The Review of Specialist Pharmacy Services in England

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The Review of Specialist Pharmacy Services in England

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Led by: Dr Keith Ridge CBE, Chief Pharmaceutical Officer

Contents

Executive summary

This report summarises the findings and recommendations of the Review of Specialist Pharmacy Services (SP Srvcs) in England. Whilst the Department of Health (DH) initiated the review because future responsibility for SP Srvcs had not been confirmed as part of the transfer of functions and responsibilities to new NHS bodies established under the NHS Health and Social Care Act 2012, this has now been resolved, as set out in the accompanying letter from NHS England's Chief Pharmaceutical Officer. NHS England has now accepted responsibility for commissioning specialist pharmacy services. The work was overseen by a project board with NHS England representation, and NHS representatives were consulted throughout.

Key recommendations

A. Organisation of the Specialist Pharmacy Service

- There should be a single NHS Specialist Pharmacy Service (SPS), which is deployed regionally and more locally to provide equitable access to specialist pharmaceutical expertise
- The primary purpose of the Service should be to enable improvements in the safety and outcomes of patient care through the better use of medicines. It should support patients, clinicians, commissioners and providers in the delivery of medicines optimisation across the NHS
- To ensure access to necessary expertise across England and achieve value-for-money, the Service should be provided at a level of organisation greater than a local health economy

B. Commissioning of the Service

- The SPS should be directly commissioned by NHS England. This recommendation is based on a thorough assessment of different options. A priority is to determine whether this can be achieved by prescribing the Service in legislation for direct commissioning or via an alternative legal mechanism for NHS England to take up these responsibilities through agreement with the Department of Health
- The SPS should be commissioned against a national specification, which provides clarity to both service users and SPS providers on access, functions, levels of service and performance
- The SPS should be commissioned from designated trusts that can meet the specification. The commissioning intention should be a consistent and system-wide service for England

C. Governance, accountability and leadership of Service

- An SPS National Management Board and Implementation Group should be established
- A leadership team comprising Head of SPS, Assistant Head of SPS (Medicines Preparation) and Assistant Head of SPS (Medicines Safety) should be appointed
- These posts should be joined by nominated leads from Medicines Information and Medicines Assurance in the Implementation Group

D. Funding of the Service

- Deployment in relation to the national specification from 2014-15 should be delivered within an agreed overall cost envelope (estimated at £7.1m as the sum of existing commissioner and provider-based funding). Detailed work on costing the national specification will be necessary
- Adjustments in relation to staff costs resulting from Agenda for Change will need to be factored into future funding agreements. Proposed new posts should be drawn from the existing establishment
- Further work is required to determine whether QA laboratory facilities currently funded by commissioners should continue to be a commissioning responsibility

In recognition of the long-standing contribution that SP Srvcs make to patient safety, coupled with the need to retain skills and expertise during a period uncertainty, DH agreed to underwrite the services financially for the period 2013-14. The aim of the review was to consider evidence, analyse options and make recommendations for the future commissioning and sustainable delivery SP Srvcs in England from 2014-15 onwards.

Since their inception in the 1970s, SP Srvcs have included at various times a number of separate disciplines. The term has been applied to:

- Medicines Procurement
  – strategic advice to policy makers and implementation support for the procurement of medicines for hospitals providing NHS services
- Medicines Information
  – specialist information and advice for health care professionals, patients, public and policy makers on medicines use
- Medicines Evaluation
  – health economy appraisal of medicines not subject to NICE guidance
- Pharmaceutical Quality Assurance
  – a wide range of activities related to audit of medicines preparation, standards, conduct of clinical trials, advice and assessment of medicines for procurement
- Medicines Use and Safety
  – enabling commissioners and providers to implement national priorities and local initiatives to improve patient safety
- Radiopharmacy
  – improvement in diagnostic services for patients and reduction in risks associated with the use of radiopharmaceuticals (This specialty is subject to a separate review by DH)

NHS organisational changes and reforms have impacted on the coordination and provision of these distinct specialties in different ways. The Review Team identified interdependencies between several of the constituent services, which mean that the maximum benefit to patients, providers of NHS care and commissioners will be achieved by organisational integration and consistent, system-wide working. As a result, the review proposes a single NHS Specialist Pharmacy Service (SPS) that is commissioned nationally, deployed regionally and more locally, and delivered through three core functional groupings of:

- Medicines Information
- Medicines Assurance (including Quality Assurance and Medicines Procurement)
- Medicines Safety

Evidence evaluated by the Review Team confirms that SP Srvcs provide a critical resource for patient safety and the optimal use of medicines. The span of their activities yields health care benefits for thousands of patients every year and also deliver significant savings for the NHS. The current overall cost of SP Srvcs in England is £7.1m per year and, without quantifying all the separate contributions of the varied SP Srvcs functions, savings of more than 4 times the cost are identified in the report (page 17). SP Srvcs involvement is also identified as vital in the delivery of up to £150m of medicines procurement savings nationally. By improving the use of existing resources, the proposed approach to deployment, governance and accountability of the SPS will increase these savings by spreading best practice nationally, reducing inequity of service provision and weaknesses in coordination.

The Review Team established a number of design principles for the SPS in the new NHS landscape and criteria to assess options. These were ratified by the Project Board and form the basis of the evaluation of deployment and commissioning options. The recommendations are presented in full on pages 47 to 49, with key points detailed in the summary box on page 3. The recommended deployment of the SPS core functional groupings is according to 10 delivery footprints across England; for Medicines Information, the preferred configuration for these 10 footprints is four Medicines Information *hubs* that work collaboratively with *spoke* services.

To support the SPS design and commissioning arrangement that ensures equity and access across and within the functional groupings, the report proposes a National Management Board and, working to the Board, an Implementation Group. The review recommends that chief pharmacists of trusts commissioned as SPS providers should have line management responsibilities for the staff that deliver these services. The purpose of this new framework is to provide appropriate governance and accountability by:

- Setting strategic direction
- Prioritising services and service developments
- Maximising collaboration and minimising duplication
- Acting on business plans, annual reports and work plans

Adoption of these recommendations will necessitate further work to develop the commissioning process and shape the deployment of the SPS in collaboration with current providers and commissioners of SP Srvcs. The priority is confirmation of the mechanism by which NHS England can take direct commissioning responsibility.

Introduction

Equality and diversity are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given due regard to the need to:

- Reduce health inequalities in access and outcomes of healthcare services, integrate services where this might reduce health inequalities
- Eliminate discrimination, harassment and victimisation
- Advance equality of opportunity and foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.

1. This report presents the findings and recommendations of a review chaired by Dr Keith Ridge, Chief Pharmaceutical Officer, to inform the future commissioning and sustainable delivery of Specialist Pharmacy Services (SP Srvcs) in England.

2. The review was undertaken because responsibility for these services had not been confirmed as part of the transfer of functions and responsibilities to new NHS bodies established under the Health and Social care Act, 2012. The Department of Health (DH), recognising the critical nature of these services for patient care, agreed to financially underwrite SP Srvcs for the period 2013-14 to support the retention of existing skills and expertise pending the outcome of this review.

3. SP Srvcs were introduced into the NHS as part of the NHS reforms of 1974 and consisted of Medicines Information (MI), Quality Assurance (QA) and Quality Control (QC) and Radiopharmacy. Since then, NHS organisational changes and reforms have impacted on the organisation and provision of the separate disciplines of SP Srvcs in different ways.

4. A stocktake of SP Srvcs by the Strategic Health Authority (SHA) Pharmacy and Prescribing Leads during 2011-12 demonstrated that, whilst the core of SP Srvcs remained a critical resource for the NHS, newer services had emerged under the SP Srvcs description to support better medicines use, including medicines safety, evaluation and procurement. Some services were available to certain parts of England only and others had different scopes of operation. Interfaces had developed with the provider-based technical specialties (such as medicines manufacturing and preparative services) and with medicines evaluation, prescribing analysis and NHS Quality, Innovation, Productivity and Prevention (QIPP) programmes. As a result, SP Srvcs need to be considered in the wider context of medicines and pharmacy in England.

Medicines and pharmacy

5. Medicines are at the centre of modern healthcare and the most common treatment offered to patients. After salary costs, medicines constitute the single largest investment that the NHS makes in patient care, representing a total spend of £13bn in England; a billion prescriptions per year are dispensed in primary care alone. For an outcome-driven health service performing in a financially constrained environment, there is a clear need to secure maximum value for patients and the public by optimising the use of medicines and medicines-related services.

6. The 2010 White Paper, *Equity and Excellence*, signalled that pharmacists, working with doctors and other health professionals, have an important and expanding role in optimising the use of medicines and in supporting better health. The pharmacy professions have an unparalleled line of sight on the medicines pathway: from discovery to market authorisation; from formulation to prescription; from effective use to the potential for waste; from successful outcomes to the risk of misadventure. The insights

drawn from this wide awareness confirm that a common set of challenges as set out below.

- A growing, relatively older population with an increasing prevalence of long-term conditions
- Harnessing innovation and the potential to expand intervention in health and disease
- Increasing expectations of patients and the public
- A need to get the fundamentals right, particularly in relation to older and vulnerable people and the extent of medication misadventures

7. Healthcare services and the pharmaceutical industry have played a substantial role in the achievements of the last decade, including a 14% reduction in cancer mortality and 41% reduction circulatory disorder mortality. The NHS faces the QIPP challenge of savings up to £20bn by 2014-15; this is currently on track and improved medicines use and procurement has made a significant contribution in achieving substantial savings to date. However, it is clear that suboptimal medicines use remains to be resolved in a number of areas.

Avoidable medicines wastage in primary care is estimated to be £150 million per year[1]
"A number of rigorous reviews have found that, in developed countries, adherence among patients suffering chronic diseases averages only 50%" [2]
Conditions that could be treated in primary care (for which hospitalisation could be avoided) account for 1 in 6 emergency admissions at a cost of £1.42bn each year[3]
Adverse drug reactions account for 6.5% of hospital admissions; over 70% of the ADRs are avoidable[4]
Care Home Use of Medicines Study finds that 70% of residents were exposed to one or more medication errors every day and that an average resident (aged 85) takes 8 different medicines[5]
General Medical Council's EQUIP study demonstrates a prescribing error rate of 8.9% in medication orders; errors were associated with all grades of doctors[6]
GMC's PRACtICe study finds 1 in 20 prescriptions in general practice contain a prescribing or monitoring error[7]
526,186 medication incident reports to NPSA between 2005 and 2010; 16% involve actual patient harm. Delayed or omitted doses (16%) and wrong dose (15%) are the commonest categories[8]

[1] *Evaluation of the scale, causes and costs of waste medicines*. York Health Economics Consortium and School of Pharmacy, University of London 2010

[2] http://apps.who.int/medicinedocs/en/d/Js4883e/

[3] *Emergency hospital admissions for ambulatory care-sensitive conditions. Identifying the potential for reductions.* Kings Fund 2012

[4] Adverse drug reactions as a cause of admission to hospital: prospective analysis 18 820 patients. *BMJ* 2004; 329: 15-19

[5] Care home use of medicines study: prevalence, causes and potential harm of medication errors in care homes for older people. *Qual Saf Health Care* 2009; 18: 341-346

[6] An in depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education. EQUIP study (www.gmc-uk.org) GMC 2009

[7] Investigating the prevalence and causes of prescribing errors in general practice: The PRACtICe study (www.gmc-uk.org) GMC 2012

[8] A review of medication incidents reported to the National Reporting and Learning System in England and Wales over six years (2005 – 2010) *Br J Clin Pharmacol* (online) 2011.

8. Taking forward medicines optimisation is about maximising value; the value that a patient derives from their medicines and the value that the whole population experiences from the NHS' investment in medicines. Optimal medicines use is a crucial step in both improving the quality of care and balancing the costs of healthcare. Improving the use of medicines is also necessary to ensure that avoidable problems do not undermine scientific and technical advances in therapy.

9. Community pharmacy offers over 11,200 points of access to pharmaceutical services in England. An estimated 1.6m people visit a pharmacy each day, of which 1.2m do so for health-related reasons; in 2011, approximately 960 million prescription items were dispensed in primary care at a cost of £8.8 billion (Information Centre 2012). Hospital pharmacy services have developed to support the safer use of medicines. The EQUIP study noted that almost all of the 11,077 prescribing errors made in 124,260 medication orders (an error rate of 9%) in 19 acute trusts were intercepted by pharmacists as part of their routine practice.

Background to the review

10. In the context of medicines optimisation, SP Srvcs are an important resource for patient safety, cost effective care and clinical advice, with a particular focus on complex issues and activities involving medicines. SP Srvcs constitute system-wide services that are relevant to commissioners and providers of NHS care.

11. Most SP Srvcs operate from NHS hospitals and service provision has been configured according to boundaries representing former NHS regions; this deployment is a cost-effective model of operation that avoids expensive unnecessary duplication of expertise in individual organisations whilst at the same time supporting equity of access to the necessary skills and assistance across the country.

12. More than 80% of SP Srvcs were commissioned and funded collaboratively by Primary Care Trusts (PCTs) in 2012-13. This maintained a comprehensive system of specialist pharmacy advice, assistance and assurance in England at a cost that is estimated to be equivalent to approximately 0.04% of the NHS' total annual investment in medicines. Remaining funding came from fee for service provision or provider-to-provider support. With the abolition of PCTs and Specialised Commissioning Groups (SCGs), coupled with the growing number of Foundation Trusts (FTs) concerned about the risk of hosting SPS, there is an urgent need to secure this funding to ensure SP Srvcs continue to operate for the benefit of patients and the NHS.

13. These services have not been prescribed in regulations to be commissioned by the NHS England. For SP Srvcs previously funded by PCTs, Clinical Commissioning Groups (CCGs) had been proposed as the responsible commissioning bodies. However, because of the complexity of the collaborative PCT arrangements, agreement has not yet been reached on how the services will be commissioned in the longer term. A significant and growing risk has emerged that SP Srvcs will not be sustained in the new system in the absence of a clear commissioning mechanism.

14. NHS England views this risk as serious and for 2013-14 a transitional arrangement has been put in place with one Commissioning Support Unit (CSU) in each of the four NHS regions to assume responsibility for commissioning or hosting of SP Srvcs, with costs underwritten by DH. A consistent approach to commissioning and service delivery is required in the new system and this review has been undertaken to inform the future design.

15. Given that the review was initiated in early January 2013, it has been necessary to focus the work plan in order to conclude the analytical, option appraisal and design recommendation stages according to the required timescale. There will need to be further work on implementation of the report during the transition year of 2013-14.

Methodology

Governance

16. The framework and scope of the review is covered by the Terms of Reference in Annex 1. Dr Keith Ridge, Chief Pharmaceutical Officer led the review, and was supported by Ron Pate (Consultant), David Webb (Director of Specialist Pharmacy Services for E&SE England) and Omar Idriss, Economic Adviser (Office of the Chief Analyst in the Department of Health).

17. A Project Board, chaired by Dr Keith Ridge, has provided oversight of the review and its progress. In respect of this, the chair reports to NHS England. The membership of the Project Board is listed in Annex 2. The Board met on five occasions during the course of the review and preparation of the interim and final reports.

Evidence and analytical methodology

18. The evidence gathered by the Review Team included:

- Expert views gathered at two stakeholder engagement events; these included criteria to use in assessing options for commissioning and deployment at the first event and exploring the interim position on design and related issues at the second
- Baseline data on SP Srvcs and their cost sourced from the SHA Pharmacy and Prescribing Leads stocktake
- Submissions completed by the services in scope of the review, covering quantitative and qualitative information on the functions, activities and outcomes of SP Srvcs
- Data from a range of routine sources (e.g. the Information Centre) on the number and location of services in the broader NHS (e.g. NHS Trusts and Foundation Trusts, CCGs, prisons etc.)
- Published evidence
- Discussions with commissioning experts on the reformed NHS commissioning architecture

19. This information was used in a number of ways to inform the review:

- Synthesizing information on the functions of SP Srvcs and mapping to the NHS system
- Using the functional information to develop new functional groupings for SP Srvcs
- Synthesizing information on the outcomes of SP Srvcs to understand value-for-money and patient impact
- Using baseline data to understand current deployment of SP Srvcs and the total cost within which SP Srvcs should be delivered in the future
- Using criteria and expert views on risks to develop an assessment of the options for commissioning of SP Srvcs, leading to a recommendation
- Using the baseline deployment, criteria and expert evidence on risks to assess the impact of different options for future deployment and make recommendations
- Mapping of services in the wider NHS to the new NHS commissioning architecture to support the next stage of implementing the report recommendations on deployment

Stakeholder engagement

20. SP Srvcs stakeholders were invited to attend a meeting to explore future options for the services on January 30, 2013 at the Royal Pharmaceutical Society in London (see Annex 3 for invitation list). The day consisted of brief plenary presentations and followed by workshops on key issues in relation to the review. In some cases, delegates were invited to include additional representatives from their organisation or their area of expertise. SHA Pharmacy and Prescribing Leads were also invited to attend.

