EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PRIMARY DENTAL SERVICES) (MISCELLANEOUS AMENDMENTS) (No. 2) REGULATIONS 2015

2015 No. 1728

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 Regulations amend:

a) The National Health Service (General Dental Services Contracts) Regulations 2005 (the GDS Regulations), which set out the framework for General Dental Services Contracts;

b) The National Health Service (Personal Dental Services Agreements) Regulations 2005 (the PDS Regulations), which set out the framework for Personal Dental Services Agreements;

c) The National Health Service (Dental Charges) Regulations 2005 (the Charges Regulations), which set out the charges that may be levied for NHS dental services; and

d) The Functions of the National Health Service Commissioning Board and the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Primary Dental Services) (England) Regulations 2013 (the BSA Functions Regulations), which direct the NHS Business Services Authority ("NHSBSA") to carry out functions relating to primary dental services.

2.2 The purpose of this instrument is to –

a) Implement the Prototype Agreements Scheme which is a new pilot Scheme being introduced by the Secretary of State to trial a possible new dental contractual system building on the learning gathered from the Capitation and Quality Scheme 2 ("Scheme 2"). This is being done by temporarily varying the standard mandatory terms of service of participating contractors to trial new ways of providing care and remunerating dentists;

b) provide that a Band 1A charge introduced for specified additional interim treatment provided under the Scheme 2 may be levied for similar courses of treatment and in similar circumstances as applied under the Scheme 2

where patients are provided with such courses of treatment under the Prototype Agreements Scheme; and

c) direct the NHSBSA to carry out functions related to the new NHS Pension Scheme 2015 on behalf of the National Health Service Commissioning Board (known as NHS England).

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

3.1 None

4. Legislative Context

4.1 Primary dental services are provided under Part 5 of the National Health Service Act 2006 ("the 2006 Act"). Under this Part, NHS England must, to the extent that it considers necessary to meet all reasonable requirements, secure the provision of primary dental services throughout England by entering into general dental services contracts (GDS contracts) or personal dental services agreements (PDS agreements) with dental contractors.

4.2 This instrument amends the GDS and PDS Regulations. These Regulations govern the way in which NHS dental services are delivered, and contain the mandatory contractual terms and conditions that must be contained in primary dental services contracts made between NHS England and primary dental contractors. Parts 2 and 3 of this instrument implement the Prototype Agreements Scheme, by making provision to provide for a temporary variation of the scheme under which NHS dental services are provided by some existing providers of NHS dental services under Part 5 of the 2006 Act, similar to the provision made in relation to the Scheme 2. This is to enable the Secretary of State to introduce the Prototype Agreements Scheme from 1st November 2015, to continue testing new ways of delivering care to patients and to remunerate providers of NHS dental services. The Regulations provide that the Prototype Agreements Scheme will terminate on 31st March 2018.

4.3 Under current provision, contractors providing NHS primary dental services through GDS contracts, or PDS agreements, are required to deliver an agreed annual level of dental service measured through units of dental activity ("UDAs"), for a specified payment in a financial year. Courses of treatment provided under GDS contracts or PDS agreements attract specified numbers of UDAs in respect of the three banded courses of treatment, which are weighted in relation to the complexity of the courses of treatments delivered. Each banded course of treatment attracts a different patient charge (as set out in the Charges Regulations), and a different UDA value payable to the contractor. So a contractor that provides a Band 2 course of treatment will be entitled to receive 3 UDAs, and for each Band 3 course of treatment, will be entitled to receive 12 UDAs. The financial value of UDAs are set by NHS England

locally. The implementing Regulations introduce a new Schedule 2A into the GDS and PDS Regulations to reflect the new UDA values attributable to courses of treatment provided under a prototype agreement.

