EXPLANATORY MEMORANDUM TO

THE HEALTHY START SCHEME AND WELFARE FOOD (MISCELLANEOUS AMENDMENTS) REGULATIONS

2017 No. 1032

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 This instrument will give the Department of Health ("DH") the flexibility to procure all forms of vitamin products as Healthy Start vitamins under the Healthy Start Scheme. It will also clarify that the NHS Business Services Authority is able, on behalf of the Secretary of State, to enter into framework agreements, contracts and other arrangements for the manufacture, storage and distribution of Healthy Start vitamins; and for the administration of both the entire Healthy Start Scheme (food vouchers and vitamins) and the Nursery Milk Scheme.

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 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are matters of interest to the House of Commons does not arise at this stage

4. Legislative Context

4.1 The Healthy Start Scheme is established by the Healthy Start Scheme and Welfare Food (Amendment) Regulations 2005 (S.I.2005/3262) ("the 2005 Regulations"). The Nursery Milk Scheme is established by the Welfare Food Regulations 1996 (S.I.1996/1434).

4.2 Healthy Start vitamins are specified currently in the 2005 Regulations as taking the form of tablets or vitamin drops. The appropriate amounts are precisely specified in those Regulations as fifty-six tablets for women and ten millilitres of drops for children for every eight-weeks of entitlement.

4.3 The specified form and quantities of Healthy Start vitamins outlined in paragraph 4.2 have existed for a number of decades. The current contracts under which the vitamins were procured will however come to an end in 2018 and DH therefore needs to conduct a new procurement exercise for the vitamin products. It wishes to use this exercise to determine whether any newer forms of vitamin products, which may be more attractive to users, could be procured at a more cost-effective price. However, given the specified form and quantities of Healthy Start vitamins in the 2005

Regulations, DH would only be able to accept bids for products which came as a container containing the form and amounts referred to in paragraph 4.2 above.

4.4 While the NHS Business Services Authority currently has a range of powers which allow it to act on behalf of DH in matters concerning the health service, these powers do not explicitly allow it to conclude contracts, manage other arrangements, nor undertake administrative functions, on behalf of the Secretary of State relating to Healthy Start vitamins.

4.5 The NHS Business Services Authority also carries out administrative functions on behalf of the Secretary of State in relation to other elements of the Healthy Start Scheme, involving the provision of food vouchers to beneficiaries. It also carries out similar administrative functions in relation to the Nursery Milk Scheme. This Scheme provides for the reimbursement to eligible childcare providers of the cost of one-third of a pint of milk per day for children under the age of five who attend the childcare setting for at least two hours per day.

5. Extent and Territorial Application

5.1 This instrument extends to England and Wales, and Scotland. As required by section 13(2) of the Social Security Act 1988 ("the 1988 Act"), DH has consulted Scottish Ministers and the National Assembly for Wales about the proposed changes.

5.2 This instrument applies to England, Scotland and Wales.

5.3 These Regulations do not amend the definition of "Healthy Start vitamins" in regulation 2(1) of the 2005 Regulations, which applies to England, Scotland and Wales. That definition recognises that the power to prescribe descriptions of food (including vitamins) has been transferred, in relation to the operation of the scheme in Scotland, to Scottish Ministers under the Scotland Act 1998 (Transfer to Functions to the Scottish Ministers etc) (No. 3) Order 2006 (S.I. 2006/3258) and, in relation to the operation of the scheme in Wales, to the Welsh Ministers under section 13(6) of the 1988 Act. These powers allow Scottish Ministers and the Welsh Ministers respectively to make regulations to describe Healthy Start vitamins differently in their own areas, should they wish to do so.

5.4 To date, Scottish Ministers have not exercised this regulation-making power, and the description of Healthy Start vitamins brought into effect by this instrument will apply in Scotland. The National Assembly for Wales has prescribed a description of vitamins in relation to the operation of a scheme in Wales in the Healthy Start Scheme (Description of Healthy Start Food) (Wales) Regulations 2006 (S.I. 2006/3108) which reflects how Healthy Start vitamins are specified currently in the 2005 Regulations. The description of Healthy Start vitamins contained in this instrument will therefore not apply in Wales. However the National Assembly for Wales have indicated that they will amend their legislation to ensure the alignment of their description with that which will apply in England and Scotland. The amendments made by regulations 2 and 3 of these Regulations apply to England, Wales and Scotland, but are subject to the definition of "Healthy Start vitamins" applying in relation to the respective schemes in those areas, in regulation 2(1) of the 2005 Regulations.

5.5 The NHS Business Services Authority carries out administrative functions in relation to the Healthy Start Scheme (both food and vitamins) and the Nursery Milk Scheme, in England, Scotland and Wales.

6. European Convention on Human Rights

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

7. Policy background

What is being done and why

7.1 In relation to regulation 2(2) and (3), Healthy Start vitamins form part of the Healthy Start Scheme ("the Scheme"). The Scheme, set out in the 2005 Regulations, aims to improve maternal diets and promote healthier eating in the early years. The Scheme provides benefits to pregnant women, new mothers and children under the age of four who are on low incomes and in receipt of certain income-related benefits. Benefits include a food voucher worth £3.10 per week which can be used in participating food retailers towards the cost of a defined range of healthy foods. Pregnant women, new mothers and children aged one to four receive one food voucher per week, and children under the age of one receive two vouchers. Currently, Healthy Start beneficiaries also receive a separate voucher for every eight weeks of entitlement which they can exchange at a local distribution outlet for a free supply of Healthy Start vitamins.

