EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD AND CLINICAL COMMISSIONING GROUPS (RESPONSIBILITIES AND STANDING RULES) (AMENDMENT) REGULATIONS 2024

2024 No. 302

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 His Majesty.

2. Declaration

2.1 Andrew Stephenson, Minister of State at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Tim Jones, Deputy Director for Cancer Policy and Performance, at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Monsoor Alom at the Department of Health and Social Care. Telephone: 0207 104 7524 or email: monsoor.alom@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do? For reference the Standing Rules refers to The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012

The purpose of this instrument is to:

4.1.1 Revoke Part 10 (funding of therapies for Multiple Sclerosis) of the Standing Rules which refers to a scheme that concluded in 2016.

4.1.2 Amend the Standing Rules to increase the rates of NHS-funded nursing care (FNC) payable by the relevant body (NHS England (NHSE) or Integrated Care Boards (ICBs)).

4.1.3 Ensure that the statutory patient right to choose a health service provider following an elective referral can be exercised by patients regardless of whether an interface service is used in the referral process, or the relevant provider has a contract with an NHS trust or foundation trust if they have taken on commissioning functions of an ICB through a delegation agreement (as per section 65Z5 of the NHS Act 2006 – the '2006 Act').

4.1.4 Amend cancer waiting times standards to replace the two-week wait standard for first appointment with the 28-day faster diagnosis standard and associated duty. The new provisions place a duty on a health service provider to make arrangements to ensure

that the waiting time period is met in at least 75% of cases concluding in each data collection period. The standard is met where a person who is urgently referred for suspected cancer or for breast symptoms (where cancer is not suspected) is provided with either a diagnosis of cancer or a ruling out of cancer within 28 days of being referred.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England only.

5. Policy Context

Funding of therapies for Multiple Sclerosis

What is being done and why?

5.1 This instrument will omit Part 10 of the Standing Rules which relates to the provision of certain disease modifying therapies (DMTs) for the treatment of multiple sclerosis. The DMTs previously funded under the scheme are now available through standard NHS funding routes.

What was the previous policy, how is this different?

5.2 The DMTs were part of an agreement between the then Department of Health and pharmaceutical companies that held the marketing authorisations for those therapies. That agreement provided therapies for a cohort of patients as part of a monitoring programme to determine the cost effectiveness of those treatments. However, the programme has now completed its work and, consequently, the relevant therapies are now made available to patients who need them through standard NHS routes. Part 10 of the Standing Rules is therefore no longer required.

NHS-funded nursing care (FNC)

What is being done and why?

5.3 FNC is the funding provided by the NHS to care homes providing nursing to support the provision of nursing care by a registered nurse for those assessed as eligible. The process for determining eligibility is set out in regulation 28 of the Standing Rules. The relevant body's responsibility to pay a flat rate contribution to the care home towards registered nursing care costs arises where a relevant body (either NHSE or an ICB) determines that a person has a need for nursing care and the person is a resident in a care home or may need to become resident in a care home. The NHS is responsible for this funding. Accommodation and social care costs are the responsibility of either the local authority and/or the individual (subject to the outcomes of a needs assessment and financial assessment).

5.4 DHSC routinely reviews the rates paid for FNC and updates the rates in the Standing Rules to reflect wage inflation for registered nurses providing such care.

What was the previous policy, how is this different?

5.5 The rates currently set out in the Standing Rules (as amended), for the 2023-24 financial year, are £219.71 per week for the flat rate payment and £302.25 per week for the high band.

5.6 DHSC conducted a cost collection survey to assess the impact of wage inflation on FNC in 2023-2024 and to inform the 2024-25 FNC rates. Based on this research, a decision has been made to increase the rate by 7.4% from the 2023-24 financial year. This accounts for the increase in the cost of care demonstrated by the survey and annual wage inflation of 4.96%. The wage inflation uplift is based on adult social care data and economic projections for the 2024-25 financial year. This instrument therefore amends the rates set out in the Standing Rules to £235.88 per week for the flat rate payment and £324.50 for the high band payment.

