EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD AND CLINICAL COMMISSIONING GROUPS (RESPONSIBILITIES AND STANDING RULES) (AMENDMENT) (NO. 2) REGULATIONS 2023

2023 No. 1105

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The purpose of this instrument is to set out provisions relating to patient choice which are required to be included by section 6E(1A) of the National Health Service Act 2006 ("the NHS Act 2006") into the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the Standing Rules"). It also sets out other provisions made to protect and promote the rights of persons to make choices in relation to treatments or other services under section 6E(1B) of that Act.

2.2 This includes preserving provisions related to patient choice which are currently set out in the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 (S.I. 2013/500) ("PPCCR 2013") by replicating them with some amendments into the Standing Rules. This is because section 80 of the Health and Care Act 2022 ("the 2022 Act") will revoke the PPCCR 2013.This instrument will also add new provisions to strengthen and clarify arrangements surrounding patient choice. This includes introducing provisions to clarify that a provider must hold a qualifying contract to be a choice for patients. It will also replicate the purpose of provisions in regulation 7 of the PPCCR 2013 (Qualification of Providers) and set out that where a provider meets the qualification criteria set out in this instrument, that a relevant NHS body (NHS England or an Integrated Care Board – ICB) must offer that provider a contract so that it may become a choice for patients. This instrument also updates the reference to the referral-to-treatment waiting times guidance in regulation 50 of the Standing Rules so that it refers to the most recent October 2022 guidance and updates regulation 46 to reflect the content of the guidance.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument will be made and laid in Parliament before sections 78 and 80 of the 2022 Act are commenced. Section 78 will amend section 6E of NHS Act 2006, which is the power to make this instrument.

3.2 The current provisions in relation to the procurement of healthcare services and patient choice are currently set out in the PPCCR 2013 and other legislation. The Health Care Services (Provider Selection Regime) Regulations 2023 ("PSR") will be made under the new section 12ZB of the NHS Act 2006 and is intended to replace the current regime

for the procurement of health care services in England. This instrument is intended to replace the current provisions relating to patient choice. It is intended that, subject to Parliamentary debate of the PSR, both instruments will come into force on the same date (1 January 2024)

3.3 It is intended that section 80 of the 2022 Act (which will revoke legislation that sets out the current regime for patient choice and the procurement of health care services in England) will be commenced at the same time as the PSR and this instrument come into force on 1 January 2024. DHSC considers that it is therefore expedient to rely on section 13 of the Interpretation Act 1978 in relation to sections 78 and 80 of the 2022 Act because it considers it more convenient and effective to revoke the current patient choice provisions and bring into force the new provisions at the same time.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England only.

5. European Convention on Human Rights

5.1 Minister of State for Health and Secondary Care, Will Quince MP has made the following statement regarding Human Rights:

"In my view the provisions of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) (Amendment) (No. 2) Regulations 2023 are compatible with the Convention rights."

6. Legislative Context

6.1 Section 78 of the 2022 Act amends section 6E of the NHS 2006 Act. New section 6E(1A) gives powers to make regulations which must make provision as to the arrangements that NHS England and integrated care boards ("ICBs") must make, in exercising their commissioning functions, for enabling persons to whom specified treatments or other specified services are to be provided to make choices with respect to specified aspects of them. Furthermore, new section 6E(1B) allows the Secretary of State to make other provision to protect and promote the rights of persons to make choices in relation to treatments or other services. This instrument makes those provisions. Section 78 will also add new sections 6F and 6G to the NHS Act 2006 which sets out NHS England's enforcement powers of the patient choice provisions in the Standing Rules and NHS England's guidance making power, setting out how those enforcement powers will be exercised (respectively).

6.2 Section 80 of the 2022 Act makes consequential amendments including revoking existing legislation on patient choice. This instrument will replace and intends to improve upon the existing legislation relating to patient choice.

