
DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No. 2) Directions 2020

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 127, 128, 272(7) and (8) and 273(1) of the National Health Service Act 2006(a).

Citation, commencement, application and interpretation

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No. 2) Directions 2020.

(2) These Directions come into force on 1st September 2020, apart from directions 9 and 10 which come into force on 1st November 2020.

(3) These Directions apply in relation to England.

(4) In these Directions—

“the 2013 Directions” means the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013(b); and

“the Emergency Declaration Directions” means the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) Directions 2020(c).

Amendment of direction 2 of the 2013 Directions

2.—(1) Direction 2 of the 2013 Directions (interpretation) is amended as follows.

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- (a) 2006 c. 41. Section 127 has been amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), Schedule 4, paragraph 64; and section 128 has been amended by the 2012 Act, Schedule 4, paragraph 65.
- (b) Signed on 12th March 2013, and amended by: the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2013, signed on 16th September 2013; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2013, signed on 6th December 2013, which also revoked the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2013; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2014, signed on 12th March 2014; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2014, signed on 5th December 2014; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2015, signed on 15th September 2015; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2016, signed on 30th August 2016; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2016, signed on 30th November 2016; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2017, signed on 29th August 2017; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018, signed on 8th March 2018; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2018, signed on 31st August 2018; and the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2019, signed on 13th March 2019, the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2019, signed on 22nd August 2019; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 3) Directions 2019, signed on 11th September 2019, the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 4) Directions 2019, signed on 24th October 2019, the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2020, signed on 6th March 2020; the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) Directions 2020, signed on 27th March 2020; and the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (England) Directions 2020, signed on 30th June 2020.
- (c) Signed on 27th March 2020. A relevant amendment was made to these Directions by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (England) Directions 2020, signed on 30th June 2020.

- (2) At the appropriate places in the alphabetical order insert—
- ““CPHCATS” means the Community Pharmacy Hepatitis C Antibody Testing Service, which is the advanced service described in direction 7BC(2);”;
- “CPHCATS service specification” means the service specification for the CPHCATS, produced by the NHSCB, which has the publication date of August 2020(a);
- “POCT” is a point of care test which tests for Hepatitis C antibodies; and
- “PWID” means a person who injects illicit drugs (for example, steroids or heroin);”.
- (3) In the definition of “CPSIVAS service specification”, for “August 2019” substitute “August 2020”.
- (4) For the definition of “National PGD”(b) substitute the following definition—
- ““National PGD” means the Patient Group Direction authorised by the NHSCB in respect of the administration of inactivated influenza vaccine in accordance with the CPSIVAS and the national flu immunisation programme 2020/21, which is valid from 1st September 2020 and has the published expiry date of 31st March 2021(c) (and which may be revised from time to time);”.

Insertion of direction 2A

3. After direction 2 insert—

Processing of data relating to service provision and remuneration and for NHS management functions

2A.—(1) The processing of data which relates to the provision of an advanced or enhanced service and is provided by a patient or an NHS chemist in the course of, or to enable, the provision of an advanced or enhanced service is—

- (a) necessary for the performance of a task carried out in the public interest; and
- (b) if the data is personal data concerning health, necessary for the management of health care systems or services,

where the processing is by or on behalf of a relevant body or an NHS chemist (including by another body on behalf of the relevant body or the NHS chemist) and is for the purposes of performing, or facilitating the performance of, the functions listed in paragraph (2).

(2) Those functions are—

- (a) remunerating the NHS chemist for providing the advanced or enhanced service;
- (b) post payment verification;
- (c) charging the patient for providing the advanced or enhanced service (if that is expressly provided for by or under any enactment); and
- (d) management functions of a relevant body relating to ensuring that the functions mentioned in sub-paragraphs (a) to (c) are performed effectively, efficiently and economically.

(3) A person who—

- (a) is employed or engaged by a relevant body or an NHS chemist, or by a body processing data on their behalf as mentioned in paragraph (1); and
- (b) in the course of being so employed or engaged is required, for the purposes mentioned in paragraph (1), to undertake the processing of data described in that paragraph,

(a) The NHS Publishing Reference for the Hepatitis C Testing Service – Advanced Service: PAR0092.
 (b) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2018, signed on 31st August 2018.
 (c) NHS England and NHS Improvement Publications gateway reference 000781.

owes a duty of confidentiality in respect of that data (whether or not that person would do so but for this paragraph), but that duty is such that, if the processing is for the purposes mentioned in paragraph (1), that person is able, lawfully, to process that data by virtue of this direction.