21. The majority of the attendees were senior staff involved in provision of SP Srvcs or pharmacy professionals from organisations that made use of the services. Invitations were also extended to patient representatives, commissioners, clinicians, chief pharmacists, the Royal Pharmaceutical Society and Guild of Healthcare Pharmacists. Delegates were assigned to facilitated work groups covering:

    - Service Users
    - Medicines Information and Medicines Safety
    - Medicines Assurance and Procurement
    - Medicines Manufacturing and Preparative services
    - Medicines Evaluation and Advice

    The work groups addressed questions that are set out in the first two tables of Annex 4, together with a summary of the responses or emergent themes.

22. A second stakeholder meeting was held on April 25, 2013 at the Royal Pharmaceutical Society. The purpose of this event was to outline design principles and to explore the interim position of the review. The programme involved a plenary session to set out progress, options for deployment, information portal, functions related to SP Srvcs and proposals for governance accountability and leadership. This was followed by workshops to gain insights from attendees and feedback on the proposals.

23. Delegates at this event were assigned to mixed work groups in the morning; for the afternoon session they selected the grouping that best represented their specialty or area of interest. Responses from the morning and afternoon sessions are summarised in the third and fourth tables of Annex 4. Findings from the January 30 and April 25, 2013 meetings formed part of the evidence base for the review.

Current definition of Specialist Pharmacy Services

24. SP Srvcs were introduced as part of the NHS reforms in 1974. This recognised that pharmacy services were of greater breadth than dispensing and that some specialist services supported medicines supply. An influential report that predated the reforms (Noel Hall) recommended that SP Srvcs should be provided at a level above that of a District General Hospital if fragmentation and ineffective services were to be avoided. At the time, these services comprised Medicines Information (MI), Quality Assurance (QA) and Quality Control (QC) and Radiopharmacy.

25. The role of these specialists was to coordinate services across their region, ensure that the expertise and training of staff was appropriate, determine standards and monitor adherence to those standards. Specialist advisory committees were established with a representative from each region to promote both sharing of practice and information exchange with DH.

26. Since their initiation, SP Srvcs have changed as new priorities and technological developments have emerged. There has been a differentiation between the regional function and roles that have come to be regarded as provider-based technical specialties in pharmacy. Similarly, other SP Srvcs have emerged to meet patient, clinical and NHS needs, such as Medicines Procurement, Medicines Evaluation (as a development from MI) and Medicines Safety.

27. In 2010, the National Prescribing Centre set out a definition of SP Srvcs as follows:

    Services that are provided across many health organisations to ensure access to pharmaceutical expertise in a range of disciplines, including quality assurance, medicines procurement, medicines information and medicines use and safety. They advise and support commissioners and providers, particularly in relation to complex or novel medicines-related services. [9]

[9] "Ensuring the delivery of prescribing, medicines management and pharmacy functions in primary and community care - An organisational competency framework and key functions checklist" Page 23
http://www.npc.nhs.uk/qipp/delivering_prescribing.php

Risks from discontinuation of Specialist Pharmacy Services

28. Loss of SP Srvcs and their associated NHS-wide networks will adversely affect the optimisation of medicines for better patient outcomes, resulting in compromised patient safety and increased costs. The main issues risks are summarised in the table below:

Issues and risks
Patient and public safety
Failure to meet the mandatory requirement for audit of compliance of NHS medicines preparation services with national standards
Collapse of the UK Medicines Information (UKMi) network that provides advice on 300,000 clinical enquiries each year
Lack of support for patient safety initiatives, co-ordination of defective medicine alerts, reporting of identified medicines defects and implementation of mitigation measures
Compromised capacity to respond effectively to acute shortages of critical medicines and reduced preparedness for emergencies such as an influenza epidemic
Inadequate governance and regulation of testing of medical gases in the UK; risk of non-compliance with Medicines Law and patient harm
Research, development and innovation
Reduced patient access to clinical trials or novel therapies
Loss of support for diffusion of innovation, evidence appraisal and adoption of NICE guidance
Costs
Failure to meet the quality-productivity challenge for medicines use and procurement
No support for the procurement of licensed medicines: increased risks to the supply chain and to patient safety from inadequately presented, packaged or labelled medicines
No independent support for outsourced pharmaceutical and healthcare services, including homecare supply of medicines
Loss of the SP Srvcs could lead to many NHS organisations replicating similar functions locally
Workforce
In the absence of SP Srvcs, duplication of roles in many organisations will lead to vacancies due to the limited supply of trained staff and result in gaps in provision across the country
Addressing vacancies will lead to lead to increased training costs and a lag time until the appropriate level of competence is achieved consistently
Loss of national leadership for specialist workforce development and succession planning: degradation and loss of an appropriately trained specialist workforce
Loss of established professional networks, specialist knowledge, expertise and advice: critical deficits will be encountered in the following activities

29. Any discontinuation of SP Srvcs would present commissioners with challenges in satisfying several recommendations from the Francis Report. These include: assuring quality of services; undertaking independent audits, inspections and investigations; setting and measuring compliance with indicators; interpreting evidence for compliance with and monitoring of standards and intervention and advice on sub-standard services.

Strategic commissioning context

30. SP Srvcs deliver critical patient safety and clinical advisory functions that satisfy governance requirements not otherwise addressed by the statutory and regulatory frameworks covering medicines and pharmacy. These functions relate to complex issues and activities and are described more fully in the following sections, but an important facet is the support provided to other professions and, for some aspects of MI, directly to patients and members of the public.

31. There have been several approaches to commissioning and delivering SP Srvcs, although the majority were funded by PCTs through collaborative mechanisms, some of them linked to SCGs. The NHS reforms introduced through the Health and Social Care Act (2012) have made the current arrangements for commissioning and funding SP Srvcs unsustainable as PCTs and SCGs have been abolished.

32. CCGs have taken responsibility for commissioning all NHS services, with the exception of a range of services, prescribed in regulations, to be commissioned by NHS England. These include specialised services, primary care, military and offender health services.

33. SP Srvcs have not been included in the prescribed set of services to be commissioned by NHS England. As a result CCGs would be assumed to be the responsible commissioning bodies. However, because of the complexity of the current arrangements, agreement was not reached between CCGs on how the services should be commissioned in the longer term. Furthermore limited consideration has been given to whether SP Srvcs are most effectively commissioned by CCGs or whether other commissioning arrangements are in fact more suitable due to the nature of the services in question.

34. The services are regarded as clinically vital, and a significant risk was identified at a late stage in the transition process that they would be lost in the absence of an identified commissioning and funding mechanism. In view of this serious risk, a transitional arrangement has been agreed for one CSU in each region to assume responsibility for the commissioning or hosting of SPS. The review aims to make recommendations for a long-term, sustainable commissioning model in the context of the reforms to the commissioning system.

35. The NHS faces multiple strategic challenges including recent reforms, delivering up to £20bn of efficiency savings by 2014-15 and responding to the 290 recommendations of the Francis Report by improving the quality and safety of patient care. The overall estimated cost of SP Srvcs, at approximately £7.1m (the aggregation of commissioner and provider funding), represents less than 0.01% of the NHS budget and the evidence compiled during the review makes a sound financial and clinical case for future delivery of SP Srvcs in a consistent manner.

36. SP Srvcs have interdependencies with providers and commissioners, interdependencies with each other and significant impacts on patient outcomes. The NHS Outcomes Framework sets out the strategic direction for improving quality of care and Domain 5 is concerned with treating and caring for people in a safe environment and protecting them from avoidable harm. SP Srvcs have a focus here, but are also relevant to the other domains, particularly in relation to outcomes from the use of medicines in complex patient care. Examples are provided in the report and the annexes of examples from each of the constituent services

Functions and evidence

Mapping SP Srvcs functions to the new NHS system

37. Based on evidence submitted to the review, some of the key functions of SP Srvcs (as currently configured) are summarised in the table below, together with their likely customers in the reformed NHS system. This demonstrates that the functions provide NHS-wide resources. In all examples, the provision of expert advice is given and not tabulated.

Mapping of specialist pharmacy service functions to the new NHS system					
Ultimately functions are for patient benefit but this row indicates the direct "customer" in the new NHS architecture	Commercial Medicines Unit	NHS England	CCGs – locally or nationally	Acute Trusts and other providers	Individual clinical advice
Note this does not cover all functions of all services, some key functions have been identified					
Medicines Use and Safety					
Collaborative benchmarking and service evaluation			X	X	
Coordination of best practice networks			X	X	
Resources and toolkits to support implementation of national guidance		X	X	X	X
Commissioning toolkits for safe and legal use of medicines		X	X		
Medicines Information					
Provision of national information by regional centres on more specialised areas (e.g. medicines in pregnancy, lactation etc)		X	X	X	X
Response to routine medicines information services locally and production of medicines Q&A for web publication for use nationally		X	X	X	X
Medicines databases (patent expiry, vaccines stability etc.)	X	X	X	X	
Current awareness and medicine evaluations		X	X	X	X
Horizon scanning and resources for medicines budgeting/QIPP	X	X	X	X	
Medicines Procurement					
Delivery of procurement activities	X	X		X	
Input to, and coordination of national strategy on procurement	X	X			
Medicines shortages management	X	X	X	X	X
Guidance on outsourcing, e.g. Homecare	X	X	X	X	
Quality Assurance					
EL (97) 52 audits of aseptic units and advice on design and commissioning		X	X	X	
Audit of NHS suppliers of medicines, devices and services	X	X		X	
Guidance on medicines preparation			X	X	X
Risk assessment and management of product recall for defective medicines	X	X	X	X	

Evidence of the role of SP Srvcs

38. A wide range of evidence was submitted on roles fulfilled by SP Srvcs. This is summarised in the following paragraphs and presented as illustrative case studies in Annex 5. The Review Team was also made aware that SP Srvcs underpinned the capacity of the NHS to undertake clinical trials and other research involving medicines. The scale of innovation is demonstrated by the fact that a teaching hospital may be active in more than 200 such clinical trials at any one time.

39. NHS hospital pharmacies currently have 260 aseptic preparation units producing approximately six million injection doses per year. Clinical services, including the provision of chemotherapy, are dependent on the operation of these units. In 1994, two children died when poor practice resulted in microbial contamination of intravenous injections. This resulted in mandatory national standards against which compliance is audited by SP Srvcs on a regular basis.

40. NHS medicines procurement contracts already yield major financial savings of around £150m[10] that are reflected ultimately in the tariffs paid by commissioners. Further plans for savings in medicines procurement are being developed, to which SP Srvcs are central. Support for NHS medicines procurement has also identified examples of medicines whose presentations are judged to pose risks to patient safety. SP Srvcs work with DH Commercial Medicines Unit (CMU) on strategic supply management and procurement of medicines, and with patient safety leads, regulators and the pharmaceutical industry, to improve pack and label design.

41. MI answers clinical enquiries from doctors, pharmacists and nurses. This service maintains access to specialist information and advisory services (such as medicines in lactation, pregnancy, renal failure and dental care), a databank of 270+ evidence-based Medicines Question and Answers and a daily news service via NHS Evidence. Support extends to horizon scanning for medicines in development, medicines budget setting and QIPP resources and the evaluation of medicines not subject to NICE technology appraisal.

42. SP Srvcs support the adoption of patient safety solutions. Specific activities include the quality assurance of the national IV injection monographs (Medusa Injectable Medicines Guide, which NHS hospitals use to support safe prescription and administration of injectable medicines) and implementation of electronic systems for reporting adverse drug reactions to the Medicines and Healthcare products Regulatory Agency. MHRA issues an average of 30-40 defective drug alerts per year. SP Srvcs are a key part of the alert cascade and ensure timely dissemination of alert information and monitoring/coordinating the NHS response.

43. SP Srvcs audit commercial service providers to the NHS, including homecare providers, medicine importers and compounding units. Risks may be associated with services that supply unlicensed medicines, such as parenteral nutrition, unless these are identified and mitigated appropriately. SP Srvcs also have oversight of the management of piped medical gases in hospitals.

44. SP Srvcs contribute significantly to undergraduate and postgraduate pharmacy education, and to knowledge and skills development that enable career progression. SP Srvcs are a priority group for the Modernising Pharmacy Careers professional board of Health Education England, in terms of workforce planning for a small specialist group.

[10] DH Commercial Medicines Unit estimate

Evidence of value of a subset of the functions of SP Srvcs

45. The review received data from SP Srvcs on the functions they undertake and data on activity and outcomes to underpin that, where available. The submissions demonstrate that the functions of SP Srvcs are numerous. It has not been possible to quantify the impacts of all the functions of SP Srvcs and an attempt to do so would be disproportionate relative to the cost of SP Srvcs and the time available to the review. However the following sections demonstrate a substantial positive impact of SP Srvcs activity. These benefits greatly exceed the estimated cost of £7.1m for SP Srvcs (detailed in the commissioning section below).

46. Selected functions of SP Srvcs and the benefits they deliver for the NHS are set out in the table below, which indicates savings of more than 4 times the cost (midpoint estimate of savings approximately £31m). This subset of evidence demonstrates the value-for-money of SP Srvcs, but is likely to be an underestimate of the total savings from the full range of functions.

Functional grouping	**Example of activity**	**Patient benefits and cost savings**
Medicines Information	Medicines Q&A	**Patient benefit** Reduced delays to patient care and potential for inappropriate clinical interventions **Cost saving** £5m to £6m estimate of staff time savings through provision of information
Medicines Evaluation	MTRAC evaluation of medicines	**Patient benefit** Optimised use of medicines and better value **Cost saving** £25m of savings in 2012 through changing of prescribing behaviour in West Midlands
Medicines Evaluation	Cancer Drugs Evaluation	**Patient benefit** Enabling 1,600 cancer patients to receive medicines more quickly through the Cancer Drugs Fund in London **Cost saving** Effective administration of a priority policy of the Government
Medicines Procurement	Procurement initiatives	**Patient benefit** Sustainable supply of medicines **Cost saving** Operational delivery of up to £150m of savings achieved by the Commercial Medicines Unit at a national level. In addition to the CMU figure, between £10m to £16m estimated savings to trusts and commissioners at a regional level (scaling of the savings calculated for two regional services)
Quality Assurance	Audits of aseptic units	**Patient benefit**

		Audit of 260 aseptic preparation units producing approximately 6m injection doses per year. The harms avoided are demonstrated by incidents in Manchester (paragraph 39) and the United States (paragraph 56) **Cost saving** Avoidance of costs associated with adverse events
Medicines Use and Safety	Supporting the NPSA/ NICE guidance on medicines reconciliation	**Patient benefit** Timely and accurate continuation of medicines during hospital admission **Cost saving** Medicine reconciliation leads to savings through reduced adverse events. In South Central, trusts are estimated to have saved approximately £2.5m in 2011/12
Medicines Use and Safety	Safer prescribing of primary care of Non-Steroidal Anti-Inflammatory drugs	**Patient benefit** Better outcomes resulting in reduced need for unplanned hospital admissions and improved quality of life **Cost saving** National roll-out would yield £10m of savings to the NHS through reduced hospital admissions; equivalent to reducing 4,500 unplanned hospital admissions
Medicines Use and Safety	Improved prescribing in care homes	**Patient benefit** Optimised use of medicines and better outcomes for care home residents **Cost saving** Supporting the review of prescribing in care home led to approximately £260k of savings in two areas of London
Total savings highlighted in bold/underlined above (excluding medicines evaluation)		£27.5m to £34.5m

Medicines Procurement

47. Medicines Procurement specialists provide advice to NHS trusts at a regional level; some provide support to the DH Commercial Medicines Unit (CMU) and strategic advice to policy makers on national procurement strategy. The service delivers competitive prices for medicines and seeks to maintain a sustainable supply chain, benefitting patients and the public. Savings attributable to CMU at a national level have been estimated as £150m (2011-12 contract savings reported against pre-tender baselines). As part of the evidence submitted to the review, specialists from two regions were able to identify savings from regional activities with commissioners and providers (i.e. not captured in the CMU figure). Scaling these estimates up to a national level on a per capita population basis gives savings of between £10m and £16m for regional medicines procurement activity.

Medicines Information

48. MI services provide information and advice for health care professionals and patients, answering more than 300,000 enquiries a year. This ensures clinicians receive appropriate advice on the use of medicines in a timely way. Five of the regional centres play a role at national level in terms of specialist advice on medicines in lactation, pregnancy, renal disease and dental care. This involves answering around 6,000 enquiries per annum.

