

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013	Post Implementation Review
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1. Review Summary

1. This report presents the results of the statutory Post Implementation Review (PIR) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the 2013 Regulations”) consistent with requirements for post legislative scrutiny.
2. This review finds that the 2013 Regulations have largely achieved the original policy objectives which remain relevant and appropriate for the regulation of NHS pharmaceutical services in England. A number of unintended consequences are however identified, particularly in relation to distance selling premises (also known as distance selling pharmacies or DSPs). Several amendments to the 2013 Regulations are recommended to address these issues.
3. This review also recommends several amendments to the underpinning guidance to improve the consistency and operational application of these Regulations, reduce the burden on business and realise opportunities to more effectively deliver against the policy objectives of the 2013 Regulations.
4. The Department of Health and Social Care (DHSC) will continue to monitor the effectiveness of these Regulations and make any required legislative amendments to ensure they remain fit for purpose and reflect any changes within the sector. A further review of these Regulations will be published by 31 March 2023.

2. Aim and scope of the review

5. Under section 28 of The Small Business, Enterprise and Employment Act 2015, the Secretary of State is legally required to undertake a review of the 2013 Regulations which:
 - (a) sets out the objectives intended to be achieved by these Regulations;
 - (b) assesses the extent to which those objectives have been achieved;
 - (c) assesses whether those objectives remain appropriate; and
 - (d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.
6. This review, reflected in regulation 121 of the 2013 Regulations, does not bring about or introduce any changes to the 2013 Regulations. Any specific recommendations in this report that would require a change to these Regulations will be subject to separate consultation.

3. Overview of the Regulations

7. The 2013 Regulations came into force on 1 April 2013. They replaced the National Health Service (Pharmaceutical Services) Regulations 2012 and the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 as the Regulations which govern the

arrangements, in England, for the provision of NHS pharmaceutical and local pharmaceutical services under Part 7 of the National Health Service Act 2006.

8. The 2013 Regulations define:
 - a system for managing applications for inclusion on the pharmaceutical list to provide NHS pharmaceutical services based on pharmaceutical needs assessments (PNAs) published by Health and Well-being Boards every three years, and for managing listing applications that can be dealt with without reference to the PNA. The system for entry onto and changes to pharmaceutical lists is known as market entry;
 - terms of service requirements for community pharmacy contractors;
 - terms of service requirements for other providers of NHS pharmaceutical services on the pharmaceutical lists and related lists (dispensing appliance contractors and dispensing doctors);
 - procedures for dealing with fitness to practise for community pharmacy and appliance contractors (collectively known in the Regulations as chemists) and for dealing with breaches of their terms of service; and
 - a system of commissioning local pharmaceutical services - a form of contractual arrangement for the provision of NHS pharmaceutical services that is separate from the pharmaceutical list system.
9. A more detailed summary of the 2013 Regulations is provided at Annex B and a history of the regulations governing NHS pharmaceutical and local pharmaceutical services is provided at Annex C.

4. Regulatory amendments since 2013

10. Since they were introduced in 2013 there have been five sets of amendments to the Regulations which have resulted from the on-going oversight of DHSC, working with the NHS Commissioning Board (NHSCB), known as NHS England, and business sector stakeholders.
11. These amendments, outlined below and further detailed at Annex D, were introduced to ensure the 2013 Regulations are up to date, reflect current practice and implement the outcome of negotiations with respect to the community pharmacy contractual framework.

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014

12. Regulations 3, 4, 5 and 7 restructure regulations 13(1), 15(1), 17(1) and 20(1) of the 2013 Regulations, which relate to pharmaceutical list applications in respect of needs for, or improvements or better access to, pharmaceutical services. The changes clarify the drafting, with no intended substantive effect.
13. Regulation 6 amends regulation 18 of the 2013 Regulations to make it clear that the NHSCB needs only to have particular regard to one of the three listed criteria when considering an application to join a pharmaceutical list on the basis of an unforeseen benefit.
14. Regulation 8(a) and (b) amend the threshold criteria in regulation 24 of the 2013 Regulations

and Regulation 9 amends the threshold criteria in regulation 26. The changes at regulation 8(c) and 9(b) are also reflected in a change to regulation 64 of the 2013 Regulations, which set the conditions of entry in pharmaceutical lists for distance selling premises.

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2015

15. These Regulations amend Regulation 25 to clarify requirements for applicants for new distance selling premises who are already included in a particular pharmaceutical list. They amend the provisions of the 2013 Regulations under which a local pharmaceutical services contractor may choose to be a “health service body” and also change the terms of service for providers that dispense both drugs and some appliances, in relation to patient advice and clinical audits.

The National Health Service (Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service) Regulations 2015

16. These Regulations removed the restrictions which prevent the use of an electronic prescription for the prescribing by instalments of buprenorphine, diazepam or drugs listed in Schedule 4 and permits the electronic prescribing of drugs listed in Schedule 2 or 3 to the Misuse of Drugs Regulations 2001.

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016

17. These Regulations substituted the review provision in respect to the 2013 Regulations in regulation 121 with a new provision that requires further reviews after the first review and sets a five year maximum interval between reviews. They also amend the terms of service relating to entitlement to non-payment of an NHS prescription and access to NHS patients’ summary care records. If pharmacists do have this access, they are required to access those records when they are providing NHS community pharmaceutical services, where it is in the best interests of a patient to do so and doing so accords with the guidance known as “The NHS Care Record Guarantee”.

The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016

18. In 2015/16 the Department, supported by NHS England, consulted stakeholders on proposals for ‘Community pharmacy in 2016/17 and beyond’. The proposals covered a wide range of issues including how to better integrate community pharmacy within primary care as well as a reduction in funding.

19. One of the resulting reforms required a change to the 2013 Regulations. This involved a change to market entry requirements to facilitate the consolidation of pharmacies. This amendment prevents a new pharmacy entering the market if a contractor closes a pharmacy through consolidation with another and a gap in provision is not created.

20. In addition to this, Part 3 of these Regulations makes a provision for the prescribing and dispensing, by therapeutic radiographer independent prescribers and dietitians who are entitled to prescribe as supplementary prescribers. There were also related prescription charges’ changes that are not relevant to this review.

21. These reforms came into force in December 2016.

5. Review methodology

22. Evidence to inform this review has been gathered by way of a stakeholder consultation process as well as internal analysis and investigation against the review questions.
23. The Department has taken a proportionate approach to the level of evidence gathered to inform this review based on the scale of the 2013 Regulations, reviews and amendments that have taken place since 2013, consultation responses, as well as the impact and cost to business.

Stakeholder consultation

24. The stakeholder engagement process included an initial workshop held on 21 July 2017 to explain the PIR process and opportunities for stakeholders to feed into the review. At this event stakeholders were invited to provide written responses and evidence to inform the review.
25. Eleven written responses were received from stakeholders including representative bodies, commissioners and businesses stakeholders. Officials collated and conducted an initial analysis of the responses which were reviewed at a second stakeholder workshop held on the 31 October 2017. At this workshop stakeholders were invited to comment on initial findings and discuss solutions to the issues identified.
26. A number of follow up meetings were also held to obtain further information about specific issues and ensure accurate interpretation of the responses. This included meetings on:
 - 29 November 2017 to explore issues specific to dispensing doctors;
 - 1 December 2017 to discuss prescription direction and examples and evidence provided by individual pharmacy contractors; and
 - 10 January 2018 to discuss issues specific to 100 hour per week pharmacies.
27. A list of stakeholders involved in the consultation process outlined above is provided at Annex E. The individual business stakeholders that took part are not identified due to the commercially sensitive nature of the information provided.

Internal analysis and investigation

28. In addition to the stakeholder consultation process, DHSC has also undertaken a series of analyses to help review the effectiveness of the 2013 Regulations and the extent to which they can be seen to have delivered against the original policy objectives. This analysis draws from a wide range of evidence, including evidence supplied during the stakeholder consultation process.
29. The following analysis was conducted to inform this review:
 - A historical and trend analysis of the community pharmacy sector, reviewing market size, location and changes over time.
 - An assessment of access to pharmaceutical services.
 - A random sample review of pharmaceutical needs assessments.

- An analysis of applications to join the pharmaceutical list.
- An investigation into DSPs, reviewing prescription origin and the distances to the patients being supplied.
- Analysis of 100 hours per week pharmacies, reviewing number, spread and usage. Figures and graphs from this analysis are provided at Annex A

6. Assessment against policy objectives

Policy objectives of the 2013 Regulations

30. The key policy objectives of the 2013 Regulations for present purposes are:

- to ensure a proportionate regulatory regime which encourages the supply of NHS pharmaceutical services without excessive provision in areas already meeting demand;
- to ensure benefits of the new entry system outweigh its costs; and
- to align provision more transparently with local needs.

Analysis against policy objectives

31. As at March 2017 there were 11,699 community pharmacies. Figure 1. records the number of pharmacies on the pharmaceutical list in England since 2006/07. This data shows that the number of pharmacies has been increasing year on year since 2006/07 and that this increase is seen to level off with the introduction of the 2013 Regulations.

32. As shown at Figure 2. the number of openings and closures began to decline sharply with the introduction of the 2013 Regulations. This is likely to be the result of new market entry controls set out at Part 2 of these Regulations. Between November 2016 and December 2017 there were 72 closures and 62 new openings, 46 of which were for DSPs. During this period there were also 161 changes of ownership and 7 consolidations.

33. As of 1 April 2013, anyone wanting to provide NHS pharmaceutical services is required to apply to NHS England and demonstrate that they are able to meet a pharmaceutical need/benefit as set out in the relevant PNA or a benefit that has been overlooked by this assessment (unforeseen benefit) or a need/benefit that is not yet in effect (future need/benefit). There are exceptions to this, such as applications to provide pharmaceutical services on a distance-selling basis. Local Authority Health and Wellbeing Boards (HWBs) produced their first PNA documents in 2015, the next iteration of PNA documents is due in 2018.

34. Between 2013/14 and 2016/17 there were 2,600 applications to join the pharmaceutical list, 2,016 (78%) were granted, 469 (18%) were refused, 115 (4%) lapsed or were withdrawn¹. One of the criteria under which contractors can apply to join the pharmaceutical list is on the basis of an 'unforeseen benefit', to secure improvements or better access to pharmaceutical services that have not been identified in the PNA. Between 2013/14 and 2016/17 there were 310 decisions on appeal for applications made under the unforeseen benefits criteria. Of these 55 (18%) were granted and 241 (78%) were refused, the remaining 14 (4%) of applications were withdrawn. This application route ensures there is flexibility within the system in circumstances whereby a PNA has not identified an opportunity to

¹ NHS Digital: General Pharmaceutical Services: England 2007/08 to 2016/17

provide improvements or better access to pharmaceutical services.

