STATUTORY RULES OF NORTHERN IRELAND

2012 No. 312

PHARMACY

The Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012

Made	-	-	-	-	8th August 2012
Coming into operation					1st June 2013

The Council of the Pharmaceutical Society of Northern Ireland makes the following Regulations in exercise of the powers conferred on it by Articles 4A(9) and (10), 5(1)(ff), (fff) and (ffg) of, and paragraphs 5(1) and (2)(b), and 15(1)(b), (2) and (3) of Schedule 3 to the Pharmacy (Northern Ireland) Order 1976(1). The Department of Health, Social Services and Public Safety(2) has approved these Regulations in accordance with Article 25A (2) of that Order(3).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012 and shall come into operation on 1st June 2013.

(2) In these Regulations—

"CPD"—

- (a) means the continuing professional development which registered persons are required to undertake in order to have their name retained in the register and to maintain competence; and
- (b) includes-
 - (i) any continuing professional development that relates to an annotation in respect of a specialist area of practice recorded against a registered person's name in the register,
 - (ii) any continuing professional development that a registered person is required to undertake by virtue of these regulations;

⁽¹⁾ S.I. 1976/1213 (N.I.22) as amended by 1981 c.45 & c.55; 1983 c. 54; S.I.1984/703 (N.I.3); S.R. 1987 No.457; S.I. 1994/429 (N.I. 2); S.R.1996 No.393; 2004 c.33; S.R. 2004 No.78; S.R. 2008 No.192; and S.R. 2012 No.308

⁽²⁾ See S.I. 1999/283 (NI 1) Article 3 (6)

⁽³⁾ Article 25A is inserted by Article 9 of S.R. 2012 No.308

"CPD framework" means the framework relating to the CPD of registered persons which is adopted by the Council under Article 4A(6)(a) of the Order;

"CPD record", in relation to a registered person, means a written record in hard copy form or electronic form which is completed by the registered person and in which details are entered by the registered person about the CPD that the registered person has undertaken since—

- (c) the date of completion of the immediately preceding review by the registrar of the registered person's CPD; or
- (d) if no review has taken place since the date on which the registered person's name was entered in, or restored to, the register, the date of that entry;

"Fitness to Practise Regulations" means the Council of the Pharmaceutical Society of Northern Ireland (Fitness to Practise and Disqualification) Regulations (Northern Ireland) 2012(4);

"Notice of Appeal" means a notice of appeal against an appealable decision;

"the Order" means the Pharmacy (Northern Ireland) Order 1976;

"remedial measure" means any requirement specified in regulation 4(1)(a) to (h);

"supplementary notice" means a notice under regulation 6(5)(b)(including a notice under that provision as it applies by virtue of regulation 6(6)).

Failure to comply with the CPD framework

2.—(1) Each of paragraphs (2) to (10) sets out circumstances in which a registered person is to be regarded as having failed to comply with the requirements or conditions of the CPD framework.

(2) The registrar is of the opinion that the registered person has failed without reasonable excuse to make an annual declaration regarding the registered person's compliance with the requirements or conditions of the CPD framework.

(3) The registrar is of the opinion that the registered person has failed without reasonable excuse—

- (a) to comply with a request by the registrar to submit a CPD record to the registrar for review;
- (b) to submit a CPD record to the registrar by the date specified by the registrar in accordance with the CPD framework; or
- (c) to submit a CPD record to the registrar which is in the form and manner specified in the CPD framework.

(4) The registrar is of the opinion that the registered person has failed without reasonable excuse to record adequately in respect of any relevant period—

- (a) the dates on which the registered person's CPD has been undertaken; or
- (b) any other information about the registered person's CPD which is required by the CPD framework.

(5) The registrar is of the opinion that the registered person has made an insufficient number of entries in respect of any relevant period in the registered person's CPD record.

(6) The registrar is of the opinion that the entries in respect of any relevant period in the registered person's CPD record do not demonstrate that the CPD undertaken is relevant to—

- (a) the safe and effective practice of pharmacy; or
- (b) a learning need for the registered person that is relevant to the current scope of the practice of pharmacy including any specialist area of practice of the registered person and the environment in which the registered person practises.