49. A published evaluation of MI services[11] based on a sample of health care professionals who used MI services (n= 179) found: 99% of enquirers used advice; 81% judged that advice had a positive impact on patient care or outcomes; in 20% of cases MI provided active advice on issues not identified by the enquirer; 19 out of 20 members of an expert panel judged the advice given had a positive impact on patient care or outcomes.

50. MI produces medicines Q&A published on NHS Evidence. In 2012 there were approximately 320,000 page downloads. If a half of these saved two hours research time for Band 6 or 7 pharmacists, this would equate to approx. £5m to £6m cost savings per annum.

51. The Patient Group Directions (PGD) website supports safe non-medical supply or administration of medicines to patients. In 2011, there were around 80,000 hits on the website. The future hosting of this platform, and the expertise that supports it, is considered in the review.

Medicines Evaluation

52. Medicines evaluation services appraise medicines not subject to NICE processes. This function provides independent advice on the use of new medicines, or new indications of existing medicines, to support clinical and commissioning decisions. Groups undertaking this work include North East Technology Appraisal Group (NETAG), Midlands Therapeutic Advisory Group (MTRAC), London New Drugs Group (LNDG) and London Cancer New Drugs Group (LNCDG). Only the latter two are supported by funded MI services. As an illustration, however, evaluation of medicines by MTRAC is estimated to have saved around £25m in the West Midlands through changing prescribing behaviour.

53. These benefits could be spread systematically to the rest of the country through better co-ordination between services that consider medicines without NICE technology appraisal.

54. LNCDG supports the effective implementation of the Cancer Drugs Fund in London through its medicines evaluation activity and has enabled around 1,600 patients to gain rapid access to new cancer treatments.

[11] http://www.ncbi.nlm.nih.gov/pubmed/23419116

Quality Assurance

55. QA undertakes a wide range of activities that impact on value-for-money and patient outcomes. This ranges from the assessment of medicines to support safer medicines procurement through to the audit of specific services to reduce patient risk. A key example is the EL(97)52 audit of unlicensed hospital aseptic units; 236 audits were undertaken in 2012. Patient impact is difficult to enumerate, as their purpose is maintain patient safety through the mitigation of risk. The outcomes of these audits are documented and trusts are required to put actions plans in place to address deficiencies.

56. In the USA where this audit function is not in place, contamination of injections made in a poorly regulated pharmacy compounding unit caused the deaths of 36 people and infected more than 400 others in 2012.

57. QA support procurement process; over 1,600 products were assessed for quality and safety in 2012. Specialists work with patient safety leads, regulators and the pharmaceutical industry, to improve pack and label design to minimise in-use risk to patient safety. The benefits of these improvements extend beyond contracting of medicines for hospital care.

Medicines Use and Safety

58. Medicines Use and Safety centred in London, South East, South East Coast and East of England, provide a range of functions to commissioners and providers that support implementation of national priorities and local initiatives to improve patient safety. Evidence for potential savings and patient benefits includes:

- **Supporting the National Patient Safety Agency (NPSA) initiative on medicines reconciliation:** Cost avoidance data and the reduction in adverse events which followed the supported change in approach led to estimates of cost savings of approximately £2.1m over 10 months, pro-rata to approximately £2.5m cost savings for a whole year.

- **Safe prescribing of Non-Steroidal Anti-Inflammatory Drugs (NSAID) in primary care:** Demonstrates the potential to reduce hospital admissions due to gastro-intestinal (GI) bleeds and other adverse events. There are around 12,000 admissions for NSAID GI induced bleeds per annum,[12] with a cost of between £400 and £7,000 per admission depending on complexity. Using a figure of £2,500, this would represent a cost of £30m to the NHS. The initiative led to identification of risks and changes in prescribing behaviour for around 65% of patients. Assuming a proportionate reduction in emergency admissions (and estimating that 50% of risks can be identified by pharmacists in a national roll out), a potential reduction of 4,500 hospital admissions per annum is possible with associated savings of almost £10m.

- **Improving prescribing in care homes:** Developing resources and workshops has supported care homes in reviewing the prescribing of the residents in two areas of London. This led to savings of approximately £260k and improved patient and staff experience.

[12] http://www.medicine.ox.ac.uk/bandolier/booth/painpag/nsae/nsae.html#Heading11

Radiopharmacy

59. Radiopharmacy was one of the original regional services under the Noel Hall proposals. Over time, it has become a provider-based technical specialty, but a focus remains on improvement in diagnostic activity, safe prescribing and reduction of risk in the use of radiopharmaceuticals. The patient benefits stem from advice on: risk assessments; safe administration; procurement of and continuity of supply of radiopharmaceuticals; investigation of defects or adverse reactions.

60. Following global shortages of particular radionuclides, this discipline is subject to separate review by DH.

Contribution to the wider safety agenda in the NHS

61. The Care Quality Commission highlighted poor medicines management in its annual report for 2011/12. In 27% of 3,747 locations where action was demanded of providers, management of medicines was among the top three key problem areas. The report stated that *our inspectors saw a worrying number of examples where safe management of medicines is being compromised, often by a lack of information given either to those taking the medicines, or those caring for them*.

62. Many of the functions of SP Srvcs (as submitted in evidence to the review and summarised in different sections of this report) relate to risk reduction and safer prescribing of medicines and therefore should have a significant role to play in driving improvements in this area.

Core outcome set

63. Evidence submitted by services in scope for this review demonstrate the potential for development of a set of core desired outcomes for SP Srvcs:

- Improve patient outcomes: in terms of reduced hospital admissions or reduced adverse events due to medication errors
- Drive better use of resources in the NHS: directly through procurement activity or by optimising the use of medicines by patients and professionals
- Developing the multi-professional workforce: supporting safer prescribing, supply and administration of medicines

Key issues arising from the review

64. Based on this evidence and the broader NHS context, two key issues emerged in the review. These are to determine who should commission these multi-functional system resources that face commissioners and providers at national, regional and local levels and how they should be deployed to maximise impact. Commissioning and deployment needs to manage the risk of service fragmentation and harness the synergies between SPS functions. This should enable equitable access to SP Srvcs in order that patients and health care professionals benefit from the safe and optimised use of medicines that these services support.

Design principles

65. The reformed NHS commissioning structures can be described at three geographical levels:

    - **Local/Area**: There are 211 CCGs, responsible for the bulk of NHS commissioning. These are supported and held to account by the 27 area teams of the NHS England, which also commission primary care and other services. Ten of the area teams have been identified as specialised services commissioning hubs.

    - **Regional**: Four NHS England regional teams provide support and co-ordination for the area teams and have a key role in overseeing large-scale change and service reconfiguration.

    - **National**: As a national organisation, NHS England policy and prioritisation is determined at this level.

66. The NHS reforms have established a principle that services should be commissioned at the level of the system closest to the patient that is consistent with ensuring high quality and value for money. It is assumed that services will be commissioned at the local level by CCGs unless there are compelling reasons of cost, quality or sustainability (or in the case of primary care, a conflict of interest for GPs), which mean that they should be commissioned at a higher level.

67. A number of structures and collaborative arrangements have been established at a supra-area level to support the commissioning system. Twenty-one Commissioning Support Units (CSUs) provide a range of services to CCGs and NHS England.

68. Supra-area features include the 12 Clinical Senates and a pattern of Strategic Clinical Networks that will provide advice and expert support to local commissioners. All of these collaborative arrangements operate within geographical areas whose boundaries are aligned with those of the 10 specialised commissioning hubs (see Figure). For clarity, these 10 NHS geographies are referred to as ‘footprints’ in this report.

69. There are clinical and operational advantages to an operating model based on these footprints, including the existence of clinical communities and relevance to patient flows, as well as workable geographies for relationships between providers and commissioners. Annex 6 shows the distribution of local organisations across each footprint and demonstrates that demand level may vary by geography.

70. Deployment and governance for SP Srvcs (the services) should be considered in terms of the 3 levels: national, regional and footprint. At each stratum, there needs to be a strong patient focus, not only because it is the right thing to do in principle, but also because it empowers services to act in the best interest of patients, which is a prime requirement post-Francis.

71. For this reason, the services should not be abstracted from patient care organisations. Instead, SP Srvcs should be provided from trusts. The trusts from which services are commissioned should be designated for that purpose with a view to achieving at-scale efficiencies across a region; in concept, this could reflect consolidation into hubs, with spokes that support the footprint. Chief pharmacists of trusts that are commissioned to provide SP Srvcs should have line management responsibilities for the staff that deliver these services.

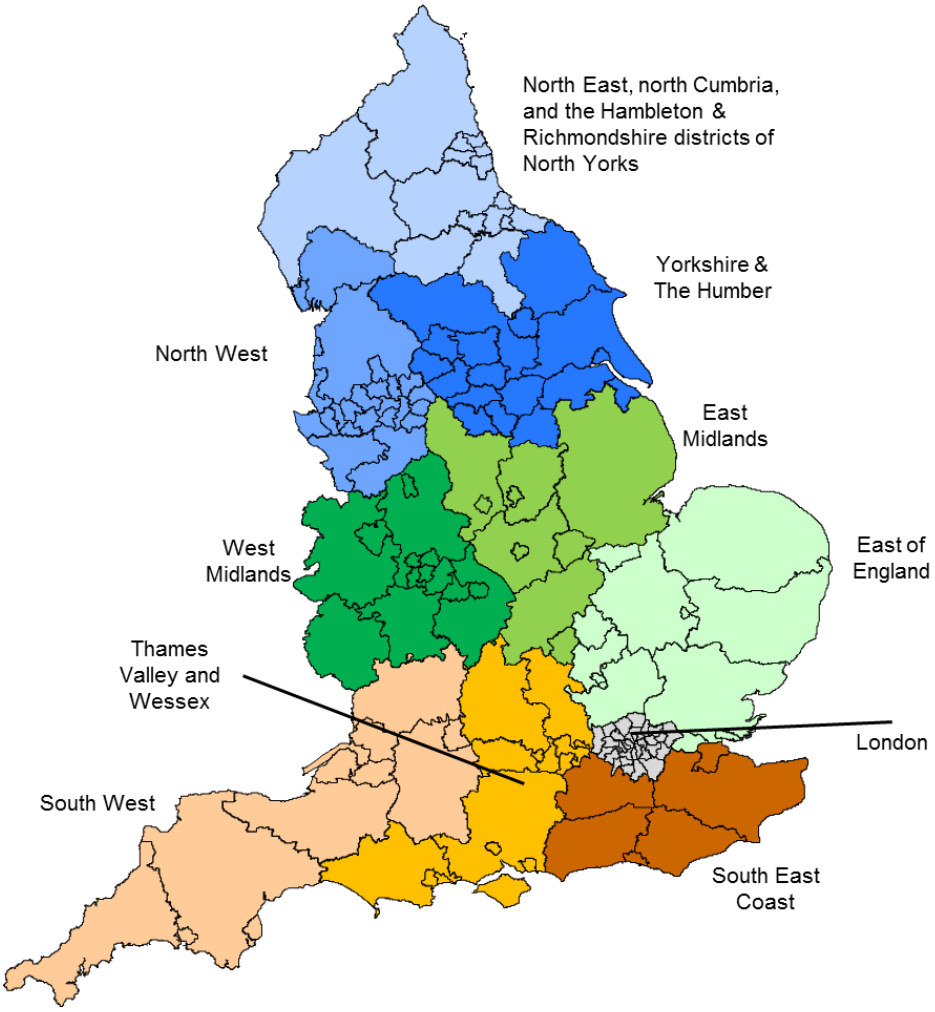


Figure illustrating the 10 NHS footprints across England

72. To ensure that synergies are achieved between different functional divisions of SP Srvcs, there is a rationale for the co-location of the constituent specialties of the services where this deployment is cost-effective and possible logistically or can be achieved virtually through the use of IT.

73. The Review Team considered if the services should be recognised as Specialist Medicines Services to emphasise their contribution to patient care and the optimal use of medicines. On balance, the consensus was that this description might not have sufficient clarity in terms of future commissioning mechanisms and that NHS SP Srvcs should be adopted. Close operating arrangements between functional divisions will support a clear focus on the delivery of NHS SP Srvcs for better patient care.

74. To achieve equity and excellence, the commissioning of SP Srvcs should ensure:

- A clear orientation to better outcomes for patients across each of the five domains of the NHS Outcomes Framework
- Improvement in the quality and equity of access the services
- National consistency in the delivery of SP Srvcs functions and minimisation of duplication

75. To deliver these commissioning intentions, the operating model for SP Srvcs should be guided by:

- Patient focus and better outcomes from the use of medicines
- Equity, consistency, sustainability and cost-effectiveness across services
- Doing once those things that should be done once
- National planning, but footprint responsiveness
- A design that reduces complexity and ambiguity
- An ethos of building bridges between, not walls around, the function divisions and the wider NHS

National

76. Provision of high quality SP Srvcs will necessitate national actions to set priorities and direction, regional actions to ensure consistency and delivery of the national strategic direction and footprint actions to provide the services in an effective and efficient manner and to support local relationships and responsiveness.

77. At the national stratum, the core requirements around SPS include:

- Establishing governance arrangements to enable consistency and the setting of national direction
- Development of strategy for the services and oversight of the commissioning and deployment arrangements
- Leading transition to the NHS SP Srvcs functions
- Prioritisation of SP Srvcs and determination of the specifications and standards
- A governance and accountability framework that ensures collaboration between the designated SP Srvcs and the technical, specialist provider functions in pharmacy; for example, aseptic services, radiopharmacy and production disciplines
- Acting as an expert resource for NHS England and other stakeholders including, but not limited to, NHS England's Medical Directorate and Chief Pharmaceutical Officer, Patient Safety and Specialised Commissioning teams

Regional

78. At the regional stratum, the deployment model for SP Srvcs needs to be consistent with the four NHS regions and compatible with the potential for professional leadership through the proposed Regional Pharmacist roles in the NHS England. The design considerations are:

- Economies of scale and reduction of duplication
- Aggregation and co-location to exploit synergies between the services and achieve critical mass for the development of expertise and succession planning
- A focus on turning strategy into reality and the harnessing of innovation
- Development of expertise and to support specific functions, for example specialist knowledge domains
- Ensuring appropriate delivery of the services into the footprints

Footprint

79. There should be alignment of boundaries between structures wherever relationships are important. This is necessary to recognise the pattern of patient flows, particularly with tertiary centres. Delivery of SP Srvcs to the 10 NHS footprints will need to:

- Reflect national standards and policies
- Manage and be responsive to local relationships including support for chief pharmacist and commissioning pharmacist networks
- Support an integrated approach to medicines optimisation in patient pathways
- Provide assistance, advice and assurance for the commissioning and delivery of medicines-related services
- Provide equitable access to the different functions of SPS

Functional groupings

80. Analysis of functions and submitted evidence confirms three divisions of activity for the design principles to recognise:

- Medicines Information
- Medicines Assurance
- Medicines Safety

81. The scope of SP Srvcs should be distinct from aggregated provider functions, which should be resourced by providers. The services should enable access to specialist expertise that would not otherwise be available to commissioners or providers. A number of related functions have also been identified and these are referred to later in this report.

Medicines Information

82. This function is discharged by Regional MI Centres that form part of the UK-wide MI network. The balance between footprint delivery and consolidation into regional centres reflecting the reformed NHS geography is explored in the deployment options section of this report.

83. A designated regional centre should act as a lead for specialist MI provision and offer leadership, development and assurance for other MI units across their region. Designated centres should work on a collaborative basis to support an agreed work programme. Shared responsibilities would include content generation for NHS Evidence, compilation and availability of answers to clinical enquiries, commissioning support in relation to evidence summaries for new medicines (in collaboration with NICE and other providers of this function) and those subject to Individual Funding Requests.

84. Operational aspects of the web portal for all SP Srvcs should be under MI responsibility, even where content is the responsibility of others. Under this function should be considered the development and assurance of monographs for Injectable Medicines Guide and their online availability.

Medicines Assurance

85. Medicines Assurance should comprise Pharmaceutical Quality Assurance and Medicines Procurement specialties. These functions are closely aligned as procurement has a significant reliance on the assurance of suppliers and quality assessment of medicinal products.

86. The proposed medicines shortages website, which would provide a focus for combined SP Srvcs actions to support the NHS response to medicines shortages, should operate under this function, as should the web-enabled Pro-File database of NHS manufactured unlicensed medicines.

Medicines Safety

87. To date this function has been available to London, South East, South Coast and East of England. It delivers programmes and projects that coordinate and support the commissioning and delivery of safe medication practices in patient settings, providing an adoption and spread mechanism for medicines safety solutions.

88. There is evidence of demand for a medicines safety function within SP Srvcs to provide support for all healthcare sectors in England, including offender health. This will require effective communication and close working with the safe medication practice and medical devices team at NHS England.