35. As at February 2018, there were 1,153 100 hours per week pharmacies in England, representing 9.8% of all community pharmacies. Figure 3. Shows this breakdown by region. In practice, these pharmacies contribute to access to pharmaceutical services for patients outside normal business hours, although there was no requirement for the NHS to make an assessment of whether they were in fact necessary or desirable before they entered the market. The exemption for this pharmacy type was removed in September 2012. This is likely to have contributed to the decrease in the number of new pharmacy openings shown at Figures 1 and 2.
36. Figures 4 and 5. show the number of pharmacies by index of multiple deprivation and health and disability decile². This data demonstrates that there are more pharmacies in the most deprived areas with these communities having 2-3 times as many pharmacies.
37. Geographical mapping of community pharmacies shows that as at 1 September 2016, 88% of the population were within a 20 minute walk of a pharmacy. This data also demonstrates that 40% of all community pharmacies were within a 10 minute walk of two or more other community pharmacies. Clustering remains and in some areas there are more pharmacies than required to ensure access to NHS pharmaceutical services.
38. The 2013 Regulations include provisions for doctors to provide pharmaceutical services in rural areas where there are fewer pharmacies physically located. DSPs also support those less able to access physical services, offering national delivery services for medicines as well as digital or telephone based support for patients. These services help ensure that patients with limited mobility can still receive their medicines and access pharmaceutical services. They allow patients the option of accessing some services online or over the phone giving patients and members of the public greater choice about how and where they access pharmaceutical services.
39. The past decade has seen a sustained growth in the number of DSPs with numbers increasing from 56 in 2008 to 343 as of November 2017. This trend, shown at Figure 6. was evident prior to the introduction of the Regulations in 2013 which are not seen to have resulted in a spike in the number of DSPs entering the market. This is because the year on year increase in number of DSPs entering the market since 2012/13 is lower than the three years prior to the introduction of the 2013 Regulations.
40. Community pharmacies dispensed 1,015million items in 2016/17, approximately 91% of all items dispensed in the community. The number of items dispensed has increased annually from 726 million items in 2007/8. As shown at Figure 7. the growth in the number of items dispensed annually is however slowing. The volume for 2016/17 represents an increase of 2% from 2015/16³.
41. According to data published by the Dispensing Doctors Association, as at January 2017 there

² The Index of Multiple Deprivation (IMD) provides a measure of relative deprivation for geographical areas based on a total of 37 separate indicators, grouped into seven domains. Each domain reflects a different aspect of deprivation experienced by individuals living in an area.

³ NHS Digital. General Pharmaceutical Services: England 2007/08 to 2016/17.

were 1,023 dispensing practices and 6,599 dispensing GPs in England. The population of dispensing patients in 2017 was approximately 3.18 million, a decrease from 3.31 million in 2013. Dispensing GPs dispensed approximately 84.9 million items in 2016/17. This represents 8% of the total number of items dispensed in the community

42. As shown at Figure 8, the number of actively dispensing appliance contractors (DACs) has remained stable over the last decade and is recorded at 111 in 2016/17. In 2016/17 DACs dispensed 8,493 million items, which represents approximately 1% of the total number of items dispensed in the community. There has been an increase in the number of items dispensed by DACs which is likely to be due to a combination of increased demand for prescriptions for appliances and patient choice. 2016/17 volumes represent an increase of approximately 53% since 2007/08, this greater than the relative increase in items dispensed by community pharmacies which has grown by approximately 29% over the same period. The proportion of items dispensed by community pharmacies, dispensing GPs and DACs for 2016/17 is set out at Figure 9.
43. Five of the eleven written stakeholder responses received set out that the 2013 Regulations have largely achieved their original policy objectives. However, suggestions were made in relation to several potential unintended consequences. In addition, further comments were provided as to how the 2013 Regulations could be amended to more effectively deliver against the original policy objectives.

Findings and recommendations

44. Based on this analysis, this review determines that:
- the 2013 Regulations have slowed the growth in the number of community pharmacies, in line with the original policy objective to mitigate excessive provision of NHS pharmaceutical services in areas already meeting demand;
 - there is flexibility within the system where an unforeseen benefit is identified;
 - access to NHS pharmaceutical services in England is good and patients generally have reasonable choice about how and where they access services; and
 - there remains a degree of 'clustering'.
45. This review finds that the 2013 Regulations have largely achieved the original policy objectives which remain relevant and appropriate for the regulation of NHS pharmaceutical services in England. This review does however recommend that the Department consults on a number of amendments to these Regulations and that changes are made to the underpinning guidance to address several unintended consequences and realise opportunities to more effectively deliver against the policy objectives.

7. Recommendations for regulatory amendments

46. Through the stakeholder consultation process, a number of potential unintended consequences were identified. These have been grouped under the following headings and are further discussed in this section:
- Distance selling premises – Misuse and prescription direction

- Minor and temporary relocations
- Dispensing doctors - Amalgamating practices and dispensing rights
- Exempted applications – 100 hours per week pharmacies
- Determination of controlled or reserved localities - 5 year application restriction
- Retrospective correction of drug reimbursement price calculation or publication errors
- Attending oral hearings for appeals
- Breach and remedial notices – Provision to rescind
- Local dispute resolution

Distance selling pharmacies – Misuse and prescription direction

47. Part 9 of the 2013 Regulations sets out the specific operating conditions for DSPs. These regulations specify that:

- DSPs must offer essential services to people based anywhere in England but these services cannot be delivered face to face; and
- DSPs, in their publicity material, must not expressly state or imply that the essential services provided at or from the premises are only available to persons in particular areas of England.

48. DSPs are exempt from the market entry criteria detailed at Section 129 of the NHS Act 2006. They are therefore not required to meet a need within a PNA, or to secure improvements or better access to services. The purpose of this exemption was to enable an increase in the number of pharmacies offering online and national direct delivery services and to give patients greater choice about how and where they access and use NHS pharmaceutical services.

49. During the consultation period two concerns about the functioning of DSPs were raised; the first in relation to subversion of the 2013 Regulations for the purpose of local supply and the second regarding direction of prescriptions to DSPs.

Subversion of the regulations for the purpose of local supply

50. Several stakeholders outlined instances where DSPs were operating on a predominantly local level, instead of delivering a national service as stipulated. Examples of DSPs discouraging 'non local' use and or lacking the infrastructure to deliver national services were supplied to the Department as part of the consultation process.

Direction of prescriptions to DSPs

51. Stakeholders also raised concerns about vested interests resulting in the direction of prescriptions to a particular DSP for personal commercial gain. Evidence and examples were supplied to the Department as part of the consultation process. This demonstrated sudden drops in the dispensing volume at bricks and mortar pharmacies following the opening of a DSP located nearby, with a corresponding spike in prescriptions at the new DSP, the vast majority coming from a single general practice.

52. General Medical Council guidelines set out that patients should be free to choose which pharmacy will dispense their medicines and that doctors must not allow any financial or commercial interests in a pharmacy to influence the advice given to patients. Failure to

adhere to these professional standards could result in an investigation for professional misconduct.

Analysis and investigation

53. A sample analysis was conducted to review the publicity of DSP services and adherence to regulation 64(3)(e) which sets out that nothing in the DSP's publicity material can expressly state or imply that the essential services provided at or from the premises are only available to persons in particular areas of England. This analysis was based on a random sample of 32 DSPs. Within this sample, 5 DSPs were found to only advertise local delivery services, two did not have a functional website and one advertised face to face essential services at its registered premises.
54. Analysis of prescription records shows that between May 2016 and August 2017, an average of 6.7% of DSPs only dispensed prescriptions to locations within a distance of 10km from the patient. Specifically in the month of August 2017, this represented 16 out of the 248 actively dispensing DSPs that month. Slightly under half of the remaining DSPs supplied to patients located between 10km and 100km from the DSP, with just over half supplying to distances over 100km. This analysis is set out at Figure 10.
55. The prescription origin of prescriptions dispensed by DSPs who dispensed more than 1,000 items a month over a 12 month period was analysed. This analysis found that 10 or 4.8% of 209 DSPs received between 90 - 100% of their prescriptions from one prescriber. 47 DSPs or 22.5% of DSPs received more than 50% of their prescriptions from their top prescriber.

Findings and recommendations

56. This analysis supports stakeholder concerns that a small proportion of the DSPs may be misusing the DSP exemption for the purpose of local supply. This review also finds strong evidence of prescription direction to some DSPs with a small number of DSPs dispensing more than 1,000 items a month receiving more than 90% of their prescriptions from a single prescriber.
57. This review recommends that the Department consults on changes to the 2013 Regulations to:
- require DSPs to declare any vested or significant interests – including if any of the business owners or partners, are themselves, or have family members who are prescribers of NHS prescriptions dispensed by the DSP; and
 - require DSP contractors to maintain functional websites which detail how their services can be accessed nationally and their arrangements for the disposal of patient returned waste medicines.
58. This review also recommends that:
- NHS England develop a complaints process to allow suspected breaches to be reported investigated; and
 - DHSC consider how the development and roll out of the electronic prescription service and patient nomination processes could help mitigate prescription direction.

Minor and temporary relocations

59. Part 4 of the 2013 Regulations covers applications in respect of providing NHS pharmaceutical services, including relocation, change of ownership, and temporary arrangements during emergency circumstances, such as a flood or a pandemic. Regulation 24 contains the requirements for an application for relocation.
60. During the consultation process several stakeholders raised similar concerns about the classification of and process for dealing with minor and temporary relocations. These issues were further discussed with stakeholders at the review workshop held on the 31 October 2017.
61. The main issue that emerged was a concern around the length of the relocation application process and the application process being applied even for very minor or temporary relocations. Examples were provided which included relocations within the same building or to a porta cabin on the same site. Stakeholders suggested that a quicker and easier process could be made available for very minor and short term relocations.

Findings and recommendations

62. This review finds that there are some types of relocation that could be fast tracked via a more streamlined and simplified application route These include very minor relocations and relocations in the event of an emergency. It is therefore recommended that:
- the Department consults on amendments to the 2013 Regulations to allow for a more streamlined application process in the event of very minor and temporary relocations; and
 - NHS England reviews and develops guidance to facilitate and administer accelerated application routes for very minor and temporary relocations.