⁽⁴⁾ S.R. 2012 No.311

(7) The registrar is of the opinion that the entries in respect of any relevant period in the registered person's CPD record do not—

- (a) include any CPD that relates to a specialist area of practice of the registered person or the environment in which the registered person practises; or
- (b) reflect any conditions as to the practice of pharmacy by the registered person which were in operation for the whole or part of the relevant period and were imposed—
 - (i) by virtue of a direction given by the Statutory Committee under paragraph 7(2)(e) or (3)(a)(v) or (b)(i) or (ii) of Schedule 3 to the Order; or
 - (ii) in the case of a visiting practitioner to whom Schedule 2B of the Order applies, by the competent authority in the practitioner's home State.

(8) The registrar is of the opinion that the entries in the registered person's CPD record do not reflect any requirement which—

- (a) by virtue of regulation 10 was imposed on the registered person by the registrar to undertake by the date specified by the registrar any additional CPD after the restoration of the registered person's name to the register; or
- (b) by virtue of regulation 10 was imposed on the registered person by the registrar to undertake by the date specified by the registrar any additional CPD after the restoration to the register of an annotation in respect of a specialist area of practice recorded against the registered person's name in the register.

(9) The registrar is of the opinion that the entries in the registered person's CPD record do not reflect any requirement imposed on the registered person by the registrar to take by the date specified by the registrar any remedial measure that was specified in a notice given to the registered person under regulation 6(2).

- (10) The registrar is of the opinion that, for any other reason-
 - (a) the amount or type of CPD undertaken by the registered person is inadequate; or
 - (b) the registered person's CPD record is inadequate or is not in a fit and proper state to be reviewed.

(11) For the purposes of paragraphs (4) to (7), references to "relevant period" are to any of the following that fall within the period covered by the CPD record of the registered person which is subject to review by the registrar—

- (a) the period that commences with, and includes, the date on which the registered person's name was entered in, or restored to, the register, and ends on 31 May following that date;
- (b) each subsequent 1 year period that commences with, and includes, 1 June 31 May; and
- (c) any part of the period referred to in sub-paragraph (a) or (b).

(12) In the application of paragraphs (4) to (7) to a period falling within paragraph (11)(c), any number or other quantity which, in accordance with the CPD framework, applies to a 1 year period is to be proportionately reduced.

Steps which the registrar may take

3.—(1) Paragraph (2) applies where the registrar is satisfied that a registered person—

- (a) has failed to comply with the requirements or conditions of the CPD framework (including any failure to comply with requirements imposed in accordance with the provisions referred to in regulations 2(8) or (9)); or
- (b) has made a false declaration about compliance with the requirements or conditions of the CPD framework.
- (2) Subject to paragraphs (3) to (5) the registrar may decide to—

- (a) impose on the registered person a requirement to take one or more remedial measures in connection with the registered person's CPD; or
- (b) remove the registered person's name from the register; or
- (c) remove an annotation in respect of a specialist area of practice recorded against the registered person's name in the register.

(3) In relation to a person ("P") who is a visiting practitioner, the registrar may not take any of the steps referred to in paragraph (2)(a), (b) or (c) unless the registrar is satisfied that it is appropriate and proportionate to take that step in view of P's continued lawful establishment in P's home State as a pharmacist.

(4) The registrar must follow the procedure set out in regulation 4(2) when imposing a requirement to take a remedial measure.

(5) If the registrar proposes to remove the name of a registered person or the annotation recorded against the registered person's name, the registrar must follow the procedure set out in regulations 5 to 8 (but this is without prejudice to regulations 7(5)(b) and (6).

(6) The fact that a registered person's failure to comply with the requirements or conditions of the CPD framework arises by virtue of regulation 2(9) does not prevent the registrar from deciding to impose on the registered person a new requirement to take one or more remedial measures.

