EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (AMENDMENTS TO PRIMARY CARE TERMS OF SERVICE RELATING TO THE ELECTRONIC PRESCRIPTION SERVICE) REGULATIONS 2015

2015 No. 915

AND

THE HUMAN MEDICINES (AMENDMENT) (No. 2) REGULATIONS 2015

2015 No. 903

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 These instruments make amendments to the Human Medicines Regulations 2012 (S.I. 2012/1916, as amended) ("the HM Regulations"), the National Health Service (General Medical Services Contracts) Regulations 2004 (S.I. 2004/291, as amended) ("the GMS Regulations"), the National Health Service (Personal Medical Services Agreements) Regulations 2004 (S.I. 2004/627, as amended) ("the PMS Regulations") and the National Health Service (Pharmaceutical and Local Pharmaceutical Services Regulations 2013 (S.I. 2013/349, as amended) ("the PLPS Regulations").

2.2 The amendments enable the electronic prescribing of drugs listed in Schedules 2 or 3 of the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) ("MD Regulations"), provided that the prescriptions are sent via the Electronic Prescription Service (EPS). The amendments to the GMS and PMS Regulations also make it clear that, in the limited circumstances in which a general practitioner, in the course of providing treatment under a general medical services contract or a personal medical services agreement, is able to prescribe products under a private arrangement, the GP may use the EPS (whether or not the prescription is for a controlled drug (CD)).

2.3 Additionally, a further amendment is made to the HM Regulations to correct an error made in transposition of section 85 of the Medicines Act 1968 into regulation 269 of the HM Regulations 2012.

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

3.1 None

4. Legislative Context

4.1 The arrangements for the provision of NHS primary care services in England are governed by Parts 4 to 7 of the National Health Service Act 2006 ("the 2006 Act"). Primary medical services (which, for the most part, are the NHS services provided by GP practices) are provided under contractual arrangements between the providers and the National Health Service Commissioning Board, which is known as NHS England. Part 4 of the 2006 Act, and the GMS and PMS Regulations, provide the framework for the two types of GP contracts that have detailed legislative requirements: general medical services contracts, and personal medical services agreements.

4.2 NHS community pharmaceutical services in England are provided on the basis of one of two sets of standard arrangements under Part 7 of the 2006 Act: arrangements for the provision of "pharmaceutical services"; and arrangements for the provision of "local pharmaceutical services" (LPS). LPS are provided under contracts with NHS England, but the great majority of NHS community pharmaceutical services are instead provided by providers on one of three types of approved lists held by NHS England. Firstly, and in the great majority of cases, these services may be provided by "pharmacy contractors" such as retail pharmacy outlets. Secondly, a more limited range of pharmaceutical services may be provided by "appliance contractors", who are not entitled to dispense drugs. Thirdly, dispensing services, but not other pharmaceutical services, may be provided by "dispensing doctors" to patients in designated rural areas, under certain conditions.

4.3 The HM Regulations were a consolidation of the law of the United Kingdom concerning medicinal products for human use. Amongst other matters, they contain requirements in respect of the manufacture, labelling, packaging, distribution, sale and supply of medicines for human use, and they also include requirements in respect of the classification of such medicines as prescription only medicines, pharmacy medicines and medicines subject to general sale.

4.4 Part 12 of the HM Regulations contains restrictions on the sale or supply of medicines, and includes, subject to a number of exemptions, a general restriction on the sale or supply of a prescription only medicine except in accordance with a prescription of an appropriate practitioner. The HM Regulations also include detail as to what is meant by sale or supply being "in accordance with a prescription", and this includes conditions relating to the use of electronic prescriptions. Part 13 of the HM Regulations contains the labelling and packaging requirements.

4.5 The Misuse of Drugs Act 1971 and the MD Regulations establish a number of controls relating to the supply of drugs listed in Schedules 1 to 5 of the MD Regulations. The listed drugs, known as CDs, are a group of medicines that have the potential to be abused, but are

essential to modern clinical care. Schedule 1 CDs have no proven therapeutic value and have potential for misuse, and are therefore heavily regulated, whereas Schedule 5 CDs present little or no risk and are lightly regulated.