Dispensing Doctors - Amalgamating practices and dispensing rights

63. Part 8 of the 2013 Regulations covers arrangements for the provision of NHS pharmaceutical services by doctors. These regulations permit GPs to apply for the right to dispense to patients who meet certain criteria, including that the patient lives within a controlled locality, at a distance of more than 1.6 kilometres from a pharmacy. New applications for outline consent and premises approval are not considered if there is a pharmacy within 1.6km of the GP premises. The aim of this provision within the 2013 Regulations was to improve access to NHS pharmaceutical services for patients in rural areas where there is not a local pharmacy.

Consultation responses

64. Responses set out a concern that the 2013 Regulations create a disincentive that could prevent dispensing doctors from participating in local partnerships designed to improve access to and quality of general medical services. This is because under Regulation 59, the amalgamation of a dispensing practice with a non-dispensing practice requires a new application for premises approval and outline consent to dispense. Entering into partnership arrangements could therefore result in practices losing their right to dispense – depending on the particular facts of how the old and the new practices are or were configured.
65. One stakeholder raised an additional concern that arrangements determining rights for doctors to dispense under either historic and/or outline consent were overly complex and

confusing for patients. In particular Regulation 48(3) was seen to cause an issue for patients who have moved to a dispensing practice without a change of home address, preventing them from accessing NHS pharmaceutical services and in doing so restricting patient choice.

Findings and recommendations

66. This review finds evidence to support stakeholder concerns that Regulation 59 could result in a disincentive to collaborative working for practices with the right to dispense. At the time of writing a consultation is underway on the development of Accountable Care Systems and arrangements for partnership working have not yet been determined. As such this review finds that any recommendations for future legislation to address this potential unintended consequence need to await further developments elsewhere. No amendments to the 2013 Regulations are suggested at this time but it is recommended that the Department monitors this situation and makes a further assessment by the 31st March 2019.
67. Regulation 48(3)(b)(ii)(cc) appropriately prevents, in historic rights cases, dispensing rights being granted to patients who have moved to a dispensing practice without a change of home address. This is because it is assumed that if a patient at a set address has been able to access NHS pharmaceutical services locally without the need for the services of a dispensing doctor, this would remain unchanged if they stay living at that address but move from one surgery to another. In the eventuality that a patient is in fact in difficulty accessing pharmaceutical services unless their new surgery provides them, they can apply for the right to access dispensing services from their new surgery on the basis of 'serious difficulty'. As such this review finds that regulation 48 is functioning as intended. It is however acknowledged that arrangements determining the rights for doctors to dispense are complicated and can result in confusion for contractors and patients. It is therefore recommended that DHSC review and consider if this element of the 2013 Regulations should be redrafted to simplify these arrangements, subsequently consulting on any proposed simplification of the regulations.

Exempted applications – 100 hour per week pharmacies

68. In April 2005, the NHS (Pharmaceutical Services) Regulations 2005 introduced four exemptions to the then market to entry test for applications which were:
- prepared to open for at least 100 hours per week;
 - in designated out-of-town large shopping centres;
 - in new large one-stop primary care centres; and
 - wholly DSPs.
69. In 2012, new Regulations removed three of these exemptions leaving only one - the exemption for wholly DSPs, which remains within the 2013 Regulations. Part 9 of the 2013 Regulations covers specific conditions for DSPs, core opening hours conditions, provision of directed services conditions and conditions relating to voluntary closure of premises.

Consultation responses

70. During the consultation process some business stakeholders raised a concern about the commercial viability of 100 hour per week pharmacies. Evidence was supplied indicating a very low use of early and late hour pharmaceutical services from this type of pharmacy, as well as data on the associated staffing costs. The impact of changes to the national minimum

wage was also highlighted. It was requested that the DHSC consider options to remove or reduce the requirements of the 100 hours per week pharmacies as set out at regulation 65.

Analysis and investigation

71. As at February 2018, there were 1,153 100 hour per week pharmacies on the pharmaceutical list in England, representing 9.8% of all community pharmacies. A breakdown by region is set out at Figure 3. The average dispensing volume of 100 hours per week pharmacies is 84,224 items; this is 650 items less than the average dispensing volume of non-100 hours per week pharmacies.
72. The number of 100 hours per week pharmacies in an area increases with the levels of deprivation and poor health, with more than 50% of 100 hours per week pharmacies situated in areas that are in the bottom three deciles on the index of multiple deprivation and health disability (Decile 1- most deprived; Decile 10- least deprived).
73. 41 100 hours per week pharmacies are part of the Pharmacy Access Scheme. At the time of writing data on clustering was available for 1,135 of the 1,153 100 hours per week pharmacies - 636 (56%) were identified as being clustered.
74. Data is not currently collated routinely at area level or centrally on notifications to permanently reduce supplementary hours for “standard” 40 hour per week pharmacies. However, in January 2018, regional NHS teams reported minor increases in the number of notifications to reduce supplementary hours for 40 hour per week pharmacies since October 2016. This is based on part data for two areas as well as anecdotal responses from local contract managers. Further data collection and analysis is required to allow for a more robust assessment of supplementary hours and trends regarding notifications to reduce them.

Findings and recommendations

75. If the viability of a pharmacy is threatened for reasons that are essentially bound up with the length of its opening hours, the only option currently available to companies with 100 hours per week pharmacies, to reduce the costs associated with this extended hours provision, is to close these pharmacies. This could negatively impact upon access and equalities. However, further data is required to better understand who accesses these pharmacies during very early or late hours and the services they are using during these times.
76. Maintaining access for people who for various reasons are unable to regularly access NHS pharmaceutical services during normal business hours remains an important objective of the 2013 Regulations. This review therefore recommends that Government conduct a review of 100 hours per week pharmacies that analyses who uses these services and considers if any amendments to the terms of service for 100 hour per week pharmacies should be made.

Determination of controlled or reserved localities - 5 year application restriction

77. Part 7 of the 2013 Regulations covers the process for determining controlled localities or reserved locations and new pharmacies within them. Any local pharmaceutical committee may challenge the status of an area. However, as per regulation 36, once a determination has been made about the rurality of an area, including a determination following an appeal, then

no further appeals or considerations can be made for a period of 5 years; unless the NHSCB (ie NHS England) is satisfied that there has been a substantial change in circumstances within this 5 year period.

Consultation responses

78. During the consultation process two stakeholders set out that in cases where an application was refused because of an error within the application, regulation 36 prohibits the consideration of a further application for 5 years. Stakeholders suggested that a provision be created to permit the consideration of another application within the 5 year period, if the first application was refused on grounds of an administrative error, rather than an assessment of rurality.

Findings and recommendations

79. This review finds the barrier to a second application, following an initial application that has been made in error, to be an unintended consequence of the 2013 Regulations. It is recommended that the Department consults on amending the Regulations to allow for a further challenge against a determination to be made, if the first application is refused or withdrawn on the basis of administrative error.

Retrospective correction of drug reimbursement price calculation or publication errors

80. Part 12 of the 2013 Regulations covers remuneration, charges and refunds. In respect to action taken to correct calculation errors, regulation 93(2) sets out that such a determination may only be published “if it is not detrimental to affected contractors”.

81. Stakeholders reported that this wording allows for a wide interpretation and as such any action taken to lower the reimbursement price to correct a calculation or publication error could be considered to have a detrimental effect on contractors.

Findings and recommendations

82. The wording set out at Regulation 93(2) has resulted in a barrier to Government intervention, prohibiting action to rectify errors and effectively deliver appropriate and accurate funding levels. This is an unintended consequence of the 2013 Regulations. As such it is recommended that the Department consults on a redraft of this regulation to more clearly define the circumstances with retrospective effect under which determinations may and may not be published.

Attending oral hearings for appeals

83. Schedule 3, paragraphs 8 of the 2013 Regulations requires a party to specify that they want to attend an oral hearing, even if they have made representations and would naturally want or be expected to attend. During the consultation process evidence was provided demonstrating several instances where individuals who were unaware of these requirements were prevented from attending the oral hearing. Two of the written responses received suggested that the wording of the 2013 Regulations should be amended to remove the requirement to formally request attendance for interested parties, including those who have made representations.

Findings and recommendations

84. The wording set out at Schedule 3 paragraph 8 has resulted in an unintended consequence. This review recommends that the Department consults on amending the 2013 Regulations to remove the requirement to formally request attendance at oral hearings for interested parties.

Breach and remedial notices – Provision to rescind

85. Part 10 of the 2013 Regulations outlines performance related sanctions and market exit. These Regulations require local dispute resolution processes and set out the conditions for serving remedial or breach notices as well the conditions for withholding payment and removing a contractor from a pharmaceutical list.

Consultation responses

86. Three stakeholders highlighted the need for a process by which NHS England can rescind breach notices which have been issued in error. Stakeholders reported that the need for this was particularly important given that outstanding breach and remedial notices can affect the ability of a company to gain contracts. This was agreed by all stakeholders at the review workshop held on 31 October 2017.

Findings and recommendations

87. This is an unintended consequence of the 2013 Regulations which do not contain a provision for rescinding breach or remedial notices. It is recommended that the Department consults on amending the Regulations to allow for such a provision.

Local dispute resolution

88. Regulation 69 sets out that the NHSCB (ie NHS England) must make every reasonable effort to communicate and co-operate with contractors with a view to resolving any dispute relating to compliance with terms of service. Regulation 69 (3)(b)(i) does however permit NHS England to proceed immediately with the issue of a notice in an instance where a listed contractor has not been open during core or supplementary opening hours without good cause.

Consultation responses

89. Four stakeholders raised three issues about the issue of remedial or breach notices.
- (i) A concern was raised about the issue of breach or remedial notices without any initial communication or attempt to resolve the matter through a local dispute resolution process first.
 - (ii) Further clarification was requested about how and to which address breach notices should be issued.
 - (iii) Further clarification was requested about any thresholds that should be, or are being, used by NHS England to determine when action should be taken to remove a pharmacy contractor or premises from a pharmaceutical list.

Findings and recommendations

90. A recommendation is made earlier in this review to amend the 2013 Regulations to include a provision allowing NHS England to repeal breach or remedial notices that have been issued in error. This provision once established can be used to repeal notices issued without the

required prior communication for the purpose of local dispute resolution.

