STATUTORY INSTRUMENTS

2020 No. 351

The National Health Service (Amendments Relating to the Provision of Primary Care Services During a Pandemic etc.) Regulations 2020

PART 3

Amendments relating to pharmaceutical and local pharmaceutical services

Amendment of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

4. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(1) are amended in accordance with this Part.

Amendment of regulation 2

5. In regulation 2(2) (interpretation), after paragraph (7) insert—

"(8) In these Regulations, where reference is made to an announcement or advice of the NHSCB that relates to a disease being, or in anticipation of a disease being imminently—

- (a) pandemic; and
- (b) a serious risk or potentially serious risk to human health,

it is to that announcement or advice, which may be withdrawn at any time, as amended from time to time.".

Amendment of regulation 11

6. In regulation 11 (terms of service of NHS chemists: general), after paragraph (2) insert—

"(3) A term of service of an NHS chemist that would otherwise be part of the arrangements mentioned in paragraphs (1) and (2) is temporarily not part of those arrangements, in the particular circumstances mentioned in sub-paragraph (c)(ii) and during the period mentioned in sub-paragraph (c)(iii), in the following circumstances—

- (a) as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (i) pandemic, and
 - (ii) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement in respect of the prioritisation of services to be provided in, or in any part of, England as part of the health service;

⁽¹⁾ S.I. 2013/349.

⁽²⁾ There are no relevant amendment instruments.

- (b) the prioritisation is in order to assist in the management of the serious risk or potentially serious risk to human health;
- (c) as part of the announcement, the NHSCB with the agreement of the Secretary of State has issued advice to the effect that NHS chemists are not to comply with a specified term of service—
 - (i) in the area to which the announcement relates,
 - (ii) in the circumstances specified in the announcement, and
 - (iii) during the period specified in the announcement; and
- (d) the NHS chemist is situated in the area to which the announcement relates and compliance with the term of service (it being the specified term of service) would, but for the effect of this paragraph, be a requirement of the NHS chemist's terms of service.".

New regulation 71A

7. After regulation 71 (breaches of terms of service: breach notices), insert-

"Issuing breach or remedial notices while a disease is or in anticipation of a disease being imminently pandemic etc.

71A. The NHSCB must not issue a breach or remedial notice in respect of a breach of a term of service by a NHS chemist in the following circumstances—

- (a) as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (i) pandemic, and
 - (ii) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement in respect of the prioritisation of services to be provided in, or in any part of, England as part of the health service;

- (b) the prioritisation is in order to assist in the management of the serious risk or potentially serious risk to human health;
- (c) as part of the announcement, the NHSCB with the agreement of the Secretary of State has issued advice to the effect that NHS chemists need not comply with a specified term of service—
 - (i) in the area to which the announcement relates,
 - (ii) in the circumstances specified in the announcement, and
 - (iii) during the period specified in the announcement; and
- (d) the NHS chemist-
 - (i) is situated in the area to which the announcement relates, and
 - (ii) has not complied with the term of service (it being the specified term of service) in the particular circumstances mentioned in sub-paragraph (c)(ii) and during the period mentioned in sub-paragraph (c)(iii).".

New regulation 102A

8. After regulation 102 (terms of service for LPS schemes: general), insert—

"Suspension of terms of schemes or of enforcement of terms of schemes while a disease is or in anticipation of a disease being imminently pandemic etc.

102A.—(1) Any term that is part of an LPS scheme as a consequence of action taken under regulation 102 or by agreement between the parties is temporarily not part of that scheme, in the particular circumstances mentioned in sub-paragraph (c)(ii) and during the period mentioned in sub-paragraph (c)(iii), in the following circumstances—

- (a) as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (i) pandemic, and

(ii) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement in respect of the prioritisation of services to be provided in, or in any part of, England as part of the health service;

- (b) the prioritisation is in order to assist in the management of the serious risk or potentially serious risk to human health;
- (c) as part of the announcement, the NHSCB with the agreement of the Secretary of State has issued advice to the effect that LPS contractors are not to comply with a specified type of term of LPS schemes—
 - (i) in the area to which the announcement relates,
 - (ii) in the circumstances specified in the announcement, and
 - (iii) during the period specified in the announcement; and
- (d) the LPS contractor is situated in the area to which the announcement relates and compliance with the term (it being of the specified type) would, but for the effect of this paragraph, be a requirement of the LPS scheme of the LPS contractor.

