KPIs but also checking of medicines procurement and service charges. Trust Standing Financial Instructions may require each product to be checked line by line and problems of matching product codes to correct prices were reported, all of which is done manually. Pharmacy resource requirement to support oversight of contracts to 3<sup>rd</sup> party providers was variable and ranged from a few hours a week to 2 whole time equivalent pharmacy technicians (a band 7 and a band 6). The monitoring and management requirement will determine the staffing resource required.
- 7.1.3.7 Other costs incurred by hospitals relating to third party provision of OPD services will also vary. Such contracts may not significantly impact on finance department

costs but estate management costs will need to be considered e.g. rent, utilities, cleaning (if provided by the hospital). We learnt of varying arrangements for these. In one instance the 3<sup>rd</sup> party service provider pays no rent or utility costs but these are discounted against the management fee the 3<sup>rd</sup> party service provider charges the Trust for service provision. In another example we were made aware of the 3<sup>rd</sup> party service provider paying the Trust a fee for the estate it occupies to cover rent and utilities (plus maintenance and cleaning if they wish to contract for this). 3<sup>rd</sup> party service providers are expected to cover their own HR, Occupational Health provision and payroll/financial services but they can subcontract this to the Trust if preferred.

7.1.3.8 3<sup>rd</sup> party service providers charge for service provision in a number of ways. One is where a professional services fee is paid to the 3<sup>rd</sup> party service provider plus an item of service fee which is price banded according to the volume of activity (i.e. reduced as volume rises). In this instance the 3<sup>rd</sup> party service provider also invoices the Trust the cost of medicines dispensed ex VAT. The VAT saved needs to fund the service/activity fee and any utility costs if incurred by the Trust. There is therefore a 'critical mass' of medicines expenditure in hospital OPD that makes outsourcing viable. We believe this is likely to be about £1.5M per annum. Since commissioners (and some Trusts) are asking for more services to be provided via homecare companies (thereby reducing Trust expenditure on OPD) this may threaten the longer term viability of outsourcing.

7.1.3.9 Cash flow can also be problematic for 3<sup>rd</sup> party providers as contract and invoice processes between Trusts, and 3<sup>rd</sup> party providers will often not match due to the different programming built into the IT systems (dates paid, contract changes etc). It is important for Trust's finance teams to be involved from the outset and on a continuing basis to understand why differences might occur. Trusts should consider building in tolerances when invoices are processed so that a £2m invoice is not put on hold for say a £1 discrepancy.

7.1.3.10 In any tender process it is critical that all hospital contract management costs are identified (e.g. pharmacy, finance, estate, utilities) and accounted for and incorporated into the overall business plan.

#### **7.1.4 Data management and information governance**

7.1.4.1 It is the responsibility of individual Trusts to determine their own auditing arrangements for the financial transactions between themselves and the 3<sup>rd</sup> party providers. To do this it is important that Trusts are allowed to have open access to all of the dispensing data which is being generated by the 3<sup>rd</sup> party provider.

7.1.4.2 There is a large amount of transactional data generated during the purchasing, dispensing and invoicing of medicines and the lack of integrated IT systems is a significant issue. This is reportedly evolving. When auditing performance (usage) some Trusts use the 80/20 rule (80% of the costs are contained within 20% of the transactions) but this would not satisfy all.

#### **7.1.5 Formulary management**

7.1.5.1 Hospital trusts and commissioners will want to ensure that the 3<sup>rd</sup> party service provider is challenging non formulary prescribing. This can be managed by the Trust simply not paying the 3<sup>rd</sup> party service provider for medicines dispensed that are outside of the formulary. Some viewed this as being a more effective control than the in-house hospital pharmacy service in managing outpatient formulary compliance.

7.1.5.2 It is expected that 3<sup>rd</sup> party service providers will comply with NHS guidance for the supply of unlicensed medicines. Such supplies will need prior agreement with the hospital and should include product specification, source and price. We were informed by some Trusts that this does not always occur.

### **7.1.6 Staff employment and training**

7.1.6.1 Skill sets are different in hospital and community pharmacy, but all (pharmacists) have the same basic training. Expertise comes with experience and post graduate training/qualifications and a view exists that there will be greater cross sector inter-changeability over time. Some 3<sup>rd</sup> party service providers consider that there should be no 'barriers' between 3<sup>rd</sup> party service provider staff and hospital clinical staff but this may not be the same for all providers / Trusts.

7.1.6.2 Having a community pharmacy service on a hospital site can make it easier to normalise cross sector requirements for pre-registration pharmacist training. This should be no different to current arrangements i.e. no cross charging, and may even be easier to set up and deliver. The same may not apply for student technician training since community and hospitals pharmacy services require different underpinning knowledge and use different Higher Education Institutions to provide the necessary training. There may be benefit in hospital and community pharmacy services collaborating to overcome this obstacle.

7.1.6.3 Hospital pharmacy staff whose job is primarily outpatient services have a right under TUPE arrangements to transfer their employment and associated rights to a third party provider of OPD pharmacy services.

### **7.1.7 Patient Added Value Services**

7.1.7.1 We were informed of a desire by some patients to see a community pharmacy outlet in their hospital similar to other retail outlets in the hospital. This provides an opportunity for visitors and patients (excluding pharmaceuticals in this instance) to purchase ad hoc goods normally available from a community pharmacy.

7.1.7.2 We learnt of examples where the 3<sup>rd</sup> party provider offered a home delivery service for medicines dispensed from their hospital outlet. This can be advantageous to patients having to take home a lot of bulky products. Other examples included an opportunity for the patients medicines to be able to be collected from any nominated branch in the 3<sup>rd</sup> party provider chain. This may be particularly advantageous for patients going on holiday provided a branch of the chain exists in their holiday destination. Whist both of these examples offer clear

patient advantage we do not believe there is significant uptake by hospital patients.

## **7.1.8 Strengths and weaknesses**

### **7.1.8.1 Strengths**

- Can bring business acumen and commercial skills to the NHS.
- Dedicated staff to provide OPD services – potentially resulting in better outpatient service (e.g. reduced waiting time, more customer focussed).
- ‘Distraction’ of providing OPD services removed from in house hospital pharmacy team allowing better inpatient and clinical service provision where needs are greater.
- Can include added value services e.g. collect from any store in the community pharmacy chain, commercial unit on the hospital premises.
- Outpatient formulary management may improve
- Large selection of OTC medicines available for sale
- Trusts have opportunity to generate additional revenue from larger retail footprint
- In line with government policy on public-private partnerships

### **7.1.8.2 Weaknesses**

- Validating the integrity of the supply chain may be problematic.
- Difficult to maintain confidentiality of NHS contract prices.
- Knowledge of NHS contract prices may be used to the wider advantage of the outsourced service provider and ultimately impact on NHS contract prices and potentially PPRS.
- Ensuring compliance with NHS contracts for medicines procured can be workload intensive and add costs.
- Potential for leakage of NHS contract stock into the community pharmacy supply chain exists.
- Additional effort required to monitor adherence to aspects of the contract
- Any reduction in product volume tendered at national level could result in lower contract prices.
- Variable levels of support from the Pharmaceutical Industry

## **7.2 Wholly owned subsidiary of a Trust**

### **7.2.1 General comments**

7.2.1.1 NHS Trusts have powers (under income generation) to establish companies (HSCA 2006). Therefore the opportunity to establish a wholly owned subsidiary company to provide an OPD service is an option available to NHS Trusts though we have been told that non-Foundation Trusts also require the support of the Secretary of State for Health. However, we are aware of conflict of opinion on the interpretation of powers of NHS Trusts to form such companies. As such, NHS Trusts should take legal advice and liaise closely with NHS Regional Offices of the National Commissioning Board and the DH when developing such schemes to ensure plans are not ultra vires.