91. The decision to remove a pharmacy contractor from a pharmaceutical list is made by regional NHS teams. This review therefore recommends that NHS England considers whether regional NHS teams would benefit from further guidance to support and standardise this decision making.
92. This review also finds that it is not possible for NHS England to assess whether there was a good cause for not opening without first making contact with the pharmacy contractor. It is therefore recommended that The Department consults on amending Regulation 69 (3)(b)(i) to better detail the circumstances under which NHS England can proceed immediately with the issue of a notice regarding opening hours or to remove this provision to require local dispute resolution processes.

8. Operational application and implementation

93. In addition to consultation on the above suggested amendments to the 2013 Regulations, this review also finds that there are several elements of the Regulations that require clarification within the supporting guidance. This follows issues raised by stakeholders, during the consultation process, that relate to the operational implementation of the Regulations which is and can be further defined within guidance. As such amendments to the 2013 Regulations themselves are not required.
94. The review consultation process raised several operational issues which are discussed under the following headings:
 - PNA quality and consistency
 - Opening hours and work breaks
 - Embedded site pharmacies
 - Emergency protocols

PNA quality and consistency

95. Part 2 of the 2013 Regulations sets out that a person who wishes to provide NHS pharmaceutical services must apply to NHS England proving they are able to meet a pharmaceutical need or improve access as set out in the relevant PNA. There are exceptions to this, such as applications for needs not foreseen in the PNA or to provide NHS pharmaceutical services on a distance-selling basis.
96. The PNA process was introduced to define the pharmaceutical needs in a specific area, for use by NHS England in determining entry onto the pharmaceutical list to ensure the adequate and appropriate provision of NHS pharmaceutical services in England. Regulation 4 and Schedule 1 of the 2013 Regulations outline the minimum requirements for PNAs.
97. The Health and Social Care Act 2012 established Health and Wellbeing Boards (HWBs). The Act also transferred responsibility to develop and update PNAs from Primary Care Trusts to HWBs. PNA documents must be updated every three years. HWBs produced their first PNA

documents in 2015; the next iteration of PNA documents is due in 2018.

Consultations responses

98. Eight of the eleven written responses received, referenced the PNA process. All of these responses raised similar concerns about the quality and consistency of these documents. The key issues reported were:

- a large degree of variability;
- insufficient levels of detail provided in some PNAs; and
- variable and insufficient consideration of the full range of service providers - for example access provided by DSPs and dispensing doctors.

99. To explore these issues, the Department conducted a random sample analysis, selecting 32 HWBs from 8 regions. An assessment was made as to the extent to which their published PNAs met the minimum requirements as set out in Regulation 4 and Schedule 1 of the 2013 Regulations.

Findings and recommendations

100. Of the 32 HWBs selected for review, two areas were excluded from the analysis; this is because for 1 area the PNA document had been temporarily removed for redrafting and for another, a merger between two HWBs had just taken resulting in their PNA document becoming defunct. The following analysis is therefore based on a sample of 30 PNA documents.

101. 29 out of these 30 PNAs were found to meet the minimum requirements as set out in Regulation 4 and Schedule 1 of the 2013 Regulations. It was considered that 1 PNA did not meet these requirements, failing to provide sufficient information for 3 of the 6 criteria. Whilst the level of detail provided regarding specific gaps in provision was seen to vary, the overall standard of the documents was considered to be good. It was noted that the majority of the PNAs reviewed had been updated and republished for 2018.

102. This review recommends that the DHSC review the guidance made available to support the development of PNA documents and consider if and how this guidance could help increase the quality and consistency of these documents, as well as how this guidance could better link with the development of Local Sustainability and Transformation Plans.

103. In particular, guidance on the development of PNAs should also set out that PNAs include a consideration of the access and support provided by all providers of pharmaceutical services, including dispensing doctors and DSPs.

Opening Hours - Bank holidays and work breaks

104. Regional NHS teams administer opening hours for pharmacies. Pharmacies must open and provide NHS pharmaceutical services for core contractual and supplementary hours. However, pharmacies are not normally expected to open on bank holidays.

105. Pharmacy contractors are encouraged to inform NHS England whether their premises will be open on bank holidays to enable NHS England to ensure and plan for pharmaceutical

service provision during holiday periods. If NHS England determines or is unable to determine that access is maintained within a local area, regional NHS teams are able to issue directions to specific pharmacies, requiring them to open on bank holidays.

Consultation responses

106. During the written consultation process, several stakeholders set out a need to standardise and improve processes designed to ensure access to NHS pharmaceutical services during bank holidays. This was further explored during the stakeholder review workshop held on 31 October 2017.
107. This issue was seen to result from regional NHS teams not always having access to accurate or sufficient information to effectively administer opening hours during bank holidays. This is because pharmacy contractors are able to amend their opening hours on bank holidays without having to notify regional NHS teams. This means that even if a pharmacy has notified NHS England that they will be open on a given bank holiday, they can amend these hours or not open at all without having to inform NHS England of the change. The impact of this issue is an inefficient use of directions as well as conflict between individual contractors and local administrators.
108. Stakeholders also highlighted the need for greater flexibility regarding work breaks and lunch cover. Stakeholders agreed that in seeking to develop more flexible arrangements that a less onerous solution than regulatory requirements should first be sought. Examples of local rota systems which could be used to plan and agree service provision on bank holidays were discussed.

Findings and recommendations

109. Since this issue was highlighted, the Pharmaceutical Negotiating Committee, NHS England and DHSC have agreed a £37.5 million quality payment for contractors who meet a set list of criteria as part of the community pharmacy contractual framework from 1 April 2018. These criteria include a requirement for contractors to record their bank holiday opening hours on NHS Choices. NHS England teams will make use of this information to minimise the need to make additional information requests of contractors.
110. This review recommends that NHS England monitor the impact of this change and work with pharmacy contractor stakeholders to develop and promote planning procedures to improve the administration of opening hours on bank holidays. It is recommended that in the first instance this group look to develop a non-regulatory solution to maintain flexibility within the system and as such no amendments to the 2013 Regulations are recommended at this time.

Embedded site pharmacies – Directions to open

111. Some community pharmacies are embedded within premises that are outside the control of the contractor, for example in shopping centres or train stations. The opening hours of these pharmacies normally reflect the opening hours of the premises in which they are situated.

This is because the pharmacist may be unable to access the premises during hours when the wider surrounding premises are closed or because the pharmacy would remain inaccessible to members of the public even if it did open.

Consultation responses

112. During the consultation process two stakeholders provided examples of ‘embedded site pharmacies’ being directed to open during occasions when the surrounding premises would be closed. Further clarity about who NHS England can direct to open was requested. In particular, examples of pharmacies in GP surgeries and supermarkets declining to open on the grounds that the surrounding premises would be closed were provided and discussed.

113. NHS England and DHSC agreed that pharmacies situated within health settings could be expected to be able to maintain access in circumstances whereby providers of other health services at the same premises, would be closed.

Findings and recommendations

114. Paragraph 25 of Schedule 4 gives rights to NHS England to direct pharmacies to open, including on bank holidays, to ensure that the needs of the local population will be met. Failure to open following a direction would constitute a breach of these terms of service. Regional NHS teams have discretion about how and when to use these powers. It is recommended NHS England reviews the relevant guidance to consider if regional NHS teams require further clarification about directions with regards to embedded site pharmacies.

115. It is recommended that NHS England work with pharmacy contractor stakeholders to establish a means by which regional NHS teams can receive information enabling them to identify embedded site pharmacies and remain informed as to the opening hours of pharmacies on bank holidays.

116. The regulations as currently drafted permit pharmacies to appeal directions to open. This provision ensures a means of resolving instances whereby a pharmacy that has been directed to open can demonstrate that the surrounding premises will be closed and is truly outside of their control.

Emergency protocols

117. Part 4 of the 2013 Regulations covers applications in respect of providing NHS pharmaceutical services, including relocation, DSPs, change of ownership and return to pharmaceutical lists, as well as temporary arrangements during emergency circumstances. Regulation 29 sets out the process for responding to emergencies, beyond the control of contractors, which require the flexible provision or temporary suspension of NHS pharmaceutical services.

Consultation responses

118. At the review workshop held on the 31 October 2017, stakeholders were asked to consider if the regulations permitted a rapid and robust response in situations of emergency.

119. Examples of inconsistent interpretation and application were provided and discussed and it

was suggested that further clarity was required with regard to specific protocols and procedures that should be applied in given situations.

120. Stakeholders also highlighted that at regulation 61 of the 2013 Regulations, dispensing doctors may dispense to patients to whom they are not otherwise entitled to provide NHS pharmaceutical services, but that this is only in the event that the community pharmacy providing access closes. Stakeholders set out that there may be instances where the pharmacy remains open but becomes inaccessible to some patients, for example as a result of flooding or road blocks.

Findings and recommendations

121. This review finds that on the whole the 2013 Regulations do contain the necessary provisions to enable an effective response to emergency situations as defined within Part 4 of the 2013 Regulations. The specific criteria determining temporary arrangements for dispensing doctors during emergencies may however limit the ability of some providers to be fully mobilised in emergency circumstances that do not result in pharmacy closures. As such this review recommends that DHSC further explore whether the criteria set out at regulation 61 remains fit for purpose.
122. This review also finds that at an operational level, further information and clarity is required to ensure a consistent and effective response. It is therefore recommended that NHS England develop protocols and procedures which can be applied in the event of an emergency. These protocols should take into consideration new provisions and requirements detailed in legislation currently being developed on pandemic flu epidemics and response procedures.

9. Other findings and clarifications

Consolidation and closure notifications

123. Several stakeholders questioned the need to make a notification to NHS England, as set out at Regulation 67, for removal from the pharmaceutical list when relocating to another site. This is a misinterpretation of the 2013 Regulations. There is no need for a closure notification to be made to NHS England in addition to giving notification of a consolidation. No further notifications are required once the consolidation is granted. No action is therefore necessary as a result of these comments.

Regulatory references

124. The 2013 Regulations make reference to the Data Protection Act which was superseded by the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) which comes into force on 25 May 2018. It is recommended that any future amendments to the 2013 Regulations seek to update this regulatory reference, if this has not already happened as part of a general updating exercise, and any other references that may be required following the subsequent development and implementation of legislation.

10. Opportunities to reduce the burden on business

125. This review finds that the current Government intervention remains the most appropriate way to achieve the original policy objectives. However, several opportunities to reduce the burden on business have been identified and a number of recommendations are made to realise this benefit. This includes recommendations:

- to consult on amending the 2013 Regulations to allow for a more streamlined application process in the event of very minor and temporary relocations;
- for DHSC to conduct a review into the 100 hour per week pharmacies to consider and respond to the issues raised, as part of this review, about the commercial viability of these terms of service;
- to consult on a provision allowing breach and remedial notices, which have been issued in error, to be rescinded; and
- for NHS England to review guidance in relation to local dispute resolution processes.