(2) The NHSCB must not take enforcement action, as provided for in an LPS scheme, in respect of a breach of a term of the LPS scheme in the following circumstances—

- (a) as a consequence of a disease being, or in anticipation of a disease being imminently—
 - (i) pandemic, and
 - (ii) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement in respect of the prioritisation of services to be provided in, or in any part of, England as part of the health service;

- (b) the prioritisation is in order to assist in the management of the serious risk or potentially serious risk to human health;
- (c) as part of the announcement, the NHSCB with the agreement of the Secretary of State has issued advice to the effect that LPS contractors need not comply with a specified type of term of an LPS scheme—
 - (i) in the area to which the announcement relates,
 - (ii) in the circumstances specified in the announcement, and
 - (iii) during the period specified in the announcement; and
- (d) the LPS contractor—
 - (i) is situated in the area to which the announcement relates, and

(ii) has not complied with the term (it being of the specified type) in the particular circumstances mentioned in sub-paragraph (c)(ii) and during the period mentioned in sub-paragraph (c)(iii).".

Amendment of Schedule 4

9.—(1) Schedule 4 (terms of service of NHS pharmacists) is amended as follows.

(2) After paragraph 22 (service outline in respect of supporting self-care) insert—

"Home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.

22A.—(1) Before dispensing any item on a prescription form or supplying it in accordance with a serious shortage protocol, an NHS pharmacist (P) must provide a home delivery option to eligible patients in respect of the item where, as a consequence of a disease being or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are advised to stay away from pharmacy premises in the area specified, in the circumstances specified and for the duration of the period specified in the announcement.

(2) If P's pharmacy premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from P's pharmacy, P must ascertain from—

- (a) an eligible patient—
 - (i) who has contacted P about the home delivery of prescription items, or
 - (ii) who is a person whom P considered, on the basis of the nature of an item on a prescription form, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a "duly authorised person") who has contacted P about the home delivery of prescription items,

whether or not the item could be supplied by a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which P must provide.

(3) Where paragraph (2) does not apply, if P's pharmacy premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from P's pharmacy, the home delivery option that P must provide must comprise—

- (a) P delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) P arranging for an item dispensed by P to be delivered by another NHS pharmacist or by an LPS contractor to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person; or

(c) if P is unable to deliver the item or arrange for its delivery by another NHS pharmacist or by an LPS contractor, P arranging for the dispensing or supply of the item by another NHS pharmacist or by an LPS contractor who would be able to deliver the dispensed item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person.

(4) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at P's pharmacy premises for the purposes of receiving dispensing services.

(5) Notwithstanding the foregoing provisions of this Part, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, P may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.

(6) Where arrangements are in place which enable an NHS pharmacist to make a delivery as mentioned in sub-paragraph (3)(a) or (b) as part of a directed service, the NHS pharmacist must deliver the item as part of that directed service.

(7) This paragraph does not apply to an NHS pharmacist in respect of distance selling premises.".

(3) After paragraph 27 (temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services) insert—

"Pharmacy opening hours: arrangements while a disease is or in anticipation of a disease being imminently pandemic etc.

27A.—(1) Notwithstanding the foregoing provisions of this Part, the core or supplementary opening hours of an NHS pharmacist (P) may be changed by the NHSCB where, as a consequence of a disease being, or in anticipation of a disease being imminently—

- (a) pandemic; and
- (b) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, the NHSCB may, in the area to which the announcement relates and in the circumstances specified in the announcement, notify NHS pharmacists of changes to core and supplementary opening hours for the period specified in the announcement.

(2) Where paragraph (1) applies, where the NHSCB notifies P of changes to P's core or supplementary hours at P's pharmacy premises, those are P's core and supplementary opening hours for the period that the NHSCB specifies in the notification (unless the NHSCB notifies P of further changes to P's opening hours).".

Amendment of Schedule 6

10. In Schedule 6 (terms of service of dispensing doctors), after paragraph 7 (dispensing doctors issuing prescription forms which may be presented to an NHS chemist) insert—

"Home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.