7.2.1.2 A wholly owned subsidiary of a NHS Trust is set up as a limited company and needs to be registered with Companies House. As such it needs to operate as any other limited company and have directors, have audited accounts sent to Companies House and pay corporation tax on profits. As the Trust is the sole shareholder no dividend is payable. However, we were told that a trust cannot receive the company surplus as income and they have concluded that this must be paid into one of the trusts charities. Further legal advice is needed on this.

7.2.1.3 The sections below describe the types of this particular model which were observed during the review. There may be alternative approaches for providing OPD services from a wholly owned subsidiary.

## **7.2.2 Contract development and financial management**

7.2.2.1 Trusts hosting a subsidiary company will need to provide the facility in which the service is to operate. To ensure the facility operates as an independent company owned by the trust, funding to support the development of the facility including stock, fixtures, fittings, computer system, automation etc is provided in the form of a loan. Interest is charged on the loan and the loan is repayable over a fixed time period. Repayments and interest are a running cost chargeable to the subsidiary company.

7.2.2.2 The subsidiary company pays the host trust rent for the space it occupies based on the same unitary rate as for other commercial organisations on the Trust premises.

7.2.2.3 The Trust charges the subsidiary company for cleaning, pharmacy warehouse services, payroll management, HR support, Occupational Health support, accountancy services and invoice management. These are charged at commercial rates. It is worth noting that if the OPD service was provided by the Trust it would have to cover these costs anyway so by forming the subsidiary company and charging for these services the Trust is recovering its own in-house costs.

7.2.2.4 The subsidiary company charges the trust for stock supplied. This is at the same price at which the stock was purchased by the trust and the subsidiary company then reclaims the VAT where paid on products purchased and dispensed to outpatients.

7.2.2.5 The Trust is charged by the subsidiary company for provision of the service at what would be seen as a market rate (in one example this equated to twice the running costs of the service). Based on the costs and income streams the subsidiary company makes a profit. In addition, the Trust has covered its costs for services provided to the company.

7.2.2.6 The subsidiary company holds a separate bank account to the Trust though this is hosted by the same bank used by the Trust Company and accounts are audited by the Trust auditors.

7.2.2.7 All matters relating to the running of the subsidiary company and associated financial management are set out in service level agreements between the company and the Trust. These may also include premises (rent, lease for automation, energy, utilities), sale of Trust services to the subsidiary company (performance management, governance etc), services to support operational delivery of the subsidiary company (order invoice processing, HR, accountancy, pay roll etc)

### **7.2.3 Management arrangements**

7.2.3.1 Directors of the wholly owned subsidiary companies we examined included directors of the host Trust with each bringing specific areas of expertise as the Trust thought appropriate e.g. finance, human resources, lawyer, commercial director and a non executive director.

7.2.3.2 A pharmacist employed by the trust is the superintendent and accountable officer of the wholly owned subsidiary. Other staff providing the OPD service are mainly employed by the subsidiary company though some staff may be employed by the trust on rotation from the inpatient pharmacy service.

7.2.3.3 The trust Chief Pharmacist role may include being the subsidiary company superintendent pharmacist or be separate. Either way we would recommend that the Chief Pharmacist remains responsible for monitoring the pharmacy services provided from the subsidiary company.

### **7.2.4 Staffing**

7.2.4.1 The subsidiary company may employ all its own staff or just some (in the cases we examined the pharmacist in charge was always employed by the subsidiary company).

7.2.4.2 Salary costs for staff working in the subsidiary company pharmacy are paid from company income. These costs were previously met by the trust.

7.2.4.3 Hours of employment are variable to allow service flexibility

7.2.4.4 NHS Agenda for Change terms were not followed by subsidiary companies. Rates of pay were broadly similar in the models seen and appeared consistent with the market in community pharmacy. However, no sick pay or pension contribution is made by the subsidiary company.

7.2.4.5 Since staff were not transferred to the subsidiary company TUPE arrangements have not been applied. Rotational staff formerly employed to cover outpatient pharmacy services in the trust have been re-deployed elsewhere within the inpatient pharmacy service with the budget associated with their employment in the trust outpatient dispensing service being lost. However other pharmacy posts have been created to oversee the interface between the subsidiary company and the trust e.g. operational standards, order/invoice processing. Overall we believe the net effect is a reduction in NHS head count.

7.2.4.6 Where OPD forms a significant (normally a majority) of an NHS pharmacy staff members employment TUPE will apply if they are to be employed by the subsidiary company. Alternatively, if their post is not redeployed elsewhere in the inpatient pharmacy service they will be eligible for redundancy.

## **7.2.5 Medicines procurement**

7.2.5.1 A subsidiary company may purchase medicines direct from the in-house pharmacy store (which necessitates the store having a wholesaler dealer license) and as such this ensures products purchased are consistent with NHS contracts, have had NHS QC/QA oversight and are easily tracked for costing and formulary compliance. It was reported that pharmaceutical companies have not voiced any objection to this arrangement.

7.2.5.2 An alternative model is where the subsidiary company purchases stock directly and separately from the hospital inpatient pharmacy. This necessitates suppliers setting up a new account for the subsidiary company and some pharmaceutical companies have raised concerns as a subsidiary has no credit rating and history. In addition, there is one wholesaler who has reportedly refused to make supplies to a subsidiary company. Other than these two examples we are not aware of other objections to making supplies to subsidiary companies.

7.2.5.3 Where the subsidiary company purchases stock directly i.e. separately from the hospital inpatient pharmacy, this necessitates using separate dedicated paperwork for each location. This can result in both the hospital and subsidiary company both ordering stock on the same day from the same supplier for delivery to the same hospital, albeit on arrival the stock is handled and held separately. Running two separate systems for order/invoice processing appears inefficient and has potential to cause confusion with suppliers.

7.2.5.4 In both examples studied the subsidiary company purchases stock at the same contract price as the hospital though where this is direct by the subsidiary company i.e. not the hospital store, this is ex VAT and where it is from the hospital pharmacy store VAT is reclaimed.

## **7.2.6 Prescription dispensing**

- 7.2.6.1 Prescriptions forms used are treated as signed orders. In addition to hospital outpatient prescriptions a small number of private prescriptions are dispensed. Medicines dispensed are recorded on the wholly owned subsidiary electronic prescription record using the same computer system as that used by the Trust host.
- 7.2.6.2 Clinical screening of prescriptions takes place by the subsidiary company for most clinical areas and exceptions to this are locally agreed.
- 7.2.6.3 The subsidiary companies are expected to apply formulary control consistent with that in the Trust.