126. Furthermore this review recommends that several of the issues which have been identified as part of this review be resolved through guidance, without the need for regulation. This will provide the required clarity for commissioners and pharmacy contractors via more flexible and less onerous governance arrangement.

11. Summary of recommendations

Recommended regulatory amendments

Distance selling premises – Misuse and prescription direction

1. DHSC consults on changes to the 2013 Regulations to require DSPs to declare any vested or significant interests and a requirement for DSP contractors to maintain functional websites which detail how their services can be accessed nationally and their arrangements for the disposal of patient returned waste medicines.
2. NHS England develop a complaints process to allow suspected breaches to be reported and investigated.
3. DHSC consider how the development and roll out of the electronic prescription service and patient nomination processes could help mitigate the issue of prescription direction.

Minor and temporary relocations

4. DHSC consults on amendments to the 2013 Regulations to allow for a more streamlined application process in the event of very minor and temporary relocations.
5. NHS England review and develop guidance to facilitate and administer accelerated application routes for very minor and temporary relocations.

Dispensing Doctors - Amalgamating practices and dispensing rights

6. DHSC monitor the developing legislation with regards to Accountable Care Systems and make an assessment by 31 March 2019 about any action required to support partnership working.
7. DHSC review and consider if within Part 8 of the 2013 Regulations, the regulations determining the rights for doctors to dispense should be redrafted to simplify these arrangements, subsequently consulting on any proposed simplification of the regulations.

Exempted applications – 100 hours per week pharmacies

8. Government conduct review of 100 hours per week pharmacies that analyses who uses these

services and considers if any amendments to the terms of service for 100 hour per week pharmacies should be made.

Determination of controlled or reserved localities - 5 year application restriction

9. DHSC consults on amendments to the 2013 Regulations to allow for a further challenge against a determination to be made, if the first application is refused or withdrawn on the basis of administrative error.

Retrospective correction of drug reimbursement price

10. DHSC consults on a redraft of Regulation 93(2) to more clearly define the circumstances with retrospective effect under which determinations may and may not be published.

Attending oral hearings for appeals

11. DHSC consults on amending Schedule 3 paragraph 8 to remove the requirement to formally request attendance at oral hearings for interested parties.

Breach and remedial notices – provision to rescind

12. DHSC consults on amending the 2013 Regulations to allow for breach or remedial notices to be rescinded.

Local dispute resolution

13. NHS England consider whether regional NHS teams would benefit from further guidance to support and standardise decision making about when to take action to remove a pharmacy contractor from a pharmaceutical list.

14. DHSC consults on amending Regulation 69 (3)(b)(i) to better detail the circumstances under which NHS England can proceed immediately with the issue of a notice regarding opening hours or to remove this provision to require local dispute resolution processes.

Regulatory references

15. DHSC consults on amending the 2013 Regulations to reflect the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679) which comes into force on 25 May 2018, if this has not already happened as part of a general updating exercise, and any other references that may be required following the subsequent development and implementation of legislation.

Additional recommendations

PNA quality and consistency

16. DHSC review the guidance made available to support the development of PNA documents and consider if and how this guidance could help increase the quality and consistency of these documents, as well as how this guidance could better link with the development of Local Sustainability and Transformation Plans.

Opening Hours - Bank holidays and work breaks

17. NHS England monitor the impact of requirements agreed as part of the community pharmacy contractual framework from April 2018 which requires pharmacies eligible for quality payments to record their bank holiday opening hours on NHS Choices.

18. NHS England work with business stakeholders to develop and promote planning procedures to improve the administration of opening hours on bank holidays. It is recommended that in the first instance this group look to develop a non-regulatory solution to maintain flexibility within the system.

Embedded site pharmacies – Directions to open

19. NHS England review the relevant guidance to consider if regional NHS teams require further clarification about directions with regards to embedded site pharmacies.
20. NHS England work with business stakeholders to establish a means by which NHS England regional NHS teams can receive information enabling them to identify embedded site pharmacies and remain informed as to the opening hours of pharmacies on bank holidays.
Emergency protocols
21. DHSC further explore whether the criteria set out at Regulation 61 remains fit for purpose.
22. NHS England develop protocols and procedures which can be applied in the event of an emergency, which take into consideration new provisions and requirements detailed in legislation currently being developed on pandemic flu epidemics and response procedures.

Annex A – Figures and graphs

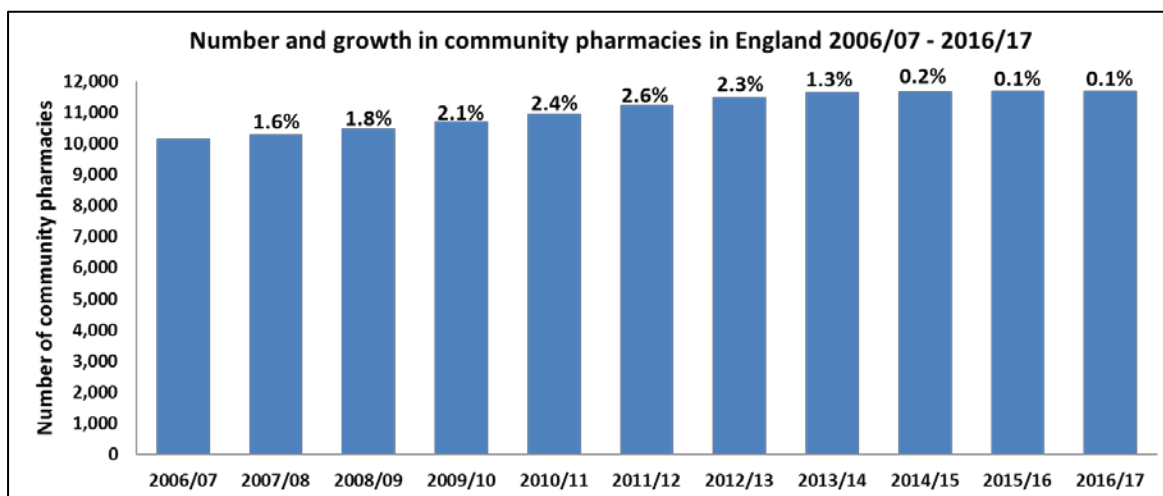


Figure 1. Number of community pharmacies in England providing NHS pharmaceutical services from 2006/07 – 2016/17. The percentages capture the year to year growth in the number of pharmacies.

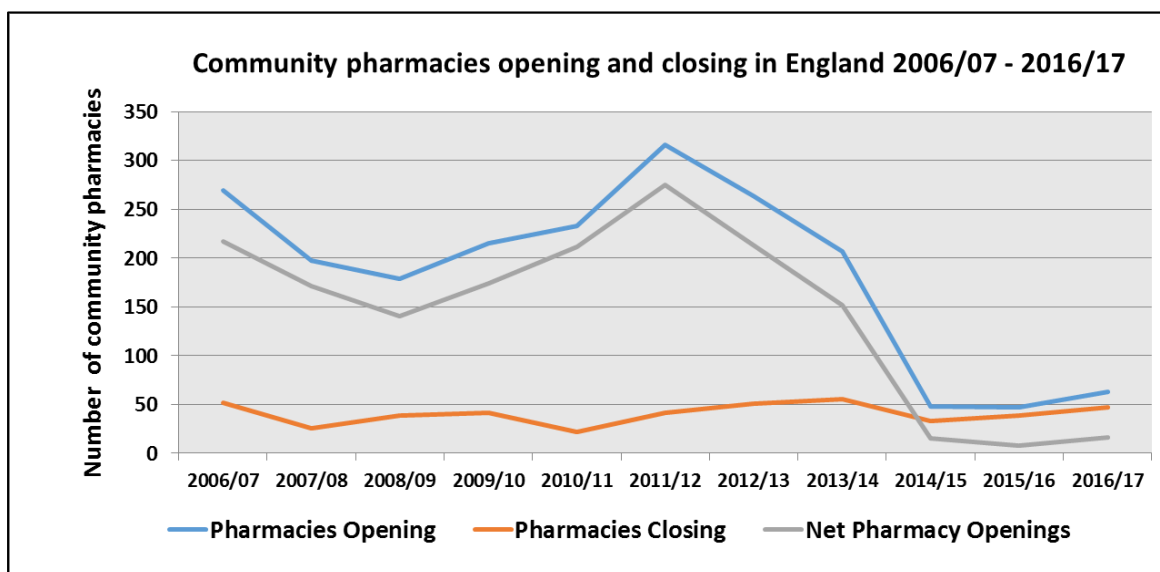


Figure 2. Openings and closures of community pharmacies in England providing NHS pharmaceutical services 2006/07 – 2016/17.

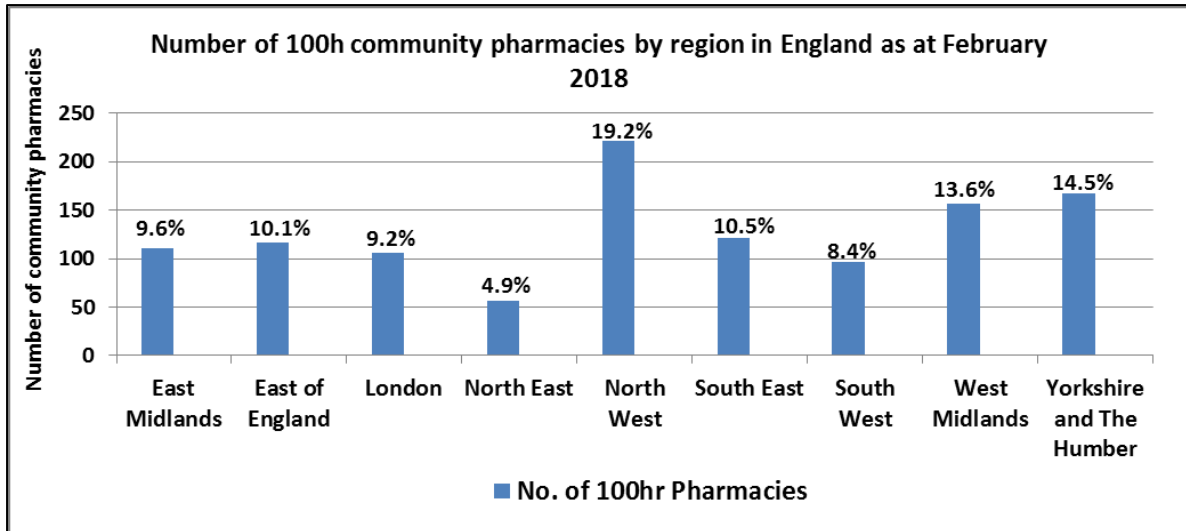


Figure 3. Number of 100 hours per week community pharmacies providing NHS pharmaceutical services by region in England as at February 2018. The percentages indicate the proportion of 100 hours per week community pharmacies in each region.