89. Under this function should sit the PGD website and advice in relation to non-medical systems of medicines supply and administration. This function could also assume lead responsibility for the Injectable Medicines Guide, working closely with MI for the development and assure of monographs.

Related functions

90. Capacity for the evaluation of new medicines evaluations is located within the MI function for some services (London North MI Service for London New Drugs Group, London and South East MI Service for London Cancer New Drugs Group and the NE Regional Drug and Therapeutics Centre). Reviews generated by these centres are considered in a variety of decision-making fora. In the West Midlands, MTRAC comprises an evaluation and recommendation function, the latter with a particular focus on commissioning advice to CCGs in the West Midlands and subsequent appropriate use (if any) in primary care.

91. Discussion with the Medicines and Prescribing Centre (MPC) at NICE has confirmed their vision for the availability of robust evidence summaries of new medicines and new indications (except those that will be addressed through technology appraisal) for all decision-making groups.

92. MPC does not have sufficient capacity to address all new medicines and technologies, indicating that there is significant scope for collaboration to deliver evidence summaries according to a shared horizon-scanning process and accredited content development. In relation to SPS, this activity should be focussed on designated regional MI Centres with the relevant experience and expertise. Consideration should be given to how existing expertise outside the definition of SPS could be utilised efficiently in collaborative approaches

93. Given that significant cancer chemotherapy expertise has developed in the Cancer New Drugs Group and the underpinning MI service, NHS England should consider how this function could be specifically supported for its potential contribution to the national chemotherapy Clinical Reference Group and to Domain 1 of the NHS Outcomes Framework.

94. There are groups with long standing experience in prescribing analysis that have provided evidence to this review of improved management of resources and impact on patient outcomes e.g. the Wolfson Unit in Newcastle and the Centre for Medicines Optimisation in Keele University. It is not proposed that these be brought within the definition of SP Srvcs, but consideration should be given as to how better use of this expertise could be made, with less replication of analytical functions across England; support could be provided to the Medicines Safety function to measure and report on changes in medicines use and linkage to patient outcomes.

Options for commissioning

95. A proposed deployment model will need to be commissioned or procured. Prior to the transitional arrangements for 2013/14 (in which CSUs are responsible for commissioning formerly PCT-funded services for a region), funding has come from two main sources:

- Collaboratively from PCTs through a lead commissioning PCT, SCG who commissioned on behalf of PCTs or through a hosted PCT arrangement
- Provider-to-provider funding or within provider baselines (i.e. part of the providers overhead)

This has led to geographical variation in the level of funding provided

PCT and provider funding of services within scope of SPS review (2012/13)					
Former SHA geography	Function (s)	PCT and provider funding (£)	Total for SHA (£)	NHS Region	Total for NHS Region
London	MI + MUS + QA + procurement	1.4m	1.4m	London	1.4m
South East Coast	MI + MUS + QA + procurement	445k	445k	South	2.2m
South Central	MI + MUS + QA + procurement	465k	465k		
South-West	QA PCT funded Procurement (provider funded) MI + QA (provider funded)	727k 100k 450k	1.3m		
East of England	MI + MUS + QA + procurement	775k	775k	Midlands	1.6m
East Midlands	MI + QA (Northants- MK) QA Procurement MI (provider baseline)	70k 105k 100k 250k	525k		
West Midlands	MI Procurement (provider funded) QA**	225k 100k 0k	325k		
North-West	QA (estimate – trading account) MI Procurement (provider funded)	250k 829k 100k	1.2m	North	1.9m
North-East and Y&H	MI (NE + Y&H + Cumbria) Procurement (NE - provider) Procurement (Y&H – provider) QA (NE + Cumbria) QA (Y&H – provider)	410k 100k 30k 95k 100k	735k		
			7.1	Total	7.1
Notes: Numbers rounded so may not tally					

**West Midlands QA decommissioned, but previously funded at £135k. Figure not included in total.
Estimates of funding based on a combination of SHA Pharmacy and Prescribing Leads scoping exercise. Provider funded procurement posts have been estimated on the basis of usual number of posts and banding.

96. The table above shows estimates of the total of commissioner and provided funded services for SPS in 2012/13 at approximately £7.1m.

Options assessment

97. The following options have been developed through engagement with commissioning experts and based on the Review Team's understanding of plausible options for commissioning of SP Srvcs from 2014-15 onwards. These options are designed to enable a differentiation between the commissioning and provision of SP Srvcs, in line with the wider NHS. The use of a *national specification* is mentioned under a number of the options. This is defined as a specification of the functions, activities and outcomes of the services and broad geographical basis on which they will be commissioned. This will be decided by the commissioner, but informed by the deployment options and management structures recommended in this report and by further engagement with the services.

Option 1: Do nothing

98. CCGs commission SP Srvcs independently without central support or action to encourage collaborative commissioning. Where arrangements are hosted, the provider may continue to fund services.

Option 2: CCG collaborative

99. Guidance for CCGs[13] sets out that in some cases they may wish to collaboratively commission health services. The guidance highlight reasons such as clinical improvement, efficiency or resilience and risk management as reasons for wanting to collaboratively commission. Collaborative arrangements can take a number of forms and involve two or more CCGs.

100. Under this option CCGs would agree to commission SP Srvcs regionally (on the basis of either the 4 NHS regions or the 10 footprints), similar to the collaborative commissioning arrangements that existed in 2012-13. This would be achieved through CSUs and reflect the transitional arrangements for 2013-14. The services could be commissioned to a national specification and configured to the preferred deployment option set out in this review.

Option 3: CSUs

101. CSUs procure, fund and provide SP Srvcs as part of their offer to commissioners and potentially to the providers they contract with. Under this option, individual CSUs, consulting with CCGs and providers, would determine which SP Srvcs to provide locally and to what level.

[13] http://www.commissioningboard.nhs.uk/wp-content/uploads/2012/03/collab-commiss-frame.pdf

Option 4: NHS England – directly commissioned and centrally funded

102. NHS England directly commissions and funds SP Srvcs against a national specification through its area teams based on the 10 footprints. The services are available to commissioners and providers according to the preferred deployment option. This could be achieved by:

- The Secretary of State (SofS) for Health prescribes SP Srvcs under section 3B 1(D) of the NHS Act 2006 as a service to be directly commissioned by NHS England, as for primary care services, offender healthcare, some services for members of the armed forces and prescribed specialised services. Or
- The SofS and NHS England make an arrangement for NHS England to undertake these functions under section 254A of the 2006 Act, which would not require any legislation. This section of the Act enables the SofS to provide support services to NHS commissioners and providers of services to the NHS or agree with NHS England or any other legal entity to do so on its behalf

103. Under the first option, services would be prescribed under Section 3B of the NHS Act 2006 and would require amendments to the existing legislation.[14] This states that the SofS for Health may require NHS England to directly commission services under regulations if it would be more appropriate for the Board to commission those services rather than CCGs. The SofS must have regard to the criteria in the box below, while obtaining expert advice and consulting NHS England, when making that decision. An assessment against these criteria for SP Srvcs is presented in Annex 8.

Prescribing services under Section 3B 1(D) of the NHS Act 2006[15]

(3) In deciding whether it would be so appropriate, the Secretary of State must have regard to the

(a) Number of individuals who require the provision of the service or facility;
(b) Cost of providing the service or facility;
(c) Number of persons able to provide the service or facility;
(d) Financial implications for clinical commissioning groups if they were required to arrange for the provision of the service or facility.

(4) Before deciding whether to make regulations under this section, the Secretary of State must

(a) Obtain advice appropriate for that purpose, and
(b) Consult the Board.

104. Under the second option a legally drafted agreement could enable NHS England to take up these commissioning responsibilities, without changes to legislation.

Option 5: NHS England – All CCGs agree that NHS England should directly commission and costs are re-charged to CCG budgets

105. All CCGs agree that NHS England should commission SP Srvcs on their behalf. Agreement is reached through an appropriate forum, for example the NHS Commissioning Assembly.[16]

106. NHS England then commissions for the system through its area teams based on the 10 footprints commissioned to a national specification. The costs of SP Srvcs are re-charged to CCGs on a per capita basis. The services are made available to commissioners and providers according to the preferred deployment option.

[14] http://www.legislation.gov.uk/ukpga/2012/7/section/15/enacted
[15] http://www.legislation.gov.uk/ukpga/2012/7/section/15/enacted
[16] http://www.england.nhs.uk/ourwork/part-rel/assembly/

Option 6: NHS England centrally procured

107. NHS England decides to procure SP Srvs on behalf of the system. It procures SP Srvcs directly as it procures legal services, for example. It makes available the appropriate level of SP Srvcs as required by the system to a national specification based on the deployment model recommended by this review. In this option, NHS England's primary interest is in SP Srvcs as a means to address its needs as a commissioning organisation.

Option 7: Decentralised fee for service model

108. Funding and commissioning of SPS is decentralised. Providers of SP Srvcs market their services to tertiary, secondary and primary care providers and clinical commissioners on a fee for service basis.

Option 8: Levy to fund SP Srvcs

109. A central organisation levies providers and commissioners and funds SP Srvcs on their behalf. Levies would be relative to provider income or commissioning budgets.

Summary of options: commissioning and funding		
Options	**Commissioner**	**Direct Funder**
1: Do Nothing	Individual CCGs	Individual CCGs
2: CCG collaborative	CCGs collaboratively	Individual CCGs
3: CSUs	CSUs	CSUs
4: NHS England directly commissioned, centrally funded	NHS England	NHS England
5: NHS England commissioned, locally funded, CCG agreement	NHS England	CCGs
6: NHS England centrally procured	NHS England	NHS England
7: Decentralised fee for service model	None	Providers, CCGs and NHS England
8: Levy to fund SPS	See below for further discussion	Providers, CCGs and NHS England

Criteria and assessment

110. The criteria used to assess the preferred option are presented in the following table. These are based on expert evidence from stakeholders and the broader context of quality and safety in the NHS following the Francis Review. Under each criterion, questions to guide the assessment are presented.

Feasibility

111. An assessment of feasibility is presented on page 32. Based on this analysis, option 8 can be ruled out as no organisation has the necessary powers to levy commissioners and providers.

Options Assessment, supporting narrative and risks

112. An assessment of the commissioning options is presented on pages 33 and 34. This has been informed by: evidence submitted as part of the review, including views on the stakeholder day; discussions with NHS England officials responsible for commissioning policy and operations; and the knowledge and interpretations of the Review Team.

113. For each criteria, the options is scored:

- +1 if the option will likely lead to improvement (thus a decrease in unit costs or overall costs to the system is scored +1)
- 0 if there will be no change
- -1 if the option would adversely affect the desired outcomes

Table of assessment criteria and accompanying questions

Commissioning options assessment criteria	**Description of criteria and questions to guide assessment**
Feasibility	Can the option be implemented? Are there legal barriers to implementation? Are there any other factors that would make this option infeasible?
Cost (of providing service)	What would the impact on financial costs be, including both: • Unit costs of providing a certain service and/or • Overall financial costs to the system (One of the criteria under Section 3B of NHS Act 2006)
Cost-effectiveness	Does this option have the potential to drive value-for-money in the NHS system this could be through reduction in costs, or more effective use of NHS resources leading to cost savings, either financial or opportunity cost or improvements in patient care
Equity of access (geographic and patient factors)	Can the option drive equity of service coverage across the system? Will it improve market penetration and use of services?
Innovation and transparency	Does this option provide the appropriate feedback loops from commissioner to provider to support innovation and service improvement? Does the option support transparency for users?
Retention and most effective use of expert knowledge	Does the option safeguard against the loss of expert knowledge embodied within the services, which are ultimately a system resource?
Sustainability	Does the option present a sustainable outcome in terms of workforce planning, service continuity and covering costs on a commercial basis

Table of feasibility assessments

Summary of feasibility assessment			
Options	**Could the option be implemented?**	**Are there currently legal barriers to implementation?**	**Other factors that render infeasible?**
1: Do Nothing	Yes	No	No
2: CCG collaborative	Yes	No	No
3: CSUs	Yes	No	No
4: NHS England directly commissioned, centrally funded,	Yes	Yes These can be overcome through changes to NHS E standing rules	No
5: NHS England commissioned, locally funded, CCG agreement	Yes – although it may difficult to obtain agreement of 211 separate organisations	No Other services are being commissioned collaboratively and framework agreements are available	No
6: NHS England centrally procured	Yes	No	No
7: Decentralised fee for service model	Yes	No	No
8: Levy to fund SPS	No	Yes There are no powers to levy	No

Option	Impact on unit costs or costs to the system	Impact on cost-effectiveness	Geographic equity and patient access	Innovation	Transparency	Retention/ effective use of expert knowledge	Sustainability	Score
Option 1: Do Nothing	-1 Likely rise in overall system cost, e.g. duplication of information provision	-1 Costs rising means reduced cost effectiveness	-1 Unlikely to be "sufficient" demand as services are not visible to individual CCGs	+1 CCG commission directly so can drive innovation, but	-1 overall coverage in the system unlikely to be transparent	-1 Likely to lead to some decommissioning of services (at least in short-run) and loss of expert knowledge	-1 Likely to lead to decommissioning of services and lack of co-ordination between services	-5
Option 2: CCG collaborative	0 Uncertain, similar to current system so potentially similar costs	0 Similar to current system	0 Similar to current system so likely to be variable	0 Unlikely to drive particular improvements, similar to current system	0 Unlikely to drive particular improvements, similar to current system	0 Collaborative option may lead to some decommissioning, but also similar to current system	0 Potential to maintain and improve services	0
Option 3: CSUs	0 Potential reduction in unit costs, but uncertain impact on overall system costs as decentralisation may drive duplication	0 Uncertain effect on overall costs and therefore cost-effectiveness	0 Decentralised system likely to be variable, may be insufficient demand due to market failures	+1 May be more innovative to market offer to commissioners	-1 Level of provision regionally or national unlikely to be transparent	0 Leads well from transitional arrangements for 2013/14, may lead to some decommissioning in the longer-term	0 Leads well from transitional arrangements in 2013.14, longer term sustainability unclear	0
Option 4: NHS England directly commissioned, centrally funded	+1 Potential to drive reduction in unit costs and control overall system costs	+1 Improve coverage of best practice to spread benefits and drive down costs	+1 Potential to drive equity and national patient coverage	+1 potential to drive innovation through commissioning to a national specification	0 May not be transparent to all CCGs and providers	+1 Potential to maintain services and retain expert knowledge	0 Potential to maintain and improve services, longer-term sustainability unclear	5

Option 5: NHS England commissioned, locally funded, CCG agreement	+1 Potential to drive reduction in unit costs and control overall system costs	+1 Improve coverage of best practice to spread benefits and drive down costs	+1 Potential to drive equity and national patient coverage	+1 potential to drive innovation through commissioning to a national specification	0 May not be transparent to all CCGs and providers	+1 Potential to maintain services and retain expert knowledge	0 Potential to maintain and improve services, longer-term sustainability unclear	5
Option 6: NHS England centrally procured	+1 Potential to drive down costs	+1 Improve coverage of best practice to spread benefits and drive down costs	+1 Potential to drive equity and national patient coverage	0 Not clear that a central procurement approach would have same potential to drive improvement	0 May not be transparent to all CCGs and providers	+1 Potential to maintain services and retain expert knowledge	0 Potential to maintain and improve services, longer-term sustainability unclear	4
Option 7: Decentralised fee for service model	-1 Likely rise in overall system cost, e.g. duplication of information provision	-1 Likely fall due to increased costs	0 Likely to be variable	0 Direct customers so can drive innovation	0 overall coverage in the system unlikely to be transparent	-1 Likely to lead to some decommissioning of services (at least in short-run) and loss of expert knowledge	-1 Likely to lead to decommissioning of services and lack of co-ordination between services	-4

Key risks associated with each option

Option	Key risk
1: Do Nothing	Services are decommissioned
2: CCG collaborative	Variation in service coverage due to variable commissioning arrangements
3: CSUs	Potential for duplication and wasted resources across CSUs
4: NHS England prescribed services, directly commissioned, centrally funded	Lack of visibility of services to CCGs
5: NHS England commissioned, locally funded, CCG agreement	High degree of difficulty in co-ordinating agreement of all CCGs
6: NHS England centrally procured	Procurement process may not drive improved outcomes as commissioning processes
7: Decentralised fee for service model	Increased costs due to limited supply of human resources; fragmentation and non-cooperation risks

Emergent solutions

114. The three highest scoring options recommend a national approach to commissioning or procuring SP Srvcs. It is necessary to consider the difference between commissioning and procurement to inform the commissioning option. A paper by Murray[17] considered this based on range of UK government evidence and policy papers, it concludes that procurement is:

The specific aspects of the commissioning cycle that focus on the process of buying services, from initial advertising through to appropriate contract arrangement

115. The commissioning process is broader and a number of stages are identified:

- A strategic needs assessment
- Deciding priorities and outcomes
- Planning and designing services
- Options appraisal
- Sourcing
- Delivery
- Monitoring and review

[17] http://academic.research.microsoft.com/Paper/13077401 and http://www.ippa.ws/IPPC3/Proceedings/Chaper%207.pdf

116. These various stages of the commissioning process are the rationale for scoring the commissioning options more highly than the procurement option in terms of the potential to drive innovation. The Review Team believes this is in line with the ethos of the reforms to the system under the Health and Social Care Act 2012. A commissioning process offers the most appropriate mechanism to deliver better outcomes for patients. Not all stages may be formally necessary, but determining outcomes, monitoring and review will be core to continuous improvement.