## **7.2.7 Data management**

- 7.2.7.1 The subsidiary company is able to access the Trust patient administration system but is not linked to the Trust inpatient pharmacy system despite using the same computer systems.
- 7.2.7.2 Transactions undertaken by the subsidiary company are recorded on its computer system and daily reports are generated and fed into the Trust main server. This facilitates costing to directorates and charging of all transactions undertaken by the subsidiary company.

## **7.2.8 Other commercial activities/opportunities**

- 7.2.8.1 Subsidiary companies examined are looking to exploit other opportunities that arise from their unique position within the trust. These include bringing homecare provision back in house and provision of other NHS services e.g. orthotics, wheelchairs and continence products.
- 7.2.8.2 Subsidiary companies reviewed have advised that they do not intend to seek to get a contract to dispense FP10s. Nor do they wish to gain a Wholesaler Dealers License to enable them to trade in medicines.
- 7.2.8.3 Registration of subsidiary company premises and activities with the GPhC is seen as essential since all were looking to sell OTC medicines. Registration of the subsidiary company with the GPhC has also allowed the inpatient pharmacy service to de-register its premises.
- 7.2.8.4 Consideration is being given as to how subsidiary companies can provide discharge medication. This is complex and VAT exemption may only apply for medicines supplied on discharge for a condition unrelated to their admission.
- 7.2.8.5 Consideration is being given as to how subsidiary companies can support home delivery of medicines either from the company or in partnership with a community pharmacy chain or homecare supplier.

## **7.2.9 Strengths and weaknesses**

- 7.2.9.1 Strengths

- Dedicated staff to provide OPD services – potentially resulting in better patient service (e.g. reduced waiting time, more customer focussed).
- ‘Distraction’ of providing OPD services removed from in house hospital pharmacy team allowing better inpatient and clinical service provision.
- Operating surplus accrued by the subsidiary company belong to the company and, since the company is owned by the Trust, stay within the NHS.
- Supply chain integrity managed and maintained (NHS contracts, product selection etc).
- Confidentiality of NHS contract prices for medicines maintained within the Trust.
- Trusts can recover in house costs it previously had to cover e.g. accountancy support, payroll management, pharmacy warehouse support, service oversight.
- No leakage of NHS contract medicines stock into FP10 service.
- Electronic data interfaces between the subsidiary company and the Trust easily established. Medicines dispensed are recorded on the wholly owned subsidiary electronic prescription record using the same computer system as that used by the Trust host.
- Provides an opportunity to repatriate some homecare services.
- Inpatient pharmacy service can de-register from the GPhC.

#### 7.2.9.2 Weaknesses

- Models developed in house do not bring in any new expertise unless staff are recruited with appropriate commercial sector expertise and experience to run the company or provide the pharmacy service.
- Limited selection of OTC medicines available for sale.
- No off-site collection service available for patients unless a partnership approach is agreed with a community pharmacy chain.
- The Trust incurs all the initial cost outlay though if this is loaned to the subsidiary company it is recoverable in time.
- Inpatient pharmacy may be de-registered from the GPhC.
- No trading history at the outset therefore obtaining supplies may be difficult.

### 7.3 Social enterprise schemes

#### 7.3.1 General comments

7.3.1.1 In healthcare, a Social Enterprise is a Care Quality Commission (CQC) registered, private, profit-forming, non NHS organisation where all the employees of the social enterprise are usually shareholders and profits are re-invested in the enterprise. Medicines related service provision in a Social Enterprise must meet the CQC’s essential standards of quality and safety for medicines management. Four key areas must be covered in a social enterprise to ensure that medicines management is fit for purpose: strategy, procurement, governance, and monitoring and evaluation.

7.3.1.2 A social enterprise will have to compete with “any qualified provider” for services and contracts in order to survive. On March 30th 2011 the DH launched its

document “Making Quality Your Business: A guide to the right to provide” to assist those NHS staff who wished to form a Social Enterprise to deliver their service. To date we are not aware of any acute hospital pharmacy service that has become a Social Enterprise though we are aware of some that have looked at the model for their outpatient dispensing provision.

- 7.3.1.3 Since the term “social enterprise” has no statutory definition we believe that there is no special tax or VAT status for such organisations and that tax issues will be broadly similar to those for a wholly owned subsidiary (see Para 8.3). Corporation tax may apply dependent upon the extent that the Social Enterprise is considered to be trading for corporation tax purposes, its commercial and legal structure and the share holders of the enterprise. However a Social Enterprise may seek charitable status (though there is no guarantee this will be granted) either through the Charity Commission or the HMRC, since the rules for such enterprises are that they reinvest any surpluses into the enterprise. There is a need therefore for the HMRC to provide clarity around the tax implications for Social Enterprises.

### **7.3.2 Examples in practice**

- 7.3.2.1 We have been able to speak to NHS staff in the acute sector who have explored a social enterprise as an option for provision of their OPD pharmacy services. Comments received are that this model is very new and there are many issues where help and clarity is required e.g. staff payroll/pensions, intellectual property management. As a result the process can be very slow and a service may emerge which is very different to that originally envisaged.
- 7.3.2.2 When a service is proposed for outsourcing, at the pre qualification questionnaire stage, a proposed Social Enterprise can ask for preferential treatment under the “Right to provide” guidance for Social Enterprises. However, generally all this means is that the scheme can move automatically to the next stage of the tender assessment process where bids are scrutinised against a scoring matrix. Such a matrix is likely to assess bids for service improvement that will be delivered for the same or reduced cost.
- 7.3.2.3 It will be challenging for a Social Enterprise model to succeed in the absence of Trust Board support. This model of service provision is new and legal advice and project management support will be needed. Funds for these will be hard to secure without Trust Board support though it may be possible to secure DH funds to meet set up costs<sup>6</sup>.
- 7.3.2.4 When Trusts have considered outsourcing of OPD pharmacy services external management consultancies are often asked to advise and appraise the various options for the Trust Board. The advice received will vary depending on which management consultancy company is used and their attitude to risk. Given that the Social Enterprise model is new, such arrangements may not score highly with

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<sup>6</sup> <http://www.dh.gov.uk/health/2012/06/social-enterprises-investment/>

a management consultancy e.g. for reasons such as lack of clarity about taxation issues and exit strategies. This may mitigate against the setting up of such schemes in the acute sector in the short/medium term.

### **7.3.3 Strengths and weaknesses**

#### **7.3.3.1 Strengths**

- Consistent with government policy.
- Employee owned.
- Profits reinvested in the business.
- Potential DH financial support for set up costs

#### **7.3.3.2 Weaknesses**

- Untried for outsourcing OPD services.
- Tax (VAT, corporation tax etc) and other arrangements (e.g. charitable status, payroll, pensions, intellectual property) remain unclear or yet to be properly tested.
- NHS staff unlikely to have commercial expertise.
- The complexity of these new arrangements may not be an attractive option for the Trust Board and who may therefore not provide the necessary support.