4.4 In 2011 and 2013 the GDS and PDS Regulations were amended to implement the Capitation and Quality Scheme and the Scheme 2, to pilot a new preventative approach to delivering care ("the preventative pathway") and measuring quality through a dental quality and outcomes framework ("the DQOF"). The implementing legislation temporarily varied the contractual obligation on participating contractors to provide specified numbers of UDAs. Remuneration was instead based on the contractors' existing contract or agreement value, with a limited amount of remuneration dependent on performance in respect of quality, and in some of the practices an element of capitation (to provide for continuing care for patients). This remuneration system was not intended to be part of any new remuneration system, but was implemented to provide the learning needed to design such a new system. The previous Schemes were time-limited. The Capitation and Quality Scheme ended on 31 March 2013. The Scheme 2 was originally due to end on 31 March 2015 but was extended to 31 March 2016 to allow pilots selected for the new Prototype Agreements Scheme who were moving to prototype agreements to do so directly without them needing to return to the UDA arrangements.

4.5 The implementing regulations for the Prototype Agreements Scheme set out the framework for a proposed new national contractual system. In addition to continuing the preventative approach to care and the measurement of and eventual payment for quality through a DQOF, the Regulations introduce a new blended system of remuneration based on capitation and activity. This blended remuneration system is intended to form the basis of any new contractual system later introduced. Two types of remuneration arrangements are being tested. Blend A and Blend B prototype agreements. The aim is that around 50% of the practices taking part in the Scheme will be assigned to a Blend A prototype agreement and will have 55% of their contract value based on capitation, and the other 50% of practices will be assigned to a Blend B prototype agreement and will have 83% of their contract value based on capitation. The remaining remuneration will be made up of payments for UDAs and quality. The proposed testing of two types of remuneration systems will help the Department to determine the appropriate split for possible implementation in a finally adopted system between capitation and activity payments.

4.6 Part 4 of this Instrument amends the Charges Regulations to provide that a Band 1A charge may be made where patients are receiving additional interim care as part of a treatment plan under the Prototype Agreements Scheme. This charge was introduced under the Scheme 2 in April 2013.

Section 176 (dental charging) of the 2006 Act provides that regulations may be made for the making and recovery of charges for NHS dental services, subject to the exemption provision made by section 177 (exemptions from dental charging), which sets out the persons who may not be charged for NHS dental treatment. The charge is predicated on the basis that additional preventative treatment provided as part of a wider course of treatment is to be regarded as a new course of treatment for which the Band 1A charge may be levied. This is similar to what currently takes place under the Scheme 2. Components of the Band 1A course of treatment are set out in Schedule 1A of the Charges Regulations. Again like the current arrangements for such courses of treatment provided under the Scheme 2, the charge may only be levied where specified components of treatments, as set out in Schedule 1A of the Charges Regulations, are provided.

4.7 The BSA Functions Regulations direct the NHS BSA to carry out functions relating to the administration of the NHS Pension Schemes 1995 and 2008. Part 5 of this instrument amends the BSA Functions Regulations to direct the NHS BSA to carry out similar functions of collecting and paying members contributions to the scheme manager and to receive specified notices, in relation to the NHS Pension Scheme 2015.

5. Territorial Extent and Application

5.1 This instrument applies to England only.

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

<u>Issues in relation to the existing primary dental services contractual system</u>

7.1 Access to NHS dental services continues to increase and oral health is steadily improving in England. Yet there is still more to do in respect of making further improvements to access to NHS dental services and to ensure that even greater numbers of the population can enjoy good oral health. The current dental contractual system is based only on remuneration for activity (UDAs). There is no remuneration for quality or for providing patients with overall ongoing care (capitation). Activity systems incentivise dentists to focus on treatment and repair rather than preventing future disease. Such systems are appropriate where there are high disease levels. But the transformation in oral health particularly in younger people, resulting from better understanding of oral hygiene in addition to widespread use of fluoride through toothpaste, means this approach has become increasingly insufficient.

7.2 NHS dental contractors have expressed a view that the financial drivers in the existing contractual system introduced in 2006 potentially discourage a focus on prevention. A key concern expressed in respect of the current system was the lack of any piloting prior to its introduction.