(4) Words and expressions used in both—

(a) paragraphs (1) and (3); and

(b) Parts 1 and 2 (preliminary and general processing) of, and paragraph 2(2)(f) of Schedule 1 (special categories of personal data and criminal convictions etc data) to, the Data Protection Act 2018(a),

bear the meanings they bear in those provisions of the Data Protection Act 2018.”.

Amendment of direction 4 of the 2013 Directions

4.—(1) Direction 4 (MUR services: general matters and pre-conditions for making arrangements) of the 2013 Directions is amended as follows.

(2) In paragraph (6)—

(a) after “who is employed or engaged by, P” insert “, where clinically appropriate,”;

(b) in sub-paragraph (a), for “by telephone” substitute “by telephone or video link”;

(c) in sub-paragraph (b), for “the telephone conversation” substitute “the telephone or video link conversation”; and

(d) omit “but only if P has obtained the approval of the NHSCB to do so on that particular occasion”.

Amendment of direction 5 of the 2013 Directions

5.—(1) Direction 5 (MUR service: ongoing conditions of arrangements) of the 2013 Directions is amended as follows.

(2) In paragraph (1), in sub-paragraph (c)—

(a) for “they are only provided” substitute “they are only provided, where clinically appropriate”;

(b) in paragraph (i), for “by telephone” substitute “by telephone or video link”;

(c) in paragraph (ii), for “the telephone conversation” substitute “the telephone or video link conversation”;

(d) omit “with P having obtained the approval of the NHSCB to do so on that particular occasion”; and

(e) for sub-paragraph (o), substitute—

“(o) P must obtain from each patient to whom P provides MUR services verbal consent and must record the patient’s consent on the pharmacy’s clinical record for the service.”;

Amendment of direction 6 of the 2013 Directions

6.—(1) Direction 6 (New Medicine Services: general matters and preconditions for making arrangements) of the 2013 Directions is amended as follows.

(2) For paragraph (10) substitute—

“(10) A registered pharmacist who is, or who is employed or engaged by, P may, where clinically appropriate, provide any services as part of a New Medicine Service other than at the acceptable location at P’s pharmacy premises if that registered pharmacist does so—

(a) 2018 c. 12.

- (a) by telephone or by video link, with the prior agreement of any patient; and
- (b) in circumstances where the telephone or video link conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer).”.

Amendment of direction 7 of the 2013 Directions

7.—(1) Direction 7 (New Medicines Services: ongoing conditions of arrangements) of the 2013 Directions is amended as follows.

(2) In paragraph (1)—

- (a) at the beginning of sub-paragraph (b), insert “subject to sub-paragraph (c),”;
- (b) for sub-paragraph (c), substitute—
 - “(c) where clinically appropriate, the New Medicine Service can be provided other than at an acceptable location at P’s pharmacy premises—
 - (i) by telephone or video link, with the prior agreement of any patient, and
 - (ii) in circumstances where the telephone or video link conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer).”; and
- (c) in sub-paragraph (f)—
 - (i) for “provided that the registered pharmacist is at P’s pharmacy premises and to the extent possible,” substitute “where clinically appropriate, and with the prior agreement of the patient, provided from another location by P by telephone or by video link”,
 - (ii) in sub-paragraph (ii), for “(for example, in a leaflet)” substitute “(for example, in a leaflet or by P directing the patient to a web link where the patient can access such information on line, where the service is being provided remotely)”; and
 - (iii) for sub-paragraph (iii), substitute—
 - “(iii) obtaining verbal consent from the patient and recording that consent on the pharmacy’s clinical record for the service, and”.

Substitution of direction 7A and 7B of the 2013 Directions

8.—(1) For directions 7A and 7B of the 2013 Directions(a) (Community Pharmacy Seasonal Influenza Vaccination Advanced Service: general matters and preconditions to making arrangements) substitute—

“Community Pharmacy Seasonal Influenza Vaccination Advanced Service: general matters and preconditions to making arrangements

7A.—(1) Until the end of 31st March 2021, the NHSCB must make arrangements for the provision of a service as part of the CPSIVAS with any pharmacy contractor (P) who—

- (a) meets the requirements set out in paragraphs (3) to (7); and
- (b) wishes to enter into such arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services).

