EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD (ADDITIONAL FUNCTIONS) REGULATIONS 2017

2017 No. 212

1. Introduction

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

2. Purpose of the instrument

2.1 The National Health Service Commissioning Board (Additional Functions) Regulations 2017 ("the Regulations") confer additional functions (duties and powers) on the NHS Commissioning Board ("the Board"). The main function conferred is the power to procure (i.e. conclude) and manage procurement framework agreements with suppliers of services, drugs, medicines and other substances and products, for use, principally, by NHS trusts and NHS foundation trusts.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 This entire instrument applies only to England. Section 271(1) of the National Health Service Act 2006 states that the functions of a minister of the Crown under that Act are exercisable only in relation to England. This applies also to the Secretary of State's power under section 13Z1 of that Act under which the Regulations are made.

3.3 In the view of the Department, for the purposes of House of Commons Standing Order 83P the subject-matter of this entire instrument would be within the devolved legislative competence of the Northern Ireland Assembly if equivalent provision in relation to Northern Ireland were included in an Act of the Northern Ireland Assembly as a transferred matter, and the Scottish Parliament if equivalent provision in relation to Scotland were included in an Act of the Scottish Parliament, and the National Assembly for Wales if equivalent provision in relation to Wales were included in an Act of the National Assembly for Wales.

3.4 The Department has reached this view because the primary purpose of the instrument is to confer a power on the Board to conclude and manage framework agreements which may be used by NHS trusts, NHS foundation trusts and others to purchase services, medicines, etc. for the purposes of the NHS in England. The power to do the same is within the devolved legislative competence of each of the three devolved legislatures in relation to the respective health services provided in Scotland, Northern Ireland and Wales. This is because the primary purpose of the subject matter of the instrument is not within Schedule 5 to the Scotland Act 1998 and is not otherwise outside the legislative competence of the Scottish Parliament (see section 29 of that Act); the primary purpose of the subject matter of the instrument is not within Schedules 2 or 3 to the Northern Ireland Act 1998 and is not otherwise outside the

legislative competence of the Northern Ireland Assembly (see section 6 of that Act); the primary purpose of the subject matter of the instrument is within paragraph 9 of Schedule 7 to the Government of Wales Act 2006 and is not within one of the exceptions listed therein, nor is it otherwise outside the legislative competence of the National Assembly for Wales (see section 108 of that Act).

4. Legislative Context

4.1 The Commercial Medicines Unit in the Department of Health is currently responsible for procuring and managing procurement framework agreements entered into with manufacturers and suppliers of services, drugs, medicines and other substances and products. The framework agreements are used, principally, by NHS trusts and NHS foundation trusts for the purposes of obtaining best value for money when purchasing services, medicines, etc. for the NHS.

4.2 The Regulations confer additional functions on the Board which provide the Board with the legal powers to take on responsibility for this activity. The Regulations are made under section 13Z1 of the National Health Service Act 2006 ("NHS Act 2006) which is the first use of this regulation-making power.

4.3 Section 13Z1 requires any additional function conferred by regulations made under it to be connected to an existing function of the Board. For the purposes of the Regulations, the 'connected' functions are those in sections 1H(2), 1H(3), 13A, 13D and 13E of the NHS Act 2006. Section 1H(2) states that, concurrently with the Secretary of State, the Board must comply with the duty in section 1(1) of the NHS Act 2006 to promote a comprehensive health service in England that is designed to secure improvement in the physical and mental health of the people of England and in the prevention, diagnosis and treatment of physical and mental illness. Under section 1H(3), the Board is the lead commissioner of NHS services; under section 13A(7), the Board must seek to comply with the objectives set out in the Secretary of State's mandate to it which includes responsibility for the overall NHS budget and improving efficiency in the NHS; section 13D places a duty on NHS England to exercise its functions effectively, efficiently and economically; and section 13E states that the Board must exercise its functions with a view to securing continuous improvement in the quality of services provided to individuals, including for or in connection with the prevention, diagnosis or treatment of illness. In addition, the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (S.I. 2012/2996) impose duties on the Board in relation to the commissioning of specialised services.

5. Extent and Territorial Application

5.1 The extent of this instrument is England and Wales.

5.2 The territorial application of this instrument is set out in paragraph 3.2 of Section 3 under "Other matters of interest to the House of Commons".

6. European Convention on Human Rights

6.1 The Parliamentary Under-Secretary of State for Health, Lord Prior, has made the following statement regarding Human Rights:

"In my view the provisions of the National Health Service Commissioning Board (Additional Functions) Regulations 2017 are compatible with the Convention rights."

7. Policy background

What is being done and why

7.1 The Commercial Medicines Unit in the Department of Health is currently responsible for procuring and managing procurement framework agreements, which NHS trusts and NHS foundation trusts can use to purchase from manufacturers and suppliers, at competitive prices for the NHS, services, drugs, medicines and other substances and products. The use of framework agreements by the NHS to purchase secondary care medical services and products leads to considerable savings in the overall NHS bill. Savings attributable to the use of framework agreements for the period April 2015 to March 2016 are £87.48 million for branded medicines and £25.57 million for generic medicines.

