

EXPLANATORY MEMORANDUM TO

THE NURSING AND MIDWIFERY (AMENDMENT) ORDER 2018

2018 No. [XXXX]

1. Introduction

- 1.1 This explanatory memorandum has been prepared by The Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 This Order amends the Nursing and Midwifery Order 2001 (S.I. 2002/253) (“the 2001 Order”) to include provisions relating to the regulation of nursing associates in England (NAs) and to make consequential amendments in that regard to other secondary legislation and to the Interpretation Act 1978 and the Value Added Tax Act 1994. This Order also amends the 2001 Order to remove provisions in that legislation relating to ‘Screeners’.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 This Order supersedes the Nursing and Midwifery (Amendment) Order 2018 which was laid in Parliament on 11th May 2018 and withdrawn on 17 May 2018. This was necessary to correct defective commencement provisions in article 1(2) of the Order. This Order is being issued free of charge to all known recipients of the Order superseded.

Other matters of interest to the House of Commons

- 3.2 Disregarding minor or consequential changes, the territorial application of this instrument varies between provisions.

4. Legislative Context

- 4.1 This Order amends the 2001 Order to allow the Nursing and Midwifery Council (NMC) to take responsibility for regulating NAs in England. The NA role is being introduced and regulated in England only. The general policy is to regulate the NA profession using the same regulatory framework the NMC uses to regulate registered nurses and midwives. Therefore, this Order amends the 2001 Order to include NAs in respect of the NMC’s functions and processes. The 2001 Order is amended in respect of:

- The NMC’s principal functions.
- Registration, as set out in Part III of the 2001 Order.
- Education and training as set out in Part IV of 2001 Order.
- Fitness to Practice, as set out in Part V of 2001 Order.
- Appeals, as set out in Part VI of 2001 Order.
- EEA provisions as set out in Part VII of the 2001 Order.
- Offences, as set out in Part IX of the 2001 Order.

- 4.2 In respect of the regulation of NAs, this order amends the 2001 Order in connection with the NMC's principal functions to:
- Include NAs as a group in respect of which the NMC's principal functions of establishing standards of education, training, conduct and performance and to ensure the maintenance of such standards are to extend.
- 4.3 In respect of the registration of NAs, the 2001 Order is amended to –
- Provide that the NMC must establish and maintain a register of NAs;
 - Provide that the NMC must establish the standards of proficiency necessary to be admitted to the NA part of the register for safe and effective practice as an NA;
 - Provide that the NMC must prescribe the requirements to be met as to the evidence of good health and good character required for registration in order to satisfy the Registrar that the person is capable of safe and effective practice as a NA (these are set out in the Nursing and Midwifery Council (Education, Registration and Registration Appeals Rules) 2004 (S.I. 2004/1767) which are also amended by this Order. NAs will be subject to the same requirements in this regards as applicants for the Nurse or Midwife Part of the register;
 - Provide that a person is to be regarded as having an approved qualification for the purposes of registration as an NA if they have an NMC approved qualification;
 - Provide for a similar process as those applicants applying for the nurses or midwives part of the register regarding approved qualifications. Where a person with a qualification gained outside the UK, including those awarded in an EEA member state, applies to be registered in the NA part of the register, the NMC must be satisfied that the person's qualification provides them with a comparable standard of proficiency as that provided by an NA qualification awarded in England. Where the NMC is not satisfied they can ask the application to undergo further assessment or development;
 - Make similar provision in respect of a person applying to be registered in the NA part of the register where they have undergone training and been awarded a qualification in Northern Ireland, Scotland or Wales. As NAs will be regulated in England only and the NMC will have power to approve NA courses in England only, applicants for the NA part of the register who have undergone comparable training in Wales, Northern Ireland and Scotland, will need to have their qualification recognised to be able to register and practise as an NA in England;
 - Provide for transitional arrangements for persons on Health Education England (HEE) pilots and approved English apprenticeship programmes who started their training prior to this Order coming into force to have their qualifications recognised by the NMC for the purpose of registering as an NA;
 - Disapply in respect of NAs, the power for the Registrar to annotate the register in an emergency giving registrants temporary prescribing rights.
- 4.4 This Order amends the 2001 Order to give the NMC power to approve courses of education or training for NAs, approve institutions for delivering an approved course of education or training and approve tests of competence or knowledge of English in respect of NAs. However, as the NA role will be a regulated role in England only, the