(2) The underlying purpose of the CPSIVAS is to enable pharmacy contractors to participate in arrangements for the administration of inactivated influenza vaccine to patients in accordance with the National PGD, as part of the NHSCB, Public Health

(a) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2018, signed on 31st August 2018.

England and Department of Health and Social Care’s national flu immunisation programme 2020 to 2021(a).

(3) P must be satisfactorily complying with P’s obligations under Schedule 4 to the Pharmaceutical Services Regulations (Terms of service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.

(4) Any registered pharmacist who is to be involved in the administration of vaccines as part of the service (including locums) —

- (a) must have been appropriately trained and be competent to do so, having regard to the requirements of the National PGD and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(b) referred to in paragraph 4.5 of that specification); and
- (b) must have completed the relevant Centre for Pharmacy Postgraduate Education declaration of competence (c), copies of which must be kept at P’s pharmacy premises.

(5) Pharmacy staff at pharmacy premises at or from which the service is to be provided, if there is any role that they may be asked to perform as part of the service, must have been appropriately trained, having regard to requirements of the National PGD and the CPSIVAS service specification.

(6) P must have in place at the pharmacy premises, or any other premises or sites from which the service is to be provided, appropriate standard operating procedures for the service (which may be available electronically where the service is being provided at sites other than the pharmacy premises), having regard to the requirements of the National PGD and the CPSIVAS service specification, about which staff (if there is any role that they may be asked to perform as part of the service) have received appropriate training and which include procedures in respect of—

- (a) cold chain integrity;
- (b) needle stick injuries;
- (c) advice to staff involved in the service in respect of vaccination against Hepatitis B;
- (d) the identification and management of adverse reactions;
- (e) the handling, removal and safe disposal of any clinical waste related to the provision of the service (whether the service is provided at the pharmacy premises or elsewhere); and
- (f) performing that activity away from the pharmacy premises.

(7) P must be able to provide the services which are part of the CPSIVAS at an acceptable location, and for these purposes “acceptable location” means—

- (a) a room for confidential consultations at P’s pharmacy premises which meets the requirements for such a room in the CPSIVAS service specification, or as part of measures put in place to assist in the handling of a pandemic, at any other location at P’s pharmacy that P considers suitable having regard to the standard operating procedures mentioned in paragraph (6);
- (b) where the service is being provided at a premises or site other than P’s pharmacy premises, such as a village hall, place of worship, mobile vaccination van or other location or site, a location or site which in the clinical judgement of P is considered to be suitable for the provision of the service, which meet the professional standards required by the General Pharmaceutical Council and the CPSIVAS service specifications;

(a) See the letters published on gov.uk with PHE publications gateway number GW-1266 and 2020153.

(b) These are available at www.gov.uk/government/publications/immunisation-training-national-minimum-standards.

(c) This is available on the CPPE website, www.cppe.ac.uk.

- (c) if P is to provide services as part of the CPSIVAS at a care home, a room or any other location in the home that P considers suitable having regard to the standard operating procedures mentioned in paragraph (6); or
- (d) if P is to provide services as part of the CPSIVAS at a patient's home, a location in the patient's home that P considers suitable having regard to the standard operating procedures mentioned in paragraph (6).

Community Pharmacy Seasonal Influenza Vaccination Advanced Service: ongoing conditions of arrangements

7B.—(1) The NHSCB must ensure that arrangements pursuant to direction 7A(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) Inactivated influenza vaccines must only be administered under the arrangements in accordance with the National PGD, and this includes the requirements of the National PGD before and after administration of a vaccine.

(3) The only inactivated influenza vaccines to be administered under the arrangements must be those listed in the NHSCB, Public Health England and Department of Health and Social Care's national flu immunisation programme 2020 to 2021(a).

(4) P must have in place and keep under review at the pharmacy premises or any other premises or sites from which the service is to be provided appropriate standard operating procedures for the service (which may be available electronically where the service is being provided at sites other than the pharmacy premises), as described in direction 7A(6), about which staff (if there is any role that they may be asked to perform as part of the service) have received appropriate training.

