

Amendments to the NHS (Pharmaceutical Services) Regulations 2005

Amendments to the NHS (Pharmaceutical Services) Regulations 2005 have been laid before Parliament on 20 August 2009, which come into effect on 17 September 2009.

See SI 2009/2205 http://www.opsi.gov.uk/si/si2009/pdf/uksi_20092205_en.pdf

There are some significant amendments, **which require the attention of pharmacy contractors.**

Community Health Council

References to CHCs are removed and replaced where necessary with LINKs.

Optometrists (Regulation 2)

Optometrists are added to the list of prescribers, so pharmacies will be able to dispense prescriptions issued by Optometrist Independent Prescribers. PSNC is preparing additional guidance on this amendment.

Necessary or Expedient (Regulations 12 and 13)

The long anticipated amendment, to bring the Regulations into step with the NHS Act 2006. The word 'Desirable' is replaced by the word 'Expedient'.

Refusal of applications for 'adjacent' premises (17A)

The Regulations are amended so that a PCT is required to refuse an application for pharmacy premises which are on the same premises or adjacent to premises already providing pharmaceutical services or for which an application has been granted, if the PCT is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services.

This will prevent a pharmacy contractor applying to include the same premises twice on the pharmaceutical list (or from using adjacent premises to do so). It would not prevent two competing businesses from applying for inclusion in the pharmaceutical list, on the same or adjacent premises.

Withdrawal from Pharmaceutical List (Change of Ownership) during fitness to practise investigations (Regulation 53(6))

If a PCT is conducting investigations into a pharmacy contractor, or has decided to remove or contingently remove a contractor from the pharmaceutical list (and has not yet given effect to that decision) or has suspended a pharmacy contractor, and an application for change of ownership is made that would have the result of the existing contractor no longer being on the pharmaceutical list, the PCT may process the application, and if appropriate grant the change of ownership, but the original contractor cannot be removed from the pharmaceutical list unless the Secretary of State consents. Instead, the original contractor's name is retained on the pharmaceutical list, but only for the purpose of the PCT carrying out its fitness to practise procedures.

Pharmacy Hours (Paragraph 22(1A))

The Terms of Service are amended so that when a pharmacist makes a return to the PCT, the pharmacist must notify PCTs of their additional hours as well as their core contractual hours, and these are defined as 'supplementary hours'.

Timing of changes to pharmacy hours (Paragraph 22(6)(b)(ii))

The PCT is given discretion to allow a change in hours to take place less than 90 days after a notification or application. This is expected to be most useful when a pharmacy intends to open for additional hours to reflect increases in surgery opening hours, where it would not be in the best interests of the public for the pharmacy to be required to wait 90 days before amending its hours.

Easter Sunday (Paragraph 22(11))

Easter Sunday is added to the list of days when a pharmacy is not required to open in order to fulfil its obligation to open for its contractual opening hours. This applies to both core contractual and supplementary hours.

Amendment to 100 hour pharmacy opening hours (Paragraph 25(1)(a) & 25(4)(c)(ii))

The regulations are amended to clarify that a 100 hour pharmacy can apply to amend its distribution of its core contractual 100 hours (but it cannot reduce those hours below 100). The changes to the distribution of hours requires an application to be made.

Inducements (Paragraph 28)

The prohibition on inducements given by a pharmacy contractor or his staff to patients is being modified. The prohibition will now also extend to inducements given or offered by persons engaged by the contractor.

Currently, the prohibition on inducements is in connection with the presentation of a prescription – the amendments extend the prohibition to include 'directed services' (for example Medicines Use Reviews and locally commissioned Enhanced services).

However, there is an exception so that a 'gift' can be given to a patient receiving a directed service where it is supplied as part of the provision of the Directed service to that patient; is directly related to the Directed service; is supplied in order to encourage or promote health or well-being or the adoption by the patient or the patient's family of a healthy lifestyle; and in the case of a gift which is not a medicine, has a monetary value not exceeding £10, or if it is a medicine, is supplied as part of the provision of a minor ailments service. This would allow pharmacies to give patients items of fruit, for example, as part of a healthy eating message, or an exercise DVD as part of healthy lifestyle advice, which would be prohibited as the regulations were formerly written.

A further amendment is made to prohibit the pharmacy contractor or any person employed or engaged by the contractor giving, promising or offering to any 'relevant person' any gift or reward (including by way of a share of, or dividend on, the profits of the pharmacist's business, or by way of discount or rebate) as an inducement to or in consideration of the relevant person recommending to any person that they present to the pharmacist an order for drugs or appliances on a prescription form or repeatable prescription; or nominate the pharmacist as their

dispensing contractor (or one of them) on their NHS Care Record; or ask the pharmacist to provide them with any directed service. A 'relevant person' means any person who performs or provides NHS services, whether on their own behalf or on behalf of another, and includes any NHS body, GMS contractor, PMS contractor or APMS contractor or another pharmacy contractor; and any person employed or engaged by any of these persons.

This prevents gifts or rewards being given to NHS professionals in return for recommending that a prescription is taken to a particular pharmacy. It would prohibit pharmacies offering discounts to surgery staff in return for recommendation that patients present prescriptions to the pharmacy.