## **7.4 Homecare**

### **7.4.1 General comment**

7.4.1.1 There are a range of potential models that should be explored to deliver benefits arising from outsourcing OPD service provision. To date, homecare has been the most widely adopted and there are reportedly 120,000 patients being supplied medicines through this route, with an estimated spend of £1bn+ per annum. Hospitals that use homecare services will routinely provide high cost medicines via this service to make the most of VAT savings. Much of the remaining outpatient dispensing will be on relatively low cost medicines.

7.4.1.2 The DH commissioned a comprehensive review of homecare, Homecare medicines – Towards a vision of the Future, (the “Hackett Report”) which reported in November 2011<sup>7</sup> and readers are advised to consult this report. In addition, below are some pertinent points which arose during our review of outsourcing OPD services.

7.4.1.3 A common view amongst those with whom we spoke was that services that keep patients out of hospitals should be seen as beneficial. However it was viewed that homecare is essentially contracting out part of a patient pathway. Some ‘homecare’ services were not viewed as homecare but medicines home delivery.

7.4.1.4 Most Trusts pursue homecare provision to reduce costs and provide improved patient services. VAT exemption for medicines supplied via homecare companies

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<sup>7</sup> Homecare Medicines – Towards a Vision of the Future. DH Gateway Reference 16691

drives the funding stream for the change in patient pathway. Some patients may just require home delivery and this could be undertaken by an outsourced outpatient pharmacy service provider, possibly at greater patient convenience. Commercial homecare services should be considered if other supply routes (e.g. home delivery by outsourced service providers) are not able to meet patients needs.

- 7.4.1.5 In meeting a patient's needs through homecare or home delivery there needs to be good alignment between the clinical team, the patients needs and the homecare or home delivery provider. Lines of responsibility and overall governance need to be clear and much of this will be covered via progression of the "Hackett Report".
- 7.4.1.6 In aligning a patient's clinical needs with the homecare provider the NHS needs to ensure the homecare provider has the information it needs to provide necessary clinical care e.g. indication for treatment, requirements for monitoring, treatment duration.
- 7.4.1.7 In all home delivery or care services patients want the staff with whom they interact to have a knowledge of their illness and their medicines (including administration). This was evidenced to us in a research paper<sup>8</sup>. Trusts need to be clear about the competencies of staff involved in provision of homecare or home delivery services.
- 7.4.1.8 Deliveries of medicines to a patients home must be agreed with the patient and be at a time and date convenient for the patient. This does not appear to be always the case and we were told of instances where a company was only able to deliver to a particular post code on certain days of the week. Trusts may therefore want to undertake some random audit of patients to see if they have actually received the medicines prescribed and at the correct time and if there were any problems.
- 7.4.1.9 Given that in any homecare or home delivery service there is a change in the patient pathway there should be both commissioner engagement and agreement to this change.
- 7.4.1.10 Many community pharmacy chains are already aligned with homecare providers and as such well placed to support home delivery as well as homecare (e.g. Boots and Central Homecare, Lloyds and Evolution Homecare, Sainsbury's and Healthcare at Home, Co-op and BUPA Homecare). Many pharmaceutical companies are also closely aligned with homecare providers.

## **7.4.2 Strengths and weaknesses**

- 7.4.2.1 Strengths
  - Keeps patients out of hospital

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<sup>8</sup> Lancet Neurol 2006; 5: 565-71

- Convenient for and welcomed by patients
- Patient support readily available
- No leakage of NHS contract stock into the community pharmacy supply chain

#### 7.4.2.2 Weaknesses

- Can be just home delivery without any accompanying care package
- Perceived lack of costing/pricing transparency in the supply chain
- Governance standards are variable (N.B. It is recognised that this will change to some extent as the “Hackett” Report is further developed and implemented )

## 7.5 Other models

### 7.5.1 Issue of FP10 (NC) prescriptions

7.5.1.1 Some hospitals do not provide any outpatient pharmacy services. In these examples either the patient is referred back to their GP with an advisory note for ongoing prescribing or they are provided with an FP10 (NC) prescription which they can take to a community pharmacy of their choice. Whilst one model keeps prescribing control (and cost) with GPs and both offer patients choice in where they obtain their medicines, neither may be convenient for patients given the additional journeys they will need to make to obtain their medicines.

7.5.1.2 Trusts operating this model may be faced with a range of resource challenges if they wish to progress any changes.

7.5.1.3 We are aware of one Trust where pharmacist prescribers issue FP10 (NC) prescriptions to patients for certain high cost medicines which require repeat dispensing/supply from the hospital. In this example a pharmacy staff member phones the patients when the next prescription is due and has a dialogue with the patient about their need for a repeat, next hospital visit, remaining stock etc. This gives an opportunity to reduce potential waste and discuss any problems with patients. If satisfied a repeat prescription is needed this is issued signed by a pharmacist prescriber and posted out to the patient for dispensing in a community pharmacy of their choice. The hospital saves the VAT element of the cost.

## **7.5.2 Contracted out NHS clinical service**

7.5.2.1 We were told of a health economy that has a contract with a company who provide the Trusts sexual health service. The company used to obtain its medicines from the hospital pharmacy but now has them provided by a community pharmacy chain. Prescriptions from the sexual health service provider are sent to the community pharmacy scheme and they then dispense the medicines and provide them to the clinic for issue to patients. We were told the VAT saved is shared between the two organisations. The community pharmacy is now offering to post these medicines to patients at home.

## **7.5.3 General comment**

7.5.3.1 Clearly the above models offer a range of challenges and opportunities for the NHS and potential private sector partners. They are mentioned in this report for information and we do not feel we could add further detail or discussion that would be helpful to this report.

## 8. Good practice guide for Chief Pharmacists when considering outsourcing outpatient hospital pharmacy supply

8.1 There are numerous issues for Chief Pharmacists (and others) to consider when considering introducing an outsourced OPD service. This outline good practice guide identifies some of the more important considerations, grouped under various headings, but is by no means exhaustive. It would be helpful for the NHS to work together to develop the list further.

### 8.2 Strategic Considerations

	Key issue	Comment
1	Outsourcing is a strategic decision	Determine the desired outcomes of the new service with the Trust Board. Consider all options before making any decisions.
2	Seek advice from both inside and outside the Trust	Talk to other Trusts that have outsourced and visit them.
3	Be clear as to the desired outcome you are looking for and take control and lead the process. Start with the end in mind and work back from there	There are many possible outcomes when looking to outsource. For example, is a 'first class clinical service' the desired outcome or is the 'generation of significant revenue from retail' the major objective etc? If both of the examples above are required then both must be commissioned and no assumptions made that services will be delivered which are not specified. If both of these are required then it might be better to issue separate tenders for each.
4	Inform commissioners of the proposals	Work with Trust Board to agree attitude to sharing savings and degree of transparency with commissioners.
5	Decide if a partnership approach is wanted then look for suitable partners	Not all commercial organisations are the same, and neither are all hospitals. It is important to choose the right partners. Introducing a new service will require good leadership and engagement widely with clinical teams etc. There is potential for a variety of models e.g. an in house subsidiary company may want to consider a partnership arrangement with a homecare company or community pharmacy for home delivery.
6	Inform estates staff	Engage with estates staff early in the process. The physical environment is important and the retail footprint is an important consideration for some Trusts.
7	Inform and work with finance staff	Engage with finance staff early in the process and keep them involved (to sort out invoice / cash flow issues etc) before they become a problem. Find out what they need in terms of data, PbR requirements etc.