4.6 In parallel to the changes being made in this instrument, the Home Office is currently in the process of making changes to the Misuse of Drugs Regulations, which amongst other matters will allow for the electronic transmission of prescriptions for Schedules 2 and 3 CDs via the EPS. These Home Office changes will only apply in relation to Great Britain, but there is a parallel legislative scheme for Northern Ireland.

5. Territorial Extent and Application

The instrument amending the GMS, PMS and PLPS Regulations applies in relation to England only. The instrument amending the HM Regulations applies to the United Kingdom, including correcting the transposition error. The practical effect of the changes in respect to the electronic prescribing of Schedules 2 and 3 CDs is limited to England; the EPS is an England only system.

6. European Convention on Human Rights

As the instruments are subject to the negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 The EPS enables prescribers in England such as GPs and practice nurses to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient's choice. This makes the prescribing and dispensing process more efficient and convenient for patients. Whilst the MD Regulations already allow for the electronic prescribing of Schedules 4 and 5 CDs via a system using an advanced electronic signature, these provisions are not used by the NHS in Scotland or Wales (nor under the different legislative regime in Northern Ireland). It has been agreed that electronic prescribing of Schedules 2 and 3 CDs should for the time being be restricted to the EPS, which necessarily restricts electronic prescribing of these drugs, for the time being, to England.

7.2 Since the introduction of the EPS, a new concern related to patient safety has arisen. This is the risk that a patient may not receive the full range of medicines prescribed to them. Currently, where Schedules 2 or 3 CDs are prescribed alongside other medicines, as the Schedules 2 or 3 CDs prescriptions cannot be sent via the EPS, this can result in prescribers generating "split prescriptions". This is where the

Schedules 2 or 3 CDs are prescribed on paper, while the other medicines are prescribed electronically. There is anecdotal evidence that this has resulted in patients not getting all of their medicines. If neither they, nor the pharmacy, realise there is both a paper and an electronic prescription, the patient may receive the medicines from only one of the prescriptions and not both. Alternatively, prescribers who do not wish to issue "split prescriptions" are not using EPS at all if Schedules 2 and 3 CDs need to be prescribed, and are instead reverting to a fully paper prescription. While this option has less of a patient safety concern, it does mean that prescribers and patients are not able to tap into the efficiency and convenience benefits of the EPS.

7.3 Additionally, whilst existing controls on CD prescribing go a long way towards minimising safety and security concerns, where a patient has a paper prescription for Schedule 2 or 3 CDs in their possession, there is the potential for them to attempt to tamper with the prescription or pass it to somebody else. Enabling the electronic prescribing of Schedules 2 and 3 CDs will further help mitigate some of those concerns as the electronic prescription is transmitted securely, directly between the prescriber and dispenser and therefore never physically enters the patient's hands.

7.4 Amendments have accordingly been made to the GMS, PMS, PLPS and HM Regulations to enable Schedules 2 or 3 CDs to be prescribed and dispensed electronically, provided the EPS is used. They have been timed to coincide with amendments that are currently in the process of being made by the Home Office, to the MD Regulations, in a separate Statutory Instrument, for which there will be a separate Explanatory Memorandum.

7.5 The use of electronic prescribing for Schedules 2 to 5 CDs will be permissive; paper prescriptions may still be used.

7.6 The opportunity has also been taken to amend the PMS and GMS Regulations to clarify that, in the limited circumstances in which GPs are entitled to prescribe privately during NHS consultations, they may issue an electronic prescriptions and they may use EPS.

7.7 Where an electronic prescription contains Schedules 2 or 3 CDs, the EPS is the only electronic system by which the electronic prescription can be transmitted.