Preferred option

117. The preferred option is direct commissioning by NHS England. This could be achieved through the SofS for Health and NHS England agreeing and using a legal mechanism to allow NHS England to take up these responsibilities (option 4) or through all CCGs reaching agreement (option 5).

118. From discussions with commissioning experts, it is apparent that there would be significant practical barriers to implementing option 5. Newly established CCGs face a range of challenges at this point in time and it would be difficult to get all 211 to reach an agreement.

119. Option 4 is therefore preferred. The most effective approach to achieving this (either through prescribing services or other mechanisms available under the NHS Act) should be the subject of legal advice and further discussion and agreement between DH and NHS England.

Summary

120. The Review Team believes that the criteria assessment provides a transparent rationale for NHS England to commission the services. The risks of option 5 (seeking to reach agreement amongst all CCGs) mean that option 4 - direct commissioning by NHS England – is the most viable option.

Leadership, governance and accountability

121. SP Srvcs commissioned by NHS England should be identified as a nationally co-ordinated service known as the Specialist Pharmacy Service (SPS). In consideration of the contemporary context for practice, the following is proposed as a definition around which commissioning and deployment options can be framed:

The NHS Specialist Pharmacy Service is delivered using specialist pharmaceutical expertise and is provided across many health organisations. It exists primarily to support improvements in safety and the outcomes of patient care through the better use of medicines. In fulfilling these functions, it supports patients, clinicians, commissioners and providers in delivery of medicines optimisation across the NHS. To ensure access to necessary expertise and achieve value-for-money, the Service is provided at a level of organisation greater than a local health economy.

122. SP Srvcs have evolved and operate in different ways across England according to agreements and arrangements with their local commissioners, providers and host organisations. This has resulted in significant variation and differential access to services working to different standards and specifications.

123. In the absence of a national strategy, decisions have been taken locally. As a result, commissioners in some of the former SHA geographies have disinvested, creating a reliance on services that have been funded by commissioners in other parts of England.

124. NHS reforms create an opportunity to design the commissioning and delivery of SP Srvcs. This should focus on putting in place the leadership, planning and co-ordination that are necessary to achieve consistent, high quality services that avoid duplication, support better outcomes for patients and deliver value for money.

Engagement and leadership

125. To provide a leadership focus, hold the SPS knowledge across the system, enable service change and secure advice from the functional divisions of the service, it is proposed that a Head of NHS SPS post be created by redesign and from within current funding as part of the commissioned provision. The post could be commissioned from a host employer of the appointee and where the appointee could be based.

126. An alternative approach could involve regional leadership of the service via the proposed Regional Pharmacist posts. However, at this stage it is not clear as to whether the latter will be established in each region. In addition, given the wide ranging role such posts are likely to fulfil, the Review Team do not envisage they would have sufficient scope to take forward the transformation of the services and delivery of the strategic direction.

127. An Assistant Head (Medicines Preparation) created by redesign and from within current funding, should support the Head of NHS SPS, working to a specific remit for provision of specialist advice on technical specialist provider activity. This will include those specialist technical activities which interface with the MHRA and collaborating with, securing advice from, and promoting co-ordination between the technical specialist provider functions (such as aseptic services, radiopharmacy, medicines manufacturing and quality control

disciplines) and enabling their interface with the range of SP Srvcs. A specific requirement would include maintenance and development of the database of NHS manufactured unlicensed medicines.

128. An Assistant Head (Medicines Safety), created by redesign and from within current funding, should also support the Head of NHS SPS, with responsibility for strengthening the profile of the SPS medicines safety function, co-ordination of work and acting as a link to NHS England's safe medication practice and medical devices team in terms of strategy development and resource.

129. There would need to be clarity on the roles of the NHS England team and the SPS medicines safety function, but in essence the SPS would be an implementation partner providing access to network and grounded experience, with the ability feed information and insight to the Patient Safety Domain Team. Specific responsibilities could include oversight of the Injectable Medicines Guide, working closely with the MI function, and the PGD website and associated expertise.

130. In terms of intent, the Head and Assistant Head roles would not be managers of a hierarchy of the SPS, but provide a leadership mechanism to deliver the requirements of a Management Board as set out below. Although new roles, the design principle would be that these are not additional posts, but part of the reframing of the existing SPS workforce.

131. Service changes will be promoted through the commissioning process, involving key performance indicators and holding to account for delivery. Chief pharmacists of trusts that are commissioned to provide the SPS should have line management responsibilities for the staff that deliver the service. Agreement of objectives and annual appraisal should be in the context of the following arrangements.

Management Board

132. A number of deployment options for the SPS are outlined in the next section of this report. Irrespective of how the Service is built from the footprint operation towards consolidation regionally, it is clear that a strategic intent needs be designed into the arrangements. Acting on behalf of the responsible commissioner and facilitating equity across England, a single Management Board is proposed for the purposes of:

- Setting strategic direction
- Prioritising of services and service developments
- Maximising collaboration; minimising duplication
- Receiving and approving cost-effective business plans
- Receiving annual reports

133. Membership of the Board should include the Chief Pharmaceutical Officer, Deputy CPhO and Deputy Domain Director (Patient Safety) from NHS England, finance/commissioning representative(s), a trust chief pharmacist who manages staff that provide SP Srvcs, a trust chief pharmacist (as a service user), CCG and/or CSU representatives, a lay member, specialised commissioning representative and the Head of the SPS. The Board should meet a minimum of twice a year.

Implementation Group

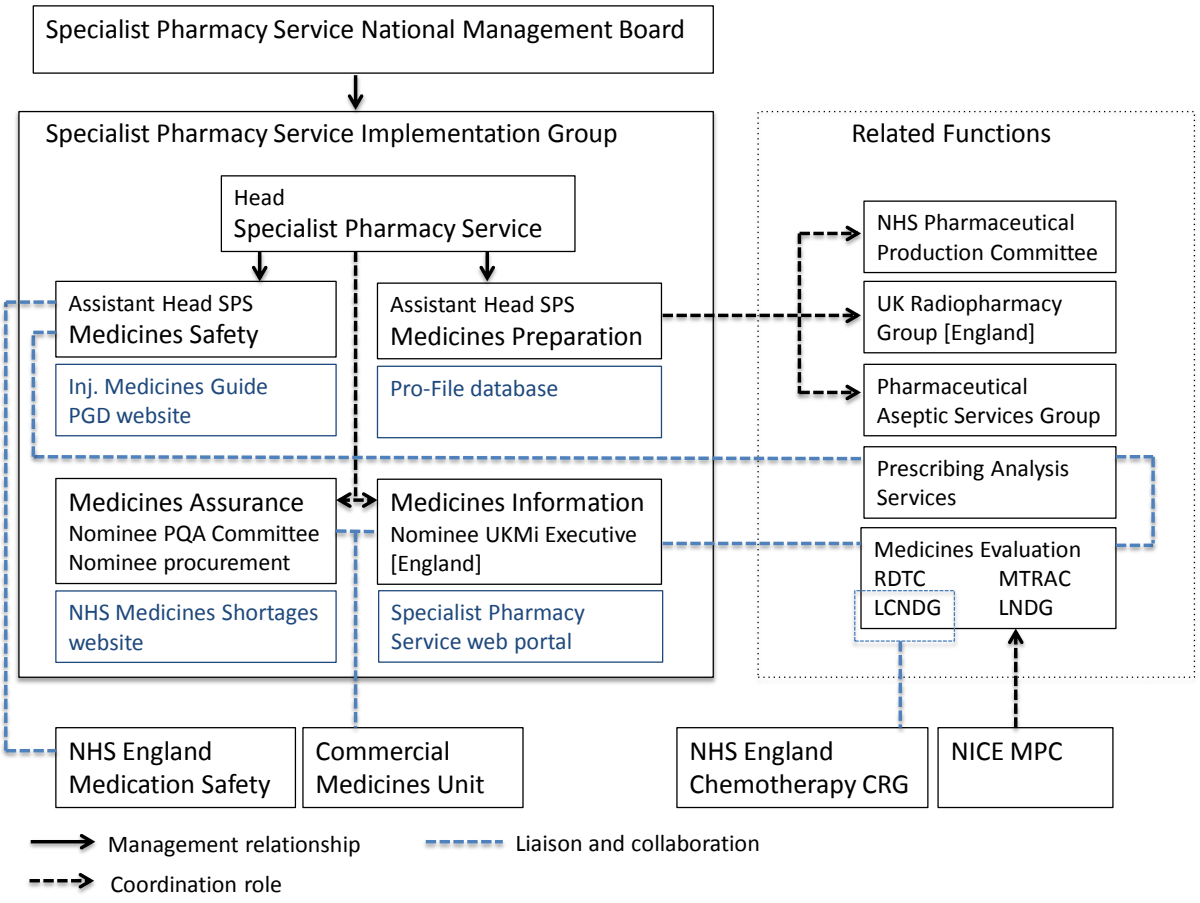
134. To support a devolved leadership approach, an Implementation Group is proposed that would:

- Support implementation of Management Board decisions
- Advise the Board on issues related to the service
- Develop work plans and annual reports
- Promote collaborative working
- Provide advice to the Management Board on the commissioning of the service

135. The Implementation Group should meet up to four times a year and comprise, as a core, the Head and Assistant Heads of the SPS, nominated senior representative of the Medicines Information and Medicines Assurance functions (number and selection to be guided by the selected deployment option), Safe Medication Practice Lead NHS England and representation from CMU. Where necessary and appropriate this group should liaise with other related functions, as indicated in the organogram.

136. At the footprint level, the SPS delivery should be actively engaged with chief, CCG and CSU pharmacist networks. This includes the provision of regular reports and briefings to those networks and capacity for local responsiveness.

SPS organogram



Options for deployment

137. This section provides the rationale for recommendations on a deployment of the SPS based on 10 delivery footprints in England. It includes the criteria used to assess a range of deployment options and the detailed assessments that informed the selection of a preferred model.

138. A baseline map of the current deployment of SPS and workforce is contained in the Annex 7 to the report. A summary for each of the current functions is given in the table below.

Current Function	**Current Deployment**
Medicines Information	9 regional centres, aligned with 10 SHA regions
Quality Assurance	Present in 7 centres aligned to 9 SHA footprints*
Medicines Procurement	Presence in 10 SHA footprints**
Medicines Use and Safety	Presence in 4 footprints
Comments	* West Midlands on a fee for service basis **One post under discussion

139. Based on new functional groupings, the options for deployment of the SPS include:

Options for deployment			
	Spectrum of options from centralised to localised		
Functional grouping	**Medicines Information**		
Options	One national centre	8 hubs and no spokes	4 hubs, one per region, and 6 spokes
Rationale	Cost-efficient, but loses local interaction	Build on existing deployment	Aligns with new delivery footprints
Functional grouping	**Medicines Assurance (includes QA and Procurement)**		
Options	4 hubs, one per NHS region	Presence in 10 delivery footprints	Trading account/ provider based
Rationale	Consolidates into NHS regional structure	Aligns with new delivery footprints	Demand led
Functional grouping	**Medicines Safety**		
Options	One national centre	4 hubs, one per NHS region	Presence in 10 delivery footprints
Rationale	Outputs should be to a common standard	Consolidates into NHS regional structure	Safety solutions depend on local engagement

140. There are several deployment options for each of the three functional groupings. The proposed concept is of a *delivery team* aligned with each footprint, drawing on an efficient scale of operation whilst maintaining a feasible interaction with providers and commissioners within the footprint. The size and composition of delivery team should be determined by demands within the footprint (see Annex 6 on demand data) and also the extent to which functions can be consolidated to a regional hub.

141. In the above table, three deployment options are outlined for each of the main functions. For MI, the 'spoke' is a deployment of MI capability within the delivery team, working in close cooperation with a regional hub. Spokes will therefore have closer engagement with local providers of NHS services, CCGs, local authorities and Health and Well Being Boards and be responsive to their needs. They will work collaboratively in delivery footprint with Medicines Assurance and Medicines Safety.

142. A regional hub will provide highly specialist services that can be undertaken once for England; for example, information and advice on the use of medicines in children, mental health, renal or hepatic impairment, pregnancy and lactation. A hub should be engaged with NHS England, NICE and DH, and support specialised commissioning processes at the regional level (for example, Individual Funding Requests, Individual Cancer Drugs Fund Requests, commissioning and clinical medicines procurement requirements). Ultimately, hubs should account for work undertaken in spokes, deliver specialist MI education and training and create tools for workforce development.

143. Consideration could be given to the use the *Specialist MI Centres* and *Specialist MI Units* as terms to describe this arrangement; aggregated functions or those requiring particular expertise could be managed by the hub, with each hub leading on specific themes for the NHS.

144. For Medicines Safety, the evidence indicates that it is the footprint engagement that drives success in local implementation and spread. The determination of deployment need to address whether the MS requirement is in relation to this more local responsiveness or to the development of medicines safety resources for sharing nationally; the latter may relate to a national or regionally held function. There is also an indication that other areas of commissioning interest, offender health for example, may wish to engage with a medicines safety function at a regional level.

Criteria for assessing options

145. The criteria to assess these deployment options are summarised in the following table. These were developed by the Review Team following discussion at the stakeholder workshop, at the Project Board and with commissioning experts and policy officials on the new NHS architecture.

Assessment

146. An assessment of the deployment options is presented on pages 43-45. This has been informed by: evidence submitted as part of the review, including views on the stakeholder day; discussions with NHS England and Department of Health officials; members of the Project Board; and the knowledge and interpretations of the Review Team.

147. For each criteria, the options is scored:

- +1 if the option will likely lead to improvement (thus a decrease in unit costs or overall costs to the system is scored +1)
- 0 if there will be no change
- -1 if the option would adversely affect the desired outcome

Assessment criteria

Criteria	Description
Feasibility	Can the option be implemented? Is it realistic to seek to move from current to proposed deployment?
Workforce development and training	Does the deployment option provide the potential for workforce development for example: • Succession planning • Training of specialist pharmacists • Training by specialist pharmacists of the wider NHS workforce • Audit of service competency • Make best use of existing expertise and specialist knowledge that currently exists
Transition costs	Will there be transitional costs to the system to move from current deployment to proposed deployment
On-going Costs	Will the on-going costs of the option be higher, lower or similar to current?
Cost-effectiveness	Will the option be more or less cost-effective than currently?
Affordability	Could the on-going costs of the option be delivered within the current funding or cost envelope?
Alignment with the wider NHS architecture and key relationships	Does the deployment support the principle of subsidiarity in the NHS and the regional or national aggregation of services where appropriate?
Equity and access	Will the option provide equitable access to patients and health care professionals?