6.3 Under section 6E(9) of the 2006 Act, where regulations under section 6E are made to come into force on a day other than 1 April, the Secretary of State must publish a statement explaining the reasons for making the regulations so as to come into force on such a day, and lay the statement before Parliament. This statement is published alongside this explanatory memorandum on legislation.gov.uk website.

7. Policy background

What is being done and why?

7.1 The 2022 Act aimed to transform the delivery of health care, through better health and care integration, leading to more joined-up patient care pathways and better outcomes. This instrument is a component of those reforms and intends to strengthen and clarify provisions surrounding patient choice. Additionally, another component of the 2022 Act is to introduce a new procurement regime for healthcare services – the PSR. To deliver the PSR, we must revoke the PPCCR 2013 to remove the provisions related to procurement (that will instead be governed by the PSR). The provisions on patient choice set out in the PPCCR 2013 will be preserved and strengthened by this instrument by setting them out in the Standing Rules.

What did any law do before the changes made by this instrument?

7.2 The PPCCR 2013 and the Standing Rules set out the provisions related to patients' statutory rights to choice of provider.

Why is it being changed?

7.3 We are strengthening and clarifying patient choice provisions to ensure that providers that can be a choice for patients are duly accredited and to improve the utilisation of choice of provider by patients. As noted above, the PPCCR 2013 will need to be revoked to deliver the PSR Therefore, this instrument also preserves and strengthens the patient choice legislation currently set out in the PPCCR 2013 by setting it out in the Standing Rules. The provisions in regulations 12, 13, 14, 15 and 16 of the PPCCR 2013 have not been transposed into the Standing Rules as there are new enforcement provisions inserted into the NHS Act 2006 (as new section 6F) by section 78 of the 2022 Act.

What will it now do?

7.4 Firstly, it will make amendments to regulation 38 of the Standing Rules to clarify that a patient's right to choice of provider still applies even when an interface service (such as a referral management service) plays a role in managing a relevant referral made by a GP, dentist, or optometrist.

7.5 Secondly, it will make amendments to regulation 39 of the Standing Rules to ensure that a provider chosen by a patient for an elective referral must not only take responsibility for providing the first outpatient appointment that a patient requires but also any subsequent treatment that the patient requires as a result of that elective referral. Further amendments to regulation 39 clarify that a provider must hold a "qualifying contract" to be a choice for patients on the NHS. As a provider only requires a qualifying contract with any relevant body ("relevant body" is defined in the Standing Rules as NHS England or an ICB) to become a choice for patients (even if there is not a contract in place between that provider and the relevant body responsible for the relevant patient), these regulations clarify that the terms of that qualifying contract apply to the commissioning of that service, even where that relevant body does not hold a contract.

7.6 This instrument also introduces regulations 42B and 42C to the Standing Rules. These amendments replicate the purpose of provisions set out in regulation 7 of the PPCCR 2013 (Qualification of Providers) to apply transparent, proportionate and non-discriminatory criteria when determining which providers can be a choice for patients,

but now provides a standard qualification criteria by which to assess providers. Regulation 42C sets out the standard qualification criteria, but relevant bodies will still be able to set local terms and conditions for the delivery of the relevant healthcare service. Regulation 42B sets out the circumstances under which a provider can ask the relevant body to be assessed against the criteria for providing a service in regulation 42C so that it can be offered an "NHS Standard Contract" (as defined in the instrument) in respect of that service. If the provider has met the criteria in regulation 42C, a relevant body must offer an NHS Standard Contract to that provider to provide the relevant services so that the provider may become a choice for patients.

7.7 This instrument also sets out a timeframe (as soon as reasonably practicable but in any event before the expiry of six weeks) during which the relevant body must assess the provider against the criteria. Finally, regulation 42D makes similar provision for modifying existing NHS Standard Contracts. Where a provider requests a modification of an existing NHS Standard Contract, for example to provide a new service or provide an existing service in a new location, once it has met the criteria and any requirements in relevant procurement legislation in relation to modification, then the contract must be modified so that that service can be offered as a choice for patients. Overall, these provisions are intended to ensure that relevant bodies effectively assess providers that may become a choice for patients in a clear and efficient way.