<b>8</b>	Governance is very important	Retain control and approve any SOPs being used by the 3 <sup>rd</sup> party provider.
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### 8.3 Tax Issues

	Key issue	Comment
<b>1</b>	VAT	Involve HMRC early on with respect to all VAT issues e.g. medicines supply, management fees to be paid and fixtures, fittings, equipment transferred or rented or utilised. Consult with both local and national HMRC offices.
<b>2</b>	Corporation tax	If a wholly owned subsidiary then corporation tax will be liable. If a Social Enterprise it may be possible to gain charitable status for tax purposes.
<b>3</b>	Tax liabilities	Check tax liabilities if assets or liabilities are transferred to 3 <sup>rd</sup> party providers and any stamp duty implications with respect to estate provision.

### 8.4 Procurement and Distribution of Medicines

	Key issue	Comment
<b>1</b>	Follow NPSG advice	Strategic NHS procurement leads are very clear that the reference document that all should be working to is the NPSG paper that was issued on 30 <sup>th</sup> September 2011.
<b>2</b>	Ensure access to NHS contract prices	Inform CMU and pharmaceutical companies of proposed new arrangements and request access to NHS contract prices by the 3 <sup>rd</sup> party provider. Deal with any issues that arise and keep NPSG briefed.
<b>3</b>	Set up systems so that the provenance of the medicines being bought and supplied by the 3 <sup>rd</sup> party provider is assured	Such governance arrangements should be clearly written into contractual agreements and then audited periodically.
<b>4</b>	Unlicensed medicines	Agree how these should be managed and write into agreements with 3 <sup>rd</sup> party providers.
<b>5</b>	Maintain NHS medicines contract price confidentiality	Insert a clause in the contract with the 3 <sup>rd</sup> party provider to ensure this.
<b>6</b>	Exporting of medicines	Insert a clause in the contract with 3 <sup>rd</sup> party provider that does not allow this.

### 8.5 Staff Issues

	Key issue	Comment
<b>1</b>	Staff concerns.	Address staff concerns early. Will job losses occur? Will roles change etc?

<b>2</b>	Shared experiences / training	In some Trusts it is important that some staff (e.g. pre-regs) still gain OPD experience and this can be provided if specified and agreed.
<b>3</b>	Training and competencies	Consider the degree of integration and separation between Trust staff / out sourced staff. Ensure that all are trained and competent for the tasks required.

## 8.6 Miscellaneous

	Key issue	Comment
<b>1</b>	Identify KPIs	Advised to think broadly about KPIs – how do they benefit the hospital as a whole (not just pharmacy), e.g. increasing patient throughput etc. KPIs should be agreed jointly at the outset as should the frequency of review.
<b>2</b>	Be mindful when reviewing tenders	OPD has been described as a low profit operation. Tenders can look very similar and when reviewing them it can be difficult to understand the difference in offers (other than price). Hospitals are advised to vigorously challenge a low price to ensure that it can deliver the quality of service required – a low tender price often equals a low quality service. If price is the main determinant, then go with lowest price but, if other factors are more important, ensure that these are tested at the tendering stage. Also consider that the main cost savings may come in later years as start-up costs can be high.
<b>3</b>	Monitoring the service	Record the benefits as the service proceeds e.g. obtain statements from users, ward stock savings, patient throughput etc.
<b>4</b>	Monitoring the contract	Establish and include costs of managing and auditing the contract delivery.
<b>5</b>	Formulary management	Trusts will want to ensure that 3 <sup>rd</sup> party providers of outsourced services comply with local prescribing policies – one solution proposed was for them not to be paid for any products supplied that are not part of the formulary.

## 9. Key Conclusions

- 9.1 The NHS needs guidance on outcomes to help them assess which outsource option best meets their patient needs and Trust objectives whilst also taking account of national strategic issues e.g. effective supply chain management.
- 9.2 Organisations need a clear vision about what they are trying to achieve for outpatients prior to developing options to achieve these goals, and then carefully consider the risks and benefits of each option before deciding on a course of action.
- 9.3 Current VAT regulations allow medicines dispensed to hospital outpatients by 3<sup>rd</sup> party providers to be zero rated. Funding released creates the potential to improve the patient experience through changes to the outpatient pathway. A number of Trusts have taken advantage of this by outsourcing their OPD service either through using a homecare care provider, developing their own in house initiative, or following an approach from a community pharmacy chain.
- 9.4 Current interpretation of HMRC regulations implies that savings accrued from the non-payment of VAT on medicines provided through outsourced OPD services must not be the sole reason for outsourcing. Direct patient benefits and service improvements arising from the outsourced service must therefore be identified in KPIs and measured.
- 9.5 Outsourcing of hospital OPD offers a wide range of benefits. These include reduced waiting time for patients, potential added value benefits for patients and cost reduction for Trusts which can then be utilised for inpatient service improvement. However there is a monetary value of OPD that makes such schemes viable. We believe this to be about £1.5m per annum.
- 9.6 Given outsourcing of hospital OPD is a change in the normal patient pathway, this new approach should be discussed in an open and transparent way with service commissioners and patient representatives.
- 9.7 There are a range of potential models that should be explored to deliver benefits arising from outsourcing OPD service provision. To date, homecare has been the most widely adopted and hospitals that use homecare services will often provide high cost medicines via this service. Two other innovative outsourcing models have emerged in recent years. One involves using a commercial provider e.g. community pharmacy and the other involves creating a wholly owned in house subsidiary company of a FT. Whilst both have a range of strengths and weaknesses, the former has an advantage in that it brings in external commercial expertise to the NHS whilst the latter model allows all 'profits' to be retained within the NHS.
- 9.8 Outsourcing OPD services needs careful consideration and a good practice guide for Chief Pharmacists when considering outsourcing needs to be developed. There is currently much duplication of effort occurring. (We have started this process with some examples in section 7 of this report).

- 9.9 There is a significant concern amongst many that the loss of commercial confidentiality of NHS contracts will threaten agreements for pricing of NHS medicines and this will be to overall NHS disadvantage. Similarly, many view that the complexity arising from outsourced OPD services and associated lack of transparency in the supply chain for medicines is of major concern and warrants further examination. Given the significance of this for the NHS and medicines pricing agreements this needs urgent consideration.
- 9.10 Opportunities exist for collaboration between all potential providers (community pharmacy, in house subsidiary company, homecare companies) of outsourced OPD services and such partnership working can maximise patient and NHS advantage.
- 9.11 IT systems between outsourced service providers and the NHS need to be aligned to meet respective needs for timely and confidential data flow whilst maintaining necessary confidentiality.
- 9.12 Given the wide range of issues raised in this report, PDIG with key stakeholders (e.g. pharmaceutical industry, 3<sup>rd</sup> party suppliers, the NHS, HMRC) should consider asking the DH, via the National Pharmaceutical Supplies Group, to conduct a review similar to that undertaken for Homecare to optimise efficiencies in the supply chain for both patients and taxpayers.