Key risks associated with each option

Option	Risks
1.1 One national centre for Medicines information	• Transition – moving staff not plausible • Lack of external stimuli/competition • Risk management/limited diversification
1.2 Eight MI hubs and no spokes	• Duplication • Uneven distribution/limited links to new structures
1.3 Four MI hubs and 6 spokes	• Transition/determining optimal geographic locations for services as not all footprint equal
2.1 Four regional hubs for Medicines Assurance	• Distant from service needs • Potential for high logistical costs
2.2 MA presence in 10 delivery footprints	• Potential for increased costs for this function • Commissioners unlikely to fund laboratory facility as part of advisory function
2.3 MA trading account/provider based	• Fragmentation of services
3.1 National Medicines Safety service	• Distant from NHS/ineffective implementation
3.2 Four MS hubs, one per region	• Increased costs for this function/limited implementation
3.3 MS presence in 10 delivery footprints	• Increased costs for this function

Medicines Information								
	Feasibility	Workforce development and training	Transition costs	On-going direct costs	Cost-effectiveness	Alignment with wider NHS infrastructure	Equity and access	Total
Option 1.1: Centralised 1 national centre	-1 Far from current deployment	-1 Succession planning and workforce engagement more limited	-1 Involves significant movement of staff	1 Consolidated deployment likely to reduce on-going costs	0 Less effective deployment (workforce, alignment, and access) balanced by reduced cost	-1 Subsidiarity not applied	-1 National centre reduces local or regional presence	-3
Option 1.2: 8 hubs and no spokes	1 Realistic move from current	1 or 0 Similar to current, centralised resources available	1 Smallest cost impact of transition	0 Similar to current	0 Similar to current	-1 Little relationship to new structures	-1 Uneven distribution of resources	0 or 1
Option 1.3: 4 hubs and 6 spokes	1 Realistic to move from current	1 Centralised resources, plus wider impact	0 Costs managed within transition	1 Similar to current, potential for reduction	1 Benefits from specialist consolidation plus local effectiveness	1 Appropriate aggregation and alignment to wide NHS architecture	1 Deployment allows for distributed presence across NHS	6

Medicines Assurance (includes QA and procurement based on current functional groupings)								
	Feasibility	Workforce development and training	Transition costs	On-going direct costs	Cost-effectiveness	Alignment with wider NHS infrastructure	Equity and access	Total
Option 2.1: 4 hubs, one per NHS region	-1 Far from current deployment	-1 Risks to succession planning and engagement	-1 Likely involves significant movement of staff	1 Consolidation of services to reduce on-going costs	-1 Reduction in cost outweighed by negative outcomes in other criteria means reduced cost-effectiveness	-1 Lack of presence close to commissioners and providers	-1 Lack of distribution across the system	-4
Option 2.2: Presence in 10 delivery footprints	1 Realistic move from current	1 Supports succession planning and wider workforce development	0 Similar to current deployment	-1 Some increase in cost	1 More effective service	1 Regional presence close to wider NHS system	1 Distributed model providing access across the system	5
Option 2.3: Trading account/ provider based	1 Realistic move from current	-1 Fee for service likely to conflict with broad development agenda	-1 Likely decommissioning of services	-1 Duplication leading to additional cost	-1 Higher costs leads to reduced cost-effectiveness	0 Service directly to commissioners and providers but no co-ordination to align	-1 Lack of co-ordination doesn't ensure equity of access across the system	-4

Medicines Safety								
	Feasibility	Workforce development and training	Transition costs	On-going direct costs	Cost-effectiveness	Alignment with wider NHS infrastructure	Equity and access	Total
Option 3.1: One national service	1 Possible to extend current deployment to national service	-1 Not close to the workforce so doesn't support development	0 Could re-shape existing service to on a national basis	0 Re-deployment of existing resource	-1 Negative scores for alignment, equity and workforce development weigh on cost-neutrality	-1 Unlikely to be an appropriate aggregation of service	-1 Unlikely to provide adequate full coverage due to inappropriate aggregation	-3
Option 3.2: 4 hubs, one per NHS region	0 Far from current deployment	0 Closer to the system, but not sufficiently bedded out to provide improvement	-1 Likely movement of staff between SPS	-1 Some increase in cost through expansion of service	1 Reduction in costs lead to improvement in cost-effectiveness	0 Provides some alignment but not to the appropriate level to support customers	0 Some parts of the country may lack access as services too aggregated	0
Option 3.3: Presence in 10 delivery footprints	-1 Far from current deployment	1 Bedded out in wider NHS system close to workforce	-1 Likely movement of staff between SPS	-1 Some increase in cost through expansion of service	1 Increase in costs outweighed by broader improvements in effectiveness	1 Bedded out and aligned with system at an appropriate level to support commissioners and providers	1 Provides for geographical coverage of service	1

Preferred deployment options

148. The service should to be delivered within the overall cost envelope for SP Srvcs (estimated as £7.1m). There will need to be some rebalancing across the SPS functions (and staff potentially taking on different roles) in order to adhere to this, whilst at the same time securing the preferred deployment options and leadership and governance goals set out in the preceding section.

149. There may be some transitional costs of moving to the new deployment configuration (and to the new commissioning and accountability structures system). These are likely to be opportunity costs in terms of some staff re-training (by other specialist pharmacists), management time in terms of setting up the new governance structures and commissioner time in commissioning the service. These activities would likely displace some other activities; however the basis for these changes is to make the SPS more effective and spread patient benefits and NHS savings more widely. While these transitional costs cannot be quantified based on the Review authors assessment of the evidence they are likely to be small and be heavily outweighed by improvements in patient care.

150. The SPS should be identified as a national service with its constituent components deployed regionally and more locally:

- For Medicines Information the preferred deployment option is based on 4 hubs (one per NHS region) and 6 spokes, which together support the 10 NHS delivery footprints
- For Medicines Assurance the preferred deployment is a presence for quality assurance and medicines procurement in the 10 NHS delivery footprints
- For Medicines Safety the preferred deployment is a presence in 10 NHS delivery footprints

Conclusions

151. This review has identified that SP Srvcs constitute a critical resource for patient safety, medicines optimisation and the delivery of cost-effective care, and the provision of specialist advice, particularly in the context of complex issues involving medicines.

152. SP Srvcs are system-wide services that provide significant financial benefits, with savings directly attributable of at least 4 times their cost and in reality significantly more than that. They provide significant clinical benefits improving outcomes and patient safety for thousands of patients who come in contact with the NHS. Without SPS the level of risk of serious patient safety incidents in the NHS would likely rise significantly. The benefits are relevant to both commissioners and providers of NHS care.

153. For the future, a national SPS should be based on cost-effective deployment, delivery of equitable and sustainable services that align with new NHS structures and robust, long-term commissioning arrangements that secure patient benefit, service improvement and the development of expertise. This will require appropriate leadership, governance and accountability arrangements.

Key recommendations

1A **Organisation of the Specialist Pharmacy Service**

- There should be a single NHS Specialist Pharmacy Service (SPS), which is deployed regionally and more locally to provide equitable access to specialist pharmaceutical expertise
- The primary purpose of the Service should be to enable improvements in the safety and outcomes of patient care through the better use of medicines. It should support patients, clinicians, commissioners and providers in the delivery of medicines optimisation across the NHS
- To ensure access to necessary expertise across England and achieve value-for-money, the Service should be provided at a level of organisation greater than a local health economy

1B **Commissioning of the Service**

- The SPS should be directly commissioned by NHS England. This recommendation is based on a thorough assessment of different options. A priority is to determine whether this can be achieved by prescribing the Service in legislation for direct commissioning or via an alternative legal mechanism for NHS England to take up these responsibilities through agreement with the Department of Health
- The SPS should be commissioned against a national specification, which provides clarity to both service users and SPS providers on access, functions, levels of service and performance
- The SPS should be commissioned from designated trusts that can meet the specification. The commissioning intention should be a consistent and system-wide service for England

1C **Governance, accountability and leadership of Service**

- An SPS National Management Board and Implementation Group should be established
- A leadership team comprising Head of SPS, Assistant Head of SPS (Medicines Preparation) and Assistant Head of SPS (Medicines Safety) should be appointed
- These posts should be joined by nominated leads from Medicines Information and Medicines Assurance in the Implementation Group

1D **Funding of the Service**

- Deployment in relation to the national specification from 2014-15 should be delivered within an agreed overall cost envelope (estimated at £7.1m as the sum of existing commissioner and provider-based funding). Detailed work on costing the national specification will be necessary
- Adjustments in relation to staff costs resulting from Agenda for Change will need to be factored into future funding agreements. Proposed new posts should be drawn from the existing establishment
- Further work is required to determine whether QA laboratory facilities currently funded by commissioners should continue to be a commissioning responsibility

Other recommendations

2A **Functional groupings**: The NHS Specialist Pharmacy Service should be identified as a nationally co-ordinated service comprising three functional groupings:

- Medicines Information
- Medicines Assurance
- Medicines Safety

2B **Definition**: Based on analysis of functions and the associated evidence, the following definition is proposed for the SPS

The NHS Specialist Pharmacy Service is delivered using specialist pharmaceutical expertise and is provided across many health organisations. It exists primarily to support improvements in safety and the outcomes of patient care through the better use of medicines. In fulfilling these functions, it supports patients, clinicians, commissioners and providers in delivery of medicines optimisation across the NHS. To ensure access to necessary expertise and achieve value-for-money, the Service is provided at a level of organisation greater than a local health economy.

2C **Scope**: The scope of functional groupings of the SPS should be distinct from aggregated provider functions, which should be resourced by providers. The Service should enable access to specialist expertise that would not otherwise be available to commissioners or providers.

2D **Deployment**: The SPS should map to the 10 footprints of the NHS in England.

- For Medicines Information, the preferred deployment option is based on 4 hubs (one per NHS region) and 6 spokes, which together support the 10 delivery footprints
- For Medicines Assurance, the preferred deployment is a presence for quality assurance and medicines procurement in the 10 NHS delivery footprints
- For Medicines Safety, the preferred deployment is a presence in 10 NHS delivery footprints
- Size and composition of hubs, spokes and delivery teams will need to be guided by information on demand, as reflected by the number and complexity of providers of NHS services, commissioners and other users of the SPS in the different footprints (see Annex 6)
- Detailed work is required to determine the aggregated functions, or those requiring particular expertise, that should be the remit of the Specialist MI hubs, and the specific areas of expertise that each hub should lead on for the NHS in England
- Chief pharmacists of trusts that are commissioned to provide the SPS should have line management responsibility for staff delivering these services. Agreement of objectives and annual appraisal should be in the context of the governance and leadership arrangements.

Related issues and further work

3A **National web-based services**: The web platform for the SPS should be under MI operational responsibility, even where content is the responsibility of other functions.

- The portal should provide web pages for MI, MA and MS
- Under the MA function should be the proposed medicines shortages website, providing a focus for combined SPS actions to support the NHS response to medicines shortages, and the web-enabled Pro-File database of NHS manufactured unlicensed medicines
- Under the MS function should sit the Patient Group Directions website and advice in relation to non-medical systems of medicines supply and administration. This function could also assume lead responsibility for the Injectable Medicines Guide, working closely with MI for the development and assure of monographs.
- The portal should provide access online access to the monographs of the Injectable Medicines Guide

3B **Evaluation of medicines**: There should be collaboration to deliver evidence summaries for new medicines and new indications according to a shared horizon-scanning process and NICE accredited content development.

- In relation to the SPS, this activity should be focussed on designated regional MI Centres with the relevant experience and expertise
- Consideration should be given to how existing expertise outside the definition of SPS could be utilised efficiently in collaborative approaches (e.g. MTRAC, RDTC and LNDG)

- NHS England should consider whether the London Cancer New Drugs Group and the underpinning aspects of the MI service could be specifically supported for its potential contribution to the national chemotherapy Clinical Reference Group and to Domain 1 of the NHS Outcomes Framework

3C **Implementation phase**: Adoption of these recommendations will necessitate further work to develop the commissioning process and shape the deployment of the SPS in collaboration with current providers and commissioners of SP Srvcs. An early priority is confirmation of the mechanism by which NHS England can take direct commissioning responsibility

Declaration of interests

Ron Pate is currently employed on a part time basis in the Department of Medicines Management at Keele University. He will retire from this post in June 2013.
David Webb is Pharmacy Advisor to the London Specialised Commissioning at NHS England. He holds professional accountability and oversight for the East and South East England Specialist Pharmacy Services.

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Annex 1 - Terms of Reference

Review of Specialist Pharmacy Services in England

Summary

The Department of Health has initiated a review of Specialist Pharmacy Services (the Services) in England to determine the need, configuration and funding mechanisms for the Services in the new system. It will consider their contribution to the NHS Commissioning Board's goals for achieving better outcomes, quality and value through medicines optimisation and the way the Services should respond to the changing NHS environment. The review will gather quantitative and qualitative evidence, the views stakeholders and actively engage with employers and commissioners. The review will propose a commissioning and/or funding model that delivers value for money and is sustainable for the longer-term.

Background

The commitment to undertake a review is part of the transitional arrangement for securing the Services during 2013-14. These terms of reference describe the scope of the review and the intended approach.

Scope of the review

In the context of the reformed health and social care system, the review will:

- Provide a definition of the Services and a mapping of the Services across England
- Describe the risks and implications of no longer commissioning and providing these services (the 'do nothing' scenario)
- Propose a model for future service provision that is outcome-based, focussed on safe, effective use of medicines and which will support optimal patient experience. The model should include the use of web based technologies.
- Propose a contemporary modus operandi for the Services that builds on existing good practice, is patient centred, outcomes based and delivers efficient modernised approaches that supports medicines optimisation
- Make recommendations on the optimal and cost effective configuration of the Services to enable equitable access and take account of national, regional and local system requirements, including that the NHS Commissioning Board is a single organisation, and the legal framework of the new system
- Propose a commissioning and/or funding model that delivers value for money, is appropriate with reference to users of the Services and is sustainable for the longer-term
- Set out what further work would be necessary to operationalise the recommendations across 2013/14

Whilst the transitional arrangement underwritten by DH during 2013-14 relates to the Services commissioned collaboratively by PCTs and SCGs, the scope of the review will include the Services funded by providers and PCTs/SCGs.

Governance

A Project Board, chaired by Dr Keith Ridge, will provide oversight of the review and its progress. The chair will report to NHS England. The review will be led by Keith Ridge, supported by David Webb, Director of Specialist Pharmacy Services for E&SE England and Ron Pate, Consultant, on behalf of the Project Board.

Proposed Board members include:

Anthony Kealey, Head of Partnerships, NHS England
Bruce Warner, Deputy Director of Patient Safety, NHS England
Clare Howard, Deputy Chief Pharmaceutical Officer, NHS England
Matthew Donaghy, Director of the Commissioning Support Hub, NHS England
Professor Liz Kay, Association of Teaching Hospital Pharmacists and Royal Pharmaceutical Society

Felicity Cox, Kent and Medway, NHS England
Bruce McElroy, Chief Pharmacist, Royal Shrewsbury Hospitals,
Keith Ridge, Chief Pharmaceutical Officer, NHS England (Chair)
Celia Davies, Lay representative
David Webb, Director of Specialist Pharmacy Services for E&SE England
Ron Pate, Consultant
Omar Idriss, Office of the Chief Analyst, DH

The Board will seek other expertise as required to deliver the recommendations, including human resources, commissioning and finance advice.

Board members will submit a declaration of interest to the Project Board Secretariat

Analytics and Secretariat

Secretariat to the project will be led by Diana Kenworthy (DH-MPI)
Analytical support will be provided from the Office of the Chief Analyst, DH

Approach

The review methodology will establish a definition of the Services and, from that, determine a baseline of availability across England, including establishment and funding. The baseline will take account of deliverables as well as characterisation of the functions, existing commitments and initiatives and planned developments.

Evidence will be gathered from stakeholders and opinion-formers on the role that the Services should perform in the new system, including criteria by which options can be assessed. This will include the implications for costs and cost-effectiveness, and the risks, of different options .This also will involve consideration of the NHS context and external factors such as technology and service user behaviour.

Comparison of the baseline with these success criteria will identify the gaps that need to be addressed. Options for closing the gaps will be formulated, from which the final report will make recommendations.

Communications

The review will engage with the specialist groups relevant to the Services, commissioners and other users of the Services, employing organisations and the SHA Pharmacy and Prescribing Leads, the Royal Pharmaceutical Society and General Pharmaceutical Council. A key line of communication with the NHS in each region will be through the SHA Pharmacy and Prescribing Leads.