7A.—(1) Before dispensing any item on a prescription form or supplying it in accordance with a serious shortage protocol, a dispensing doctor (D) must provide a home delivery option to eligible patients in respect of the item where, as a consequence of a disease being or in anticipation of a disease being imminently—

(a) pandemic; and

(b) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are advised to stay away from listed dispensing premises in the area specified, in the circumstances specified and for the duration of the period specified in the announcement.

(2) If D's listed dispensing premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from D's premises, D must ascertain from—

- (a) an eligible patient—
 - (i) who has contacted D about the home delivery of prescription items, or
 - (ii) who is a person whom D considered, on the basis of the nature of an item on a prescription form, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a "duly authorised person") who has contacted D about the home delivery of prescription items,

whether or not the item could be supplied by a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which D must provide.

(3) Where paragraph (2) does not apply, if D's listed dispensing premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from D's premises, the home delivery option that P must provide must comprise—

- (a) D delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) D arranging for an item dispensed by D to be delivered by another dispensing doctor, or by an NHS pharmacist or an LPS contractor, to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person; or
- (c) if D is unable to deliver the item or arrange for its delivery by another dispensing doctor, or by an NHS pharmacist or by an LPS contractor, D arranging for the dispensing or supply of the item by another dispensing doctor, or by an NHS pharmacist or an LPS contractor, who would be able to deliver the dispensed item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person.

(4) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at D's listed dispensing premises for the purposes of receiving dispensing services.

(5) Notwithstanding the foregoing provisions of this Schedule, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would need to be made with reasonable promptness, D may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.".

Amendment of Schedule 7

11. In Schedule 7 (mandatory terms for LPS schemes), after paragraph 10 (further activities in connection with repeat dispensing) insert—

"Home delivery service while a disease is or in anticipation of a disease being imminently pandemic etc.

10A.—(1) Before dispensing any item on a prescription form or supplying it in accordance with a serious shortage protocol, an LPS contractor (C) must provide a home delivery option to eligible patients in respect of the item where, as a consequence of a disease being or in anticipation of a disease being imminently—

- (a) pandemic; and
- (b) a serious risk or potentially a serious risk to human health,

the NHSCB with the agreement of the Secretary of State has made an announcement to the effect that, in order to assist in the management of the serious risk or potentially serious risk to human health, eligible patients are advised to stay away from listed chemist premises in the area specified, in the circumstances specified and for the duration of the period specified in the announcement.

(2) If C's listed chemist premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from C's premises, C must ascertain from—

- (a) an eligible patient—
 - (i) who has contacted C about the home delivery of prescription items, or
 - (ii) who is a person whom C considered, on the basis of the nature of an item on a prescription form, might be an eligible person and accordingly, in the ordinary exercise of professional skill and judgement, made the appropriate checks and determined that they were; or
- (b) a person who may make an application for pharmaceutical services on behalf of that eligible patient (a "duly authorised person") who has contacted C about the home delivery of prescription items,

whether or not the item could be supplied by a duly authorised person, and if it could, then supplying the item via a duly authorised person is the home delivery option which C must provide.

(3) Where paragraph (2) does not apply, if C's listed chemist premises are in the area specified in the announcement, during the period when, in the circumstances specified in the announcement, eligible patients need to stay away from C's premises, the home delivery option that C must provide must comprise—

- (a) C delivering the item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person (for example, a care home where the patient is temporarily residing);
- (b) C arranging for an item dispensed by C to be delivered by another LPS contractor or by an NHS pharmacist to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person; or
- (c) if C is unable to deliver the item or arrange for its delivery by another LPS contractor or by an NHS pharmacist, C arranging for the dispensing or supply of the item by another LPS contractor or by an NHS pharmacist who would be able to deliver the dispensed item to the eligible patient's home or to an alternative address agreed with the patient or a duly authorised person.

(4) Paragraph (1) does not apply where the eligible patient or a duly authorised person is already at C's listed dispensing premises for the purposes of receiving dispensing services.

(5) Notwithstanding the foregoing provisions of this Schedule, in any case of a supply in accordance with a home delivery option, if but for this sub-paragraph that supply would

need to be made with reasonable promptness, C may instead, in the exercise of professional skill and judgment, make the supply within a reasonable timescale.".