## 10. Recommendations

- 10.1 A range of issues identified in this report need to be explored. Below is a sample of those issues we feel should be considered. Please note this list is not exhaustive.
- 10.2 A national group needs to be established under the auspices of the National Pharmaceutical Supplies Group to expand on some of the issues that emerge from this report. It is suggested that these could be considered and developed via workshops during a study day, possibly limited to an invited audience (including stakeholders such as NHS, community pharmacy, pharmaceutical industry, homecare companies) and where necessary specialist advisers e.g. HMRC. The outputs from this could then inform a range of guidance on outsourcing OPD (e.g. contracting, KPIs, financial and clinical governance) that is in the interests of patients, taxpayers and the NHS whilst maintaining the integrity of the medicines supply chain.
- 10.3 There is an urgent need to develop systems (preferably IT systems that support verifiability) to provide the NHS and pharmaceutical industry with the necessary assurances needed to maintain the integrity of the medicines supply chain.
- 10.4 An NHS group should further develop the “Good Practice Guide” for Chief Pharmacists included in section 7 of this report. This checklist should be informed by this report and a wide range of other reports elsewhere in the NHS community. The resulting document should be made available to the wider NHS as a support or implementation tool.
- 10.5 Consideration should be given to the development of an outline tender specification for outsourced OPD services that includes essential and desirable criteria. This can be used to inform hospitals and those looking to provide services.
- 10.6 A series of questions/scenarios should be drafted for HMRC to consider and provide answers for the NHS with respect to:
- application of VAT regulations to various arrangements that may apply to medicines use by patients during their hospital attendance
  - tax implications for Social Enterprises
  - other relevant taxation issues and implications arising from outsourcing OPD services e.g. stamp duty, corporation tax, transfer of ownership
- 10.7 Stakeholders (NHS, community pharmacy and pharmaceutical industry, homecare companies) to engage and propose a core range of KPIs (essential and desirable) for consideration in local agreements when outsourced OPD service provision is being considered.
- 10.8 A collaborative review between NHS providers and commissioners should be undertaken to set out issues relating to sharing of savings accrued from outsourced OPD service provision (including ex PbR medicines) and propose a range of options.

- 10.9 A GPhC opinion should be sought regarding the legal status of hospital pharmacy prescriptions dispensed by outsourced service providers.
- 10.10 Related to the above a GPhC opinion may then need to be sought on whether the direction of patients to a hospital outsourced service provider is contrary to regulations on patient choice for dispensing of their prescriptions.
- 10.11 IT systems between outsourced service providers and the NHS need to be developed to meet respective needs for timely and confidential data flow whilst maintaining necessary protection for confidentiality purposes.
- 10.12 A service specification needs to be agreed with outsourced service providers on data capture and provision to the NHS, pharmaceutical industry, CMU and IMS Health (and possibly others) to meet needs for procurement contracting and monitoring of medicines use.
- 10.13 An agreement needs to be reached between outsourced providers, the pharmaceutical industry and NPSG on how trading accounts should be established to supply medicines at NHS contract prices.
- 10.14 A framework needs to be explored between outsourced service providers and DH Department of NHS Finance, Performance and Operations that sets out payment arrangements to ensure payment schedules to outsourced service providers are not unnecessarily disruptive and sufficiently timely to support reasonable cash flow.
- 10.15 Clarity should be sought from the DH Department of NHS Finance, Performance and Operations, on how post corporation tax surpluses generated by in house subsidiary companies can be paid into FT Hospital accounts.
- 10.16 A database of progress with outsourcing OPD services would be useful to support lessons learnt and develop documents that may arise when outsourcing / considering outsourcing.
- 10.17 From evidence with which we have been provided there are clearly a range of people who have given much thought to issues relating to outsourcing OPD services. These talents should be harnessed and their expertise utilised in addressing issues that are highlighted by this report e.g. in any subsequent work streams.

## **11. Acknowledgements**

We wish to express our gratitude to all the people with whom we met or spoke for giving their time and for their open and frank responses to our questions.

We also wish to thank those people who freely furnished us with information, comment and data on outsourced hospital pharmacy outpatient services. We have been almost overwhelmed by the volume of data and information given and this has been helpful to us in writing our report.

Finally we wish to thank GHP/PDIG for commissioning this piece of work

## Appendix 1

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# GHP

*Guild of  
Healthcare  
Pharmacists*

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Dear Chief Pharmacist

**Re OPD Review: To compare and contrast the various models for the provision of the supply of medicines to outpatients in hospitals in England and to comment on potential strategic implications.**

A range of models for third party provision of outpatient pharmacy services now exist. There has been much interest in the potential operational and strategic implications of service redesign arising from third party provision of outpatient pharmacy services, including impact on the pharmaceutical supply chain. To date there has been no comparison of the relative merits or issues that arise from each of these models.

The Guild of Healthcare Pharmacists, Procurement and Distribution Interest Group (GHP/PDIG) have commissioned an independent review of current services to inform Chief Pharmacists who have outsourced their outpatient pharmacy service, and those contemplating such action. This review has arisen out of discussions within the Association of Teaching Hospital Pharmacists (ATHP) and as such has their support together with wider support from NHS medicines procurement groups.

We are pleased to inform you that Ron Pate (former hospital chief pharmacist and West Midlands SHA secondary care pharmacy lead) together with Martin Anderson (former hospital chief pharmacist and ABPI director) have been commissioned to undertake this review. Over the next few weeks Ron and/or Martin will contact you to arrange a suitable time to telephone or visit to seek evidence to inform their report.

We hope that since this report is likely to prove valuable to both yourself and the wider NHS, that you or knowledgeable members of your team will engage positively and provide Ron and Martin the necessary time and information they require. Please note that any data gathered and information provided will be anonymised in the report and remain confidential unless your explicit authorisation for disclosure is given.

It is intended that the report will be submitted to GHP/PDIG, NPSG and PMSG for consideration in May and that a presentation will be provided to the biannual PDIG meeting to be held on June 14<sup>th</sup> in Birmingham.

Should you wish to discuss this matter please feel free to contact us by email or telephone as below. We look forward to your participation in this review

Yours faithfully

**Allan Karr**

Chairman, PDIG  
PDIG Committee and Pharmacy & Business Distribution Centre  
UCL Hospitals Foundations Trust  
Tel: 0203 447 9730

**Tony West**

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Guys and St Thomas's Hospital  
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## Appendix 2

### VATHLT6120 - Dispensing by a pharmacist: Scope of the zero rate

#### a. Community pharmacies

Most dispensing in a traditional high street retail pharmacy is zero rated under item 1 or one of the concessions outlined in [VATHLT6070](#) and [VATHLT6080](#). Hospitals or nursing homes that do not have their own pharmacy (e.g. a cottage hospital or a specialist clinic) usually obtain qualifying goods from a high street pharmacist. Supplies to them by the pharmacist will normally be standard-rated. When dealing with hospitals and nursing homes, pharmacists may only zero-rate the dispensing of prescribed qualifying goods if the goods are for an individual named patient and they are satisfied that either:

- the goods will not be used while the patient is within the institution; or
- one of the concessions outlined in [VATHLT6070](#) & [VATHLT6080](#) applies.

