EXPLANATORY MEMORANDUM

The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013.

This Explanatory Memorandum has been prepared by the Department of Health and Social Services and is laid before the National Assembly for Wales in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 ("the Regulations"). I am satisfied that the benefits outweigh any costs.

Mark Drakeford Minister for Health & Social Services

DATE :17 April 2013

Description

The Regulations revoke and replace the National Health Service (Pharmaceutical Services) Regulations SI 1992 / 662.

Matters of special interest to the Constitutional and Legislative Affairs Committee

The Regulations revoke and replace the National Health Service (Pharmaceutical Services) Regulations SI 1992 / 662 ("the 1992 Regulations").

The 1992 Regulations have provided the statutory framework for the provision of NHS pharmaceutical services in Wales since 1992.

Legislative Background

The Regulations are being made in exercise of powers conferred by sections 15, 80, 83, 84 86, 88, 104, 107, 110, 115,116,118, 203(9) and (10) and 205 of the National Health Service (Wales) Act 2006.

The Regulations are subject to the negative resolution procedure.

Purpose and intended effect of the legislation

Policy Background

The provision of NHS pharmaceutical services across Wales is currently underpinned by a regulatory framework which is set out in the NHS (Pharmaceutical Services) Regulations 1992 ("the1992 Regulations") as amended.

The 1992 Regulations applied in relation to England and Wales until 2005 when England introduced the NHS (Pharmaceutical Services) Regulations 2005 and revoked the 1992 Regulations in relation to England. Since then the 1992 Regulations have remained in force in relation to Wales only.

The 1992 Regulations currently set out the processes for applications to Local Health Boards (LHBs) for inclusion in and amendment to pharmaceutical lists; applications to be included in a dispensing doctor list and for appeals to Welsh Ministers against decisions made by LHBs. They also set out the Terms of Service for pharmacists, NHS appliance contractors and dispensing doctors.

The 1992 Regulations have been amended numerous times since their coming into force and have become difficult to interpret. Appeals have become common place as result of difficulties in interpreting the 1992 Regulations.

Purpose and Effect

The Regulations will consolidate the many amendments which have been made to the 1992 Regulations and will present them in a simplified way that will be more easily interpreted. These Regulations will also change some of the regulatory requirements and processes governing the determination of applications to provide NHS pharmaceutical services. The key changes to the regulatory framework are as follows:

- Within a three year time period, applications relating to the same neighbourhood as previous applications that have been determined as neither necessary nor expedient can be dismissed by the LHB, provided there have been no significant changes to the neighbourhood;
- The maximum period of preliminary consent (before a full application is made) will be reduced from 12 months to 6 months;
- Removal of the requirement for a minor relocation to be within the same neighbourhood, provided that for patients who are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
- Introduction of an option for temporary relocation for those pharmacies that are unable to continue to provide services at their current location because, for example, they have been flooded or need to undertake structural building work;
- Extension of the necessary or expedient test to applications by doctors in rural areas to become dispensing doctors. This will ensure that applications to provide pharmaceutical services are determined using the same criteria regardless of whether the application is made by a pharmacist or doctor; and
- Introduction of a range of checks and safeguards to help ensure providers of NHS pharmaceutical services are suitable and fit to be included in the LHB pharmaceutical list.

It is intended that these Regulations will allow for a structured approach in determining where NHS pharmaceutical services are located in Wales and also reduce the

administrative burden on LHBs associated with processing applications to provide NHS pharmaceutical services and on the Welsh Ministers in processing subsequent appeals.

A summary of the content of the Regulations is as follows:

Part 1 contains introductory provisions.

Part 2 sets out the requirements for each LHB to prepare and maintain; lists of pharmacists and appliance contractors who undertake to provide NHS pharmaceutical services from premises within the LHB area (so called pharmaceutical lists); and lst of doctors who undertake to provide pharmaceutical services from premises within the LHB area (so called dispensing doctor list).

