EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (GENERAL DENTAL SERVICES CONTRACTS) REGULATIONS 2005

2005 No.3361

1. This explanatory memorandum has been prepared by the Department of Health and is laid before the House of Commons by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 The Health and Social Care (Community Health and Standards) Act 2003 ("the 2003 Act") provides the legislative framework for the establishment of primary dental services. It is intended that the new contracting arrangements will underpin modernised, locally sensitive primary dental services properly integrated with the rest of the NHS.

2.2 The National Health Service (General Dental Services Contracts) Regulations 2005 ("the GDS Regulations") replace the NHS (General Dental Services) Regulations 1992 (SI 1992/661)("the 1992 Regulations") which provide for general dental services under sections 35 of the National health Service Act 1977 ("the 1977 Act").

2.3 Contracts made under these Regulations are for the provisions are for primary dental services.

2.4 From 1 April 2006 it is intended to establish new contractual arrangements for high street dentists which move away from the general dental services item of service remuneration to an annual payment no longer directly related to the dentists activity. This will enable dentists to spend more time with their patients and adopt a more preventive approach to oral health care.

2.5 Breaking the direct link between remuneration and items of treatment provided requires a new system of dental charging, no longer based on the dentists' remuneration. The National Health Service (Dental Charges) Regulations 2005 ("the Dental Charges Regulations"), currently before Parliament, introduce a new system of charging for dental services based mainly on a 3 banded system, where treatment provided or appliances supplied will attract one of the 3 set charges depending on the complexity of the treatment provided.

2.6 An alternative form of local contracting will be provided for through the National Health Service (Personal Dental Services Agreements) Regulations 2005, to be laid shortly. These Regulations are part of the legislative framework underpinning primary dental services which include the Regulations mentioned in paragraphs 2.7 and 2.8.

2.7 The National Health Service (Performers Lists) Amendment Regulations 2005, to be laid later in December, replace arrangements for the inclusion of principal dentists in dental lists under Regulations 4 and 5 of the 1992 Regulations and the listing of assistants in the Supplementary Lists under the National Health Service (General Dental Services Supplementary List) Amendment Regulations 2003 (SI 2003/250).

2.8 The Functions of Primary Care Trusts (Dental Public Health) (England) Regulations 2005 made under section 16CB, inserted by section 171 of the 2003 Act give PCTs new functions in relation to dental public health and complete the regulatory reform package in relation to primary dental services.

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

3.1 The Department notes the comments of the JCSI on regulation 3(1) of both S.I 2005/2415 and S.I 2005/2531 in its Ninth Report of Session 2005-06. It might be thought that similar issues arise in respect of regulations 4 to 7 of, and paragraphs 69 to 71 of Schedule 3 to, the GDS Contracts Regulations. However, the GDS Contracts Regulations do not make any provision in respect a conviction of an offence and sentence being quashed or reduced on appeal.

3.2 The intention is not to allow contracts to be entered into whilst appeals are pending. It is also the intention to enable contracts to be terminated whilst appeals are pending. Once an appeal is determined and if successful, a contract may entered into. The policy rationale is to ensure patient safety and that might be comprised should a contract be entered into or not terminated pending a determination on appeal.

4. Legislative Background

4.1 The 2003 Act provides for new arrangements to be made for primary care trusts and general dental practitioners and amends the NHS Act 1977. Amendments made to the 1977 Act include provisions in relation to general dental services contracts, the “permanence” of personal dental services (PDS) pilot agreements and for dental charging. The GDS Regulations is the first instrument to be made under new section 28K to section 28O of the 1977 Act, inserted by section 172 of the 2003 Act.

4.2 The arrangements for the move from general dental services under section 35 of the 1977 Act and PDS piloting under the Primary Care Act 1997 will be provided for through the General Dental Services and Personal Dental

Services Transitional Provisions Order 2005 made under the 2003 Act

4.3 The GDS Regulations rely for activity monitoring purposes on the banded charging system. They are being made now to come into force in January 2006 to allow a three month preparatory period for contractors and primary care trusts to agree contracts for April 2006.

5. Extent

5.1 This instrument applies to England only.

6. European Convention on Human Rights

As the instrument is subject to negative resolution, no statement is required.

7. Policy background

7.1 PDS piloting under the National Health Service (Primary Care) Act 1997 has proved popular with dentists and their patients. Under these pilot arrangements, dentist are better able to use their professional skills to relate dental services more closely to patients' oral health needs. Patients with lower treatment needs are seen less frequently and courses of treatment become simpler. Evidence from over 5 years of piloting PDS shows at least a 10% reduction in dentists' overall activity (courses of treatment and individual items of treatment) can be expected with an improvement in clinical effectiveness, cost effectiveness and appropriateness of treatment provided.

7.2 By adopting the new ways of working demonstrated in the PDS pilots, dentists are able to undertake fewer courses of treatment and yet see greater numbers of patients. This has the potential to improve the working lives of dentists and their teams and also improve access to NHS dental services.