7.3 Any proposed new approach will have to meet the needs of, in oral health terms, an increasingly segmented population. While younger people have in many cases little or no dental decay, older people, while often having little new or active disease, tend to have a legacy of heavily filled teeth that will need increasingly intensive levels of repair. There are also high rates of decay in children in deprived socio-economic groups. Patients therefore have increasingly segmented treatment needs, but all need access to high quality preventative care, and access to advice on how to maintain good oral health. In order to ensure dentists are able and motivated to meet dental needs appropriately, the remuneration system for the provision of primary dental services has to align financial incentives both with the need for treatment and with prevention.

Government's proposals for reform

7.4 In response to the immediate and pressing concerns about the current system of NHS dental contractors, and in the light of the longer term changes in oral health needs referred to above, the then Government committed in 2010 to reforming the current dental contractual framework, with thorough pre-piloting. The goal of reform as stated at the time, and which remains the case, was to increase access to NHS dentistry and implement improvements in oral health.

7.5 The broad elements of the proposed new approach were set out in 2010, which were:

- A clinical approach focussed on prevention as well as treatment
- Measurement of quality through a Dental Quality and Outcomes Framework (DQOF)
- Remuneration based on quality and capitation rather than activity only

Initial piloting (Capitation and Quality Scheme and Scheme 2)

7.6 Reflecting the widespread concerns about the lack of piloting in 2006, the Government committed to thoroughly piloting any proposed changes to the arrangements for the provision of NHS dental services, before making any national changes. In 2011, 70 dental practices elected to participate in the Capitation and Quality Scheme and began piloting the new clinical approach which focussed on prevention (through the preventative pathway) and a pilot DQOF. The remuneration approach adopted for the Capitation and Quality Scheme and the Scheme 2 suspended the obligation to provide UDAs.

7.7 The remuneration models used in these Schemes were explicitly not intended to be possible new national remuneration approaches, but were instead designed to deliver the key learning needed to design a new national

remuneration system. Pilots were remunerated in one of three ways. Around two thirds of the original group participating in the Capitation and Quality Scheme were assigned to a Type 1 group who were not paid in respect of activity or capitation. For this Type 1 group, their existing contract value was guaranteed and was not dependant on how much treatment they delivered or how many patients they saw. The remaining third of the original group, the Type 2 and 3 groups, had up to 2% of their contract value linked to the number of patients they saw.

7.8 The Capitation and Quality Scheme was first evaluated in 2012. The evaluation report from the contract reform evaluation and learning group chaired by Professor Jimmy Steele found that the approach to care was popular with dentists and patients, although it was too early to determine at that stage any clinical impact. A link to this evaluation can be found here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212999/NHS-dental-contract-pilots-early-findings.pdf.[1] The Capitation and Quality Scheme was succeeded by the Scheme 2 in 2013. This Scheme added a further 20 practices to the existing group of 70 participants in the Capitation and Quality Scheme. Two thirds of the initial group of participants in that Scheme were assigned to Type 1 pilots. To ensure that there were more equal numbers in each Type group, for the purposes of evaluation and learning, all new entrants to the Scheme 2 were required to become Type 2 or Type 3 pilots. In addition two practices providing community dental services joined the Scheme. Providers of community dental services typically provide primary dental services to patients with additional needs and/or who have difficulty in accessing high street services. This enabled the preventative pathway (the content of which is described in paras 7.13 to 7.15) to be tested in these services.

Learning from the Capitation and Quality Scheme and the Scheme 2 pilots

7.9 The second evaluation and learning report was published in 2013. This confirmed that the clinical approach was widely supported by dentists and found the first evidence that the new systematic approach focussed on prevention was delivering improvements in oral health. But evaluation of the pilot data also showed that treatment volumes had fallen, in some cases further than expected, and that numbers of patients seen had dropped significantly. This suggested that any new remuneration system needed to strike a balance between supporting prevention, but also ensuring dentists were incentivised to provide treatment for patients with high needs. A link to the second evaluation can be found here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282760/Dental_contract_pilots_evidence_and_learning_report.pdf.[2]

[1] A hard copy of this document can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS.