7.8 There are some medicines that GPs are not entitled to prescribe under their GP contracts, or may only prescribe under limited circumstances – known generally by the profession as 'black list' and 'grey list' drugs, which are listed in the Schedules to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (S.I. 2004/629, as amended). Grey listed drugs include, for example, some treatments for erectile dysfunction. Again, there is a concern to avoid "split prescriptions", and so the sort of

problems identified in paragraph 7.2 above, because the private prescriptions have to be paper prescriptions. Up until now, the EPS has only been available for NHS prescribing, so this change to GPs' terms of service will need to be supported by software changes before GPs will be able to use the EPS in this more flexible way.

7.9 The opportunity presented by the making of the Human Medicines (Amendment) (No. 2) Regulations 2015 has also allowed the Department to correct an error in the HM Regulations, which occurred during the consolidation exercise that led to the HM Regulations. The Court of Appeal concluded in the case of *R v Lee* [2010] EWCA Crim 1404 that the words "carried on by him" in section 85(5) of the Medicines Act 1968 had particular significance – requiring in effect, in the great majority of cases, prosecution of employers, rather than employees, for the labelling offences covered by that subsection. However, these words were not carried forward into the HM Regulations. Similar wording has now been inserted into regulation 269(1) of the HM Regulations to correct this oversight. This is important to the work of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board[1], especially in relation to its proposal to create a defence to the criminal sanction in sections 63 and 64 of the Medicines Act 1968, in respect of inadvertent dispensing errors made by registered pharmacy professionals. The fear of criminal prosecution has a negative impact on the reporting of dispensing errors, and in turn the learning from errors which would increase patient safety. The error in regulation 269 has the effect of broadening the scope of the labelling offence. This was not a policy decision, and creates a risk, as a pharmacist or pharmacy technician, not just a pharmacy owner, may come within its provisions. Accordingly, the Rebalancing Programme Board supports the action being taken to restore the position that existed prior to the consolidation into the HM Regulations 2012.

Consolidation

7.10 The changes made by these Instruments are small in scale, and the making of them has not changed the Department's position on whether or not any of the Regulations they amend require amendment. A consolidation exercise in relation to the GMS and PMS Regulations is on-going.

8. Consultation outcome

8.1 A joint Home Office and Department of Health public consultation on proposals to allow the EPS to be extended to Schedules 2 and 3 CDs,

[1] The Programme Board's terms of reference can be found at:
https://www.gov.uk/government/groups/pharmacy-regulation-programme-board
A paper copy of this information can be obtained by emailing mpig.support@dh.gsi.gov.uk

both in NHS and private settings, was undertaken between July and October 2014. It was published at https://www.gov.uk/government/consultations/extending-the-scope-of-the-electronic-prescription-service[2] and the response to the consultation was published on 24th March 2015 at www.gov.uk/dh[3]. The majority of respondents favoured the extension, both for NHS and private prescriptions. Advice was sought from the Advisory Council on the Misuse of Drugs (ACMD) following a positive response to the consultation. This advice was received on 10th March 2015.

8.2 ***Amendments to the HM Regulations***

The amendments to the HM Regulations, apart from the correction of the error mentioned in paragraph 7.9, are direct results of the outcome of the public consultation and the consultation with the ACMD.

8.3 ***Amendments to the GMS and PMS Regulations***

Customarily, the Department seeks the views of the General Practitioners' Committee of the British Medical Association over proposed changes to the GMS Regulations – and NHS Alliance, the National Association of Primary Care and the Family Doctors Association are consulted over changes to the PMS Regulations. There is also collaborative engagement with NHS England. The length of time afforded for comment varies dependent on the nature of the amendment, its potential impact and the amount of involvement stakeholders have had throughout the process. The British Medical Association and Family Doctors Association have been pursuing the enabling of these proposals for some time, and the majority of stakeholders had responded positively to the public consultation. Therefore, the Department invited early comment from these organisations in March 2015. We had prompt responses from the General Practitioners' Committee of the British Medical Association in respect of the GMS Regulations, and from the Family Doctors Association for the PMS Regulations, who confirmed that they were happy with the proposals. No comments were received from the National Association of Primary Care or NHS Alliance.