Where a pharmacist is called on to supply prescription-only medicines in an emergency, the zero rate will apply if these emergency supplies are made on the direction of a doctor and if the doctor provides a prescription within 72 hours. If the request for an emergency supply is made by a patient, then the conditions of item 1 are not met (because the goods are not supplied on the prescription of a doctor) and so the supply cannot be zero-rated.

#### b. Hospital pharmacies

Where an NHS hospital pharmacy supplies qualifying goods to out- or discharged patients as part of the NHS's statutory obligation of care, this is not a business supply for VAT purposes. Other than this, hospital pharmacies may zero rate dispensing of qualifying goods to out- or discharged patients for their personal use, including dispensing by:

- pharmacies in private hospitals;
- independent pharmacies situated in NHS hospitals (e.g. where the pharmacy is run by a private company) ( see c below) ; or
- NHS hospital pharmacies dispensing to private patients.

#### c .External pharmacy companies in NHS hospitals

To improve services to patients, a hospital may enter into a contract with a third party pharmacy company to operate a pharmacy in the hospital to dispense qualifying goods to out-patients. The same criteria for zero-rating applies to pharmacy companies within a hospital as to normal community pharmacies.

If such an arrangement is entered qualifying goods can only be zero-rated if they meet all the conditions listed in [VATHLT6020](#) above.

Drugs administered to the patient whilst they are an in-patient or attending a hospital clinic are not covered by the zero-rating provision.

Where a pharmacy company has a contract to operate a pharmacy in an NHS hospital pharmacy a typical system will operate as follows:

- A hospital consultant / doctor will issue a prescription to a patient.
- The patient will take the prescription to the pharmacy where their qualifying goods will be dispensed by a pharmacist.
- The patient will take the qualifying goods home and self administer.
- The pharmacy company will invoice the hospital for the goods dispensed and the dispensing fee. These will both be zero-rated as with a community pharmacy.

Any other charges made (e.g. management or administrative) will follow their normal VAT liability as they are not covered by the zero-rating provisions for qualifying goods.

## Appendix 3

### **Brief for Chief Pharmacists prepared by the Commercial Medicines Unit (CMU) on behalf of the National Pharmaceutical Supply Group (NPSG)**

#### **NHS contracting for the provision of pharmacy out-patient dispensing services and service provider access to CMU framework agreement prices**

NHS trusts are increasingly examining opportunities to contract out for the provision of out-patient dispensing services. <sup>(Note 1)</sup> In doing so they need to understand whether their service providers will be able to access CMU framework agreement prices that are confidential and protected by contractual arrangements.

This brief provides Chief Pharmacists with background information to inform local initiatives.

Whilst the contents of the brief have not been formally agreed with manufacturers and suppliers, service providers or the NHS, the information is consistent with ongoing dialogue with these parties and their representative organisations.

#### **Scope**

NHS trusts contract with commercial providers for the provision of a variety of pharmaceutical services including dose banding, over-labelling, specials' manufacture, homecare medicines supply and out-patient dispensing.

CMU broadly bands these external service providers together as Independent Sector Pharmaceutical Service Providers (ISPSPs). And whilst there are issues common to all these services, this brief is limited to the provision of out-patient dispensing services by ISPSPs to acute trusts. <sup>(Note 2)</sup>

It is based on the way these contracted services have been configured to date and does not capture emerging models that reflect the changing nature of public sector service provision, eg, the establishment of social enterprises and direct contracting by commissioning organisations. The general aim will be to review and expand the scope of the brief in the light of further consultation and NHS experience as it becomes available.

#### **The issue**

Problems arise when NHS trusts award service contracts without taking into account, beforehand, whether or not the service provider will be able to access CMU framework agreement prices. These prices are protected by contractual arrangements and access to them should only follow appropriate agreement. If the general assumption has been that access automatically follows this cannot be assumed.

When a 'trailblazer' trust (Heartlands) awarded a service contract (to Alliance Boots), in the absence of any national agreement with suppliers concerning access to its framework agreement prices, CMU encouraged the trust to approach manufacturers and suppliers directly to request this access on the basis that this was best dealt with between the trust and its suppliers.

At the same time, to provide a focus for national discussion, NPSG recognised the following aim for CMU:

- to support an NHS environment, wishing to contract for out-patient service provision, to treat NHS patients, through access to framework agreement prices, whilst preserving the integrity of the contracts <sup>(Note 3)</sup>.

With this in mind, following separate discussion with manufacturers and suppliers, CMU and NPSG proposed a 'checklist' of criteria, the aim being that if the criteria were met then access would, ideally, follow.

Subsequently there was a meeting involving manufacturers, PMSG and CMU, with presentations from major service providers to review the validity of the approach and to confirm the checklist. The outcome of this meeting was positive.

National dialogue with the manufacturers is ongoing and in the interim several trusts have awarded contracts aligning their local approaches to the national dialogue (particularly the checklist) and the number of service providers has grown.

### **Pathfinder trusts**

CMU identifies Heartlands, Derby and York as being pathfinder trusts in this arena. All maintained a close dialogue with CMU throughout their approach.

### **Recognised objectives and guidance**

The NPSG agreed checklist remains at the heart of CMU's approach and its discussions with manufacturers at national level. However as these discussions are on-going, general guidance for Chief Pharmacists is best left as a narrative or in the form of objectives, for the present, recognising the following points (all are based on either Industry or NHS dialogue, legal advice to CMU or proposed 'best practice').

1. ISPSPs cannot be party to CMU framework agreements and the NHS cannot therefore mandate or direct access. NHS trusts can only request access to the prices from manufacturers and suppliers.
2. In the relationships between the manufacturers and suppliers and ISPSPs, NHS Terms and Conditions do not apply (though a longer term strategic aim is that they might be replicated somehow).
3. This means that the NHS can only request access from manufacturers and suppliers and there can, currently, be no guarantee that this will automatically follow.
4. NHS trusts cannot delegate their authority to request access to framework agreement prices, from manufacturers and suppliers, to an ISPSP. Not only does this lead to confusion, it abuses the confidentiality associated with the framework agreements.
5. Neither must trusts share contract information direct with ISPSPs. NHS trusts must make their own requests direct to manufacturers and suppliers individually reflecting the references of the framework agreements that they are party to.

6. In awarding contracts to ISPSPs, NHS trusts are encouraged to make sure that the ISPSP is financially robust. Manufacturers and suppliers are unlikely to enter into trading arrangements if they have underlying concerns about cash flow.
7. In addition ISPSP operating models should not be considered in isolation from the longer term likelihood of strategic success where an NHS trust decides to out-source its out-patient dispensing.

For example NHS trusts should recognise that the ability of service providers to separate and manage stock, and maintain systems and associated data flows, so as to ensure that framework prices are accessed and medicines supplied to patients only against hospital orders, for dispensing services for which they are directly responsible for providing (that is excluding FP10 dispensing), and in a fashion that is fully auditable, will more likely result in a successful outcome.

8. Although the activities might be perfectly legal, manufacturers, suppliers and the DH share concerns about trading activities particularly where parallel exportation of product affects access for NHS patients. The Chief Pharmacist has provided guidance to the NHS on this matter.