NMC will not be able to exercise this power in Scotland, Wales or Northern Ireland, see paragraph 5.1

- 4.5 In respect of appointing visitors to inspect and report on the nature and quality of NMC approved NA courses, the 2001 Order is amended to provide that one visitor must be registered in the nursing part of the register or in the nursing associate part of the register. This differs from the provision regarding nursing and midwifery education where at least one visitor must be registered in the same part of the register as the profession in respect of which the education and training they are to report on is concerned see paragraph 7.11.
- 4.6 This Order amends the 2001 Order to extend the scope of the NMC's fitness to practise functions to NAs who will be subject to the same fitness to practise provisions as nurses and midwives. It will include NAs in the appeals provisions in connection with appeals against the Registrar's decisions regarding registration and to provide that a NMC panel considering an appeal from an NA must include a person who is registered in the NA or the nursing part of the register. This differs from appeals brought by a nurse or midwife where a panel must include a registrant from the nurse part of the register or from the midwives part of the register as the case may be, see paragraph 7.13.
- 4.7 In relation to NAs, the 2001 Order is amended to provide that the appropriate court to which an appeal must be made against a decision of the Fitness to Practise Committee is the High Court in England and Wales and to provide that an appeal by an NA against:
- i) the Investigating Committee's order that an entry may be removed from the register on the grounds of fraud and
 - ii) the NMC's decision on an appeal from the Registrar's decision around registration is to the county court, see paragraph 7.6.
- 4.8 This Order inserts into the 2001 Order a provision for visiting NAs from EEA countries and Switzerland who benefit from the European Union (Recognition of Professional Qualifications) Regulations 2015, to have their qualifications and training recognised in England and to be registered.
- 4.9 In respect of offences, this Order inserts provisions into the 2001 Order to provide that the offences in article 44(1)-(3) of that order apply in England only with regard to the NA profession. See para 7.7.
- 4.10 This Order also makes amendments to the following subordinate legislation as a consequence of the amendments to the 2001 Order in respect of the regulation of NAs:-
- Amendment of the Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004 (S.I. 2004/1765) to open a Nursing Associate Part of the register and to close Sub-Part 2 of the Nurses Part of the register.
 - Amendments of the Schedule to the Nursing and Midwifery Council (Fitness to Practise) Rules Order of Council 2004 to include in the definition of "lay" in connection with a Case Examiner, reference to a person who is not and never has been a nursing associate and to make a minor amendment to rule 3 to include as a persons who must be given notice of a referral of an allegation, an employer of an NA or a person with who the NA has an arrangement to provide services as an NA. (S.I. 2004/1761).

- Amendment of the Schedule to the Nursing and Midwifery Council (Education, Registration, and Registration Appeals) Rules Order of Council 2004 to provide that NAs will be subject to the same rules regarding registration and renewal of registration as nurses and midwives. They will also have the same right of appeal against registration decisions that nurses and midwives have. As discussed above at paragraph 4.6, an appeal panel hearing the appeal can include a person who is registered in the nurses' part or in the nursing associates' part of the register. These rules are also amended to make the same provision for visiting NAs from EEA countries and Switzerland as for visiting nurses and midwives from those countries. (S.I. 2004/1767).
- Amendment of the European Union (Recognition of Professional Qualifications) Regulation 2015 to include nursing associates as a profession regulated by law for the purposes of the NMC's duties and functions as the competent authority under those regulations (S.I. 2015/2059).
- Amendment of the Schedule to the Nursing and Midwifery Council (Midwifery and Practice Committees) (Constitution) Rules Order of Council 2008 to amend the definition of "non-registrant" to include reference to a person who is not and never has been an NA and to provide that in specified circumstances a person may be disqualified from appointment as a member of the Investigating Committee or the Fitness to Practise Committee or may be removed from those committees if the NMC consider their membership or continued membership would be liable to undermine public confidence in the NA profession (S.I. 2008/3148).
- Amendment of the Nursing and Midwifery Council (Constitution) Order 2008 to include in the provisions relating to the disqualification and the removal of Council members in specified circumstances, that a person whose membership or continued membership of the Council would undermine public confidence in the nursing associate profession can be disqualified from membership or removed from the Council(S.I. 2008/2553).