Remedial measures

4.—(1) The remedial measures that the registrar may impose under regulation 3(2)(a) on a registered person in connection with the registered person's CPD are—

- (a) a requirement for the registered person to make entries in the registered person's CPD record in the form and manner specified in the CPD framework;
- (b) a requirement for the registered person to make entries in the registered person's CPD record that accurately reflect the CPD activities already undertaken by the registered person;
- (c) a requirement for the registered person to undertake additional CPD activities;
- (d) a requirement for the registered person to undertake CPD activities which relate to the safe and effective practice of pharmacy;
- (e) a requirement for the registered person to undertake additional CPD activities which relate to a learning need for the individual registered person that is relevant to—
 - (i) the current scope of the practice of pharmacy,
 - (ii) any specialist area of practice of the registered person,
 - (iii) the environment in which the registered person practises,
 - (iv) the management or recording of a registered person's CPD;
- (f) a requirement for the registered person to undertake CPD activities which relate to any condition as to the practice of pharmacy by the registered person which was imposed—
 - (i) by virtue of a direction given by the Statutory Committee under paragraph 7(2)(e) or (3)(a)(v) or (b)(i) or (ii) of Schedule 3 to the Order, or
 - (ii) in the case of a visiting practitioner to whom Schedule 2B of the Order applies, by the competent authority in the practitioner's home State;
- (g) a requirement for the registered person to undertake CPD activities which relate to any requirement as to CPD which—
 - (i) by virtue of regulation 10 was imposed on the registered person on the restoration of the registered person's name to the register,

- (ii) by virtue of regulation 10 was imposed on the registered person on the restoration of an annotation in respect of a specialist area of practice recorded against the registered person's name in the register;
- (h) a requirement for the registered person to undertake CPD activities which relate to any requirement as to CPD which was previously imposed on the registered person by a remedial measure specified under paragraph (2).

(2) If the registrar decides to impose on the registered person a requirement to take one or more remedial measures, the registrar must notify the registered person of—

- (a) the measures to be taken;
- (b) the reasons for imposing the requirement; and
- (c) the date (if any) by which the registered person must comply with each measure.

Notice of Intention to Remove: stage 1

5.—(1) Where the registrar proposes to remove the name of the registered person or the annotation recorded against the name of a registered person ("R") from the register under regulation 3(2)(b) or (c), the registrar—

- (a) must consider whether the matter calls into question R's fitness to practise; and
- (b) if no such question arises, may serve on R a Notice of Intention to Remove which notifies R in writing that the registrar is considering whether to remove R's name or the annotation recorded against R's name (as the case may be) from the register.

(2) If it appears to the registrar on reasonable grounds that R's fitness to practise is called into question, the registrar must determine whether to refer the matter—

- (a) to the Scrutiny Committee in accordance with paragraph 5(1) of Schedule 3 to the Order; or
- (b) to the Statutory Committee in accordance with whichever of regulation 5(5) or (8) of the Fitness to Practise Regulations the registrar considers to be appropriate in all the circumstances of R's case.

(3) Paragraph (2) applies irrespective of whether a Notice of Intention to Remove has already been served.

(4) Before serving on R a Notice of Intention to Remove, the registrar may make such inquiries, including the instruction of external agents or investigators, and the commissioning of medical experts, as the registrar considers necessary or expedient.

(5) A Notice of Intention to Remove must—

- (a) set out the grounds for believing that R—
 - (i) has failed to comply with the requirements or conditions of the CPD framework, or
 - (ii) has made a false declaration about compliance with the requirements or conditions of the CPD framework;
- (b) be accompanied by copies of evidence (in a form that can be copied) on which the registrar would seek to rely in any proceedings under these Regulations to remove R's name or the annotation recorded against R's name;
- (c) invite R to submit written representations, and any relevant evidence, to the registrar as to why R's name or the annotation recorded against R's name should not be removed from the register;
- (d) inform R that any such representations or evidence must be submitted no later than 28 days after service of the notice;
- (e) invite R to indicate whether or not R wishes the matter to be considered at a hearing;

- (f) inform R that the matter will be considered without a hearing unless written representations have been submitted; and
- (g) inform R that, if R fails to submit written representations to the registrar within the 28 day period referred to in sub-paragraph (d), R's name or the annotation recorded against R's name may be removed from the register.

Subsequent action by the registrar: stage 2

6.--(1) Where---

- (a) the registrar has served a Notice of Intention to Remove on a registered person; and
- (b) has not received any representations from the registered person within the 28 day period referred to in that notice (see regulation 5(5)(d), (f) and (g)),

the registrar may remove the name of the registered person, or the annotation recorded against the registered person's name in respect of a specialist area of practice, from the register.