Patient Choice and Delegation Arrangements

What is being done and why?

5.7 The provisions which amend regulations 38 and 39 of Part 8 of the Standing Rules will respectively (a) change the definition used for interface services for the purposes of Part 8 of the Standing Rules and (b) ensure that current patient choice policy (that a patient with a statutory right to choose their provider may choose a provider with whom any NHS commissioner has a contract) continues to apply even if that NHS commissioner is a NHS trust or foundation trust who has taken on delegated commissioning functions under section 65Z5 of the 2006 Act.

What was the previous policy, how is this different?

5.8 The current position in legislation (Part 8 of the Standing Rules) is that a patient with a statutory right to choose a provider for their treatment can choose any provider who has a valid contract with an ICB or NHSE. This instrument will enable patients to also have access to providers that have contracts with NHS trusts/foundation trusts if those organisations take on the commissioning functions of an ICB through a delegation agreement under section 65Z5 of the 2006 Act. This is to ensure that the current choice policy is extended into commissioning arrangements entered into by NHS trusts and foundation trusts and so will ensure the consistent application of current patient choice policy across all NHS commissioners in England.

5.9 Additionally, this instrument will change the definition of ‘interface services’ in Part 8 of the Standing Rules. The practical effect of this is to ensure that patients retain their right to choose their healthcare provider even when an interface service (such as a referral management centre) plays a role in the referral made by the GP. Provisions to this effect already exist in the Standing Rules and in practice – but this instrument will tighten the definition to ensure clarity and ensure that the provisions apply where the relevant interface service has been commissioned by an NHS trust or foundation trust in accordance with a delegation agreement under section 65Z5 of the 2006 Act.

Cancer Waiting Times Standards

What is being done and why?

5.10 This instrument amends the Standing Rules to replace the two-week wait standard from urgent referral for suspected cancer to seeing a specialist within two weeks (two-week wait standard), with the 28-day Faster Diagnosis Standard (FDS) and associated duty.

What was the previous policy, how is this different?

5.11 The two-week wait cancer standard for urgent referrals for suspected cancer is a process-based target focussed on time to first appointment with a specialist. The two-week wait standard will continue to apply with respect to persons referred prior to 1

April 2024. Thereafter this standard will be replaced by the FDS which is an outcome-based target focussed on what matters to patients; a diagnosis or the ruling out of cancer. The 28-day FDS will also place a more explicit focus on outcomes rather than process. The FDS incentivises earlier diagnosis by setting a duty to make arrangements to ensure that at least 75% of patients within the one month data collection period who receive a diagnosis or the "all clear" in each data collection period will have got their diagnostic outcome within 28 days; evidence shows early diagnosis rates can improve cancer survival rates. In addition, as the two-week wait standard was a process-based target, it meant that the care pathway was designed to include an early outpatient appointment in a way which acted as a barrier to the adoption of newer straight to test pathways and further innovations.

5.12 This amendment to the Standing Rules is part of a process to modernise cancer waiting times standards and refocus performance measures on the critical NHS Long Term Plan objective of earlier and faster diagnosis. These measures will help to ensure that we are always holding the NHS accountable for delivering the best patient care. It will also deliver a new, simplified set of patient-centred standards appropriate to modern cancer care that are understandable both clinically and to the public.

6. Legislative and Legal Context

How has the law changed?

6.1 Section 6E of the 2006 Act was inserted by section 20 of the Health and Social Care Act 2012. It gives a duty to the Secretary of State to impose requirements by regulations on NHSE and ICBs when they are exercising their functions of commissioning health services.

6.2 The Standing Rules have been amended several times since 2012 for a number of purposes including updating FNC payment rates and to make changes to patient choice and cancer waiting times legislation to reflect evolving policy.

Why was this approach taken to change the law?

6.3 Making regulations that amend the Standing Rules is the only possible approach to make the necessary changes to achieve the policy purposes set out in this Explanatory Memorandum.

7. Consultation – Cancer waiting time standards review

Summary of consultation outcome and methodology

7.1 In March 2022 NHSE published a consultation paper setting out proposed new cancer standards, the rationale for the changes, and the evidence collected in support of the proposals.