7.3 Building on the experience of PDS piloting, the GDS Regulations will enable PCTs to enter into contracts for the provision of primary dental services. Remuneration of providers under the contract will be by annual contract value as under the PDS piloting arrangements.

7.4 The GDS Regulations and PDS Regulations will provide for a contract: general dental services (GDS) contracts and an agreement : personal dental services (PDS) agreements. Under a GDS Contract, the contractor will be required to provide a range of dental services set out in Regulation 14 of the draft GDS Regulations 2005. New PDS agreements will be the 'permanent' version of PDS piloting and provide for greater flexibility in the services to be provided. Additionally, a wider range of potential providers are permitted to hold contracts including healthcare professionals other than dentists. PDS agreements will, for example, be used for commissioning specialised services such as orthodontics.

7.5 The current general dental services system of item of service fees will cease on implementation of these local contracts on 1 April 2006. A new system of patient charges, not related to the fees for the provision of items of treatment, is therefore needed. The change in charging structure is also provided for in the 2003 Act which implements all these changes by amending the provisions 1977 Act.

7.6 When the GDS Regulations come into effect on 1 April 2006, the 1990 Regulations as amended will in the main be revoked.

7.7 In response to the public consultation on the proposed banded dental charging system, Which? welcomed the Government's package of reforms intended to modernise dental provision, including the new dental contract, system of patient charges and PCT commissioning of services. They also commented that sustained reform and investment would hopefully re-establish dentistry as an integral part of the NHS and significantly improve access to NHS dentistry in those communities that are currently hardest hit.

7.8 The draft NHS (General Dental Services Contracts) Regulations 2005 and the draft NHS (Personal Dental Services Agreements) Regulations 2005, published for information on the 1st of August 2005. In response to issues raised by stakeholders the following amendments were made:

Regulation 2 "normal surgery hours"
not prescribe nationally a "core hours" period or an "out-of-hours" period, but make it unambiguously the responsibility of the PCT to agree during what hours services are available from local dentists and during what hours it is the PCT's responsibility to arrange treatment of dental emergencies.

Regulation 19
allow dentists to carry forward up to 4% (rather than 2%) of contracted activity into the next financial year, provided the under-performance is made up.

Schedule 2 paragraph 3(2)
provide for "interceptive orthodontics" for younger children by allowing a weighting of three units of orthodontic activity for these treatments.

Schedule 3 paragraph 1(3)
Enable practices to provide children and exempt adult-only services (or give priority to these groups) where this is agreed by the PCT. This enables, subject to the agreement of the PCT, services to be targeted at specific groups such as children or adults exempt from dental charges by virtue of section 79 and Schedule 12ZA inserted into the 1977 Act by the 2003 Act.

Schedule 3 paragraph 11
repair or replacement of a restoration should generate units of dental activity (but still with no charge to the patient).

Schedule 3 paragraph 28
contractual requirements governing training of practice staff should not necessarily have to cover non-clinical staff

Schedule 3 paragraph 64
revert to the original intention of mirroring the new GMS termination provisions, which allow the PCT to terminate only where there is breach of contract.

8. Impact

8.1 A Full Regulatory Impact Assessment is attached to this memorandum.

8.2 The Dental Practice Board (DPB) is currently responsible for all payments to, and monitoring of, dentists providing services under the current general dental services. The DPB is to be replaced by the NHS Business Services Authority (BSA) in 2006. The intention is that the DPB (and thereafter the BSA) will be used in the same way in the new regime as in the old i.e. to pay and monitor providers of dental services. This will significantly reduce the impact on the public sector.

8.3 It is planned to delegate PCTs' administrative functions in relation to GDS Contracts and PDS Agreements to the DPB/BSA . The DPB/BSA will verify patient charges in relation to the appropriate treatment band and provide the PCT with regular monitoring information. PCTs' administrative costs should not increase. As it will be easier to track patient charge levels, the DPB/BSA will also gain from the reduced bureaucracy of the new contracting arrangements and patient charging regime.

8.4 For patient charge verification under the current system, it is necessary for dentists to record and transmit to the DPB information on each of the items of service provided. The move to a banded charging system will significantly reduce the information burden on dental practices and their staff. The Department is preparing training material to familiarise dentists and their staff with new forms and reporting requirements.

8.5 The dental practice software systems suppliers are working with the DPB to ensure the electronic submission of data will be effective from the start of the new arrangements. The Department has been in discussion with the major IT suppliers and it is believed major suppliers will be upgrading most modern systems free of charge.

9. Contact

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can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

The National Health Service (General Dental Services Contracts) Regulations 2005
The National Health Service (Personal Dental Services Agreements) Regulations 2005.

2. Purpose and intended effect of measure

(i) The objective

To implement provisions in The Health and Social Care (Community Health and Standards) Act 2003 to create a new locally led primary dental service which is far more sensitive to the variety of ways in which patients now wish to access NHS dentistry. The new system is to be in place on 1 April 2006.