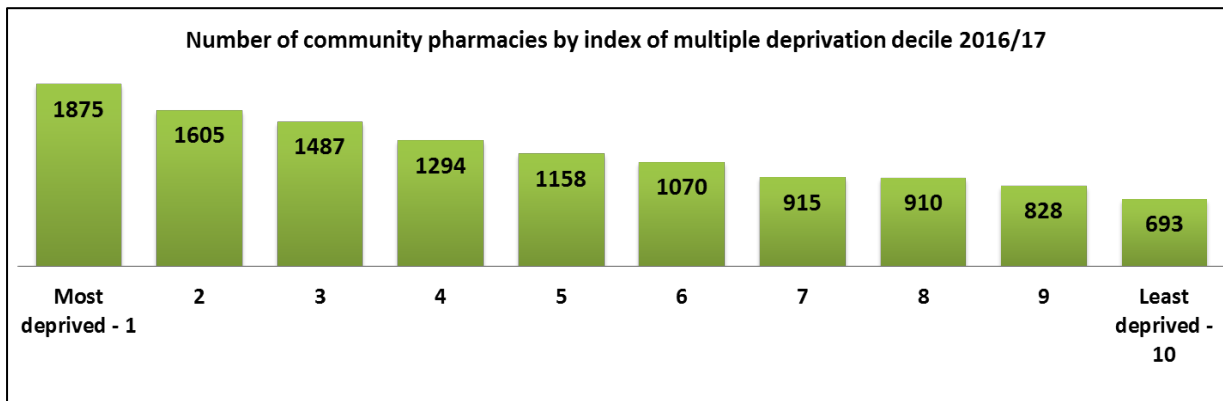


Figure 4. Number of community pharmacies by index of multiple deprivation decile in 2016/17.

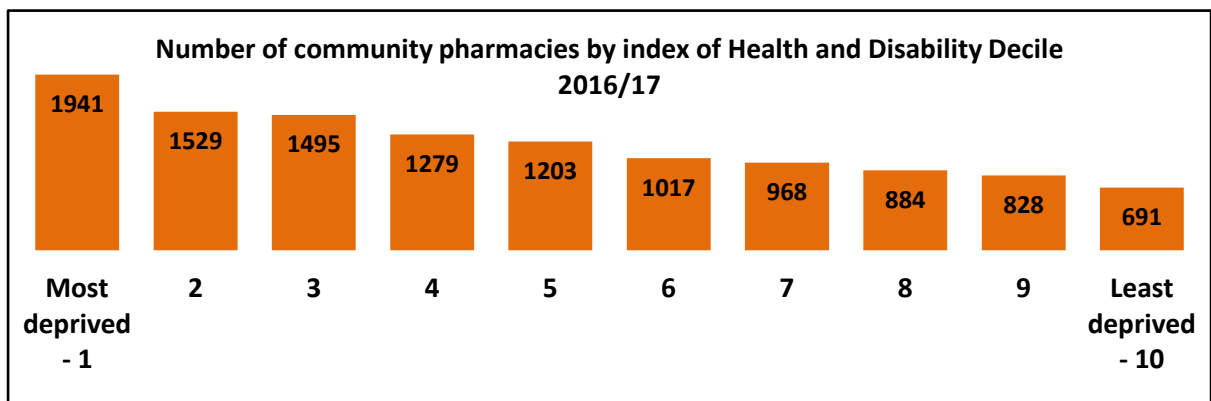


Figure 5. Number of community pharmacies by index of health and disability decile in 2016/17.

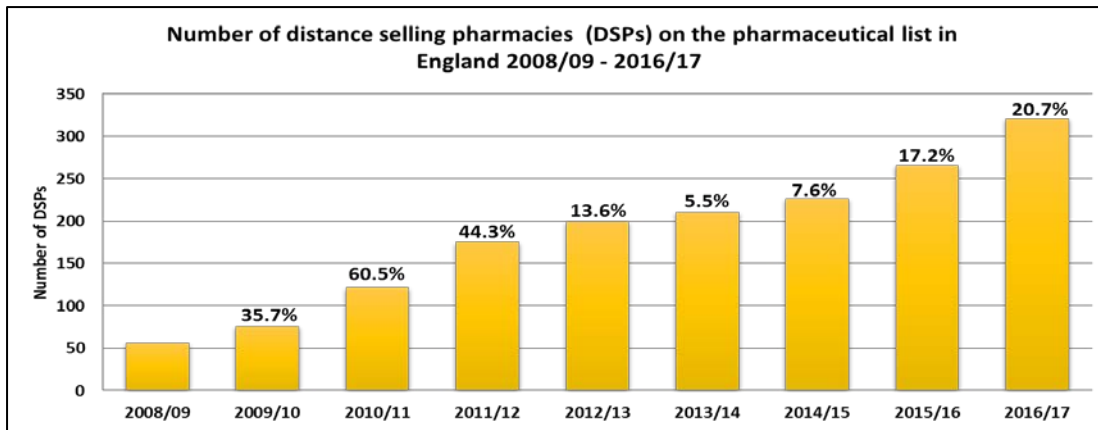


Figure 6. Number of distance selling pharmacies (DSPs) on the pharmaceutical list in England 2007/08 - 2016/17. The percentages capture the year to year growth in the number of DSPs.

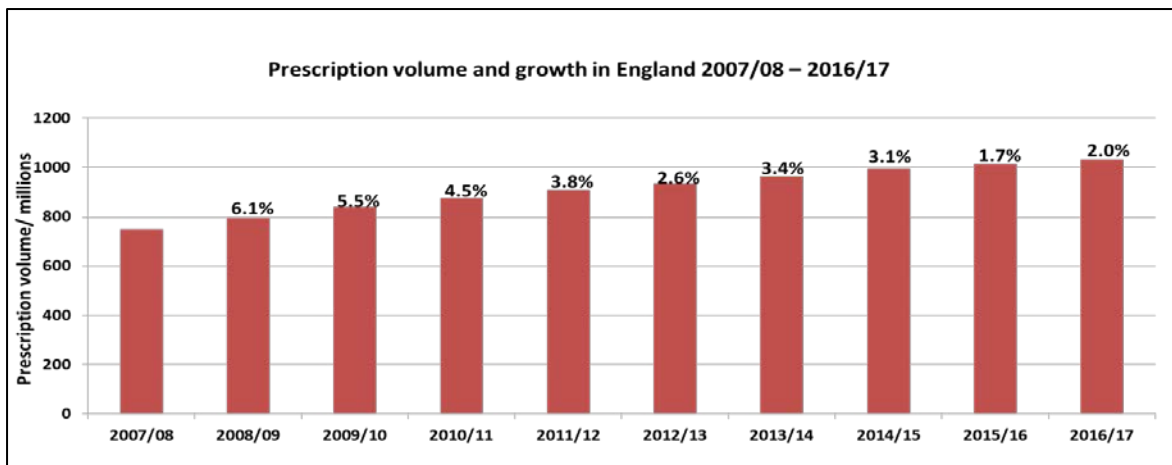


Figure 7. Prescription volume dispensed by community pharmacies in England 2007/08 – 2016/17. The percentages capture the year to year growth in prescription volume.

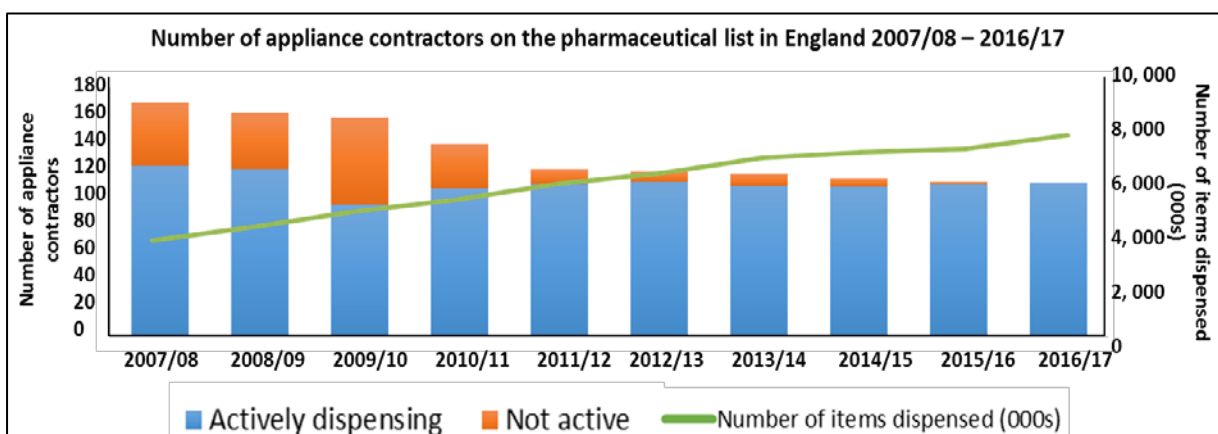


Figure 8. Number of appliance contractors on the pharmaceutical list in England, active and inactive, and the number of items they have dispensed annually from 2007/08 - 2016/17