(5) Vaccines must only be administered under the arrangements by a registered pharmacist, and that registered pharmacist (including if he or she is a locum)—

- (a) must have been appropriately trained and be competent to do so, having regard to the requirements of the National PGD and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(b) referred to in paragraph 4.5 of that specification);
- (b) must have completed the relevant Centre for Pharmacy Postgraduate Education declaration of competence(c), copies of which must be kept at P's pharmacy premises;
- (c) must be authorised by name under the National PGD before working to it; and
- (d) must adhere to—
 - (i) the National PGD,
 - (ii) the relevant requirements of the publication known as the Green Book(d), and,
 - (iii) as appropriate, to the standard operating procedures referred to in paragraph (4).

(6) P must only provide the service at an acceptable location, and for these purposes, "acceptable location" has the same meaning as in direction 7A(7).

(7) In respect of each occasion on which P intends to administer vaccines at a site other than the pharmacy premises as part of the CPSIVAS—

(a) See the letters published on gov.uk with PHE publications gateway number GW-1266 and 2020153, and in particular Appendix B to the letter of 5th August 2020.

(b) These are available at <https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners>.

(c) This is available on the CPPE website, www.cppe.ac.uk.

(d) Available at www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.

- (a) P must ensure that appropriate arrangements are in place at the care home or the patient's home, or any other location at which the service is being provided, (having regard to the standard operating procedures mentioned in direction 7A(6)) for the handling, removal and safe disposal of any clinical waste related to the provision of the service;
- (b) where vaccinations are administered at—
 - (i) a care home, P must ensure that vaccinations are only administered in a room or any other location which P considers suitable having regard to the standard operating conditions mentioned in paragraph (4),
 - (ii) a patient's home, P must ensure that vaccinations are only administered in a location which P considers suitable having regard to the standard operating procedures referred to in paragraph (4), or
 - (iii) any other acceptable location within the meaning of direction 7A(7), P must ensure that vaccinations are only administered in a location which P considers suitable having regard to the professional standards required by the General Pharmaceutical Council and the CPSIVAS service specifications; and
- (c) P must ensure that appropriate infection control is available at the care home, the patient's home, or any other location at which the service is provided.

(8) P must ensure, in so far as is practicable, that services which are part of the arrangements are available and on offer at P's pharmacy premises throughout its core opening hours and supplementary opening hours (as defined in the Pharmaceutical Services Regulations(a)).

(9) P must ensure the service is accessible, appropriate and sensitive to the needs of all service users, and that no eligible patient is excluded or experiences particular difficulty in accessing or using the service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age (subject to the requirements of the National PGD).

(10) P must ensure the patient's verbal consent to the administration of the vaccine is obtained and recorded on the pharmacy's clinical record for the service, and this information must be shared on request with the NHSCB, where it is needed for assurance and post payment verification.

(11) As regards each patient vaccinated under the arrangements who is registered with a general practitioner, P must ensure that the patient's general practitioner is notified in accordance with the CPSIVAS service specification, in the manner provided for in that service specification.

(12) If —

- (a) a patient vaccinated under the arrangements presents with an adverse drug reaction which is or may be linked to that vaccination; and
- (b) a pharmacist who is P or who is employed or engaged by P believes the adverse reaction is of clinical significance,

P or a person employed or engaged by P must ensure that, having managed the patient's condition appropriately, the patient's general practitioner and where appropriate the Medicines and Healthcare products Regulatory Agency (under the Yellow Card Scheme) are notified as soon as possible, in the manner provided for in the National PGD and the CPSIVAS service specification.

(13) P must keep a record of all patients receiving treatment under the arrangements—

- (a) in the manner required and for the purposes specified in the National PGD and the CPSIVAS service specification, including the requirements relating to signature

(a) See regulation 2(1) of those Regulations for the relevant definitions.

and dating by the immuniser and, in the case of electronic records, password protection; and

- (b) for the purposes specified in the National PGD and the CPSIVAS service specification.

(14) NHSCB must terminate any arrangements that are entered into or still in force on 31st March 2021 with effect from the end of 31st March 2021.”.

Amendment of direction 7BA

9.—(1) Direction 7BA (NHS Community Pharmacist Consultation Services: general matters and preconditions to making arrangements) is amended as follows.

(2) In paragraph (2) for “via the NHS 111 service or an IUC CAS” substitute “via the NHS 111 service, an IUC CAS or a GP surgery”.

Amendment of direction 7BB

10.—(1) Direction 7BB (NHS Community Pharmacist Consultation Service: ongoing conditions of arrangements), is amended as follows.

(2) In paragraph (2), in sub-paragraphs (a), (b), (f) and (g), for “NHS 111 service or an IUC CAS” substitute “via the NHS 111 service, an IUC CAS or a GP surgery”.