Timetable

January 2013	Review commences
30th January 2013	Proposed date of stakeholder workshop
Early March 2013	First draft of report for the Project Board
End March 2013	Final report submitted

Annex 2 - Project Board members

Anthony Kealey	Head of Partnerships, NHS England
Bruce Warner	Deputy Director of Patient Safety, NHS England
Clare Howard	Deputy Chief Pharmaceutical Officer, NHS England
Matthew Donaghy	Director of the Commissioning Support Hub, NHS England
Professor Liz Kay	Association of Teaching Hospital Pharmacists and Royal Pharm. Soc
Felicity Cox	Kent and Medway NHS CB AT
Bruce McElroy	Chief Pharmacist Royal Shrewsbury Hospitals
Keith Ridge	Chief Pharmaceutical Officer, NHS England
Celia Davies	Lay representative
David Webb	Director of Specialist Pharmacy Services for E&SE England
Ron Pate	Consultant
Omar Idriss	Office of the Chief Analyst, DH

Annex 3 – Stakeholder event list and letters of invitation

Trevor Beswick, Chair UKMi Executive

Mark Jackson, Chair NHS QA Committee

Steve Brown, ATHP Chair

David Miller, President GHP

Sue Dickinson, Director of Pharmacy, Regional Drugs and Therapeutics Centre, Wolfson Unit, Newcastle upon Tyne

Prof S R Chapman, Medicines Management Keele University

Andy Alldred, Chair National Pharmaceutical Supply Group

Dennis Lauder, Chair Pharmacy Market Support Group

Maria Palmer, Chair UK Radiopharmacy Group

Jeanette Kendall, Chair National Pharmaceutical Production Committee

Peter Rhodes, Chair Pharmacy Aseptic Services Group

Susan Keeling NHS Injectable Medicines Guide

Angela Bussey – Content manager, PGD website

Linda Dodds – Director of Medicines Use & Safety, E&SE England Specialist Pharmacy Services

David Cousins – Director Medicines Safety NHS CB

Bruce Warner – Director Patient Safety NHS CB

Malcolm Qualie – Pharmacy Lead, Specialised Commissioning, NHS CB

Jonathan Horgan, Birmingham and Black Country CSU

Gaye Lewington, Associate Partner, Medicines Management, Kent and Medway CSU)

Beryl Bevan, Chair, Pharmaceutical Advisers Group

Dr Stuart Ward Hampshire AT

Felicity Cox, Kent and Medway NHS CB AT

Jonathan Underhill, NICE

David Erskine, London Cancer New Drugs Group

Will Horsley, North East Treatment Advisory Group

SHA Pharmacy and Prescribing Leads

Helen Gordon, Chief Executive, Royal Pharmaceutical Society

Duncan Rudkin, Chief Executive and Registrar, General Pharmaceutical Council

Bernadette Sinclair Jenkins, MHRA

Andrew Kenworthy, Director of CSU Transition

Anthony Kealy, Head of Partnerships, NHS CB

Omar Idriss, Economic Adviser, Financial Planning, Monitoring and Analysis, DH

Tim Root, Specialist Pharmacist, Clinical Governance & Technical Services

Ron Pate and David Webb, Review Leads

Dear Colleague

Review of Specialist Pharmacy Services in England
Stakeholder day January 30th at the Royal Pharmaceutical Society

Further to my letter dated January 11th regarding Specialist Pharmacy Services (copy attached) I can confirm that the proposed stakeholder day to explore options for future provision, delivery and deployment of SPS will be held on January 30th at the Royal Pharmaceutical Society, 1 Lambeth High street London. Tea/coffee will be available from10 am with the meeting starting at 10.30 am and be expected to close by 4pm. The day but will consist of two scene setting plenary presentations followed by workshops designed to inform key issues in relation to the review.

Please note you are invited to send up to X people, including yourself if available (or an appropriate substitute), to represent your organisation/area of expertise at this meeting. SHA Pharmacy and Prescribing Leads are also invited to attend. Please confirm attendance with Carla Glanville (Carla.Glanville@dh.gsi.gov.uk) no later than January 24th.

Yours sincerely

Dr Keith Ridge CBE
Chief Pharmaceutical Officer

Dear Colleague

Review of Specialist Pharmacy Services in England
Stakeholder day April 25th at the Royal Pharmaceutical Society

Further to my letter dated March 8th thanking you for your contributions to the review of Specialist Pharmacy Services and setting out progress with the review (copy attached) I can confirm that another stakeholder day is to be held to consider recommendations arising from the review. This will be held on April 25th at the Royal Pharmaceutical Society, 1 Lambeth High street London. Tea/coffee will be available from10 am with the meeting starting at 10.30 am and be expected to close by 4pm.

The day will consist of scene setting plenary presentations followed by workshops designed to inform key issues arising from recommendations in the review including practicalities, risks and benefits of operationalisation. Further details will be provided nearer to the date of this meeting. The purpose of this letter is to give you advance notification of the date and adequate time to identify suitable attendees.

Please note you are invited to send up to X people, including yourself if available (or an appropriate substitute), to represent your organisation/area of expertise at this meeting. SHA Pharmacy and Prescribing Leads are also invited to attend. Please confirm attendance with Carla Glanville (Carla.Glanville@dh.gsi.gov.uk) no later than April 16th.

Yours sincerely

Dr Keith Ridge CBE
Chief Pharmaceutical Officer

Core questions: morning session of January 30, 2013

What functions of SP Srvcs does the system need and at which NHS organisational level? What are the risks in the absence of these?	• SP Srvcs are inextricably linked and all need to work collaboratively • Standards setting and guidance for SP Srvcs is needed • A core national definition of SP Srvcs is needed • Needs to be focussed on patient outcome • Must utilise added value from experts • A strong national specification for services is needed • Risks – loss of efficacy, unnecessary service duplication, reduction in value for money and quality, loss of patient safety, patient harm
What functions of SP Srvcs could be core to a national specification? Is a national specification appropriate?	• National delivery needs a national specification • SP Srvcs requirements at a local level will be for local decision but there will be synergies between national and local SP Srvcs that drive value • Service transformation is needed to meet the needs of the new NHS landscape including assurance of quality standards in care homes, support for patients and professionals, leadership on clinical standards, data sharing • Consideration should be given to a new name
How could SP Srvcs be cost-effectively configured for the new NHS? What reporting arrangements and accountabilities should be in place?	• SP Srvcs need to be nationally funded but locally commissioned with line of sight through to the NHS England and DH • Hub and spoke model may be the way forward • SP Srvcs may be co-dependent but don't have to be co-located • Regional arrangement offers economies of scale, presents an opportunity for centres of excellence and SP Srvcs leadership that supports sustainability and local delivery • Exploit opportunities from technology/mobile working • Matrix system and do it once and share approach needed • Oversight via scrutiny board involving patients and the NHS England
How should SP Srvcs be commissioned or funded: locally, nationally, hybrid or a different approach? What are the strengths/weaknesses? What criteria should we use to assess the options?	• Equity of SP Srvcs availability and consistency in delivery is important • There is value in nationally commissioned services based around providing equity for patients • SP Srvcs need to have and demonstrate leadership

Additional questions: afternoon session January 30, 2013

Consider web requirements for SP Srvcs and opportunities to consolidate other web resources	• SP Srvcs should be accessed through a single portal with areas for patients and professionals • NHS strategies should be captured through networks • Medicines safety needs to be core in NHS model and perhaps patient.co.uk • Transparency of service delivery and outcomes needed
Consider centralisation of services, specialist files, event centres majoring on particular therapeutic topics/patient groups and web-based platforms	• Accessing from web must not be the only way to access this information, as not all patients will have web access • Need to think about mobile devices as many NHS professionals work outside their base
Consider if there is still a need for medicines evaluation (e.g. growing role of NICE) and if so whether advice should be to NHS England specialised commissioning, Area Prescribing Committees, providers or CCGs. What are the opportunities for collaboration?	• SP Srvcs have a role with CCG and the relationship with NICE needs to be described if this is not implemented • NICE does not have local level of engagement so we need to make sure SP Srvcs give them a degree of authorisation so it is fit for purpose • It would be enabling to the development of SP Srvcs, in delivering what GGGs want, if NHS England would endorse SP Srvcs • Medicines optimisation quality standards have been referred to NICE • The Medicines Prescribing Centre will have regional posts that sit within the NICE Implementation Team
Consider technical services interaction with SP Srvcs, particularly relating to rationalisation of services and products (including “Pro-File”), and sustainability	• Opportunity to build links around patient safety • Agenda across primary and secondary care need much more connectivity
Consider medicines wastage and shortages and links with Quality Assurance and purchasing for safety	• The NHS sees/needs SP Srvcs as a resilience crisis specialist service to get you out of a problem • The QA/procurement work done in secondary care could be translated to primary care e.g. work on shortages • There is an expectation to move to a more commercial NHS to provide a range of functions. These functions will need to be worked through and some part of the service will need to be more innovative • There are economies of scale in having services together. If separated there would need to be a fairly sophisticated contracting model

Table of stakeholder responses: morning session of April 25, 2013

How should resources be matched to the different footprints? Are there new clients/users to be considered?	• Determining the distribution of resources across the system may have different criteria for different functions (QA may have different requirement to procurement and be affected by local activities, e.g. manufacturing units) • Footprint should be matched to need • A national service framework should determine equity of resource allocation • New customers may include community pharmacy, GPs (formulary database example), CCGs (shortages information system), PH, LAs and care homes • There is a need to co-ordinate and work with other services, as with pandemic flu
How should the concept of the information portal be progressed from the current range of web platforms?	• One portal should point to different websites; or two portals (NHS evidence and SPS) • A task and finish group to address this and the governance arrangements • International clients should pay for access • Use for posting of quality or other alerts and links to manufacturing units or other pro-active information
What should be the key steps, and what are the likely issues, in an implementation process for the Specialist Pharmacy Service?	• Determine equity of access, a national service specification and customer base • Underpin service specification with a business case; business cases needed for service development • Map resources and transition and control funding centrally and redistribute accordingly • For Medicines Safety, identify how it is currently provided in places where not in the scope of SP Srvcs • Develop KPIs and core service definition plus contract duration, spend to save initiatives etc? • Address risks including loss of input to specialist committees, destabilising services, business continuity, conflicts of interest, redundancy and transition costs • Define best hosting model • On-going communications process needed
What other efficiencies might be gained in changing from current service provision?	• Best practice models • Link with professional networks; do once and share • MI Databank to move to a national platform • Engagement with community pharmacy to improve medicines optimisation • Consolidate back office functions in footprints • Common products and service specifications

Consider medicines wastage and shortages and links with Quality Assurance and purchasing for safety	• Matrix working between QA, MI and MS to provide evidence to support product entry (e.g. biosimilars) and incident data to support Medicines Procurement • Work closely with industry and regulatory authorities on safety • Collaborative working between QA, MS and MP will be important in managing shortages

Stakeholder responses - afternoon session of April 25, 2013

Medicines information • What activities and functions should sit in the regional MI hubs? • What should be the role of the MI 'spokes' in supporting local footprints and relating to MI hubs? • How should collaborative arrangements for medicines evaluation be progressed with NICE?	• Hub: define what is highly specialist for MI and can be done once for England e.g. medicines for use in children and mental health, renal, pregnancy, breast milk etc, cancer drugs fund (CDF); engage with NHS England and DH; horizon scan for new medicines, support contractual arrangements for PbR excluded drugs (IFRs via one centre) and advise accordingly; account for work and E&T undertaken in spokes; create tools for workforce development • Spokes: engage with CCGs / Health and Well Being Boards / LAs; need to be reactive and devolved; link with Medicines Assurance and Medicines Safety, local GPs and community pharmacies, NICE implementation and IFR CCG decision process; support local delivery footprint and national services • Collaboration with NICE needs clear set of processes and tasks; spokes could have a role in implementing evidence summaries locally
Medicines Safety • How should MS relate to the delivery footprints? • How should the relationship between MS and medication safety team at NHS England be developed?	• Grow MS roles out of MI and QA; identify roles that currently have MS responsibilities but are not in scope of the SPS • Facilitate exchange of good practice and cascade; facilitate local organisations to manage risks • How to measure activity: incident reporting, harm reduction, deaths, processes, website hits and effectiveness in primary car • Identify appropriate way to obtain data analysis skills • Define responsibilities of MS leads (one per delivery footprint) and the deliverables • Enable other disciplines in the SPS align with MS agenda

Medicines Assurance • How should Medicines Procurement and Quality Assurance work more closely to promote safety and cost-effectiveness, manage shortages and reduce waste? • Should laboratory functions be provided funded?	• QA and MP can build on existing good practice e.g. NHS Supply Chain Excellence Programme and quality elements built into procurement process • QA to increase activity due to growing demand for unlicensed medicines e.g. vetting medicines suppliers, global sourcing of medicines, risk register of suppliers to support sustainability • Decrease waste by improving shelf life and developing better stability data • Working closer to promote cost effectiveness • Laboratory services should be provider funded
Leadership • What should be the key responsibilities of the Technical and Medicines Safety leads posts (given that these do not have direct line management links to the service)? • How should medicines manufacturing, aseptic services and radiopharmacy work with the Technical lead?	• Visibility and marketing; outward facing to commissioners • Co-ordination, horizon scanning and communications from senior team and between services including networks • Assure that services are adequate, e.g. clinical trials • Accountability for public safety • Lead on assurance, standards, peer review and audit to ensure service is custodian and advocate of patient safety and a conduit for spreading best practice • Change description of the Technical Lead role

Annex 5 - Case studies of the contribution of SP Srvcs

NB Selected examples are included; it is not intended to be a comprehensive summary from each constituent service

Medicines Information

- **Answering complex clinical enquiries about medicines**
  UKMi provides bespoke advice to clinicians to help treat individual patients safely about 300,000 times a year. This improves the quality of prescribing, and prevents errors and patient harm. Over 230 commonly asked questions about medicines have been answered and published on NeLM. These evidence-based "Q&As" are reviewed regularly to ensure currency, and each one is used by around 1000 people every year. A Q&A may save the user around 1 hour of work each time its accessed, which mean available Q&As save around 200 000 hours of work (80 WTE) across the NHS per year.
- **Delivering health promotion messages**
  UKMi delivers a regular bulletin about medicines to support practitioners during major national health campaigns. During the recent pandemic influenza campaign, UKMi delivered multiple information resources to prevent duplication at Trust and PCT level.
- **Horizon scanning for new medicines likely to have a budgetary impact**
  UKMI produce two key horizon scanning resources for the NHS – New Drugs On-line which is a free database updated daily (currently 1470 registered users) and the annual Prescribing Outlook Series – available electronically and sent as hard copy to key decision makers (2350 hard copies sent out and a further 1070 downloaded in 2009). These resources are the most commonly used by Hospital Trusts and PCTs to develop their local development plans each year. If we assume that each copy distributed prevents 20 hours work at a local level these products reduce work duplication by almost 70,000 hours (equiv to 40 WTE across the NHS)
- **Providing an MI-run patient-helpline**
  The CQC routinely survey patients about support provided for medicine-related problems after discharge. A suitably advertised MI-run patient helpline is an ideal way to ensure that this requirement is met and to provide early warning about areas of risk.

Source: Evidence Submitted to the Review by UKMi

Medicines Procurement

- **National supply chain resilience**
  To improve the national resilience around the Intravenous (IV) fluid supply chain, a Commercial Medicines Unit (CMU) funded trial in one NHS Region was undertaken to gauge the acceptability of semi-rigid IV fluid containers. These containers proved acceptable in most settings which meant that an additional supplier of IV fluids was available to the UK market. This benefited the UK by demonstrating that semi-rigid containers, which are prevalent in the European market, can be transferred to the UK market. This improves the resilience of the supply chain by adding another organisation to the IV fluid market. The Region benefited financially by about £200k as the semi-rigid containers were more cost-effective than those currently used.
- **Information for patients on shortages of cancer medicines**
  A half a day session per week of specialist procurement pharmacist time was funded by a Cancer Network to provide specialist advice around Patient Access Schemes (PAS) and development of a scheme whereby information around shortages of cancer medicines was disseminated directly to relevant clinicians. This improved the speed of

information flow and allowed patients to be given relevant and appropriate information in a timely way instead of them hearing via the national press. This reduced the sense of alarm in patients and gave them greater confidence that the problem was being managed. This system was tested and the benefit proved during a recent shortage of BCG vaccine for treating bladder cancer, during which clinicians were kept fully informed of the progress of the shortage, availability of acceptable replacement products and the risks associated with some of the unlicensed alternatives available globally.

Source: Evidence submitted to the Review by North-East Procurement

Medicines Use and Safety

- **Improving prescribing in Care Homes**
  Medicines Use and Safety in London provided support to improving prescribing in care homes, by running workshops and developing a 'top tips' resource for staff. This supported the QIPP agenda, to improve quality and release cost savings from inappropriate and wasteful prescribing in the care home environment. Approximately 300 patients in nine care homes in Lambeth were reviewed using the top tips. Direct annual cost savings of £100,000 were identified from GP prescription changes, plus significant quality issues addressed (polypharmacy, reduced waste, improved medicines handling processes). Changes were innovative and led to a positive patient and staff experience. In Hounslow the top tips document savings of £162,000 over one year were achieved. As a result the project has been continued for 3 years
- **Improving IV therapy service provision in primary care**
  This supports the move to care closer to home by improving the safety and governance of IV therapy in the patient's own home (specifically outpatient parenteral antibiotic therapy (OPAT). It included a collaborative audit of practices in community health services and development of a Commissioning for Quality and Innovation (CQUIN) payment framework for OPAT services for 2013-14. The results of the audit were shared with pharmacy and nursing colleagues. Major issues in communication, governance and safety highlighted with current services and the CQUIN was adopted by local commissioners. A fully functioning OPAT service can save 8,500 bed days pa. At an average cost of £200 per bed day, this would realise savings of approximately £1.7m to the organisation. In year one of adopting the CQUIN up to £500K could be realised by the organisation initiating the service. Benefits would also include improved quality of care, better patient experience and reduced hospital-acquired infections.
- **Improving prescribing in Offender Health**
  MUS provided an overview of the prescribing and handling of medicines used in the treatment of neuropathic pain in prisons (Gabapentin and Pregabalin). There is known abuse potential for these medicines in offender health. The volume of prescribing across prisons and immigration removal centres (IRCs) was unknown with no usual method for collecting benchmarking collaborative data. Patient safety issues have been associated with the prescribing of both of these drugs including deaths in custody and diversion.
  MUS were supported by Offender Health Commissioners and the Ministry of Justice to extend a project across all English prisons to provide the first ever opportunity to analyse prescribing in detail across the prison/IRC sector. This included a collaborative audit and survey offered to all prisons (127) and IRCs (12) in England to provide benchmarking and comparative analyses of: governance, use and prescribing of these medicines in prisons. 97 sites participated in the audit/survey with a total of 1,822 prisoners taking these medicines (provisional pending final report Q1 2013/14). The audit determined that 2.82% of the prison population are taking these medicines, about

double the rate in the general primary care population, identifying the potential for reduction and cost savings.