In addition the underlying purpose behind CMU frameworks is supply to NHS secondary care patients. The frameworks are not there to create opportunities within the community sector for service providers to increase their margins.

The above concerns are best addressed through the combined recognition of the following:

- following agreed access to a framework agreement price by an ISPSP, the use of its access in relation to either FP10 or FP10HP dispensing would be an abuse.
  - that currently ISPSPs must, by location, dedicate their activities to contracted out-patient service provision and must not dispense FP10 prescriptions on the same site (it is not considered practical to control stock by price appropriate for the activity undertaken if community and hospital dispensing is undertaken side by side).<sup>(Note 4)</sup>  
The out patient dispensing models operating successfully at present are on site at the NHS trusts involved. Services are not being provided off site by community pharmacists.
  - the separation of function by provider system is also helpful. Established industry (wholesaler/distributor) models separate sourcing and pricing from pharmacy (dispensing). They can manage variations of price, by supplier, product and customer for individual dispensing accounts against the appropriate framework agreements.
9. CMU awards its framework agreements, on behalf of the NHS, by purchasing group with security of supply in mind. As a result framework agreement prices vary by trust. ISPSPs should therefore be accessing the framework agreement prices associated with each individual trust that they serve (as opposed to 'going for the cheapest').

Failures here undermine the credibility of the current NHS sourcing model by compromising manufacturer forecasts. Where this occurs it introduces risk and when supply problems arise it makes management of supply harder to deal with.

10. From an NHS perspective the use by ISPSPs of its framework agreement prices to leverage better prices from competing manufacturers would be an abuse of the access to the prices. Access is not provided for this purpose.
11. The UK medicine market operates within an environment determined by the Health Act. As a result the DH requires information to understand how the market is working and to understand how PPRS is performing. It follows that information has to be available to the DH to provide the same level of visibility associated with community pharmacy dispensing (ePACT) and hospital supply (Pharmex) when services are contracted out.

In addition suppliers need to be confident that access to framework agreement prices is not being abused (that is, the product supplied is being used to support only the delivery of the contracted service to treat the trusts' NHS patients).

Both these requirements are best achieved through the availability of month end files in consistent format incorporating recognised data standards.

### **This current guidance and the longer term vision**

The guidance provided here does not reflect any formal agreement between either the NHS, or the CMU, with the Industry. It can only be offered at present with the aim of 'making things work' and with recognition that it may be subject to adjustment and change as the NHS restructures and develops.

If successful practices can be established though, and confidence developed around them, it should be possible to establish a solid foundation on which to create efficiencies in the longer term e.g. the centralisation of activity.

It is therefore important to consider the guidance in terms of what the longer term operating model might look like.

The current 'vision' for this involves:

- a national framework of understanding agreed between industry trade associations, the NHS and CMU to support local NHS-determined relationships and activities.
- NHS trust recognition of award criteria when awarding contracts for out-patient service provision, against the background of this framework of understanding.
- certainty that NHS trusts and their ISPSPs will be able to secure framework agreement prices when awarding out-patient dispensing contracts, by supplier, by product, subject to an agreed national framework of understanding being in place and specific NHS service award criteria being met in contracts with service providers.
- some form of centralised support to enable operational efficiencies in the setting up of local arrangements (eg, web publication to facilitate access dialogue).

As this work progresses there will be a broader requirement to bring the information and understanding to the attention of trust CEOs and finance directors. In addition providers may wish to use the brief as a starting point to inform discussion with commissioners.

Finally trusts currently engaged in awarding service contracts, and not wishing to delay progress, are encouraged to retain the flexibility to implement changes reflecting the finalisation of any national framework of understanding so as to maximise opportunities for the NHS.

**Note 1:** Whilst the most generally recognised approach is for trusts to contract directly with a commercial service provider, there are variations to this 'theme' that CMU will seek to include in pursuing agreement of national guidance, e.g. social enterprises and FP10 dispensing, by trusts, if they are able to obtain the relevant contracts.

**Note 2:** Mental Health Trusts (MHTs) are identified as widely engaging in contracting for the provision of dispensing services. However the MHT service model is not generally associated with a requirement to access contract prices except for the occasional high price medicine.

**Note 3:** This reflects a slight revision of wording.

**Note 4:** In consulting to prepare this brief an NHS trust explained to CMU that it anticipated that its out-patient dispensing contractor would be dispensing FP10 prescriptions. However it expected the product supply for its trust (non-FP10) business to be processed through its JAC system. If this outcome can be realised this may change the guidance being drafted here. Ultimately though, the decision as to whether to allow access would remain with the individual suppliers and the onus would be with the trust and its service provider to demonstrate that the stock, and associated data flows, could be separated appropriately for the specific purpose of 'trust', as opposed to FP10, dispensing.

Commercial Medicines Unit (prepared on behalf of NPSG)

30 September 2011

## Appendix 4

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### NHS Hospital Chief Pharmacists in England

26<sup>th</sup> February 2010

Dear Colleague

#### EXPORTING MEDICINES FOR PROFIT

On the 14<sup>th</sup> July 2009, I wrote to you expressing my serious concern about reports that some hospitals were considering exporting, or selling for export, medicines for the purpose of profit.

In the letter I pointed out this was unacceptable. I remain of that view as export of medicines could threaten the medicines supply chain and, in turn, threaten patient care. This is contrary to professional behaviour. Indeed the Royal Pharmaceutical Society of Great Britain issued a law and ethics bulletin in July 2009 which stated:

“The Code of Ethics requires pharmacists to make the care of patients their first concern. Pharmacists are advised that the export of medicines for commercial or financial gains could be considered a breach of Principle 2 of the Code of Ethics.”<sup>9</sup>

The NHS Chief Executive, David Nicholson, has now written<sup>10</sup> to NHS Trust Chief Executives to highlight that engaging in the trade of medicines jeopardises both patient care and NHS contracts for medicines, and asks Chief Executives to ensure that their organisation is neither engaged in, nor planning to engage in, such activities. Monitor will be writing to NHS Foundation Trusts in similar terms.

I fully support this action and if necessary, I will ensure that any registered NHS hospital pharmacist involved in exporting medicines for profit, to the detriment of patients, is called upon to justify his or her actions. I am asking through this letter that SHA pharmacy leads and members of the National Pharmaceutical Supply Group provide me with the full details of any NHS hospital they know to be exporting medicines for profit.

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<sup>9</sup> <http://www.rpsgb.org/pdfs/LEBexportmedicines.pdf>

<sup>10</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_113129](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113129)

I should point out that I am fully aware that the vast majority of hospital pharmacists would not remotely contemplate exporting medicines for profit and always focus their efforts entirely on providing high quality patient care.

Yours sincerely

**Dr Keith Ridge**

Chief Pharmaceutical Officer

Cc

Bill Scott Chief Pharmaceutical officer for Scotland

Jeremy Savage Acting Chief Pharmaceutical Adviser for Wales

Dr Norman Morrow Chief Pharmaceutical Officer for Northern Ireland

Jeremy Holmes CEO RPSGB

Wendy Harris Director of Regulation, RPSGB

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SHA Pharmacy/Prescribing Leads

National Pharmaceutical Supplies Group