7.2 Lord Carter, in the final report of his review of the productivity of NHS hospitals, "Operational productivity and performance in English NHS acute hospitals: Unwarranted variations, 2016", recommended that consideration be given as to whether the Commercial Medicines Unit would be best located within the Department of Health or the NHS, working alongside the Boards' specialist pharmacy services and specialised commissioning functions. The report is available at the following link: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf

7.3 In the light of this recommendation (which reflects the move towards the Department of Health undertaking a more strategic, rather than operational, role in relation to the NHS), the Secretary of State has agreed with the Board that most of the functions of the Commercial Medicines Unit (in particular those relating to framework agreements to facilitate the purchase of NHS medicines, etc.) should, in the future, be exercised by the Board. Other factors taken into account include the fact that such functions are connected to and will complement current responsibilities of the Board (for example, the commissioning of specialised services and its day-to-day responsibility for the NHS budget). In addition, there are potential benefits to be gained in bringing together relevant expertise in the procurement of medicines, etc. for the NHS.

7.4 As the NHS Act 2006 does not confer a power on the Board to procure and manage the procurement framework agreements to which the Regulations relate, these Regulations confer an additional function on the Board in order for it to undertake this work. In addition, to ensure that the relevant expertise and tools are available to the Board in undertaking this work, the Regulations will be supplemented by two transfer schemes made under section 300 of the Health and Social Care Act 2012 which will transfer the relevant staff, property, rights and liabilities from the Department of Health to the Board.

7.5 The Commercial Medicines Unit also provides support to other units within the Department of Health in the delivery of the Secretary of State's wider health-related functions. For example, from time to time, for the purposes of assisting the Secretary of State in the exercise of functions relating to the health service, it provides other units within the Department of Health with data, or an analysis of data, generated and managed as a consequence of its work. To ensure that this support continues to be available when the Board takes on responsibility for exercising the functions relating to framework agreements, the Regulations impose a duty on the Board to provide any assistance requested by the Secretary of State for the purposes of the Secretary of

State's health-related functions. This duty to assist applies only in relation to the exercise of the power to procure and manage framework agreements, i.e. in how the Board is to exercise the power in light of the Secretary of State's other health-related functions or assistance that the Board is able to provide as a consequence of exercising the power (for example, analysing information generated by the exercise of the power).

7.6 In performing its procurement function, the Commercial Medicines Unit undertakes extensive consultation and works closely with stakeholders, specifically chief pharmacists from NHS trusts and NHS foundation trusts. This collaboration includes deciding which medicines, etc. are to be the subject of framework agreements. Currently, the National Pharmaceutical Supply Group (which represents NHS hospital pharmacists) provides a strategic lead to the Commercial Medicines Unit on the medicines procurement strategy for the NHS. This is for the purposes of maintaining the continuity of supply of medicines, etc. and related services for all patients and to ensure effective communication channels with chief pharmacists of NHS trusts and NHS foundation trusts. To ensure that this continues, the Regulations impose a further duty on the Board to consult and collaborate with registered pharmacists of trusts in relation to the procurement of the framework agreements to which the Regulations relate.

Consolidation

7.7 These Regulations do not amend another statutory instrument.

8. Consultation

8.1 No public consultation has been undertaken. This is because the Regulations, in effect, simply provide for the relocation of an operational unit from the Department of Health to the Board, with no substantial change envisaged in how the Board will carry out these activities or any change in the end-result (save for the Secretary of State being replaced by the Board as a party to the framework agreements). Public interest in the Regulations is, therefore, considered to be minimal.

8.2 As mentioned in paragraph 3.2 above, the Regulations apply only to England but the devolved administrations currently use a few of the existing framework agreements to purchase certain blood-related products for use in secondary care health settings. The Department of Health and the Board are, therefore, consulting the devolved administrations as to whether they would wish to be able to use any subsequent framework agreements should the responsibility for procuring them be transferred to the Board in the future. The consultation is also looking at the formal arrangements that will need to be put in place between the Board and each of the devolved administrations for the Board to be able to continue to provide this facility to the devolved administrations. Preliminary views indicate that the devolved administrations are keen for this facility to continue to be available to them as this will enable economies of scale to continue to be achieved and reduce duplication of efforts. In addition, the on-going UK-wide co-operation in relation to the procurement of the products covered by the relevant framework agreements together with the equity of access, on a national basis, to such products at competitive prices for patients are considered to be beacons of good practice. The Board has confirmed that it is content in principle for the devolved administrations to make use of future agreements.

8.3 An information and consultation exercise on the transfer of staff, their terms and conditions and other employment related issues is also being undertaken with employee representatives of members of staff from the Commercial Medicines Unit who will transfer to the Board when it takes on responsibility for the Commercial Medicines Unit's functions. This will identify any additional employment issues arising from the transfer not already covered by the statutory staff transfer scheme, and inform decisions by the Board on the appropriate steps and measures required to address these issues. The transfer is being effected by a staff transfer scheme, but applying the principles of the Cabinet office Statement of Practice, meaning that continuity of employment and terms and conditions will be protected upon transfer.