Part 3 makes provision for an LHB to determine whether or not a particular area within the area for which the Local Health Board is established is, because it is rural in character, a controlled locality or part of a controlled locality. It also makes provision for a Local Medical Committee or Local Pharmaceutical Committee to make an application to the LHB to make such a determination.

Where a particular area is determined to be a controlled locality, doctors may provide pharmaceutical services to certain of their eligible patients subject to those doctors being included in a dispensing doctor list. The procedures that an LHB must follow in determining a question as to whether an area is a controlled locality or part of a controlled locality are set out in Schedule 2 to the Regulations. Rights of appeal to the Welsh Ministers in respect of decisions made by LHBs are set out in Schedule 3.

Part 4 sets out the types of applications for inclusion in or amendment to a pharmaceutical lists. The part sets out the tests which an LHB must apply to determine those applications. Under regulation 8 (applications to be included in or for amendment to a pharmaceutical list) and regulation 12 (applications for preliminary consent and effect of preliminary consent) applications can be granted only if the LHB is satisfied that it is necessary or expedient to grant the application to secure in the neighbourhood in which the premises specified in the application are located, the adequate provision of all or some of the services specified in the application, this is referred to as the necessary or expedient test.

If the premises are located in a controlled locality the LHB must be satisfied that to grant any application will not prejudice the proper provision of primary medical, dispensing or pharmaceutical services in any locality, this is referred to as the prejudice test. The exception to this is where the premises specified in an application are determined, by the LHB, to be in a reserved location under regulation 11. Reserved locations are controlled localities in which fewer than 2,750 people on a GP practice list live within 1.6km of the proposed pharmacy would be located although in some circumstances an LHB may determine a location not to be reserved despite the population being below 2,750.

Certain applications are not required to be determined by either the necessary or expedient test or the prejudice test. A person already included in a pharmaceutical list can apply to relocate the premises from which he or she provides pharmaceutical services where the move can be considered to be a minor relocation. Regulation 13 sets out when an LHB must grant such an application. Similarly, applications that fall within regulations 14, 15 and 16 are not assessed in accordance with the necessary or expedient test or the prejudice test. The procedures that an LHB must follow in determining applications under Part 4 are set out in Schedule 2 to the Regulations, and rights of appeal to the Welsh Ministers in respect of decisions made by LHBs are set out in Schedule 3.

Part 5 sets out the applications which doctors can make in order to be able to fulfil the conditions on which they can then make arrangements with an LHB to provide pharmaceutical services to their eligible patients. Doctors may only provide pharmaceutical services in controlled localities. Before doing so they must apply for outline

consent and premises approval under regulation 24 and LHBs must consider such applications in accordance with the necessary or expedient test, the prejudice test and the proximity of the premises from which the doctor wishes to provide pharmaceutical services to nearby pharmacies. A doctor who has been granted outline consent and premises approval may then make arrangements with an LHB to provide pharmaceutical services under regulation 20. The procedures that an LHB must follow in determining applications under Part 5 are set out in Schedule 2 to the Regulations, and rights of appeal to the Welsh Ministers in respect of decisions made by LHBs are set out in Schedule 3.

Part 6 deals with fitness grounds and inclusion in and removal from pharmaceutical lists. It provides for the deferral and refusal of applications for inclusion in a pharmaceutical list on fitness grounds and provides for an inclusion in a pharmaceutical list being subject to conditions (regulation 33). For certain fitness matters, including where a person has been convicted in the United Kingdom of a criminal offence and has been sentenced to a term of imprisonment of over six months, a Local Health Board must remove a person from a pharmaceutical list pursuant to regulation 35.

Part 7 deals with payments to NHS pharmacists and NHS appliance contractors. Regulation 41 provides for the publication of the Drug Tariff. There are also provisions for supplemental matters including overpayments and payments to NHS pharmacists and NHS appliance contractors.

Part 8 deals with miscellaneous matters, including transitional provisions for applications and appeals made under the 1992 Regulations before the Regulations come into force.