4.11 This Order also amends the following primary legislation as a consequence of the regulation of NAs by the NMC:-

- The Interpretation Act 1978 (c. 30) to include NAs in the definition of "registered".
- The Value Added Tax Act 1994 (c. 23) to include the supply of services by an NA as an exempt supply for the purposes of that Act.

4.12 The primary focus of the Order is on delivering the regulatory framework for NAs. However, an opportunity has also been taken to remove a provision in the 2001 Order regarding 'Screeners' to provide clarity of process. The NMC has never used its powers to make rules for the appointment of Screeners and it is considered appropriate to remove these provisions from the NMO. see paragraph 7.17

5. Extent and Territorial Application

5.1 This Order extends to the United Kingdom.

5.2 The territorial application of this Order varies between provisions. Paragraph 1 of Schedule 1 to this Order inserts a provision to the 2001 Order that, the provisions of the 2001 Order that apply to nursing associates, to the extent that they apply to nursing associates, apply in respect of England only.

6. European Convention on Human Rights

- 6.1 Stephen Barclay Minister for State of the Department of Health and Social Care has made the following statement regarding Human Rights:

“In my view the provisions of the Nursing and Midwifery (Amendment) Order 2018 are compatible with the Convention rights.”

7. Policy background

What is being done and why

- 7.1 The Shape of Caring Review, published in March 2015, made a series of recommendations to strengthen the capacity and skills of the nursing and caring workforce in England. One key recommendation was to explore the need for a defined care role to act as a bridge between the unregulated care assistant workforce and the registered nursing workforce.
- 7.2 The findings of this review were considered by HEE and it engaged widely with relevant stakeholders before the HEE executives approved the recommendations in the review and the government announced a plan to create a new nursing support role for England. HEE carried out a public consultation on a proposal to introduce a new NA role to support the registered nurse workforce. Most respondents supported the development of the role.
- 7.3 The creation of the NA role raised a question about the level of regulatory oversight needed for the role. After considering feedback from the HEE consultation and receiving advice from the Professional Standards Authority (PSA), the Chief Nursing Officer for England and nursing leads from HEE, NHS Improvement and NHS England, it was decided that statutory regulation of the new NA role was the most effective means of assuring the highest standards of practice and the safety of patients.
- 7.4 This Order focuses on the framework of how the NA role will be regulated in England. With the few exceptions discussed at paragraphs 7.6-7.13, the NMC’s governing legislation will apply to the NA profession in the same way as for nurses and midwives. This will ensure that NAs and nurses have similar safeguards in place and work to professional standards that are aligned.