7.2 DH procures the vitamin products which are used in the Scheme and the current products have remained unchanged for many years. The contracts under which the current products are manufactured will come to an end in September 2018 and DH needs to undertake a procurement exercise to procure the manufacture of vitamin products.

7.3 The amendments made by regulations 2(2) and (3) remove the restriction that Healthy Start vitamins be supplied in tablet or drop form only, with the effect that they may be procured in any form in future. The vitamin product for children will need to be reformulated in any event as the current formulation is no longer compliant with Government advice on recommended daily vitamin D intake, and the new product will be procured as a food supplement rather than as a licensed medicine as it is now. Take-up rates of Healthy Start vitamins have been historically very low and DH therefore wishes to establish whether newer forms of vitamin products could be procured (for example, gels or capsules) which would be more attractive to users and could therefore help to increase take-up, as well as at a more cost-effective price. If the changes to regulations set out in this instrument are not made, DH would only be able to procure tablets for women in containers of fifty-six and drops for children in ten millilitre bottles, and none of the potential advantages of procuring different products will be able to be realised.

7.4 The overall policy aims of the Healthy Start Scheme remain unchanged. This draft Statutory Instrument does not change entitlement under the Scheme. The description of "entitlement" is recast in these amending regulations (regulation 2(2)) to refer to "for every four weeks of entitlement" as opposed to "for every eight weeks of entitlement" stated in the current regulations. This will allow the Department the flexibility to procure products in different volumes. It has no practical effect on beneficiaries, who will remain entitled to receive free supplies of vitamins for so long as they remain on the Healthy Start Scheme. However, there is the possibility that offering Healthy Start vitamins in different product forms could help to increase what have been historically low take-up rates.

7.5 In relation to regulation 2(4), the frameworks and contracts for the delivery of vitamins element of the broader Scheme will be closely tied into the arrangements that DH will procure to replace the current NHS Supply Chain arrangements, when these expire at the end of September 2018. As the NHS Business Services Authority will conclude the frameworks for the broader NHS Supply Chain arrangements, they will also need to be able to manage all the arrangements for the delivery of Healthy Start vitamins as well to ensure that any performance issues can be effectively handled and resolved. These arrangements will include the frameworks for the manufacture of the vitamins products, a contract for the storage and distribution of the products, and arrangements for the administration of the Scheme, on behalf of the Secretary of State.

7.6 Similarly, the amendments in regulations 2(4) and 3 will explicitly allow the NHS Business Services Authority to carry out the administrative functions described in paragraph 4.5 above on behalf of the Secretary of State.

Consolidation

7.7 None.

8. Consultation outcome

8.1 DH has not undertaken a formal consultation on the policy intention which will be delivered by the instrument, although informal discussions have been held with healthcare professionals and service commissioners, and with vitamin manufacturers as part of the pre-procurement supplier engagement work. In addition, DH receives correspondence from time to time about the Scheme from people in receipt of Scheme benefits and from others with an interest in the Scheme.

8.2 While no specific issues have been raised regarding the Healthy Start vitamin tablets for women that might indicate that the current product is a barrier to increasing take-up and use, both correspondence and informal discussion have highlighted issues with the current children's product, particularly difficulties in extracting a precise daily dose of five drops from the current bottle. DH has received a number of reports of users deciding to discontinue use of the products on these grounds. This is one of the key reasons why DH wishes to establish whether it is possible to procure different products.

9. Guidance

9.1 No guidance or other communications have been prepared to accompany this instrument. However, DH intends to undertake a programme of communication in the six months before the newly procured products are first released for public use, to ensure that service commissioners, healthcare professionals, and Healthy Start beneficiaries are aware of the newly procured products and any new instructions for their use.

10. Impact

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

10.2 The impact on the public sector is minimal.

10.3 An Impact Assessment has not been prepared for this instrument. This instrument imposes no new duties, burdens or obligations on any private, public, or voluntary sector organisations. Any impact arising from this instrument will be minimal and will

only be felt by those local authorities and NHS organisations involved in the local distribution of Healthy Start vitamins to Healthy Start beneficiaries.

10.4 Any impact on those organisations will depend on the types of vitamin products procured, and how they may need to alter their storage and distribution arrangements as a result. As the products have not yet been procured it is not possible to establish whether there will be an impact on storage and distribution, or what that impact might be.

11. Regulating small business

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

12. Monitoring & review

12.1 No specific plans have been made to monitor or review the changes put in place by this instrument. However, monitoring and evaluation will be built into the procurement and subsequent contract management processes which this instrument underpins.

13. Contact

13.1 Judith Hind at the Department of Health Telephone: 0207 2102734 or email: Judith.hind@dh.gsi.gov.uk can answer any queries regarding the instrument.