Implementation

It is intended that these Regulations will come into force on 10 May 2013 and will revoke and replace the 1992 Regulations as amended.

Consultation

Consultation was conducted as detailed in the Regulatory Impact Assessment.

Summary

The Regulations simplify the existing Regulatory framework contained in the 1992 Regulations which had become very complex to interpret as a result of numerous revisions over a 21 year period; provide, in Part 6, a regulatory framework in relation to fitness to practice matters and introduce a number of policy changes which can be summarised as follows:

- Provision for applications that must be determined under the necessary or expedient test to be dismissed by an LHB for a period of up to 3 years where, in that period, the test has been considered in relation to a previous application and, in the opinion of the LHB, there has not been a significant change of circumstances in the neighbourhood;
- Reduction to the maximum period of grant of preliminary consent;
- Reduction to the maximum period before which an applicant must commence service provision;
- Removal of the requirement for a relocation to be within a neighbourhood in order that it can be considered minor and therefore exempted from the need to satisfy the necessary or expedient test;

- Requirements that pharmacies who undertake a minor relocation provide services from that location for at least 12 months before applying for a further relocation;
- Provision for temporary relocations in some circumstances;
- Extension of the necessary or expedient test to applications by doctors in rural areas to become dispensing doctors. This will ensure that applications to provide pharmaceutical services are determined using the same criteria regardless of whether the application is made by a pharmacist or doctor; and
- Introduction of a range of checks and safeguards to help ensure providers of NHS pharmaceutical services are suitable and fit to be included in the LHB pharmaceutical list.

REGULATORY IMPACT ASSESSMENT

1. Introduction

1.1. The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 ("the Regulations") will govern the provision of NHS pharmaceutical services in Wales. They regulate how, where and by whom such services are provided in Wales; this is referred to as "Control of Entry".

1.2. The Regulations also set out the contractual obligations of those persons providing NHS pharmaceutical services (be they pharmacists, doctors or appliance contractors); and these are referred to as the "Terms of Service".

1.3. The Regulations introduce "Fitness to Practice" requirements for community pharmacy contractors providing NHS pharmaceutical services for Wales.

1.4. The principles which underpin these regulations were the subject of a consultation, which opened and 1 February and closed on 27 April 2012, entitled "*Proposals to Reform and Modernise NHS (Pharmaceutical Services) Regulations 1992*", the outcome of which was that the majority of respondents supported the proposal for new NHS pharmaceutical services regulations in Wales. A majority of respondents supported the proposals to simplify the structure of, and regulatory processes contained within, the NHS(Pharmaceutical Services) Regulations 1992.

1.5. The Regulations revoke and replace the National Health Service (Pharmaceutical Services) Regulations 1992 (S.I.1992/662) (as amended) ("the 1992 Regulations").

2. Legislative background

2.1 The National Health Service (Pharmaceutical Services) (Wales) Regulations 2013 ("the Regulations") are made by the Welsh Ministers using the powers contained in sections 15, 80, 83, 84, 86, 88, 104,107,110 115, 116, 118 203(9) and (10) and 205 of the National Health Service (Wales) Act 2006. The Regulations follow the negative resolution procedure.

3. Purpose & intended effect of the legislation

<u>Control of Entry</u>

3.1 In 2010 the Minister for Health and Social Services established a Task and Finish Group to review the 1992 Regulations, to consider Welsh Government policy on control of entry and the provision of pharmaceutical services by health professionals other than pharmacists (e.g. doctors), and to make recommendations for changes to the 1992 Regulations., if appropriate, to bring about a long term, cost-effective and sustainable system which will afford patients appropriate access to pharmaceutical services.

3.2 The issues of most concern identified by the Task and Finish Group were that :

- As a result of their amendment the 1992 Regulations were difficult to interpret; amendments have been made over 20 years and there were discrepancies in the language, style and format of the amendments which made their interpretation difficult.

- The 1992 Regulations were complex and there was scope to simplify and clarify their structure.