The total annual cost of prescribing in prisons for these two medicines based on the data is £1.27m with most of this cost being due to pregabalin use (£940k). This work demonstrated that 63% of prescriptions originated within prisons (not primary care). If prescribing was reduced to that of primary care savings would be in the region of over £600k annually to the national primary care prescribing budget. Within prisons cost savings would reduce the need for nursing capacity to administer the drugs (54% of patients surveyed had every dose of these medicines supervised)

Source: Evidence submitted to the review by Medicines use and Safety Division – East and South-East England Specialist Pharmacy Services

- **MUS and Evaluation: potential for collaboration**
  As part of the Review the authors assessed evidence submitted by the different services that constitute SPS. There were clear overlaps across the services, where closer collaboration would be beneficial. For example, medicines use and safety and medicines evaluation units submitted work that had been done on the evaluation and safety of non-steroidal anti-inflammatory drugs NSAIDs and gastro-intestinal (GI) bleeds. Data to support comparative analysis and value estimates required by the medicines and safety unit, but to which they did not have access, was easily available to the medicines evaluation unit. There was clear potential for effective collaboration which would improve the potential for medicines safety improvements for patients.

Pharmaceutical Quality Assurance

- **Response to the flu pandemic – stability of Tamiflu (Oseltamivir) oral solution**
  NHS Manufacturing units and Regional QA services through the Pharmaceutical Quality Assurance (PQA) committee responded to a Department of Health request to safely manufacture Oseltamivir (Tamiflu) oral solution in response to a national flu pandemic. The oral solution was unavailable from commercial pharmaceutical companies, placing patients at risk who could not take tablets (e.g. children). The PQA committee co-ordinated research and development of a formulation and the associated stability study was carried out by an NHS Regional laboratory. This allowed medicines to be safely manufactured to high quality and the extended stability data allowed the medicines to be stockpiled by the NHS in anticipation of an influenza outbreak.
- **Packaging & Labelling for safety; collaboration with the Pharmaceutical industry to reduce the risk of medication errors**
  To support the prevention of adverse medication related events for patients and provide financial benefits through tendering. Regional Quality Assurance (QA) specialists frequently work with the Pharmaceutical industry to improve medicine packaging and labelling to mitigate the risk of medication errors. One example is where a Regional QA specialist worked with a company to promote a “design for safety culture” to reduce the risks of selection errors in dispensaries. This case study demonstrated an effective outcome relating to a complete redesign of the corporate livery following on from a quality assessment during a generic medicine tender.

Source: Evidence submitted to the Review as part of National QA submission

Annex 6 – Demand data to support recommendations for geographical configuration of the SPS

Footprint[18]	Name of Area Teams (ATs) *[specialised lead]*[19]	ATs	Clinical Senates[20]
NE, N Cumbria and Hambleton & Richmondshire	(1) Durham, Darlington & Tees (2) Cumbria, Northumberland, Tyne & Wear *[specialised lead-R]*	2	NE, N Cumbria and Hambleton & Richmondshire Districts
Yorkshire & The Humber	(1) North Yorkshire and The Humber (2) South Yorkshire & Bassetlaw *[specialised lead]* (3) West Yorkshire	3	Yorkshire & The Humber
North West	(1) Cheshire, Warrington & Wirral *[specialised lead]* (2) Greater Manchester (3) Lancashire (4) Merseyside	4	Gr Manchester, Lancs and S Cumbria; Cheshire & Merseyside
East of England	(1) East Anglia *[specialised lead]* (2) Essex (3) Hertfordshire & the South Midlands	3	East of England
East Midlands	(1) Derbyshire & Nottinghamshire (2) Leicestershire & Lincolnshire *(specialised lead-R]*	2	East Midlands
West Midlands	(1) Arden, Herefordshire & Worcestershire (2) Birmingham & the Black Country *[specialised lead]* (3) Shropshire & Staffordshire	3	West Midlands
South West	(1) Bath, Gloucestershire, Swindon & Wiltshire (2) Bristol, N Somerset, Somerset & S Gloucestershire *[specialised lead]* (3) Devon, Cornwall & Isles of Scilly	3	South West
Thames Valley and Wessex	(1) Wessex *[specialised lead-R]* (2) Thames Valley	2	Thames Valley; Wessex
South East Coast	(1) Kent & Medway (2) Surrey & Sussex *[specialised lead]*	2	South East Coast
London	(1) North East London (2) North West London (3) South London; London region *[specialised lead-R]*	3	London
England total	27 Area Team	27	12 Clinical senates

[18] Specialised commissioning footprints

[19] Source: NHS CB website - http://www.commissioningboard.nhs.uk/files/2012/11/op-model.pdf

[20] Clinical senates briefing pack http://www.commissioningboard.nhs.uk/resources/networks-senates/

Commissioners, providers and populations

Footprint	CCGs[21]		Health and Well-Being Boards[22]		Population (000s)[23]		NHS acute trust providers[24]		Mental health trusts[25]		Prisons[26]	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
NE, N Cumbria and H&R	13	6%	13	9%	3,077	6%	10	6%	2	4%	11	7%
Yorkshire & The Humber	23	11%	15	10%	5,352	10%	14	9%	6	11%	18	11%
North West	32	15%	22	14%	6,425	12%	26	16%	8	15%	19	12%
East of England	22	10%	13	9%	6,621	13%	21	13%	6	11%	16	10%
East Midlands	17	8%	8	5%	3,607	7%	6	4%	5	9%	17	10%
West Midlands	22	10%	14	9%	5,421	11%	19	12%	7	13%	15	9%
South West	11	5%	13	9%	4,476	9%	15	9%	6	11%	15	9%
Thames Valley and Wessex	19	9%	15	10%	4,535	9%	11	7%	4	7%	19	12%
South East Coast	20	9%	6	4%	4,302	8%	12	7%	3	5%	23	14%
London	32	15%	33	22%	7,758	15%	27	17%	8	15%	12	7%
England total	211		152		51,574		161		55		165	

[21] Calculations based on grouping local area teams along current SHA footprints, except for Cumbria, Northumberland, Tyne & Wear which included as part of the North-East https://www.wp.dh.gov.uk/commissioningboard/files/2012/06/lat-senates-pack.pdf

[22] Calculations on the same basis as for CCGs

[23] Based on GP registered practice lists for CCGs in the area

[24] Based on DH postcode mapping of acute providers using information from the Organisation of Data Services (note: there are 5 providers missing)

[25] Based on Hospital Episode Statistics break down of provider by SHA and NHS Choices list of MH trusts and FTs which provide MH services

http://www.ic.nhs.uk/hes

http://www.nhs.uk/ServiceDirectories/Pages/MentalHealthTrustListing.aspx

[26] List of prisons from Organisation of Data Services *(add link)* and Review Team mapping to regions

Medicines spend

Region	Medicines spend, primary care[27]		Medicines spend secondary care, dispensed in community[28]		Medicines spend secondary care, issued in hospital[29]	
	Amount (£m)	%	Amount (£m)	%	Amount (£m)	%
NE, N Cumbria and H&R	420	6%	5	3%	173	6%
Yorkshire & The Humber	913	12%	10	6%	319	11%
North West	1,293	17%	24	14%	387	13%
East of England	809	11%	22	12%	232	8%
East Midlands	680	9%	13	7%	182	6%
West Midlands	750	10%	12	7%	236	8%
South West	646	8%	22	12%	271	9%
Thames Valley and Wessex	426	6%	19	11%	141	5%
South East Coast	709	9%	15	8%	184	6%
London	959	13%	34	19%	760	26%
England total	7,604		175		2884	

[27] Data for 2011-12; Source: Information Centre and DH mapping. Original data for PCTs, mapped to CCGs based on GP practices membership of respective CCG and PCT. Apportionment made based on GP registered lists, where mapping from PCT to CCG is not one-to-one

[28] Data for 2011-12; Source: Information Centre and DH mapping, based on mapping to SHA regions as per drug spend in hospital (next footnote)

[29] Commercial Medicines Unit – based on pharmex data, this break down is based on 10 Strategic Health Authority break down. This is not a direct mapping to specialised commissioning footprint. In this case no adjustment has been made for Cumbria, Northumberland, Tyne and Wear and Dorset which are areas that have "moved" regions. Nominal gross amounts provided commercially in confidence so supressed in this table

Annex 7 – Baseline map of Specialist Pharmacy Services

NHS England Region	Service	Bases / Location	FTEs (sourced from SHA leads stock take or data submission templates)	Footprint
North	Medicines Information	**North West Medicines Information Centre** Liverpool PCT **North-East Regional Medicines Information Service** Newcastle upon Tyne NHS FT	9.9 FTEs (Includes NHS D) 8.53 (includes NHS D)	North West (plus national library for medicines in dentistry) North East and primary care in Y&H (plus national library for medicines in pregnancy)
	Quality Assurance	**North West** Stockport NHS Foundation Trust and Liverpool PCT **North East** Newcastle-upon-Tyne NHS Foundation Trust **Yorkshire and Humber** Leeds Teaching Hospital NHS Trust	Estimate of regional QA = 3.5 FTE (Trading account with providers) 0.9 FTE 1 FTE	Providers in N West, Y&H, West Midlands North East and North Cumbria Provider funded
	Medicines Procurement	**North West** Regional Specialist Procurement Pharmacist Northwest **North East** NE Pharmacy Procurement Group **Yorkshire and Humber** Leeds Teaching Hospitals NHS Trust	0.8 FTE 1 FTE 0.5 FTE estimated for SP Srvcs	North West providers North East Yorkshire and Humber providers

NHS England Region	Service	Bases / Location	FTEs (sourced from SHA leads stock take or data submission templates)	Footprint
	Medicines Use and Safety	No service	No service	No service
	Medicines Evaluation	**North East** RDTC		North East and Manchester
Midlands and East	Medicines Information	**Trent MI** University Hospitals Leicester **West Midlands MI** Good Hope Hospital (Heart of England NHS Foundation Trust). **E&SE England Service** Ipswich Hospital	Pharmacists 2.5 FTE; admin 1 FTE Pharmacists 2.8 FTE; admin 1.4 FTE 4.48 FTE	East Midlands (excl. MK) and South Yorkshire West Midlands East Anglia and
	Quality Assurance	**E&SE England Service** NHS Norfolk **West Midlands** **East Midlands** Nottingham University Hospital	2.81 FTE Decommissioned 1 FTE	East of England and Northampton Decommissioned East Midlands (excl. Northants & MK)
	Medicines Procurement	**E&SE England Service** Southend University Hospital **West Midlands** **East Midlands** University Hospitals Leicester	0.8 FTE 1 FTE proposed 0.4 FTE	East of England and London East Midlands

NHS England Region	Service	Bases / Location	FTEs (sourced from SHA leads stock take or data submission templates)	Footprint
	Medicines Use and Safety	**E&SE England Service**	0.8 FTE WTE (SC, 1.0; SEC, 1.2; London 3.4; Midlands and East 0.8)	East of England & Beds
	Medicines Evaluation	**West Midlands** MTRAC **East of England** Support to LNDG		West Midlands (with reviews made public nationally) Nationally available reviews
London	Medicines Information	**E&SE England Service London (N)** Northwick Park **E&SE England Service London (S)** Guy's and St Thomas' NHS Foundation Trust	9.87 FTE (Includes 0.87 for NHSD) 8.77 FTE (Includes 0.2 for NHSD)	N. London, Hertfordshire, Essex and LNDG S. London, South East Coast and LCNDG
	Quality Assurance	**E&SE England Service** Guy's and St Thomas' NHS Foundation Trust **E&SE England Service** Chelsea and Westminster	4 FTE 1 FTE	London, SE Coast, South Central and Milton Keynes Technical services and clinical governance
	Medicines Procurement	**E&SE England Service** North West London Hospitals	1 FTE	London and East of England
	Medicines Use and Safety	**E&SE England Service** North West London Hospitals	3.4 FTE	London and hub for E&SE England Service

NHS England Region	Service	Bases / Location	FTEs (sourced from SHA leads stock take or data submission templates)	Footprint
	Medicines Evaluation	**London** London New Drugs Group and London New Cancer Drugs Group	1 FTE (plus other posts embedded in MI)	London (plus products made available nationally)
South	Medicines Information	**Wessex** University Hospital Southampton **South West MI** University Hospitals Bristol NHS FT **E&SE England Service London (S)** See London entry	4.71 FTE 5.0 FTE (includes NHS D) See London entry	South Central and MK South West (provider funded) South East Coast
	Quality Assurance	**South West** North Bristol NHS Trust South Devon Healthcare NHS FT **E&SE England Service** Guy's and St Thomas' NHS FT	7.3 FTE (includes lab functions) 1.5 FTE See London entry	South West (provider funded) South East Coast, South Central and MK
	Medicines Use and Safety	**E&SE England Service** Several employers in SE C & SC **South West** No service	2.2 FTE	SE Coast and S Central
	Medicines Procurement	**South West** Peninsula Alliance **South Central** Host provider **South East Coast** Collaborative procurement hub	1 FTE 1 FTE 1 FTE	South West South Central South East Coast

NHS England Region	Service	Bases / Location	FTEs (sourced from SHA leads stock take or data submission templates)	Footprint
National Infrastructure	Medicines Information	**UKMi**	No posts funded specifically; regional directors undertake national functions	National
	Quality Assurance	**NHS Pharmaceutical Quality Assurance Committee**	No posts funded specifically; regional directors undertake national functions	National
	PGD website	**London (S) MI Service** Guy's and St Thomas' NHS FT	0.6 FTE	National
	(Proposed) Medicines shortages website			Proposed
	Pro-File	Content managed by Technical Services Specialist London	No funded support	National
	Injectable Medicines Guide/Medusa	**Imperial Healthcare**	No post funded specifically	National
	SPS website	Transitional arrangement on www.medicinesresources.nhs.uk	Not funded as part of NHS Evidence	National availability (previously NeLM)
	SPS leadership function	E&SE England Service NW Service	1 FTE 0.5 FTE (estimated)	

Annex 8 – Assessment against criteria for prescribed services

Assessment of SP Srvcs against four criteria the SofS for Health needs to have due regard to when deciding to prescribe services for direct commissioning by NHS England:

Criteria	Assessment
a) **the number of individuals who require the provision of the service or facility**	The proposed options for deployment of the services that NHS England would commission are either at a regional or national level. At a national level this would mean one service/facility for approximately 55m patients and 1.2 million NHS staff. At a local area team level this would be between 3 million and 10 million patients per area.
b) the cost of providing the service or facility	The costs of SP Srvcs are relatively small as a proportion of the NHS budget and on a per capita basis throughout the country. They are also small relative to the size of medicines spend. However the non-financial costs of CCGs commissioning these services individually would likely be disproportionate. Previously PCTs had a collaborative mechanism through which a high level of expenditure on specialised services was commissioned. This provided a mechanism to commission SP Srvces with proportionate cost (i.e. the additional costs of commissioning SP Srvcs were low, given that all other specialised services were being commissioned through this mechanism). The local collaborative mechanism for commissioning specialised services will not exist from 2013/14 onwards; separate arrangements for SP Srvcs would have to be put in place at disproportionate time and effort. If single CCGs commissioned independently the economies of scale in the commissioning process would be lost.
c) **the number of persons able to provide the service or facility**	There are a limited number of persons with the specialist expertise who can provide these services. Most are senior NHS staff, with considerable experience. There is also national expertise embodied within regional and local centres. A commissioning approach at national/regional level will maximise national use of the relatively small number of people who can deliver this service
d) **the financial implications for clinical commissioning groups if they were required to arrange for the provision of the service or facility**	The direct financial implications costs of commissioning the services are relatively small, however the non-financial costs in individual CCGs or CCGs collaboratively commissioning are considered disproportionate as discussed under (b) above. As these services are most suited to regional deployment, individual CCG commissioning would likely lead to duplication of effort and therefore increased costs to the NHS overall