Prototyping a new system

7.10 Based on this learning, Ministers announced in spring 2014 their decision to move to a new system using the piloted approach to care and measurement of quality, but with a remuneration system that included activity as well as capitation and quality. These themes were set out in an engagement exercise targeted at dental stakeholders over summer 2014. A link to this engagement exercise can be found here: https://www.gov.uk/government/consultations/improving-dental-contracts[2]. Proposals for the new system to be prototyped were published in January 2015 by the Department together with a call for expressions of interest from practices. A link to these proposals can be found here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/395384/Reform_Document.pdf.[2]

Details of the Prototype Agreements Scheme

7.11 The Prototype Agreements Scheme consists of the following key elements:

- Preventative standardised clinical approach (preventative pathway)
- Measurement and payment for quality (DQOF)
- Remuneration through capitation, activity and quality

7.12 Around 100 practices are expected to start prototyping during the remainder of 2015/16. These practices have been selected both from the existing pilots and from new practices which will join the Prototype Agreements Scheme from GDS contracts and PDS agreements which use the UDA system. The practices have been selected from across England to provide a reasonable mix of geography, size type of practice and patient mix.. If the Scheme is successful then the numbers will be increased from 2017/18.

Quality - Preventative Pathway

7.13 Patients receiving treatment under a prototype agreement will receive a comprehensive Oral Health Assessment (OHA) when they first visit a participating practice, where the dentist will assess their oral health using a standardised approach. The outcome of that assessment helps the dentist to determine when the patient should be asked to return for a further assessment known as the Oral Health Review and what preventative advice and care a patient needs in addition to treatment of any active disease.

7.14 If the patient needs additional preventative advice or care between assessments (and any treatment associated with that assessment) they may be asked to return after 3, 6 or 9 months for this extra preventative care. Such a course of treatment, known as an Interim Care course of treatment, was

[2] A hard copy of these documents can be obtained by writing to Dental and Eye Care Services, Policy and Legislation Unit, NHS Group, Room 201 Richmond House, 79 Whitehall, London, SW1A 2NS

introduced under the Scheme 2 and has to date only been used in that Scheme. This approach will now be used under the Prototype Agreements Scheme.

7.15 The pathway approach which supports dentists to focus on preventing future disease and to encourage patients' self-care, was tested in the Capitation and Quality Scheme and Scheme 2 pilots. The learning from those pilots was that, used appropriately, it benefited patient care. It does not replace or supersede a dentist's clinical judgement but acts as decision support. The Prototype Agreements Scheme intends to test the impact of the newly developed remuneration model on this now fairly established approach, in addition to providing a further period in which to refine the pathway approach, to ensure that when it is rolled out, the approach is as efficient as possible.

Quality -DQOF

7.16 The prototype agreements will be measured, and in part remunerated on performance, against a range of clinical, safety and patient experience measures set out in the DQOF. Up to 10% of contract value will be attributed to performance against the DQOF. The DQOF was introduced in the Capitation and Quality Scheme and continued to be used in the Scheme 2. It is being continued, and the metrics are being refined, in the Prototype Agreements Scheme. Though the Capitation and Quality Scheme, and Scheme 2 pilots also had 10% of contract value attributed to the DQOF, the data quality during these Schemes was not robust enough to use as a basis for payment. The Government has stated, based on the learning from the pilots, that measurement and payment for quality will be part of any proposed new system. The aim of the Prototype Agreements Scheme is to refine the DQOF and to improve data collection to allow payments made under it to be tested prior to any national roll out of this Scheme.

Remuneration – Capitation and Activity

7.17 The blend of capitation and activity being implemented in these Regulations has not been piloted prior to the Prototype Agreements Scheme. The approach reflects the learning derived from the pilots which demonstrated that there is a need to support both prevention and treatment. Payment systems based on capitation are particularly challenging for more complex dental treatment, as the cost of individual treatments is high, and the need for such treatments relatively unpredictable. Capitation payments, even weighted for such factors as age, gender and socio-economic factors, can produce unfair results in these cases.