- As a result of the position referred to above there was potential for there to be poor decision making and poor understanding of decisions by applicants and interested parties, inevitably leading to appeals being made to the Welsh Ministers.

- There were, each year, a high number of applications, the result of which was no, or little, net change in community pharmacy numbers. Administering this status quo was costly and unnecessary.

3.3 The Regulations implement the proposals of the task and finish group, which in summary, were to revoke and replace the regulations to:

- Consolidate the many amendments which have been made to them since 1992 and which will present them in a simplified way that will be more easily interpreted; and

- Make changes to the regulatory requirements and processes governing the determination of applications to provide NHS pharmaceutical services.

3.4 By introducing this legislation the Minister is seeking to improve the way in which decisions regarding the provision of NHS pharmaceutical services are made by improving the way in which the Regulations are used thereby reducing their administrative burden. This will improve the system and resultant decision making for applicants, existing contractors, and Local Health Boards (LHBs).

Fitness

3.5 The Regulations introduce a range of checks and safeguards to help ensure providers of NHS pharmaceutical services are suitable and fit to provide such services to patients; so called "Fitness to Practise". They are more complex for pharmacy than other contractor groups because of the control of entry system. But current measures are inadequate and time-consuming when LHBs need to take effective action, for example, in cases of serious crime. The provisions in Part 6 of the Regulations will apply not only to "individuals " who are NHS pharmacists or NHS appliance contractors but also to companies providing pharmaceutical services (usually termed "bodies corporate") and the directors and superintendent pharmacists (who are required to be appointed by the Medicines Act 1968 where a company provides pharmaceutical services, but who might not be directors) of such companies.

3.6 The provisions in Part 6 of the Regulations bring arrangements in Wales in line with those which have been in place in England for some time.

4. Options

Option One

Do nothing, retain the 1992 Regulations and do not introduce fitness checks for pharmacy contractors.

Option Two

Move to a system of exemptions to control of entry for NHS pharmaceutical services in some circumstances, revoke the 1992 Regulations replacing them with regulations governing terms of service and fitness only.

Option Three

Revoke the 1992 Regulations and replace them with new regulations which present them in a way that will be more easily interpreted, which simplify the regulatory requirements and processes and introduce fitness checks.

5. Costs & benefits

Option One – Do Nothing

Control of Entry

5.1 The Regulations, which were originally made to apply in Wales and England but which have been revoked in relation to England, have been in force since 1992. Over the years, the Regulations have been heavily amended and this does not assist in their interpretation and application. Through amendment their language and the interpretation terms has become inconsistent, this has further contributed to difficulty in their application. There is, therefore potential for there to be poor decision making and poor understanding of decisions by applicants and interested parties, inevitably this leads to appeals being made to the Welsh Ministers.

5.2 There are, each year, a high number of applications, the result of which is no, or little, net change in community pharmacy numbers. Administering this status quo is costly and unnecessary.

5.3 For example in 2010/11 there were 47 applications to LHBs to open a community pharmacy in Wales, a further 28 applications were made to relocate an existing pharmacy. Of these a high proportion ended in appeal. Despite a high number of applications and appeals the net change in the number of pharmacies in Wales from the previous year was one. This represents a considerable regulatory burden on LHBs, who determine the applications; Welsh Government, who administer the appeals process; and community pharmacy contractors, who are required to manage the uncertainty which comes with applications to open new community pharmacies in areas which are already well served.

5.4 Maintaining the current position potentially benefits only those pharmacy contractors already providing NHS services in Wales, since the low net change in pharmacy numbers suggests that they enjoy a relatively secure position in the market. However the current arrangements can require existing contractors to invest significant time in responding to new applications this may impact adversely on decisions by pharmacies to invest in improvements to premises.

5.6 Doing nothing means that the inadequacies in the administration of the current regulations will persist, the numbers of applications and appeals will remain high. Unnecessary administrative costs for all parties will continue.

5.7 The majority of respondents to the consultation were in favour of reform highlighting that there is broad agreement on the need for change.