(2) The following paragraphs apply where the registrar has received representations from the registered person within the 28 day period referred to in the Notice of Intention to Remove.

- (3) The registrar-
 - (a) must consider the representations and any evidence received; and
 - (b) may make such further inquiries (including obtaining legal advice) as the registrar considers necessary or expedient.

(4) The registrar must close the matter and notify the registered person accordingly where the registrar is satisfied that the registered person did not—

- (a) fail to comply with the requirements or conditions of the CPD framework; or
- (b) make a false declaration about compliance with the requirements or conditions of the CPD framework.

(5) Where the registrar is not so satisfied and, in making a determination, proposes to rely on evidence that was obtained as a result of the registrar's further inquiries under paragraph (3)(b), the registrar must send to the registered person—

- (a) copies of that evidence (in a form that can be copied); and
- (b) if the registered person has not already requested a hearing, a notice (referred to in these Regulations as a "supplementary notice") which—
 - (i) invites the registered person to submit written representations, and any relevant additional evidence, to the registrar as to why the name of the registered person or the annotation recorded against the registered person's name should not be removed from the register,
 - (ii) informs the registered person that any such representations or evidence must be submitted no later than 28 days after service of the supplementary notice,
 - (iii) invites the registered person to indicate whether or not the registered person wishes the matter to be considered at a hearing, and
 - (iv) informs the registered person that the matter will be considered without a hearing unless written representations have been submitted.

(6) Paragraphs (3) to (5) also have effect in relation to any further representations from the registered person which the registrar receives within the 28 day period referred to in a supplementary notice.

(7) Unless the registrar determines the matter in accordance with paragraph (4), the registrar must proceed to determine it under regulation 7—

- (a) in any case where paragraph (5) does not apply; or
- (b) if that paragraph does apply, once the requirements of paragraphs (5) and (6) have been fully complied with.

Decisions in contested cases: stage 3

7.—(1) Where the registered person does not request a hearing or is not entitled to one, the registrar must determine the matter—

- (a) if the registrar was required to serve one or more supplementary notices on the registered person, after the expiry of the 28 day period referred to in the supplementary notice or, if more than one supplementary notice was served, the most recent supplementary notice; or
- (b) if no supplementary notice was required to be served, after the expiry of the 28 day period referred to in the Notice of Intention to Remove served on the registered person under regulation 5.

(2) Where the registered person has requested a hearing (in response to the invitation in the Notice of Intention to Remove or a supplementary notice—

- (a) the registrar may determine the matter without a hearing if (and only if)—
 - (i) the registrar no longer proposes to remove the name of the registered person or the annotation recorded against the registered person's name, and
 - (ii) a referral under sub-paragraph (b)(i) has not already been made;
- (b) otherwise-
 - (i) the registrar must refer the matter to the Statutory Committee,
 - (ii) the Statutory Committee must hold a hearing in accordance with regulation 32 of the Fitness to Practise Regulations (procedure in relation to hearings of registration and CPD cases before the committee), for the purposes of making findings of fact in relation to the matter and advising the registrar accordingly, and
 - (iii) once the registrar has received the advice of the Statutory Committee, the registrar must determine the matter.
- (3) Where the registrar determines that the registered person did not—
 - (a) fail to comply with the requirements or conditions of the CPD framework; or
 - (b) make a false declaration about compliance with the requirements or conditions of the CPD framework,

the registrar must close the matter and notify the registered person accordingly.

- (4) Paragraph (5) applies where the registrar determines that the registered person did—
 - (a) fail to comply with the requirements or conditions of the CPD framework; or
 - (b) make a false declaration about compliance with the requirements or conditions of the CPD framework.
- (5) The registrar may—
 - (a) remove the name of the registered person, or the annotation recorded against the registered person's name in respect of a specialist area of practice, from the register; or
 - (b) if the registrar considers it is appropriate to do so having regard to all the circumstances of the case, impose on the registered person a requirement to take one or more remedial measures in connection with the registered person's CPD.

(6) In imposing a requirement to take a remedial measure, the registrar must follow the procedure set out in regulation 4(2).

