EXPLANATORY MEMORANDUM TO

THE HEALTHY START VITAMINS CHARGING (ENGLAND) REGULATIONS 2014

2014 No. 3099

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 enables the sale of Healthy Start vitamins by NHS organisations in England for pregnant women, breastfeeding mothers and young children who have no entitlement to a benefit in the form of Healthy Start vitamins under the 2005 regulations

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 These Regulations are being made under sections 187 and 272(7) and (8) of the National Health Service Act 2006.

4.2 Healthy Start vitamins are available free of charge as a benefit to certain categories of people who qualify under the Healthy Start Scheme and Welfare Food Amendment Regulations 2005 (the 2005 Regulations). This entitlement is primarily based on receipt of income support, income based jobseekers allowance or child tax credit.

4.3 In addition to free entitlement, for those who did not qualify under the 2005 Regulations, Healthy Start vitamins were available for sale in England and Wales by Health Authorities under the Sale of Goods to Mothers and Children (Designation and Charging) Regulations 1976 (S.I. 1976/516) (the 1976 Regulations) which are regulations treated as if they were made under s. 187 of the National Health Service Act 2006 (the 2006 Act). However, the Health and Social Care Act 2012 (the 2012 Act), which amended the 2006 Act, abolished and replaced certain health bodies in England which had the effect of making the 1976 Regulations ineffective because those regulations no longer referred to the bodies created by the 2012 Act. The need to amend the definition of Health Authorities and Primary Care Trusts was overlooked in relation to the 1976 regulations when the 2012 Act was being drafted.

4.4 Without the 1976 Regulations applying the general prohibition on charging for NHS services contained in s. 1(4) of the 2006 Act applies to the sale of Healthy Start Vitamins.

4.5 The result is that current NHS organisations wishing to sell the Healthy Start vitamins to pregnant women and young families not entitled to receive them for free have been unable to do so.

4.6 The legislative position in Wales is different to that in England which means that the 1976 Regulations can still be applied in Wales. In Scotland and Northern Ireland different legislation applies, permitting the sale of the vitamins in those countries.

5. Territorial Extent and Application

5.1 This instrument applies to England.

5.2 The Sale of Goods to Mothers and Children (Designation and Charging) Regulations 1976 still apply in Wales. Scotland has their own regulations that permit their sale and the Healthy Start Scheme in Northern Ireland also has its own regulations.

6. European Convention on Human Rights

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 The Healthy Start Scheme provides a nutritional safety net to women and children in low income and disadvantaged families across the UK. The scheme provides around 500,000 households with vouchers they can use to buy milk, plain fresh and frozen fruit and vegetables and infant formula. Healthy Start vitamins are also made available via the NHS free of charge to these families. The Healthy Start vitamins provide pregnant women, breastfeeding mothers and children under the age of 4 with the daily dose recommended by the Government, (folic acid and vitamins D and C for women and vitamins A, C and D for children.)

In February 2012 the Chief Medical Officers wrote to health professionals to restate the advice about recommending vitamin D supplements to those groups of the population at risk of a vitamin D deficiency. The UK Health Departments recommended that all pregnant and breastfeeding women, infants and young children aged 6 months to 5 years should take a daily supplement of vitamin D.

In the year to September 2012, NHS Supply Chain distributed 377,000 bottles of women's tablets and around 397,000 bottles of children's drops. Over the same period NHS organisations claimed reimbursement for 50,000 and 90,000 bottles respectively. Although DH only collects data on the number of reimbursements claimed it is reasonable to assume that a proportion of the 634,000 distributed but not reimbursed by DH were sold.

Some health systems choose to make Healthy Start vitamins available more widely through universal schemes. Prior to April 2013 many health systems also chose to

sell the Healthy Start vitamins in health centres and children's centres. In the financial year 2013/14 NHS Supply Chain distributed 398,000 bottles of women's tablets and 531,371 bottles of children's drops and NHS organisations claimed reimbursement for 33,500 and 59,500 respectively.

Interest in vitamin supplementation is growing, often with reference to Healthy Start vitamins. The National Institute for Health and Care Excellence will publish imminently the Public Health Guidance *Vitamin D: Implementation of existing guidance to prevent deficiency*. Their consultation on the draft report indicates there will be a number of recommendations relating to Healthy Start vitamins including making them available for sale

Feedback from Health Professionals through informal contact and a recent survey indicates they are strongly in favour of being able to sell the vitamins through their NHS organisations.

At the same time as laying this Statutory Instrument the Department of Health is making arrangements for community pharmacists to sell Healthy Start vitamins should they choose to do so (regulations are not required for this).

These actions will contribute to reducing health inequalities with respect to the benefits that people can obtain from the health service. People who fall just outside the eligibility criteria for free vitamins will now also have access to the same vitamins, albeit they will have to pay if they want them.

8. Consultation outcome

8.1 There is no legal requirement contained within the primary powers to consult. Informal discussions with, and a subsequent survey of, Healthy Start stakeholders indicated a strong preference to be able to sell the vitamins within NHS facilities including children's centres.

8.2 Stakeholders were also asked what maximum percentage mark-up on the purchasing cost would be reasonable and a majority (over 69% of respondents) indicated a preference for a mark-up of up to an additional 50% on top of the cost price of the vitamins. Stakeholders also asked if the price could be 'rounded up to facilitate ease for those selling' and the SI reflects this by rounding up to the nearest 5 pence

8.3 The Devolved Administrations have been informed.

9. Guidance

9.1 Sale of the vitamins to non-Healthy Start beneficiaries by NHS organisations is optional. Communications will be sent to the commissioners who have a statutory responsibility to make Healthy Start vitamins available and the leads who manage the schemes locally. In addition the Healthy Start web site will be updated to include information that the vitamins can be sold again in England. The Statutory Instrument is explicit in the charge that can be made.

10. Impact

10.1 There is no impact on business, charities or voluntary bodies. This instrument only applies to NHS organisations

10.2 The impact on the public sector is negligible. Health professionals working with pregnant women and young children already give advice and information on healthy diet. This change will make it easier for them to do this as they no longer have to determine whether the client is a Healthy Start beneficiary.

10.3 This is a mechanical change to re-instate the policy position from before April 2013, therefore an Impact Assessment is not required for this instrument.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The impact of this change will be reviewed through monthly monitoring of sales by NHS Supply Chain.

13. Contact

Tricia Morris at the Department of Health Tel: 020 7210 5373 or email: tricia.morris@dh.gsi.gov.uk can answer any queries regarding the instrument.