Fitness

5.8 No change could benefit the very small minority of contractors who would risk losing their right to provide NHS services as a result of concerns over their fitness.

5.9 Currently in Wales LHBs are not required to have in place checks and safeguards which ensure providers of NHS pharmaceutical services are suitable and fit to provide such services to patients. This is at odds with the arrangements for doctors, dentists and optometrists in Wales and pharmacy contractors in England.

5.10 Current measures are inadequate and time-consuming when LHBs need to take effective action, for example, in cases of serious crime. Whilst it is recognised that the responsibility for determining the fitness of individual pharmacists is now a matter for the General Pharmaceutical Council there remain concerns that LHBs have limited powers to take steps which protect patients and the public where there is reason for the LHB to have concern regarding the fitness to practice of a pharmacy contractor.

5.11 Doing nothing means that in Wales the checks and safeguards which exist for other contractors in Wales and for pharmacy contractors in other parts of the UK will not be in place.

Option Two – Exemptions to Control of Entry with Fitness Checks

Control of Entry

5.12 Prior to the introduction of control of entry legislation in the mid 1980s regulations controlled neither the location nor the number of pharmacies providing NHS pharmaceutical services. As a result of free market entry the number of pharmacies in the UK at any one time was highly dependent on the remuneration arrangements in place for pharmacy contractors at that time. For example under the remuneration arrangements in place in the 1970s pharmacy numbers declined sharply but rose sharply when the “cost plus” system was introduced in the 1980s. This has the potential to create large swings in the numbers of pharmacies as Government seeks to balance the availability of pharmaceutical services with incurring excessive expenditure as numbers rise.

5.13 Whilst remuneration arrangements for pharmacy contractors now make it less likely that pharmacy numbers would proliferate, because the total funding available to pharmacy contractors in Wales is a fixed sum, relaxation of control of entry could result in significant changes to the location and distribution of pharmacies across Wales. In a market in which some applications were exempt from control of entry it is conceivable that pharmacies would seek to exploit the exemptions in order aggregate in locations which maximise their share of income derived from dispensing prescriptions. The number and location of pharmacies could fluctuate significantly as new pharmacies enter the market in competition with existing pharmacies, in such a scenario the viability of either business will be uncertain and may result in one or both reducing the provision of services or even ceasing to trade. Ultimately this competition could create an environment which would jeopardise trust and relationships between pharmacist and patient. Furthermore an unstable pharmacy network is unlikely to be seen as the place for either pharmacy contractors or the NHS to invest in delivery of services, this could mean that the opportunities identified by Welsh Government for an increased role in health service delivery by pharmacists, for example through provision of the minor ailment service, is missed. The adverse effect of exemptions may be felt particularly in rural parts of Wales.

5.14 Deregulation could have a significant impact on existing contractors by reducing the value of their businesses by increasing market entry. In 2003 the Office of Fair Trading (OFT) estimated the typical value of a pharmacy was between £250,000 and £300,000. Currently

much of this value represents the premium for holding the right to provide NHS dispensing in a relatively stable market.

5.16 Additionally there could be higher demand for pharmacists which may lead to higher pay this would have a significant impact on:

- The profitability, and therefore sustainability, of NHS community pharmacies, as higher pay eroded margins.

- Recruitment and retention of pharmacists in the managed sector. It is possible that recruitment and retention of pharmacists working in LHBs and NHS Trusts would be adversely affected by the potential for higher salaries in community pharmacy.

- Continuity for patients. It is likely that companies would compete for the pharmacist workforce by offering better salaries or benefits. This could lead to pharmacists moving between employers, and pharmacies, frequently with associated disadvantages for service continuity.

5.17 Deregulation could benefit those currently wanting to enter the market. It is probable that large retail chains would benefit most from deregulation, as they will have the resources to capture the most lucrative trading positions. This will be at the expense of the smaller retailer. On the other hand improved access to the NHS pharmacy market may result in reduced costs of purchasing a pharmacy business, as a result of the reduction in premiums associated with rights to dispense prescriptions; this could make it easier for pharmacists starting in business to raise the necessary capital.