7.8 The intention is to promote greater choice of accredited, viable and high-quality providers for patients, supporting patients to take greater control of their healthcare and access the healthcare that is most suitable for them. This could help improve the efficiency of patients accessing healthcare services by introducing new providers or expanding the services provision of existing providers in the NHS and letting patients choose providers whose services are best suited to their individual circumstances. For example, a patient may be able to choose a provider that is further away than their nearest local provider but is more convenient and efficient because that provider has a shorter waiting list and is located near family members who can support the patient. This right to choose a provider is already set out in legislation and is in operation – however we intend to strengthen that by setting out a standardised criteria to assess potential providers that can become a choice for patients.

7.9 This instrument also adds a new regulation 42A to the Standing Rules to replicate the rights for patients to choose their General Practitioner under regulation 11 of the PPCCR 2013.

7.10 This instrument also makes transitional provisions related to the treatment of pre-existing contracts (those in place before this instrument comes into force). This instrument provides that the instrument does not affect any existing contract unless, on or after 1st January 2024, the provider expresses an interest to a relevant body in being assessed against the standard qualification criteria in accordance with regulation 42B or 42D.

7.11 It also makes transitional provisions in relation to complaints and resulting enforcement action related to patient choice that preceded the coming into force of this instrument. NHS England may commence or continue any investigation of an ICB in relation to a complaint under regulation 13(1) PPCCR 2013 as though it were an investigation commenced on or after that date under section 6F of the NHS Act 2006. New section 6F sets out NHS England's enforcement powers in relation to patient choice and will be commenced at the same time as this instrument

7.12 Finally, Regulation 50 of the Standing Rules requires NHS England and ICBs to have regard to specific guidance when carrying out their duties under regulations 45 and 48, in relation to waiting times. The purpose of the amendment to regulations 46 and 50 of the Standing Rules (see regulation 2(7) and 2(2)) is to update those provisions so that they refer to and align with the latest version of the guidance – which is entitled "Referral to treatment consultant-led waiting times: rules suite (October 2022)[1]".

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union or trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 This instrument does not consolidate any other instrument.

10. Consultation outcome

10.1 There is no statutory duty to consult on the policy underpinning this instrument.

11. Guidance

11.1 NHS England will update published statutory guidance (made under section 14Z51 of the NHS Act 2006) on patient choice for when this instrument comes into force. The current statutory guidance is available here.[2]

11.2 NHS England will also publish statutory guidance under section 6G of the NHS Act 2006, to explain how they will exercise their enforcement functions as set out in section 6F, for when this instrument comes into force.

12. Impact

12.1 There is no, or no significant, direct impact on businesses, charities or voluntary bodies.

12.2 There is no, or no significant, direct impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because this SI relates to the maintenance and clarification of existing regulatory standards.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses in that it relates to existing legislation which governs the contracting of healthcare services by the NHS – which may at times be with small businesses. This SI does not impose regulatory burdens on small businesses and, therefore, no specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is reviewing annually and updating as required.

14.2 This instrument does not include a statutory review clause.

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[1] https://www.gov.uk/government/publications/right-to-start-consultant-led-treatment-within-18-weeks/referral-to-treatment-consultant-led-waiting-times-rules-suite-october-2022

[2] https://www.gov.uk/government/publications/procurement-patient-choice-and-competition-regulations-guidance

15. Contact

15.1 Richard Corbett at DHSC. Telephone: 07596 889 415 or email: Richard.corbett@dhsc.gov.uk can be contacted with any queries.

15.2 Sam Boyd, Deputy Director for Health Reform and Strategy, at DHSC can confirm that this Explanatory Memorandum meets the required standard.

15.3 Minister of State for Health and Secondary Care, Will Quince MP at DHSC can confirm that this Explanatory Memorandum meets the required standard.