Regulation in England only

- 7.5 The nursing associate role has been developed in England to meet the specific needs of the English nursing workforce and the decision to regulate was based on the specific risk profile of NAs in England. Regulation of health and care professionals is a devolved matter in Northern Ireland and in Scotland it is devolved for new groups of healthcare professionals and those regulated since the Scotland Act 1998. Both administrations have decided not to introduce or regulate the nursing associate role within their respective workforces at this time. While professional regulation is not a devolved matter in Wales, the Welsh Government does not want to implement or regulate the NA role in Wales at this time.
- 7.6 While the provisions of the 2001 Order will mainly apply to NAs in the same way as for nurses and midwives, there are however a few differences. These are in respect of visitors, registration appeals panels, offences and the power for the Registrar to annotate the register in an emergency to provide registrants with temporary prescribing rights in an emergency. Also paragraph 27 of Schedule 1 to the Order

amends article 38 of 2001 Order to provide that appeals against a registration decision in respect of an NA should be made to the county court only and appeals brought by an NA against a decision of the Fitness to Practise Committee is to the appropriate court, which means the High Court of Justice in England and Wales. This is to reflect that Nursing associates are regulated in England Only.

Offences

- 7.7 As NAs will be regulated in England only, the amendments to the NMO introduced by this Order makes provision for the current offences under article 44(1) to 44(3) of the 2001 Order to be offences in relation to the nursing associates' part of the register, nursing associate qualifications or the use of the nursing associate title only when false representations are made, fraudulent procurement or attempted procurement occurs, or a person uses the title, in England. However, a person who elsewhere in the UK falsely represents themselves to be an NA, registered on the register as an NA or who falsely claims to have an NA qualification, may still be liable for prosecution under existing offences such as fraud (in Scotland) or fraud by false representation (in Wales or Northern Ireland). As the NA role will be regulated in England only, the risk of this offence being committed in the Devolved Administrations is low. It is therefore considered disproportionate to make this offence UK wide. The offence at Article 44(4) of the 2001 Order remains a UK wide offence. This means a person residing in any part of the UK would be guilty of committing an offence if, without reasonable excuse, they failed to comply with a requirement imposed by the NMC's Council or a Practice Committee to produce documents, give evidence or attend a fitness to practise hearing. This enables the NMC to compel the disclosure of information by relevant witnesses during fitness to practise proceedings regardless of the country in which the witness lives.

Annotation of the Register in an Emergency

- 7.8 Article 6A of the 2001 Order provides a power for the NMC to annotated its register to allow Nurses and Midwives to prescribe in national emergency, for example in flu pandemic, this would be to ensure that there are adequate persons available to prescribe in an Emergency. This Order amends the 2001 Order to disapply article 6A, in respect of NAs and thereby exclude NAs from being able to prescribe in the event of a national emergency.
- 7.9 As NAs have not been assessed by the Commission on Human Medicines in terms of their suitability for providing, supplying and administering medicines, they will not be capable of acquiring prescribing responsibilities, even in an emergency.
- 7.10 The Government's view is that it is not appropriate to give the NMC's Registrar the power to provide for NAs to prescribe in an emergency because the risk to public safety outweighs the desirability to have flexibility in the legislation to adapt the workforce in an emergency.

Visitors

- 7.11 Article 16 of the 2001 Order provides that the NMC can appoint visitors to inspect report on educational institutions that offer or propose to offer education and training for nurses and midwives, hold nursing or midwifery exams or other assessments or conduct competency tests. This Order amends the 2001 Order to extend this power so that visitors do the same in respect of NA education and training. Where visitors are to report on the education and training of nurses least one of the visitors must be

registered in the nurses part of the register. Likewise with midwifery education and training, at least one of the visitors must be registered in the midwives part of the register. However, where visitors are to report on the education and training of NAs, it is provided that one of the visitors must be registered in the nurse's part or the NA part of the register.

- 7.12 Whilst in principle, the favoured approach in due course would be for nursing associates to inspect institutions offering nursing associate qualifications, it will not be possible to select visitors for nursing associate courses from the profession until there are an adequate number of sufficiently experienced nursing associates for this purpose. To address this it is proposed that the NMC would be permitted to select either a nurse or nursing associate as a visitor to inspect nursing associate education and training programmes.