9. Guidance

9.1 No guidance is being provided as it is intended that staff from the Commercial Medicines Unit will, subject to Parliament's approval of the Regulations, transfer to the Board on the same date that the Regulations come into force. The framework agreements will also continue to be procured and managed, substantially, in the same way as they are currently procured and managed.

10. Impact

10.1 There is no impact on business, charities or voluntary bodies.

10.2 The impact on the public sector is limited to the administrative costs involved in effecting the transfer of responsibility for procuring and managing framework agreements, staff, property, rights and liabilities to the Board.

10.3 An Impact Assessment has not been prepared for this instrument as there is no significant cost impact to the public sector, and no cost impact to the private or voluntary sectors. We anticipate that the benefits attributable to the procuring of framework agreements for the NHS, as mentioned in paragraphs 10.6 to 10.10 below will continue if the Board were to take on this work and that there will be additional benefits from this change, as referenced in paragraph 10.11 below.

10.4 The impact of these Regulations, in the context of the public sector equality duty ("PSED"), has been considered. The intention is simply to effect the transfer of responsibility for procuring and managing framework agreements to the Board, with no substantive change to the nature of the function, how it is to be exercised and the outcomes in exercising the function. For this reason, it is not believed that the Regulations will have any negative impact on any members of the public who share one or more of the protected characteristic specified in section 149 of the Equality Act 2010 when compared with those who do not share the same protected characteristic(s).

10.5 For those staff transferring, whilst broad impacts have been considered it is not possible to state exactly what specific impact there may be. The Department and the Board will need to inform employee representatives of, and consult with them on, any staff-related measures that might need to be taken in connection with the transfer and any impact these may have on staff with protected characteristics. The information and consultation will provide a means of highlighting any areas which need specific consideration, which will be duly undertaken as each issue arises. However, for several reasons it is believed that there will not be a significant negative impact on any employees who share a protected characteristic when compared with those who do not share the same protected characteristic. Those reasons include the fact that,

staff will transfer with their current terms and conditions of employment intact and, as a public sector organisation, the Board is also subject to the PSED and will have policies in place to ensure it will comply with the PSED requirements.

10.6 In considering the Secretary of State's general duties under the NHS Act 2006, the relevant duties that are engaged are:

- Securing continuing improvement in the quality of services (section 1A);
- Having regard to the NHS Constitution (section 1B), in particular the principle that the NHS will provide the best value for taxpayer's money and the most effective, fair and sustainable use of finite resources;
- Reducing inequalities (section 1C);
- Promoting autonomy (section 1D); and
- Promoting research (section 1E).

10.7 It is considered that the transfer of responsibility for procuring and managing framework agreements to the Board will provide a continuing focus on ensuring best value for money for the NHS in relation to the procurement of medicines, medical devices, other medical products and services which goes towards fulfilling the principle in the NHS Constitution identified above of providing best value for taxpayers' money, etc.

10.8 In addition, the procurement of framework agreements by the Board will continue to contribute to the reduction of inequalities between the people of England with respect to the benefits they can obtain from the NHS - this is in terms of enabling potential reductions to be made in geographical inequalities in the provision of services, medicines, etc. that are provided as part of the NHS. This, in turn, will support the maintenance and improvement of service quality in all areas in England.

10.9 The Board will also continue to deliver the Commercial Medicines Unit's responsibilities in relation to the sharing of information, including sharing information with the Secretary of State for the purposes of the Secretary of State's wider health-related functions, including for research on, and reviews of, the NHS.

10.10 The autonomy of NHS trusts and NHS foundation trusts will continue to be respected when responsibilities transfer to the Board, as trusts will continue to be under no obligation to use the framework agreements in fulfilling their procurement responsibilities, and the Board will have discretion as to how it fulfils the duty to consult and collaborate imposed by these Regulations.

10.11 Conferring a function on the Board to procure and manage framework agreements will result in the sharing of expertise and the development of co-ordinated approaches between the team responsible for this function and those teams at the Board that are responsible for specialised commissioning and common procurement issues. This will potentially bring about improvements to NHS procurement and commissioning, with subsequent beneficial impacts on value for money, quality of services and supporting reductions in geographical inequalities in provision.

10.12 Consequently, it is believed that the proposal for the Board to conclude and manage framework agreements in the future complies with the Secretary of State's duties under the NHS Act 2006.

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 exercise by the Board of the functions conferred on it by these Regulations will be kept under review by the Secretary of State when considering the business plan the Board is required to publish under section 13T of the NHS Act 2006, and the annual report the Board is required, under section 13U of that Act, to lay before Parliament and provide to the Secretary of State.

13. Contact

13.1 Stephen Lock at the Department of Health (Telephone: 020 797 25392 or email: Stephen.Lock@dh.gsi.gov.uk) can answer any queries regarding the instrument.