8.4 ***Amendments to the PLPS Regulations***

Customarily, the Department seeks the views of the Pharmaceutical Services Negotiating Committee, the British Medical Association and the Dispensing Doctors' Association on changes to the PLPS Regulations. There is also collaborative engagement with NHS England. The length of time afforded for comment varies dependent on the nature of the amendment, its potential impact and the amount of involvement stakeholders have had throughout the process. The British Medical Association has pursued the enabling of electronic prescribing for these drugs for some time. Further, the Department's original

[2] A paper copy of this information can be obtained by emailing mpig.support@dh.gsi.gov.uk
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intention was to include provisions for dispensing of electronically prescribed Schedules 2 and 3 CDs in the package of changes to contractors terms of service that was included in the National Health Service (Pharmaceutical Services and Local Pharmaceutical Services) (Amendment and Transitional Provision) Regulations 2015 (S.I. 2015/58), and so we formally invited the views of these organisations in December 2014. All were content with the proposed amendment Regulations. With a view to completeness, we consulted them again in March 2015 and all agreed.

9. Guidance

9.1 NHS contractors will be advised of changes to their terms of service by NHS England via its normal communication channels. NHS England will also be communicating with its regional teams about the effect of the changes.

10. Impact

10.1 The EPS amendments in these instruments are enabling and facilitative in that they will remove current legislative restrictions which prevent the use of electronic prescriptions for the purposes of prescribing Schedules 2 and 3 CDs – and will facilitate private prescribing by NHS GPs, where this is permitted under their contracts. As the regulatory changes are enabling and facilitative, they do not create or impose direct costs on business. Paradoxically, this is an example of regulatory change enabling greater flexibility and delivering improvements to patients and business. We therefore do not consider a business impact assessment needs to be produced.

10.2 The generally beneficial nature of these instruments means that no adverse impacts are foreseen in the context of the discharge of the Secretary of State's Public Sector Equality Duty or his general duties under the 2006 Act. In particular, these changes will support the continuous improvement in the quality of NHS services, as mentioned in section 1A of the 2006 Act.

10.3 The NHS regulations governing the provision of primary medical care and community pharmaceutical services set out the overarching framework and contractual requirements for delivery of these services. As such, they are outside the scope of the Government's Better Regulation initiative and the One in Two Out (OITO) rule (i.e. for every regulation introduced, two are removed).

10.4 Whilst the HM Regulations are considered in scope for OITO, the CD related amendments proposed here involve a minor alteration, which essentially facilitates greater use of electronic prescribing for CDs. These changes simply extend the medicines that can be prescribed electronically, albeit only if use can be made of the EPS, and have no impact on the main provisions of the HM Regulations. They are

therefore not considered to trigger OITO. The correction of the error in relation to the labelling offences essentially limits the number of people who may be prosecuted, and is therefore also not considered to trigger OITO.

11. Regulating small business

11.1 The legislation applies to small businesses, including firms employing up to 20 people. However, as the GMS, PMS and PLPS Regulations concern the provision of NHS services in England on the basis of nationally determined terms of service, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed nation-wide standards and practices in the provision of such services as part of the nationally determined contractual frameworks.

11.2 GP practices are exempt from the Small Firm Impact Test as they are considered part of the public sector due to their provision of primary medical services for the NHS. Public sector organisations are exempt from this test.

11.3 The changes to the HM Regulations are also of a nature where it would not be practicable to differentiate between businesses according to their operational turnover or size.

12. Monitoring & review

12.1 The Department monitors the implementation and efficient operation of the Regulations amended by these instruments, and in the case of the changes to the PMS, GMS and PLPS Regulations, has regular discussions with interested parties including the NHS and contractors' representatives mentioned in paragraph 8.3 and 8.4 above on any problems identified.

12.2 As part of ongoing monitoring arrangements we will be alerting NHS England Controlled Drugs Accountable Officers to ensure their local networks are aware of the new arrangements and consider any local governance issues.

13. Contact

Helen Batty at the Department of Health Tel: 01132 252249 or e-mail: helen.batty@dh.gsi.gov.uk can answer any queries regarding the instrument.