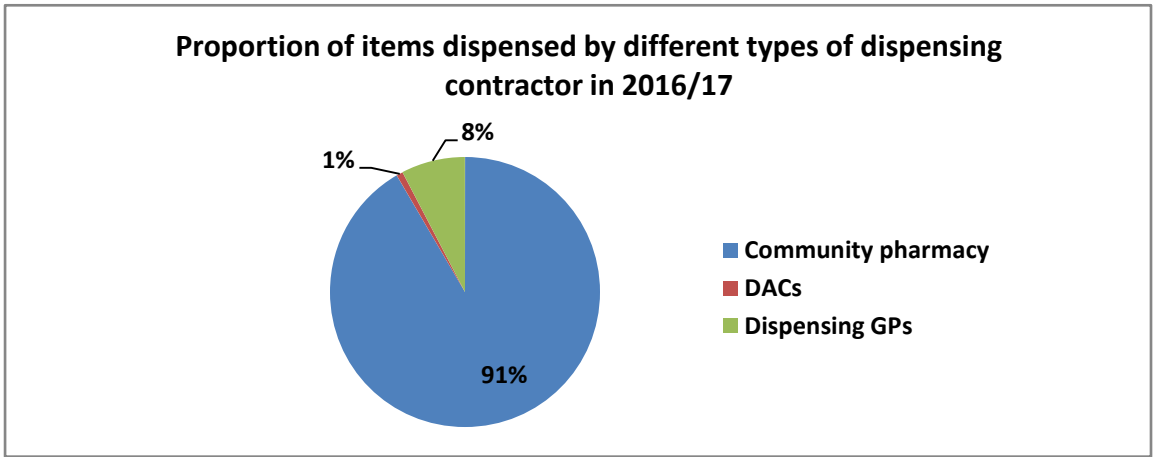


Figure 9. Proportion of items dispensed by different types of dispensing contractor in 2016/17

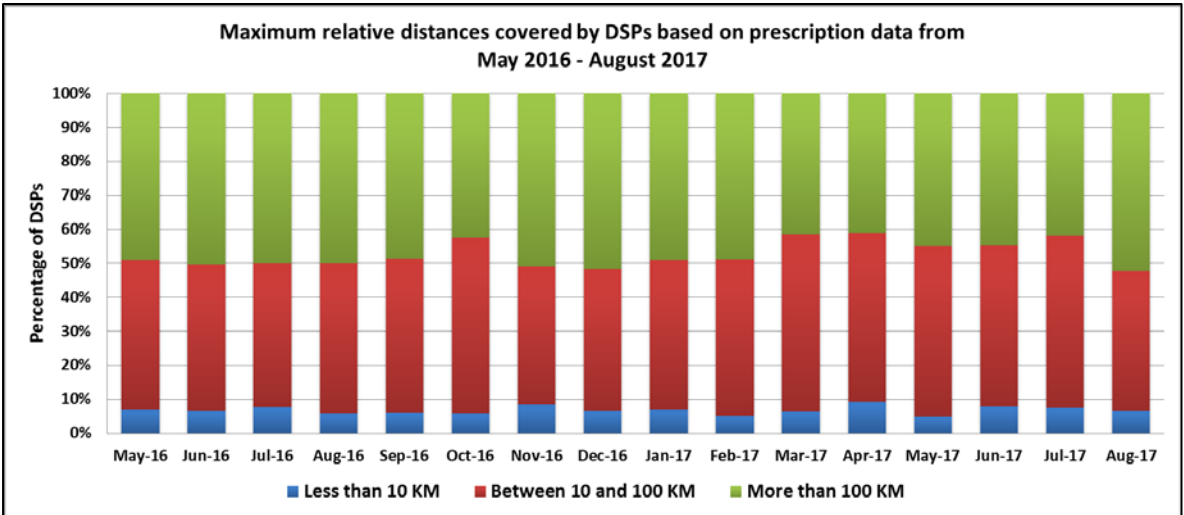


Figure 10. For dispensed prescriptions, the maximum distance to the patient for each DSP relative to all DSPs.

Distances are based on the patient’s home address from the dispensing DSP. For each DSP the minimum, median, and maximum distances of prescription items that individual DSP dispensed, were collated. Figure 10 reflects the furthest distance from a patient that a DSP dispensed a prescription item each month. It shows, as a proportion of all DSPs, the percentage of DSPs for which their furthest dispensed prescription item was less than 10km, between 10 and 100km and over 100km to the patient.

Annex B - Summary of the 2013 Regulations

Part 2 - requirements relating to pharmaceutical needs assessments (PNAs)

Part 3 - requirements for pharmaceutical lists and routine applications for market entry based on PNAs:

- current needs;
- future needs;
- improvements or better access to current service;
- future improvements or better access; and
- unforeseen benefits.

Part 4 - requirements relating to “excepted” applications (that do not have to pass the “market entry” test):

- relocations that do not result in significant change;
- distance-selling;
- change of ownership;
- temporary listing arising out of a suspension;
- right of return (from LPS); and
- temporary arrangements during emergencies etc.

Parts 5 and 6 - grounds for NHS England refusing, deferring or conditionally including applicants on a pharmaceutical list:

- not linked to fitness grounds – same/adjacent premises, language etc.;
- linked to fitness (suitability, fraud and efficiency);

Part 7 - requirements relating to rural areas (determination of controlled localities and new pharmacies)

Part 8 - requirements relating to rural areas (dispensing doctors)

Part 9 - requirements for conditional inclusion on pharmaceutical lists for certain applications, opening hours etc

Parts 10 and 11) - procedures for NHS England to deal with breaches of terms of service by community pharmacy and appliance contractors (*Part 10*) and fitness issues

Part 12 and Schedule 8 - financial matters (drug tariff, remuneration)

Part 13 - requirements for local pharmaceutical services contracts

- Schedules:
 - information to be contained in PNAs (*Schedule 1*);
 - procedures for market entry applications (*Schedule 2*) and appeals to the Secretary of State (*Schedule 3*);

- terms of service for: pharmacy contractors under the pharmacy contractual framework (*Schedule 4*); appliance contractors under their contractual framework (*Schedule 5*); and dispensing doctors (*Schedule 6*); and
- mandatory terms for LPS schemes (*Schedule 7*).

Annex C - A history of relevant regulation

- Health and Social Care Act 2001 – fitness to practise requirements for primary care contractors and individual practitioners and Local Pharmaceutical Services introduced;
- 1 April 2005 – the NHS (Pharmaceutical Services) Regulations 2005 come into force (Regulations under the NHS Act 1977) – community pharmacy contractual framework, local pharmaceutical services and balanced package of measures introduced;
- Health Act 2006 amends NHS Act 1977 to give PCTs power to charge fees for dealing with applications and enables two or more applications to be considered together;
- 1 April 2006 – the NHS (Local Pharmaceutical Services) Regulations 2006 come into force;
- June 2006 - review of progress on reforming the Control of Entry system for NHS pharmaceutical contractors published;
- 2006 – NHS Act 1977 consolidated into NHS Act 2006;
- March 2008 – review of contractual arrangements report published;
- Health Act 2008 – transfer of “global sum” to PCTs;
- Health Act 2009 – introduced pharmaceutical needs assessments (PNAs) and a market entry system by means of PNAs, performance sanctions for breaches of terms of service and enabling strategic health authorities to set up LPS schemes;
- 1 September 2012 – the NHS (Pharmaceutical Services) Regulations 2012 come into force;
- Health and Social Care Act 2012 – amended PNA and market entry system and other parts of the NHS Act 2006 to fit the new NHS architecture; and
- 1 April 2013 - the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 come into force.

Annex D - Amendments to the regulations since 2013

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the 2013 Regulations”). The 2013 Regulations govern the arrangements, in England, for the provision of pharmaceutical services and local pharmaceutical services (apart from the terms of service of piloted services) under Part 7 of the National Health Service Act 2006.

Regulations 3, 4, 5 and 7 restructure regulations 13(1), 15(1), 17(1) and 20(1) of the 2013 Regulations, which relate to pharmaceutical list applications in respect of needs for, or improvements or better access to, pharmaceutical services (or to pharmaceutical services of a specified type) which are identified in pharmaceutical needs assessments (“PNAs”). Pharmaceutical lists are lists of permitted providers of pharmaceutical services held by the National Health Service Commissioning Board (“NHSCB”) and PNAs are assessments of pharmaceutical services provision, including of potential gaps in service provision, produced by the Health and Wellbeing Boards of local authorities. The changes clarify the drafting, with no intended substantive effect.

Regulation 6 amends regulation 18 of the 2013 Regulations, which relates to pharmaceutical list applications where the applicant is seeking to offer what were unforeseen benefits at the time the relevant PNA was produced. The 2013 Regulations identify three desirable characteristics of such applications and the amendment makes it clear that the list of these three is disjunctive, so that the NHSCB needs only to have particular regard to the desirability of one of these three when considering an unforeseen benefits application.

Pharmaceutical list applications that offer either benefits identified in a PNA or unforeseen benefits are together known as “routine applications”. Pharmaceutical list applications that offer neither of these types of benefit generally have to be refused by the NHSCB, but there are a number of types of “excepted application” which can be granted even if they do not offer these types of benefit, one of which is applications for relocations that do not result in significant change to pharmaceutical services provision locally. Regulation 8(a) and (b) amend the threshold criteria in regulation 24 of the 2013 Regulations for granting these applications so that the requirement is that the NHSCB is not of the opinion that granting the application would cause significant detriment to proper planning, rather than the NHSCB positively needing to satisfy itself that granting the application would not cause significant detriment to proper planning.

The threshold criteria for this type of relocation application are also changed so that, if the relocation is of distance selling premises (typically, internet pharmacies), the NHSCB must be satisfied that the general conditions that apply for the granting of new distance selling premises applications also apply to the grant of applications for relocations of distance selling premises that do not result in significant change to pharmaceutical services provision locally (regulation 8(c)).

Change of ownership applications are another type of “excepted application”, and regulation 9(b) amends the threshold criteria in regulation 26 of the 2013 Regulations for granting these applications (which may sometimes be combined with a relocation

application) so that if the application relates to distance selling premises, the NHSCB must be satisfied that the general conditions that apply to the grant of new distance selling premises applications also apply to the grant of change of ownership applications for distance selling premises.

The changes in regulation 8(c) and 9(b) are also reflected in a change to regulation 64 of the 2013 Regulations, which sets the conditions of entry in pharmaceutical lists for distance selling premises. The change is to make sure that, going forward, the specific conditions of entry that apply to distance selling premises apply to all distance selling premises, not simply those distance selling premises that have resulted from the grant of an application pursuant regulation 25 of the 2013 Regulations and the provisions that preceded it (regulation 15).

It is possible, however, that prior to 1st April 2014, distance selling premises may have relocated, or been given permission to relocate, under the previous arrangements to the same site as a provider of primary medical services with a patient list. A transitional provision is included in these Regulations so that, if that has indeed happened, the term of service that would prevent the distance selling premises being on the same site as a provider of primary medical services with a patient list is disapplied (regulation 16).

Some pharmaceutical list applications have needed to be refused if the proposed premises were part of the same site as the premises of an existing provider of pharmaceutical services, and regulation 10 amends regulation 31 of the 2013 Regulations so that this restriction now applies to all types of pharmaceutical list applications.