7.18 The aim of testing two blends of agreements (the Blend A and Blend B prototype agreements) is to determine where the boundary between capitation and activity payments is most effectively placed. Capitation will make up a majority of the remuneration in both blends. It will form either approximately 55% or 83% of total prototype agreements remuneration depending on the blend of agreement. For Blend A agreements, the capitation element will cover

diagnosis and prevention, and activity payments will be made for all routine and complex treatments. For Blend B agreements, capitation will cover diagnosis, prevention and routine treatment, e.g. fillings. The activity elements will cover complex care only, e.g. crowns.

7.19 Weighted capitation was piloted under the Capitation and Quality Scheme and the Scheme 2. The intention is to use weighted capitation in any nationally rolled out system. However, the Prototype Agreements Scheme will not use weighted capitation. This is to ensure the remuneration system for this Scheme is kept as simple as possible at this stage for participants. The intention is to use weighted capitation in any future national system and this will be developed drawing on the learning from Capitation and Quality Scheme and Scheme 2.

7.20 The activity element of the prototype agreements will be remunerated through a modified form of UDAs. The use of UDAs as the activity metric is for the Prototype Agreements Scheme only. The longer term aim is to develop a new activity metric for any proposed rolled out system. This will be informed by the learning from the Prototype Agreements Scheme. For this Scheme the Department is using the existing and well understood activity currency. However the number of UDAs a weighted CoT attracts is modified for the Scheme (see new Schedule 2A inserted into the GDS and PDS Regulations by this Instrument).

7.21 For Blend A prototype agreements, a course of treatment that triggers a traditional Band 2 course of treatment will earn two UDAs towards the expected activity level, in the activity element of the prototype agreement. Only two UDAs will be earned because one of the UDAs has already been allocated to the capitation element of the prototype agreement. This is the amount of remuneration attributable to the Band 1 aspect (examination, diagnosis and any prevention) of the Band 2 CoT. Similarly, in Blend A prototype agreements, a Band 3 course of treatment will earn 11 UDAs towards the activity element. For Blend B prototype agreements, UDAs are earned for treatment that triggers a Band 3 course of treatment. A practice will earn 9 UDAs for the provision of this course of treatment. The reasoning is similar: 3 of the 12 UDAs have been transferred to the capitation element of the prototype agreement which covers resources provided for examinations, prevention and routine care.

	Band 1	Band 2	Band 3
UDA system	1 UDA	3 UDAs	12 UDAs
Blend A	Capitation	2 UDAs	11 UDAs
Blend B	Capitation	Capitation	9 UDAs

Patient Charges

7.22 NHS patient charges contribute around 23% of the gross dental primary care budget. Dentists collect patient charges on behalf of the NHS. Such charges are passed onto the NHS in their entirety and form no direct part of the individual dentist's remuneration. All NHS charges collected by dentists are fully deductible from payments made to dentists holding GDS contracts and PDS agreements under payment directions made by the Secretary of State, (see paragraph 3.8 (deductions in respect of NHS charges) in the General Dental Services Statement of Financial Entitlements 2013 available on www.gov.uk). Total revenue from patient charges fell during the Capitation and Quality Scheme and the Scheme 2 pilots. This was not unexpected as patient charge systems are designed around the wider system they support. The existing system is designed for the UDA system rather than a system focussing more on prevention.

7.23 In respect of the Prototypes Agreements Scheme, the intention is to continue the modification made to patient charges as was implemented for the Scheme 2. No further changes are envisaged. This means that this Instrument will provide that a charge may be made for specified items of preventative treatment which are provided as part of an Interim Care course of treatment under a prototype agreement. This will be a Band 1A charge, which is set at the same level as an existing Band 1 charge (currently £18.80).

7.24 The Band 1A charge was first introduced in the Scheme 2 in April 2013. This charge will only apply to the additional preventative care delivered under the Prototype Agreements Scheme as interim care, and similarly to what took place under the Scheme 2, patients can choose whether to accept these courses of treatments. To date, there have been no complaints from patients raised with the Department in respect of the Band 1A charge.

7.25 Similarly to the Scheme 2, minimal changes are made to the existing patient charge system under the Prototype Agreements Scheme to avoid confusion or unfairness to patients moving between practices. The Prototype Agreements Scheme is expected to provide learning in relation to whether any nationally rolled out new system will require a new system of patient charges, or just further modifications of the existing system.