Notification of removal of the name of a registered person or the annotation recorded against the registered person's name under regulation 6 or 7

8.—(1) Paragraph (2) applies in any case where the name of a registered person or the annotation recorded against the registered person's name is removed from the register under regulation 6 or 7.

(2) The registrar must send a written statement to the registered person giving notice of-

- (a) the removal of the registered person's name or the annotation recorded against the registered person's name;
- (b) the reasons for it; and
- (c) the registered person's right of appeal to the Statutory Committee under Article 4A(12) of the Order.

Suspension from the register pending appeal

- 9.—(1) Where—
 - (a) the registrar has decided to remove the name of a registered person from the register; and
 - (b) a Notice of Appeal is served under Article 4A(12) of the Order,

the registrar may suspend the registered person's entry in the register pending the final outcome of the appeal.

(2) The provisions of paragraph 8(2) to (10) of Schedule 3 to the Order are to have effect in relation to the registrar's decision to suspend an entry under paragraph (1) as if that decision were an interim suspension order made by the Statutory Committee under paragraph 8(1)(a) to Schedule 3 of the Order.

Restoration of a name to the register

10.—(1) Subject to the following paragraphs, an applicant whose name has been removed from the register under regulation 6 or 7, may apply for the restoration of their name to the register.

(2) An application under this regulation must be made to the registrar using the relevant application form, which must be in such form as the Council may from time to time determine.

- (3) The application form may, in particular—
 - (a) require the applicant ("A") to-
 - (i) specify the applicant's full name, home address and contact details (including a telephone number and electronic mail address, where possible),
 - (ii) declare—
 - (aa) that A agrees, upon their name being restored to the register, to adhere to any standards set by the Council under Article 4A (1)(b) of the Order relating to the continuing professional development that it is necessary for a registered person to maintain in order to have their name retained in the register,
 - (bb) A's intention to adhere to the standards set by the Council under paragraph 1 (1)(a) of Schedule 3 to the Order relating to the conduct, ethics and performance expected of registered persons,
 - (cc) that A is not aware of any investigation by any enforcement or regulatory body, or proceedings brought by such a body, that relate to A's fitness to practise, or of any act or omission on A's part that might render A liable to an allegation being referred to the Society that A's fitness to practise is impaired, and

- (dd) that A understands that, in the event that A is found to have given false or misleading information in connection with the application, A's name may be removed from the register,
- (iii) specify-
 - (aa) whether any of the matters referred to in paragraph 4 (1)(d) to (j) of the Order exist in relation to the registered person which have not previously been notified to the Society; or
 - (bb) whether, in relation to the registered person, there have been any findings of impairment of the registered person's fitness to practise made by a regulatory body which have not previously been notified to the Society, and
- (iv) provide any necessary supporting documents, information or evidence as mentioned in the application form;
- (b) include a demand that the applicant pay the prescribed fees in respect of the application; and
- (c) require the applicant to sign and date the application.

(4) The applicant must also provide such additional documents, information or evidence as the registrar may reasonably require for the purposes of verifying the information in, or determining, the application.

(5) The registrar must consider—

- (a) whether the applicant should be required to undertake any additional education, training or experience before the applicant's name is restored to the register; and
- (b) whether the applicant should be required to undertake any additional continuing professional development after the applicant's name is restored to the register,

and, where necessary, the registrar may determine the additional education, training or experience or additional continuing professional development that is appropriate for the applicant to undertake in the circumstances of the applicant's case.

(6) The registrar may grant an application under this regulation subject to the condition that the applicant agrees to comply with such undertakings with regard to continuing professional development as the registrar considers appropriate in the applicant's case.

(7) The registrar may refuse any application under this regulation which is not accompanied by the necessary supporting documents, information or evidence as mentioned in the application form or otherwise required by the registrar.

(8) The registrar must refuse the application under this regulation—

- (a) if A's name was removed from the register because of a failure to provide any document, evidence or information and that document, evidence or information is not included in the application; or
- (b) if A has not paid, or has not made arrangements with the registrar to pay by direct debit, the prescribed fees in respect of the application.

Restoration of an annotation to be recorded against a registered person's name in the register.