5.18 LHBs will incur increased costs for each new entrant as a result of the additional administration required to ensure that the pharmacy is providing appropriate NHS services (e.g. additional contract monitoring visits).

5.19 Other fixed costs such as establishment payments and the cost of connectivity to the NHS intranet for each new entrant will be incurred by LHBs. These costs are currently met from Welsh Government allocations to LHBs which, as a result, may need to increase. Currently establishment payments and NHS connectivity costs are £25,100 and £2,400 per contractor per annum respectively. In the short term these costs would result in pressures on LHB allocation although over time they would be absorbed within the overall fixed contractual sum for pharmacy in Wales through, for example, reductions in dispensing fees. Any added costs would have to be weighed against the benefit of an overall rise in pharmacy provision.

<u>Fitness</u>

5.20 LHBs and businesses will face additional costs arising from new fitness procedures for pharmacy contractors. These will be offset in part for LHBs as the new procedures reflect those in place for other primary care contractors (doctors, dentists etc). The impact on LHBs and businesses would be further reduced by:

- Allowing a body corporate, or partnership, with pharmacies in more than one LHB area to undergo a fitness check in a host LHB rather than each LHB in which they provided NHS pharmaceutical services.

- Not requiring any body corporate that had submitted the necessary declaration previously to undergo a further check in relation to new applications.

5.21 Brand new providers applying to provide NHS pharmaceutical services would be required to comply from the date on which the Regulations come into force with existing contractors given a further 6 months to comply.

5.22 Assuming the average pharmacy contractor has 3 directors (including the superintendent pharmacist) and there are 100 existing contractors, who provide NHS pharmaceutical services in Wales, providing information to LHBs which takes around 1 hour to compile per director. At a staff cost of £50 per hour the cost to existing contractors would be **£15,000 (£150 per contractor) in the first year only**.

5.23 The cost of new entrants is likely to be small. Assuming 70 new pharmacies open each year as a result of deregulation and that 10 of these are owned by individuals, partnerships or bodies corporate that do not already provide NHS pharmaceutical services (and therefore have not had a previous check) the additional cost to business would be **£1,500 per annum**.

5.24 There would also be costs for LHBs who would be required to check references and declarations made by contractors. The NHS Wales Shared Services Partnership is experienced in this through similar procedures for other primary care contractors and there may be economies of scale which can be realised although these are not estimated.

5.25 It is estimated that checking applications would take 2 hours per applicant at £20 per hour. The year one cost would therefore be **£12,000** with a subsequent **annual cost of £1,200**.

5.26 Against any cost will need to be balanced that LHBs will be able to take prompt action where necessary in relation to fitness. The procedures would be applied consistently to all contractors in Wales and create parity with England. This would enhance certainty and safety for patients and the NHS.

Option Three – New Regulations with Fitness Checks

Retain Control of Entry with specific revisions

5.27 This would benefit existing contractors, LHBs and patients. (Whilst new applicants are unlikely to benefit from the reform (because it would not create any exemptions to the existing "control of entry" tests) neither are they disadvantaged relative to the current arrangements. In many regards new applicants will benefit as a result of the simplification of the regulations which will make the application and decision making process more transparent. For all parties administrative burden will be reduced and confidence in the system will increase.

5.28 Existing contractors and LHBs could find that the market is perceived to be more stable than under existing arrangements, although given the market is already very stable the reality is unlikely to be significantly changed. A perceived improvement in market stability could encourage pharmacy contractors and LHBs to invest more readily in delivering and planning additional health services from a pharmacy

5.29 Appeals to Welsh Ministers against LHB decisions should be reduced as a result of fewer speculative applications, LHBs having powers to dismiss applications in specified circumstances and better decision making. The administrative cost to LHBs in determining speculative applications will be reduced.

5.30 Where appeals are made, Welsh Ministers will find determining them simpler as a result of improved clarity in the decision making process by LHBs.