Data collection of private patient data

7.26 In addition to the information collected in respect of treatment delivered to patients using the standard reports all contractors are required to make, contractors participating in the Prototype Agreements Scheme will also be required, as a contractual term, to collect data relating to all private treatment provided to capitated patients, for the purposes of the DQOF and the evaluation of the Scheme. This data will be collected electronically. The ability to be able to transmit data electronically is an eligibility requirement for entry to the Scheme.

7.27 Data on private treatment received by NHS patients is required to enable the evaluation required to assess the full cost of an NHS capitation scheme. The Capitation and Quality Scheme and the Scheme 2 made provision for the collection of data related to private treatment delivered as an alternative to NHS care. Data was collected in the Scheme 2 relating to private treatment delivered within a mixed NHS/private course of treatment.

7.28 The legislation is now being extended to oblige contractors to collect data in respect of private treatment provided to capitated patients attending the practice, whether or not it is associated with NHS treatment, and to send this data to the Board. This obligation will only apply in respect of data relating to private treatment provided to capitated patients, that is, patients who have received NHS treatment in the past three years, prior to treatment.

7.29 Participant contractors are required under the Regulations to provide all patients attending their practices with a privacy notice informing them about this obligation. This notice will explain the reasons for requiring this data and what the data will be used for, and will set out any other bodies with whom the data may be shared. In the event that patients object to their data being shared, they can choose to go elsewhere for treatment. Though this will impact on contractors and patients to a degree, we consider that we have a legitimate healthcare need for this data to be collected, and that our approach is proportionate to our legitimate need. In requiring this information we have ensured that we meet both the conditions for the fair processing of data under the Data Protection Act 1998, and that our approach is consistent with guidance produced by the Information Commissioner which emphasises transparency and fairness.

Terms and Conditions

7.30 In addition to the terms and conditions of service for prototypes agreements implemented by this Instrument, additional terms and conditions of service that will apply to prototype agreements are implemented by the National Health Service (Dental Services) (Prototype Agreements) Directions 2015, which are published alongside this Statutory Instrument and Explanatory Memorandum on legislation.gov.uk. Payments for services provided under prototype agreements will be made in accordance with payment directions made by the Secretary of State under the Prototype Agreements Scheme Statement of Financial Entitlement ("SFE"). The SFE sets out the details of how remuneration is based on the combination of delivery of treatment to numbers of patients and delivery of activity.

Changes to the BSA Functions Regulations

7.31 This Instrument also amends the BSA Functions Regulations which direct the NHS Business Services Authority to carry out functions relating to primary dental services. These Regulations are being amended to direct the NHS BSA to carry out functions relating to the new NHS Pension Scheme

2015 which was introduced in April 2015, similarly to those carried out in relation to the NHS Pensions Schemes 1995 and 2008. These directions must be made in regulations due to statutory handling procedures set out in the National Health Service Act 2006.

- Consolidation

7.32 As the majority of dental practices are not involved in the Prototype Agreements Scheme, it is necessary to maintain the GDS and PDS Regulations alongside these new regulations. Consolidation of regulations will be considered as part of any further work to develop a national contractual system.

8. Consultation outcome

8.1 During the development of the Prototypes Agreements Scheme three key groups have been engaged through the Dental Contract Reform National Steering Group, and other close bilateral contacts. These groups are:

- The British Dental Association ("BDA") representing the profession
- NHS England representing commissioners
- Patient groups putting forward the patient voice.

8.2 The National Steering Group is a reference group supporting the development of policy on contract reform. Wider dental stakeholders and the public have also been engaged through the 2014 engagement exercise on the outcome of the Scheme 2 and thinking on the prototype model.