(3) In paragraph (5), in sub-paragraph (b), for “NHS 111 service or an IUC CAS” substitute “via the NHS 111 service, an IUC CAS or a GP surgery”.

New directions 7BC and 7BD of the 2013 Directions

11. After direction 7BB (NHS Community Pharmacist Consultation Service: ongoing conditions of arrangements), insert the following directions—

“Community Pharmacy Hepatitis C Antibody Testing Service: general matters and preconditions to making arrangements

7BC.—(1) From 1st September 2020 to 31st March 2022, the NHSCB must make arrangements for the provision of a service as part of the CPHCATS with any pharmacy contractor (P) who—

- (a) meets the requirements set out in paragraphs (3) to (9); and
- (b) wishes to enter into such arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services).

(2) The underlying purposes of the CPHCATS are—

- (a) to offer PWIDs who are not engaged in community drug and alcohol treatment services the opportunity to receive a Hepatitis C antibody test at a community pharmacy; and
- (b) where the Hepatitis C antibody test produces a positive test, to refer the PWID for further testing and treatment.

(3) P must register to provide the service through the NHS BSA Manage Your Service platform on the NHS BSA website.

(4) P must be satisfactorily complying with P’s obligations under Schedule 4 to the Pharmaceutical Services Regulations (Terms of service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.

(5) P must have in place at the pharmacy premises from which the service is to be provided standard operating procedures which include procedures to ensure health and safety and infection control procedures are maintained (including a needle stick injury

procedure), as provided for in and in line with the relevant guidelines referred to in the CPHCATS service specification.

(6) All pharmacy staff, including locums, at pharmacy premises from which the service is to be provided, who are to be involved in the provision of the service, must be competent to be so involved, and in particular—

- (a) must be familiar with the standard operating procedures;
- (b) if they may conduct POCTs, must be familiar with the manufacturer's instructions in respect of how to conduct POCTs; and
- (c) if they may conduct POCTs, must have been appropriately trained (including watching the NHSCB training video) and made aware of the risks associated with the handling and disposal of clinical waste.

(7) P must be able to provide the service in a room for confidential consultations at P's pharmacy premises which meets the requirements for such a room in the CPHCATS service specification.

(8) Pharmacy professionals at the pharmacy premises from which the service is to be provided must have access to, and be able to use—

- (a) NHSmail (including the shared mailbox); and
- (b) the Hepatitis C Registry, as mentioned in the CPHCATS service specification.

(9) All pharmacy staff, including locums, at the pharmacy premises at or from which the service is to be provided, who are to be involved in the provision of the service, must have been advised—

- (a) that as there is a small risk that they could come into contact with blood borne viruses, they should consider being vaccinated against Hepatitis B; and
- (b) of the risks should they decide not to be vaccinated.

NHS Community Pharmacy Hepatitis C Antibody Testing Service: ongoing conditions of arrangements

7BD.—(1) The NHSCB must ensure that arrangements pursuant to direction 7BC(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) P must comply, and must ensure that their pharmacy staff including locums comply, with the requirements of the CPHCATS service specification, in particular in respect of—

- (a) who may conduct POCTs;
- (b) the availability of POCTs;
- (c) determining eligibility to receive POCTs;
- (d) referral of persons who are not eligible for a POCT as part of the CPHCATS to an alternative service as part of which they are eligible for a POCT or to their GP;
- (e) which POCT is to be used;
- (f) storage of POCT materials;
- (g) the pre-test discussion between a person who is being offered a POCT and the pharmacy professional who would conduct the test;
- (h) obtaining a person's oral consent to being tested, and recording the patient's consent on the pharmacy's clinical record for the service;
- (i) advising a person who has been tested on the outcome of the test;
- (j) in a case where there is a negative antibody result, advising the person who has been tested about re-testing, as provided for in the CPHCATS service specification;
- (k) in a case where there is a positive antibody result—