Pharmacy contractors should ensure that their arrangements do not breach this new prohibition.

This new provision does not prevent the payment of a fee by an appliance contractor to a pharmacy for referral under the agency schemes, although it is expected that those payments will be prohibited from 1 April 2010 when amendments are made to the arrangements for provision of appliances.

Notification of changes to Directors / Superintendent pharmacist (Paragraph 34(3A) and (3B))

Where a body corporate appoints a new superintendent or director who was not listed on the original application by that body corporate for inclusion on a pharmaceutical list, the pharmacy contractor must, within 28 days of the person's appointment, supply to the Primary Care Trust the information mentioned in paragraphs 4 to 7 of Part 3 of Schedule 4 about that person (these paragraphs detail the fitness to practise incidents and the requirement for any superintendent pharmacist or pharmacist directors to produce the names of two referees).

This applies to all future changes, but the Regulations also have retrospective effect. If a body corporate appointed a new superintendent pharmacist or director before 17 September 2009 and that person is still in post on 17 September 2009, and the information has not already been supplied to the PCT, then the body corporate must supply that information to the PCT by 17 March 2010.

Contractors that are bodies corporate should establish for any current director or superintendent pharmacist whether the information has been supplied to the PCT, and if not, make arrangements to do so by 17 March 2010. Forms for the purpose of notifying the PCT have been developed, and are included on the Regulations (Fitness to Practise) section of the PSNC website. FtP3 is the template for notification as and when changes occur, and FtP4 is the template to notify the PCT of all changes which occurred before 17 September 2009 and which have not otherwise been notified to the PCT.

Emergency situations

Under the NHS Act 2006, the Secretary of State may issue Directions to PCTs authorising (or requiring) them to take action in cases of an emergency arising out of a threat to human welfare which is caused or may be caused by human illness. As we are in a Pandemic situation, the Regulations are being amended to set out the extent to which those Directions may operate.

The Directions set out the conditions that must apply and can also impose limitations. When issued, the Directions will operate for the period specified in the Directions, and whilst a number of Regulations may be affected, the Directions could authorise some but not all of the activities.

These emergency provisions affect the following provisions.

Relocation of / additional pharmacy premises (in emergency situations) (Regulation 7A)

A pharmacy contractor already on a pharmaceutical list will be able to apply to temporarily relocate his premises or open additional premises in cases where the PCT is satisfied that it is necessary or expedient, by reason of the emergency, for him to do so. The relocation or additional premises authorisation will be temporary, and the PCT will be required to stipulate when that temporary period will end, and it will also be able to curtail the authorisation before the end of the period. The period may not exceed the period specified in the Secretary of State Directions. The contractor will be able to revert to the original premises by giving at least 24 hour notice. There will be no right of appeal against the granting of the application or against the refusal of such an application.

Emergency change to opening hours of a pharmacy (Paragraph 25A)

Where, due to circumstances beyond the control of the pharmacist, a pharmacy is unable to open, there is no breach of terms of service if the pharmacy notifies the PCT and uses all reasonable endeavours to re-open (paragraph 22(9)).

As part of the pandemic preparedness, the regulations are being amended so that in an emergency situation, in which the Secretary of State has issued Directions (see above) a pharmacist may apply to a PCT to temporarily vary its hours or to close, giving 24 hours notice, and setting out reasons why the application should be granted. If the pharmacy is in a rural area, this may trigger other changes – see dispensing doctor arrangements below.

The PCT will not need to grant the application in advance. However if the PCT when it considers the application, decides that the reasons given by the pharmacy are inadequate, the PCT must notify the pharmacist who will be required to revert to the 'normal' hours from the day after the day on which the PCT gives notice to the pharmacist.

Dispensing Doctors – Dispensing for 'non-dispensing' patients (Regulation 60(8A))

In an emergency situation (see above), a PCT may require dispensing doctors to dispense for those of his patients who are not on his dispensing list. The PCT may exercise this discretion only where the Secretary of State has issued Directions authorising this course of action; and where, as a result of the temporary closure of premises from which medicines are normally dispensed, the PCT considers that it is necessary to require the dispensing doctor to supply in order to secure continuing adequate provision of pharmaceutical services; the period must be specified (which must be no longer than the Secretary of State's Directions). The PCT may extend or curtail the period (but shall not exceed the period in the Directions). There is no right of appeal, but the doctor is able to notify the PCT that he is unwilling to dispense for patients not on his dispensing list. Therefore if a rural pharmacy is forced to close by the Pandemic, a dispensing doctor may be authorised to dispense for all patients.

Dispensing Doctors – temporary new or additional premises (Regulation 65A)

In an emergency situation, triggered by the Secretary of State's Directions (see above) a dispensing doctor can apply to dispense from additional or relocated premises on a temporary basis. The additional or relocated premises application would be granted only where the PCT is satisfied that it is necessary or expedient to grant the application, because of the emergency situation. The application can be granted only for a specified period which can be curtailed or extended (but which must not exceed the period specified in the Secretary of State Directions). As with additional or relocated pharmacy applications, there is no appeal right.