Registration and Appeals Panels

- 7.13 This Order amends article 37 of the 2001 Order regarding appeals against the Registrar's decision in respect of registration matters to provide that rules that the NMC must make in this regard must provide that the panel considering an appeal concerning NAs must include a registrant registered in either the nurses' part or the NA part of the register. Where such appeals concern a nurse or a midwife, the provision is that the panel must have a registrant in the nurses' part of the register or in the midwives' part of the register, as the case may be. However, for the reasons given above at paragraphs 7.12 until there are a sufficient number of experienced NAs for this purpose, the NMC should use its judgment to include a nurse or an NA registrant in the appeals panel to ensure the panels have sufficient experience.

Transitional provisions

- 7.14 Under the current registration provisions in the 2001 Order all applicants trained in the UK must have completed a qualification approved by the NMC in order to be eligible for registration with the NMC.
- 7.15 Following extensive engagement with key stakeholders, HEE established a pilot two year NA training programme in January 2017. These pilot programmes were not approved by the NMC as they commenced in advance of statutory regulation of the NA role. Similarly, NA apprenticeships, as defined in the NA apprentice standard published by the Institute for Apprenticeships, were not approved by the NMC, as they commenced prior to the introduction of regulation by the NMC.
- 7.16 The transitional provisions under new article 13A in the 2001 Order will allow applicants who have started or completed a NA qualification from the HEE pilot or through the apprenticeship route, before the NMC set education requirements for nursing associate programmes or begun programme approvals, to have their qualification deemed comparable in terms of standards of proficiency to an NMC approved qualification for the purposes of registration.

The removal of the Screener provision

- 7.17 The 2001 Order gives the NMC a rule making power to appoint Screeners to whom allegations can be referred. These rules must provide that any matter referred to the Screeners must be considered by a panel of at least 2 Screeners. The rules must also give the Screeners the function of considering an allegation and deciding whether or not the allegation is a matter which the NMC has power to deal with it. This power

has never been used by the NMC as it is of the view that convening such a panel is too time consuming and an unnecessary burden for the initial assessment stage of the process. The NMC put in place a screening team, which consists of a team of NMC employees rather than the sitting of a formal panel, who initially look at enquires, check that the person being enquired about is on the NMC register and the nature of the referral is something the NMC should be dealing with. If satisfied that the allegation should be referred for further investigation, the screening team refer the enquiry on to the case examiners for them to consider whether there is a case to answer in respect of an allegation. The Government's view is that the NMC's current process for initially screening potential fitness to practise cases is sufficient. Therefore, it does not feel it appropriate for there to be provisions for a screener panel in the NMC's legislation as it does not currently use them and does not plan to do so in the future.

The closure of Sub-part 2 of the Nurses' part of the register

- 7.18 This Order amends the Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004 ("the 2004 Order of Council") to close to new applicants for registration, Sub-Part 2 of the nurse's part of the register. Registration on either sub-part 1 of the Nurse Part of the register enables an individual to be known as a 'Registered Nurse: first level' and or sub-part 2 of the Nurses Part of the register enables individuals to be known as a 'registered nurse: second level. There is currently no restriction on scope of practice between the two levels. Most nurses on sub-part 2 have undertaken further training and are now also registered on sub-part 1. Sub-part 2 of the register will remain open to current registrants allowing them to renew their registration and apply to readmission and restoration to sub-part 2 but no new applicants will be able to be entered on to sub-part 2 from the date of its closure which will be the day after the date on which this Order comes into force (we are anticipating that this will be a date in July 2018).
- 7.19 Sub-part 2 of the nurses 'part of the register was the route by which UK-trained second level nurses, known as State Enrolled Nurses, would enter the register. Sub-part 2 has in practice been closed to UK trained nurses since the late 1990s when Project 2000 training removed the distinction between the two levels of nursing education. Since then there have been no new UK-trained entrants to sub-part 2 of the nurses' part of the register. The only individuals who now enter sub-part 2 are a very small number, 16 between 2000 and 2014 of nurses from outside the UK whose qualifications are not sufficient for registration to sub-part 1. Nurses from outside the UK would be able to apply to sub-part 1 of the nurses' part of the register, where they can enter the register if they meet the requirements for that sub-part. Alternatively applicants will be able to apply to the NA part of the register and either remain in that part of the register or subsequently convert to a registered nurse by undertaking further training. Closing sub-part 2 to new applications will also ensure clarity is maintained between the roles of a nurse and a nursing associate.
- 7.20 This Order also amends the 2004 Order of Council to create a new Part of the register for Nursing Associates in England. This will ensure that Nursing Associates are identified as a separate profession with different qualifications and education and training to nurses and midwives. This will also ensure clarity for the public and employers as to whether an individual is a registered nurse, midwife or nursing associate.