- (i) referring the patient for further testing and where appropriate suitable treatment,
 - (ii) providing the patient with the relevant literature, as provided for in the CPHCATS service specification, and
 - (iii) if the patient has a GP and so consents, notifying the patient's GP of the test, the result and any onward referral for further testing and where appropriate suitable treatment;
- (l) the escalation process, if a person who has been tested fails to return for their results (including the capturing of data in respect of that person, as provided for in the CPHCATS service specification);
 - (m) the removal and safe disposal of any clinical waste related to the provision of the service;
 - (n) ensuring that the records of, or the records needed for, service provision (including the recording of the patient's consent on the pharmacy's clinical record for the service and the records needed for post payment verification) are maintained as provided for in the CPHCATS service specification;
 - (o) ensuring that the documentation, including electronic documentation, that needs to be duly completed for P to be paid the due amount for the service is duly completed and submitted;
 - (p) ensuring that, where a person who has been tested so consents, information about them is included in the Hepatitis C Registry, as provided for in the CPHCATS service specification;
 - (q) ensuring that the governance arrangements for the service are complied with, as provided for in the CPHCATS service specification; and
 - (r) ensuring that the service evaluation arrangements for the service are complied with, as provided for in the CPHCATS service specification.
- (3) P must have in place and keep under review at the pharmacy premises from which the service is to be provided standard operating procedures, which include procedures to ensure health and safety and infection control procedures are maintained (including a needle stick injury procedure), as provided for in and in line with the relevant guidelines referred to in the CPHCATS service specification.
- (4) P must ensure that all pharmacy staff, including locums, at pharmacy premises from which the service is to be provided, who are to be involved in the provision of the service, are competent to be so involved, and in particular—
- (a) are familiar with the standard operating procedures;
 - (b) if they may conduct POCTs, are familiar with the manufacturer's instructions in respect of how to conduct POCTs; and
 - (c) if they may conduct POCTs, have been appropriately trained (including watching the NHSCB training video) and made aware of the risks associated with the handling and disposal of clinical waste.
- (5) P must provide the service in a room for confidential consultations at P's pharmacy premises which meets the requirements for such a room in the CPHCATS service specification.
- (6) P must ensure that pharmacy professionals at the pharmacy premises from which the service is to be provided have access to, and are able to use—
- (a) NHSmail (including the shared mailbox); and
 - (b) the Hepatitis C Registry, as mentioned in the CPHCATS service specification.
- (7) P must ensure that all pharmacy staff, including locums, at pharmacy premises at or from which the service is to be provided, who are to be involved in the provision of the service, have been advised—

- (a) that as there is a small risk that they could come into contact with blood borne viruses, they should consider being vaccinated against Hepatitis B; and
- (b) of the risks should they decide not to be vaccinated.

(8) P must ensure, in so far as is practicable, that the service is available at P's pharmacy premises at the times throughout its core opening hours and supplementary opening hours (as defined in the Pharmaceutical Services Regulations(a)).

(9) P must ensure that the service is accessible, appropriate and sensitive to the needs of all service users, and that no eligible patient is excluded, or experiences difficulty in accessing or using the service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

(10) P must ensure that the NHS.UK profile of P's pharmacy indicates that a blood-borne virus testing service is provided at the pharmacy and is kept updated to indicate any temporary or the permanent cessation of the service.

(11) If P is to cease providing the service permanently, P must do so in the manner provided for in the CPHCATS service specification.”.

Amendment of direction 11 of the 2013 Directions

12.—(1) Direction 11 (establishing and maintaining appliance use review services for specified appliances) of the 2013 Directions is amended as follows.

(2) In paragraph (2), for “or when a patient visits listed chemist premises” substitute “, when a patient visits listed chemist premises or, where clinically appropriate and with the agreement of the patient, by telephone or video link, in circumstances where the telephone or video link conversation cannot be overheard (except by someone whom the patient wants to hear the conversation, for example a carer)”.

Amendment of direction 12 of the 2013 Directions

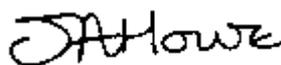
13.—(1) Direction 12 (requirements applying to appliance use review services) of the 2013 Directions is amended as follows.

(2) In paragraph (4), in sub-paragraph (b), for “must obtain the patient’s prior written consent to receiving the service” substitute “must obtain the patient’s verbal consent to receiving the service and must record the patient’s consent on the pharmacy’s clinical record for the service”.

Amendment of the Emergency Declaration Directions

14. In direction 2 of the Emergency Declaration Directions 2020 (declaration of emergency requiring the flexible provision of pharmaceutical services), for “1st September 2020” substitute “30 November 2020”.

Signed by authority of the Secretary of State for Health and Social Care



28th August 2020

Jeannette Howe
Head of Pharmacy
Department of Health and Social Care

(a) See regulation 2(1) of those Regulations.