11.—(1) Subject to the following paragraphs, applicants for the restoration of an annotation in respect of a specialist area of practice to be recorded against their name in the register, which annotation has been removed under regulation 6 or 7, may apply to the registrar.

(2) An application under this regulation must be made to the registrar using the relevant application form, which must be in such form as the Council may from time to time determine.

- (3) The application form may, in particular—
 - (a) require the applicant to—
 - (i) specify the applicant's full name, home address and contact details (including a telephone number and electronic mail address, where possible),
 - (ii) provide any other necessary supporting documents, information or evidence as mentioned in the application form;
 - (b) include a demand that the applicant pay the prescribed fees in respect of the application; and
 - (c) require the applicant to sign and date the application.

(4) The applicant must also provide such additional documents, information or evidence as the registrar may reasonably require for the purposes of verifying the information in, or determining, the application.

- (5) The registrar must consider—
 - (a) whether the applicant should be required to undertake any additional education, training or experience before the annotation to be recorded against the registered person's name is restored to the register; and
 - (b) whether the applicant should be required to undertake any additional continuing professional development after the annotation to be recorded against the registered person's name is restored to the register,

and, where necessary, the registrar may determine the additional education, training or experience or additional continuing professional development that is appropriate for the applicant to undertake in the circumstances of the applicant's case.

(6) The registrar may grant an application under this regulation subject to the condition that the applicant agrees to comply with such undertakings with regard to continuing professional development as the registrar considers appropriate in the applicant's case.

(7) The registrar may refuse any application under this regulation which is not accompanied by the necessary supporting documents, information or evidence as mentioned in the application form or otherwise required by the registrar.

(8) The registrar must refuse the application under this regulation—

- (a) if an annotation recorded against the registered person's name was removed because of a failure to provide any document, evidence or information and that document, evidence or information is not included in the application; or
- (b) if the applicant has not paid, or has not made arrangements with the registrar to pay by direct debit, the prescribed fees in respect of the application.

Sealed with the Common Seal of the Pharmaceutical Society of Northern Ireland on 8th August 2012



Roberta Tasker Trevor Patterson PresidentChief Executive

The Department of Health, Social Services and Public Safety hereby approves the foregoing regulations.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 8th August 2012



Diane Taylor A senior officer of the Department of Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations approve the Council of the Pharmaceutical Society of Northern Ireland (Continuing Professional Development) Regulations (Northern Ireland) 2012 ("the Regulations"). The Regulations were made by the Council of the Pharmaceutical Society of Northern Ireland ("the Council") under the Pharmacy (Northern Ireland) Order 1976 ("the Order"). The Regulations set out matters relating to non-compliance by registered persons with the requirements or conditions of the continuing professional development framework adopted by the Council under Article 4A(6)(a) of the Order. The framework relates to standards of proficiency for the safe and effective practice of pharmacy that are set by the Council under Article 4A(1)(a) of the Order.

Regulation 2 sets out the circumstances in which a registered person is to be regarded as having failed to comply with the requirements or conditions of the framework or as having made a false declaration as to compliance. The steps which the registrar can take on being satisfied that a registered person has failed to comply, or has made a false declaration, are set out in regulation 3.

One of the steps available to the registrar is to require a registered person to take remedial measures and regulation 4 contains further provision about such measures and notifying the registered person about them.

The other steps set out in regulation 3 are to remove an entry, or annotation, in respect of a registered person from the register. The procedure for such cases is set out in regulations 5 to 8. Under regulation 5, the registrar must determine whether to refer the matter to the Council's Scrutiny Committee or Statutory Committee if there are reasonable grounds to consider that the registered person's fitness to practise is called into question. If not, the registrar serves a notice to inform the registered person of the proposal to remove the entry or annotation from the register. Regulation 5(5) sets out the information that must be provided in the notice. The registrar then determines the matter in accordance with regulations 6 and 7. Regulations 6, 7 and 8 include provision about the circumstances in which a hearing is held and about notifying the registered person of the registered person's case.

Regulation 9 sets out where the registrar may suspend a registered person's entry in the register and regulations 10 and 11 outline the procedure for the restoration of a registered person's name to the register and the restoration of an annotation to be recorded against a registered person's name in the register.