8.3 The BDA, as well as being very closely engaged with the reform work on an ongoing basis, have been consulted on these Regulations and associated Directions including the SFE. The BDA raised a number of points in relation to the proposed new legislation, and Departmental officials met with the BDA to discuss their comments with them. A number of their points have helpfully been taken into account in the finalised legislation. Key comments that were made, and the amendments to reflect those comments were:

- The Scheme has been renamed the Prototype Agreements Scheme rather than the Prototype Contracts Scheme, as the BDA considered that the former name implied that the Scheme was the new contractual system rather than a blue print for such a system. There is no legal significance in the change of name of the Scheme.

- NHS England now "may" consider exiting contractors from the Scheme on various specified performance grounds rather than what applied previously, which was that the Directions referred to NHS England "must" consider withdrawing from a prototype agreement in specified circumstances. This does not constrain NHS England from exiting contractors but addresses the BDA's concern that the use of the word "must" implied a bias towards exit.

- The Regulations now specify that private treatment data must be collected in respect only of patients who are capitated. These are patients who have received NHS treatment in the preceding three years.

- Failing to return specified data within 5 days of the appointment that generated it has been removed as a possible ground for exit from the Scheme. The deadline for such returns remains, but has now been changed to 7 calendar days, but failure to make such returns will not in itself now be a ground for exit. We agreed with the BDA that this was potentially too draconian. We have retained the power to exit participants for more general failures to make returns under the Scheme and in circumstances where there are significantly late returns.

8.4 There has also been close engagement with patient groups. The Department has held briefing meetings with key patient groups, Citizen Advice, Healthwatch and Which?, and this engagement will continue through the reform process. The main interest of patient group's during these engagements has been the impact of the new pathway approach on patients and the Band 1A charge for interim care courses of treatment, but to date, no patient group has actually raised concerns about either of these issues or the wider contract reform agenda.

9. Guidance

9.1 In relation to the amendments made to the GDS Regulations, the PDS Regulations and the Charges Regulations, the Department does not propose to issue guidance on the impact of these Regulations.

9.2 Participants in the Prototype Agreements Scheme will receive the following support and guidance:

- Guidance documents will be produced to explain the Scheme and the payment mechanisms
- Tailored training events for those taking part in the Scheme to familiarise them with the approach to clinical care (the care pathway, the payment mechanisms, new IT software and the evaluation and monitoring requirements of the Scheme).

9.3 A Patient Information Leaflet will be produced to explain how treatment will be provided under the Prototype Agreements Scheme to patients and is published alongside this Statutory Instrument and Explanatory Memorandum on legislation.gov.uk. Contractors participating in the Prototype Agreements Scheme are required as a term of service to display this leaflet in their practices.

10. Impact

10.1 There is no impact on charities or voluntary bodies.

10.2 NHS dental contractors are exempt from the Small and Micro Business Assessment as they are considered part of the public sector due to their provision of primary dental services for the NHS. Public sector organisations are exempt under this test and as a result an Impact Assessment has not been prepared.

10.3 The General Public Sector Equality Duty is not simply limited to eliminating, discrimination, harassment and victimisation but also includes positive obligations to promote equality of opportunity and to foster good relations between those who are likely to suffer discrimination and those who are not. When making legislation, Ministers are obliged to have due regard to all aspects of this duty. We have not identified any specific equalities issues. We have also considered the impact of the Secretary of State's general duties under the NHS Act 2006, for example in relation to promoting autonomy and the duty in regard to improvement in the quality of services. Again, we do not consider there are specific issues in respect of these duties.

11. Regulating small business

11.1 The Regulations apply to small businesses, including firms employing up to 20 people. As these Regulations concern the provision of NHS dental 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 framework.

12. Monitoring and Review

12.1 The Prototype Agreements Scheme will be subject to evaluation at regular intervals with a focus on the key areas being tested, which are: access – numbers of patients accessing NHS dentistry; the quality of care; and value for money. The evaluation of the Prototype Agreements Scheme will seek to inform the safe implementation of any new contractual system for providing NHS primary dental services, incorporating the care pathway. The Scheme will be evaluated to enable the wider system (the care pathway, the payment mechanisms, the financial levers, the approach to access to NHS dentistry, and the measurement of quality) to be understood and adjusted, to provide for the most effective implementation of any nationally rolled out new system.

13. Contact

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