Applications for new NHS chemist premises sometimes include a best estimate of where the new premises are to be located, rather than an exact location, and in some cases where an exact location is given, change of that exact location is permissible after the application has been granted. Regulation 17(c) and (d) amend paragraphs 31 and 32 of Schedule 2 to the 2013 Regulations to provide that, when an exact location, or a different exact location, is given after an application has been granted, that location also cannot be part of the same site as the premises of an existing provider of pharmaceutical services.

Regulation 11 amends regulation 32 of the 2013 Regulations so that a designation of an area or premises under Part 13 of the Regulations – which is a potential preliminary for a tendering exercise for a contract to provide local pharmaceutical services – now acts as a ground for deferring all types of routine applications in the area, or for the premises, covered by the designation – not just some types of routine applications.

Applications for entry on a pharmaceutical list may be deferred or refused on some specified grounds relating to the fitness of the potential provider of pharmaceutical services to be a provider of such services. Previously, the refusal and deferral provisions applied only to potential providers who were individuals or bodies corporate, but regulations 12 and 13 amend regulations 33 and 34 of the 2013 Regulations so that these refusal and deferral provisions now also apply to the partners in applications from partnerships. The changes to regulations 33 and 34 of the 2013 Regulations also correct drafting errors.

Regulation 14 amends regulation 40 of the 2013 Regulations, which includes a rule requiring the refusal of applications for new pharmacies in certain rural areas for a period of five years, where dispensing services are provided in the relevant location by dispensing doctors, if an application for a pharmacy within 1.6 kilometres of the proposed new pharmacy has

been refused in the previous five years. The changes prevent a new five year period being triggered within an existing five year period by an application for a new pharmacy that has to be refused because of the rule. It also requires the NHSCB to decline to apply the rule if it is satisfied that the pharmacy application was motivated wholly or partly by a desire for the application to be refused, thus triggering a five year bar on further applications.

Providers of pharmaceutical services that provide certain types of specialist appliances may provide telephone care lines for users of the appliances during their normal opening hours. Regulations 18 and 19 amend provisions in Schedules 4 and 5 of the 2013 Regulations to provide that those providers must ensure that, during out of hours periods, if advice is not available to those users via those telephone lines, contact details are given via those telephone lines for alternative sources of NHS advice. Previously, contact details had to be given of NHS Direct National Health Service Trust, which is to be abolished.

Regulations 9(a), 17(a) and (b) and 20 correct drafting errors in the 2013 Regulations.

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2015

These Regulations made the following amendments to the 2013 and 2014 Regulations:

- amended regulation 25 to make it clear that an applicant for new distance selling premises who is already included in a particular pharmaceutical list but who is seeking replacement premises in the same local authority area is subject to the requirements in respect of distance selling premises applications in regulation 25;
- corrected an error in the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2014 that amended regulation 32 of the 2013 Regulations so that the NHSCB was required to refuse pharmaceutical list applications that related to a neighbourhood or premises covered by such a designation, rather than simply giving the NHSCB the power to defer such an application. (Under regulation 99, the NHSCB may designate premises or a neighbourhood for the purpose of giving priority in that place to the development of schemes for the provision of local pharmaceutical services;
- amended the Regulations so that a local pharmaceutical services contractor may choose to be a “health service body” and so for their contract to be an NHS contract – and if they do, they may also choose to cease to be such a body and so for their contract to cease to be an NHS contract. Where a local pharmaceutical services contractor does choose to cease to be a health service body, the amendments made by these Regulations have the effect of providing that all disputes relating to the period when their contract was an NHS contract are to be dealt with via the NHS dispute resolution procedure. An exception is made in a transitional provision which provides, in effect, that if a dispute was already the subject of legal proceedings before these Regulations came into force, that dispute is to be determined in accordance with the relevant legislation as it applied at that time (regulation 10). Before these Regulations came into force, disputes under a local pharmaceutical services contract that was not an NHS contract, but which related to a time when the contract was an NHS contract, could only

be dealt with via the NHS dispute resolution procedure (if they had not been referred to that procedure when the contract was an NHS contract) with the contractor's consent;

- corrected drafting errors;
- amended the Regulations in respect of lapsed applications. Applicants for inclusion in a pharmaceutical list may be granted subject to a condition that relates to the applicant's fitness to provide pharmaceutical services. If that condition is appealed by the applicant, and the appeal is lost, the application may lapse if a required notification is not given by the applicant. In respect of cases where the applicant makes a subsequent pharmaceutical list application, the application procedures are amended so that the applicant must make reference in the new application to the earlier lapsed application (regulation 6(a)). The pharmaceutical list applications procedures are also amended so that in all cases where the applicant is seeking the listing of premises that are the same as, or in close proximity to, premises that are already listed, the applicant must explain why they believe the application should not be refused under regulation 31 of the 2013 Regulations, which prevents the granting of applications where the proposed and existing premises should be treated as the same site (regulation 6(b)); and
- amended the terms of service of providers of pharmaceutical services on pharmaceutical lists that dispense both drugs and some appliances so that they are required to give appropriate advice about the benefits of repeat dispensing to specified categories of patients. In addition, their audit programme requirements are amended so that rather than in all cases having to undertake two clinical audits, they are required to undertake a clinical audit of their choice, and either a clinical or policy based audit as specified by the NHSCB (regulation 8).

The National Health Service (Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service) Regulations 2015

These Regulations removed the restrictions which prevent the use of an electronic prescription for the prescribing by instalments of buprenorphine, diazepam or drugs listed in Schedule and permits the electronic prescribing of drugs listed in Schedule 2 or 3 to the Misuse of Drugs Regulations 2001 (as amended).

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2016

These Regulations made the following amendments to the 2013 Regulations:

- corrected two typographical errors;
- substituted the review provision in regulation 121 with a new provision that requires further reviews after the first review (which previously had been provided for), sets out in greater detail what the reports following each review are to include, and sets a five year maximum interval between reviews; and
- amended the terms of service of chemists that provide NHS community pharmaceutical services:

- before providing a drug or appliance that has been ordered on an NHS prescription, if entitlement to non-payment of an NHS prescription charge is being claimed, the chemist must ask for evidence of that entitlement. If evidence is not supplied, the chemist is now required, before the drug or appliance is supplied, to advise the person who was asked to produce that evidence that checks are routinely undertaken to ascertain entitlement to non-payment of NHS prescription charges, where this is claimed, as part of the relevant arrangements for preventing or detecting fraud or error; and
- some chemists have access to NHS patients' summary care records, which are electronic records under the management of the Health and Social Care Information Centre. If chemists do have this access, they are required to access those records when they are providing NHS community pharmaceutical services, where it is in the best interests of a patient to do so and doing so accords with the guidance known as "The NHS Care Record Guarantee".

The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016

These Regulations principally amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations"). The 2013 Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of pharmaceutical services and local pharmaceutical services.

The 2013 Regulations provide for pharmaceutical services provision by, amongst others, retail pharmacy businesses, and for pharmaceutical lists to be held by the National Health Service Commissioning Board ("the NHSCB") of the retail pharmacy businesses entitled to provide pharmaceutical services, which are kept by reference to the areas of the Health and Wellbeing Board ("HWB") of a local authority.

Retail pharmacy businesses that are included in a particular pharmaceutical list may wish to consolidate the services provided on two or more sites onto a single site. Such consolidations could require a change in the ownership of one of the businesses in question. Part 2 of these Regulations puts in place a process to facilitate such consolidations.

Applications to consolidate will be dealt with as "excepted applications" under the 2013 Regulations, which means in general terms they will not be assessed against the local plan known as the pharmaceutical needs assessment ("PNA") produced by the HWB. Instead, they will follow a simpler procedure, the key to which is whether or not a gap in pharmaceutical service provision would be created by the consolidation. Some provision is also made in respect of continuity of services – for example, if the NHSCB intends to commission from the applicant "enhanced services" (additional pharmaceutical services, such as minor ailments schemes, that are commissioned locally) that have been provided at or from the closing premises, the applicant is required to provide undertakings to continue to provide those services (regulation 11). If the NHSCB is satisfied that the consolidation would create a gap in pharmaceutical services provision, it must refuse the application (regulation 7). The opinion of the HWB on this issue must be given when the application is notified locally and representations are sought (regulations 12 and 13). If the application is

granted and pharmacy premises are removed from the relevant pharmaceutical list, if the HWB does not consider that a gap in service provision is created as a consequence, it must publish a supplementary statement published alongside its pharmaceutical needs assessment recording its view (regulation 3). Also, if the NHSCB does grant the application, it must then refuse any further applications known as “unforeseen benefits applications” by other chemists seeking inclusion in the pharmaceutical list, if the applicant is seeking to rely on the consolidation as a reason for saying there is now a gap in provision, at least until the next revision of the PNA (regulations 5 and 6).

Various supplementary amendments are made in relation to the new process, or to align the existing processes with the new process, including in relation to the undertakings to be given by applicants (regulation 11), enabling businesses to relocate onto an existing site in this particular context (regulation 8), notification by the NHSCB of decisions on consolidation applications (regulation 15), the notices to be sent by pharmacy businesses when premises close or open (regulations 9, 10 and 15 to 18), the NHSCB’s responsibilities to notify HWBs of changes to lists (regulation 4), and in relation to appeals (regulations 19 and 20).

Part 3 of these Regulations makes provision for the prescribing and dispensing, as part of NHS primary care services of prescriptions written by therapeutic radiographer independent prescribers and dietitians who are entitled to prescribe as supplementary prescribers – and for prescription charges to be levied in respect of such prescriptions (regulations 21 to 24).

Part 4 of these Regulations makes provision which allows prescription charges to be levied by providers of pharmaceutical or local pharmaceutical services who undertake emergency supplies of medicines at the request of a patient in accordance with specified types of arrangements with the NHSCB for the making of such supplies (regulation 26). However, providers of pharmaceutical services on pharmaceutical lists who have such arrangements are not obliged to publicise them as part of their clinical governance programme (regulation 25). Clinical governance programmes are not required terms of local pharmaceutical services contracts.

Annex E - A list of stakeholders involved in the review consultation process

<u>Stakeholder</u>
Company Chemists Association
Urology Trade Association
Dispensing Doctors Association
British Healthcare Trades Association
Pharmaceutical Services Negotiating Committee
National Pharmacy Association
Royal Pharmaceutical Society
NHS England
Greater Manchester Partnership
NHS Litigation Authority
Association of Pharmacy Technicians UK
Health Education England
General Pharmaceutical Council
Business stakeholders