7.2 The consultation was a public consultation and responses were received from those who identified themselves as patients, members of the public, as an NHS employee or individuals providing a formal organisational response. NHSE received 283 responses to the online survey, and 22 pieces of correspondence (letters and emails) were received.

7.3 Overall, 65% (183) agreed with the proposal to replace the expectation of an appointment within two weeks with the proposal that people receive a definitive diagnosis or ruling out of cancer within 28 days of referral. Just 8% strongly disagreed.

7.4 When analysing top themes by respondent type, NHS England identified those in agreement felt that the proposal will support quicker diagnosis and that the 28-day FDS is clear and realistic. Only one theme of disagreement was noted from the patient/public group, that 28 days is too long to wait for a definitive diagnosis or ruling out of cancer (12 respondents). Of the correspondence on replacing the two-week wait standard with FDS, 22 themes in agreement were raised. Those in agreement felt the proposal will support quicker diagnosis, improve monitoring and reporting, improve quality of diagnosis, and improve service efficiency. Of those in disagreement, the most common theme related to concerns that the current 75% FDS threshold was too low. The full consultation response can be found here: https://www.england.nhs.uk/wp-content/uploads/2023/08/PRN00654i-cancer-waiting-times-review-consultation-response.pdf

7.5 The provisions related to patient choice, FNC and disease modifying therapies are extremely limited and specific and do not change current policy or the operation of patient choice of providers in the NHS. No public consultation has been undertaken. Although no public consultation has been undertaken, relevant experts have been consulted in making these provisions.

8. Applicable Guidance

8.1 NHS England has issued updated Cancer Waiting Times guidance here[1].

8.2 Guidance on NHS-funded Nursing Care is available in the National Framework for NHS Continuing Healthcare and NHS-funded Nursing Care July 2022[2] and in the NHS-funded Nursing Care Practice Guidance July 2022[3].

8.3 NHSE has published guidance on patient choice here[4].

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because there is no, or no significant, impact on business.

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies across this instrument.

9.3 For the cancer related amendments, removing the two-week waiting time standard could increase consultant capacity due to some patients being sent straight-to-test in line with clinical best practice timed pathways. However, placing the faster diagnosis standard as a duty on providers may increase the burden on the diagnostics end of a pathway. The financial cost to the public sector has not been quantified due to the complexity of cancer pathways which vary by tumour type, stage diagnosis and multiple other factors. The Government's £2.3 billion capital funding in community diagnostic centres, 154 of which have opened thus far is designed to meet this increased need. No impact is anticipated for small or micro businesses.

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[1] https://www.england.nhs.uk/wp-content/uploads/2023/08/PRN00654-national-cancer-waiting-times-monitoring-dataset-guidance-v12.pdf
[2] https://www.gov.uk/government/publications/national-framework-for-nhs-continuing-healthcare-and-nhs-funded-nursing-care
[3] https://www.gov.uk/government/publications/nhs-funded-nursing-care-practice
[4] https://www.england.nhs.uk/long-read/patient-choice-guidance/

9.4 The impact to the public sector for the patient choice and delegation provisions is as outlined in the policy section of this document. We do not anticipate any wider public sector impacts. No impact is anticipated for small or micro businesses.

9.5 For FNC, there is a flat rate of funding covering the provision of nursing care by a registered nurse. This helps to minimise the impact of the requirement on small or micro businesses. This funding is provided regardless of the size of the care home or business. We do not anticipate any significant impacts on public bodies due to this increase in FNC rates.

9.6 There is no requirement for an impact assessment on business in relation to DMTs for the treatment of multiple sclerosis.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 With respect to FNC, the approach to monitoring this legislation is to review the rate annually and, if required, update the rate by amending the legislation.

10.2 The Department of Health and Social Care and NHS England will continue to monitor the policies for patient choice, disease modifying therapies and cancer waiting times on an ongoing basis and consider changes as required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 (“relevant European Union Acts”).