Consolidation

- 7.21 The NMC will publish a consolidated version of the legislation on its website.

8. Consultation outcome

- 8.1 The Regulation of Nursing Associates in England Consultation process ran from 16th October until 26th December 2017. The Department received 373 consultation responses from individuals mostly working in the NHS or the Healthcare Delivery Sector. A consultation report was published on 30th April 2018 which gives full details of the responses to the consultation.
- 8.2 The key messages from the consultation are that there was widespread support for the provisions setting out how the NA Role will be regulated by the NMC. With 91% of respondents agreeing that NAs should be entered in a separate part of the NMC's register. In terms of whether NAs should be subject to the same regulatory requirements as nurses and midwives, 85% of respondents agreed with this provision.
- 8.3 As a whole the majority of responses were positive towards what was set out in the consultation document. However, it was noted that there was a degree of misunderstanding of the question which asked "Do you agree that the NMC's Registrar should not have the power to annotate a nursing associate's entry in the register to enable them to prescribe in an emergency". From the responses received it was clear that some respondents had misinterpreted the question to meaning an everyday hospital emergency. In terms of the definition of an "emergency situation", this refers to a national emergency declared by the Secretary of State, such as a pandemic outbreak, rather than a day to day hospital emergency. An NA will not be able to prescribe in either situation. Full details of the consultation and the Government's response can be found at:
<https://www.gov.uk/government/consultations/regulation-of-nursing-associates-in-england>

9. Guidance

- 9.1 The Department of Health and Social Care does not propose to issue any guidance in relation to this Order. However, the NMC are developing guidance on standards for registered NA professionals which will be published for consultation.

10. Impact

- 10.1 The impact on business, charities or voluntary bodies is minimal so a regulatory triage assessment will accompany this Explanatory Memorandum in the form of a cost benefit analysis as Regulatory Policy Committee guidelines state that a full impact assessment only needs to be completed if the impact on business is over £5 million.
- 10.2 The impact on the public sector is that there will be an initial impact on central government as the Department of Health and Social Care is providing funding for the initial set up costs of regulating NAs. There is also expected to be an impact on Higher Education Institutes and further Education Colleges. This impact is due to the setting up, maintaining and accrediting of courses. However, the impact of this is not yet quantifiable due to a lack of evidence.
- 10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation does not apply to activities that are undertaken by small businesses.

12. Monitoring & review

12.1 The duty under section 28 of the Small Business, Enterprise and Employment Act 2015, for a Minister of the Crown to make provision for review in secondary legislation, does not apply in respect of this Order which is an Order made by Her Majesty in Council under the powers conferred by section 60 of the Health Act 1999.

12.2 The Professional Standards Authority for Health and Social Care (PSA) conducts annual performance reviews of each of the health and care professional regulatory bodies. It is anticipated the PSA, when performing such reviews, will take into account the changes introduced by this Order and provide insight into the establishment of these measures. The Department will also keep these measures under review as part of its role in developing and maintaining the professional regulatory landscape.

13. Contact

13.1 Jamie Samuel at the Department of Health and Social Care (Telephone: 0113 254 6747 or email: Jamie.Samuel@dh.gsi.gov.uk) can answer any queries regarding the instrument.