Specific revisions to Control of Entry

5.31 Allowing LHBs to dismiss applications where, in the previous 3 years an LHB, or on appeal the Welsh Ministers, has determined that it was neither necessary nor expedient to grant an application which relates to the same neighbourhood will benefit LHBs because they will no longer be required to determine such applications unless they consider that there has been a significant change in circumstances since the previous determination. This will reduce the administrative burden on LHBs. There will be a benefit for existing contractors who are currently notified of every application and have to consider whether they have to make representations to their LHB and endure uncertainty whilst the application is being determined by the LHB.

5.32 New applicants will not benefit from, but neither will they be disadvantaged by, the change. New applicants will be required to make the case for significant change in a neighbourhood since a previous application in order for the LHB to determine their application. There is a right of appeal to Welsh Ministers for applicants if a LHB determines not to consider an application on the grounds that there has not been a significant change in the neighbourhood. New applicants will benefit from the changes which require LHBs to publish their determinations made under the regulations as transparency is increased. Applicants will be better informed when identifying potential locations for pharmacy applications.

5.33 Reducing the maximum period of preliminary consent for inclusion in the pharmaceutical list will benefit LHBs, patients and applicants wishing to provide pharmaceutical services by reducing the time between an application being granted and services commencing. Preliminary consent allows applicants, who had yet to find or build premises, to identify whether their application was likely to be successful before incurring any unnecessary expense, however it can have the unintended effect of freezing the market in a given location because the LHB has no means to enforce provision. This effectively prevents other contractors from applying to move in. The Task and Finish Group and respondents to the consultation felt that preliminary consent could be used by existing contractors to block applications from new ones and that this had the potential to prevent inadequacies in the provision of pharmaceutical services being addressed.

5.34 Reducing the maximum period of preliminary consent will impact on those applicants who may have used the existing arrangement to block the market entry of competitors. Increased competition is likely to reduce the value of those businesses affected however the entry of new pharmacies only occurs in response to inadequacy in the availability of pharmaceutical services. Any impact on individual businesses is therefore outweighed by achieving adequate service provision for patients.

5.35 Reducing the maximum period between final grant of an application and commencing services will benefit patients and LHBs by ensuring that applicants progress from approval to commencing services timeously; the availability of necessary or expedient services will not then be unduly delayed.

5.36 Reducing the maximum period between final grant of an application and commencing services could have an impact for those applicants (who wish to apply well in advance of a proposed GP practice or residential property development). This might be in order to secure premises. Whilst this might make planning more difficult for the pharmacy and the developer it is unlikely to have any impact on patients since typically such applications are made well in advance of any increase in demand or need for pharmaceutical services.

5.37 Removing the requirement for a relocation to be within a neighbourhood before it can be considered minor will benefit those pharmacies and LHBs that have previously wished to relocate premises but have been prevented from doing so because, despite the relocation being minor, the proposed site was outside the pharmacy's current neighbourhood. In applying

a new test; that “for the patients accustomed to accessing pharmaceutical services at the existing premises the location of the new premises is not significantly less accessible ” and continuing to require the relocation to be “minor” in nature, it is not envisaged that there will be any adverse impacts associated with this revision.

5.38 Allowing pharmacies to temporarily relocate in certain situations will benefit those pharmacies that are unable to continue to provide services at their current location because, for example, they have been flooded or wish to undertake structural building work. In these situations currently pharmacies must either cease the provision of services or apply for a minor relocation, which may take several months to finally determine. Temporary relocations will benefit those pharmacies that need to relocate urgently or in order to improve their premises, their LHBs and their patients, it is not envisaged that there will be any adverse impacts associated with this revision.

5.39 Extending the necessary or expedient test to applications by dispensing doctors in rural areas will ensure that applications to provide pharmaceutical services are determined using the same criteria regardless of whether the application is made by a pharmacist or doctor. This essentially is a question of equity which will ensure that pharmaceutical services are provided only where it is necessary or expedient to do so. Existing pharmacies and dispensing doctors will potentially benefit. In the case of pharmacies this is because applications from dispensing doctors to provide dispensing services will have to demonstrate that there is inadequate provision of pharmaceutical services before they can begin dispensing. This is not the case currently. In the case of dispensing doctors this is because they will in future be included in the dispensing doctor list because they are addressing an identified inadequacy in pharmaceutical service provision; subsequent applications will then need to demonstrate that there is no prejudice to the proper provision of dispensing services as a result of a pharmacy opening. Existing dispensing doctors will be considered to have passed the necessary or expedient test.

5.40 Removing the requirement for an eligible patient to apply in writing before their doctor can provide them with pharmaceutical services will reduce unnecessary bureaucracy.

5.41 New applicants, whether pharmacists or doctors, will be disadvantaged by the change as they are likely to find it more difficult to gain inclusion in either the pharmaceutical or dispensing doctor list. This is because LHBs will have to consider prejudice to the services provided by dispensing doctors when determining pharmacy applications and because, in the case of dispensing doctors, the additional requirements of the necessary or expedient test must now be satisfied. This change will not however disadvantage patients since applications can only be turned down where existing services are determined as being adequate.

Fitness

5.42 The costs and benefits will be similar to those presented under option 2 although costs after year one will be reduced under this option as the number of new market entrants is expected to be lower.

6. Costs to others sectors

6.1 We do not anticipate that the regulations will have a significant impact on other sectors.

7. Consultation

7.1 A formal consultation on the proposals contained in these regulations, entitled "*Proposals to Reform and Modernise NHS Pharmaceutical Services Regulations in Wales 1992*", was undertaken between 1 February 1 and 27 April 2012. Those consulted included representatives of pharmacy contractors and dispensing doctors and appliance contractors, LHBs, Community Health Councils and individual pharmacists and pharmacy contractors. Those consulted were identified as being representative of the organisations and individuals who have an interest in and are effected by the regulatory framework, that being the 1992 Regulations, which underpins the provision of NHS pharmaceutical services in Wales.

7.2 46 consultation responses on "*Proposals to Reform and Modernise NHS Pharmaceutical Services Regulations in Wales 1992*" were received.

7.3 The vast majority of respondents supported the need to revoke the 1992 Regulations and replace them with new regulations and the need to present them in a way that will be more easily interpreted by simplifying the regulatory requirements and processes. The majority of respondents supported the introduction of fitness to practice checks.

7.4 A summary of the responses to consultation "*Proposals to Reform and Modernise NHS Pharmaceutical Services Regulations in Wales 1992*" and the Welsh Government response to the responses is attached at Annex A.

7.5 A consultation on the draft Regulations was undertaken between 30 August 2012 and 22 November 2012. Those consulted included representatives of pharmacy contractors and dispensing doctors and appliance contractors, LHBs, Community Health Councils and individual pharmacists and pharmacy contractors.

7.6 A summary of the responses to the consultation on the draft Regulations and the Welsh Government response to the responses is attached at Annex B.

7.7 The Regulations have been drafted in light of the consultation responses.

8. Competition Assessment

The competition filter test	
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	Yes
Q5: Is the regulation likely to affect the market structure, changing the number or size of businesses/organisation?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing	No

The competition filter test	
suppliers do not have to meet?	
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	Yes

9. Post implementation review

9.1 The effect of the changes made by this legislation will be monitored by officials and by Local Health Boards. It will be possible to measure the number of applications and appeals against Local Health Board determinations and therefore any variance in the number of applications and / or appeals.

9.2 Officials will review the effect of the introduction of the Regulations at 1 year intervals for up to 3 years.

ANNEX A

SUMMARY OF CONSULTATION
"*Proposals to Reform and Modernise NHS Pharmaceutical Services Regulations in Wales 1992*",

ANNEX B

SUMMARY OF CONSULTATION ON DRAFT NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES)(WALES) REGULATIONS 2013