(ii)Background

In the main, NHS dental care and treatment is currently provided by "high street" dentists under general dental services arrangements under section 35 of the National Health Service Act 1977 ("the 1977 Act"). About 70% of these dentists' earnings are derived from fees for the individual items of service they provide. The remaining 30% is derived from other monthly NHS payments which are not directly related to treatment provision but are intended to reimburse the dentists for the provision of facilities in relation to the NHS. These payments to dentists are set out in the Statement of Dental Remuneration (SDR). Patient charges under the general dental services are regulated by the National Health Service (Dental Charges) Regulations 1989 ("the 1989 Regulations") and are set at 80% of the treatment fees paid to the dentist, subject to a maximum charge per course of treatment of £384: the NHS pays the remaining 20%.

Since 1998 an alternative system of dental service provision has been piloted under the National Health Service (Primary Care) Act 1997 ("the Primary Care Act"). Under these Personal Dental Services (PDS) pilots an annual contract sum is agreed between the provider of the service and the Primary Care Trust commissioning the service for an agreed level of NHS commitment. Payments under the PDS agreement are made in twelve instalments. The Primary Care Act requires dental charges paid by the patient under a PDS pilot scheme to be the same as if the treatment had been provided under the general dental services arrangements.

Remuneration payments to dentists both under general dental services and PDS pilots are undertaken by the Dental Practice Board ("DPB") for England and Wales established under section 37 of the 1977 Act. The DPB is also responsible for establishing the probity of NHS payment claims and the verification of dental charges in relation to each course of treatment. A Special Health Authority, the NHS Business Services Authority ("BSA") is to be established and will take over the

functions of the Dental Practice Board. Payments to dentists under both systems are made net of the dental charges due under the 1989 Regulations.

PDS piloting has proved popular with dentists and their patients. Under these pilot arrangements, dentist are better able to use their professional skills to relate more closely dental services to patients' oral health needs. Patients with lower treatment needs are seen less frequently and courses of treatment become simpler. Evidence from over 5 years of piloting PDS, shows at least 10% reduction in dentists' overall activity (courses of treatment and individual items of treatment) can be expected with an improvement in clinical effectiveness, cost effectiveness and appropriateness of treatment provided.

In general dental services, 53% of courses of treatment involve examination, scale and polish and no other dental intervention. At least some of these courses of treatment are of questionable health gain. By adopting the new ways of working demonstrated in the PDS pilots, dentists are able to undertake fewer courses of treatment and yet see greater numbers of patients. This has the potential to improve the working lives of dentists and their teams and also improving access to NHS dental services.

Building on the experience of PDS piloting, provisions in the Health and Social Care (Community Health and Standards) Act 2003 ("the 2003 Act") will underpin modernised, locally sensitive primary dental services properly integrated with the rest of the NHS. Under the new arrangements PCTs will be able to enter into contracts for the provision of primary dental services to meet all reasonable requirements or provide the services themselves. Remuneration of providers under the contract will be by annual contract value as under the PDS piloting arrangements.

Following implementation of the 2003 Act, the 1977 Act will provide for two types of contracting: general dental services (GDS) contracts and personal dental services (PDS) agreements. Under a GDS Contract, the contractor will be required to provide a range of dental services set out in the GDS Contracts Regulations. New PDS agreements will be the 'permanent' version of PDS piloting and provide for greater flexibility in the services to be provided. Additionally, a wider range of potential providers are permitted to hold contracts including healthcare professionals other than dentists. PDS agreements will, for example, be used for commissioning specialised services such as orthodontics.

In other material respects the mandatory terms of contracts are similar under both the National Health Service (General Dental Services Contracts) Regulations 2005 ("the 2005 GDS Regulations") and the National Health Service (Personal Dental Services Agreements) Regulations 2005 ("the 2005 PDS Regulations").

The 2005 GDS Regulations and 2005 PDS Regulations were published in draft on the Department of Health website on 1 August 2005. In response to comments from the British Dental Association, General Dental Practitioner's Association and the British Orthodontic Society a number of amendments were made to address concerns raised by stakeholders.

Both sets of Regulations will apply in England only.

The National Health Service (General Dental Services) Regulations 1992 ("the 1992 Regulations"), as amended, will be revoked when the 2006 GDS Regulations come into force for the provision of services on 1 April 2006.

Part 1 of the Primary Care Act (c. 46) (power to make pilot scheme for the provision of personal medical and dental services) will cease to have effect when the 2005 PDS Regulations come into force on 1 April 2006.

A new system of patient charges under the National Health Service (Dental Charges) Regulations 2005 will also come into force on 1 April 2006 alongside the new contracting arrangements. When the National Health Service (Dental Charges) Regulations 2005 come into effect on 1 April 2006, the 1989 Regulations will be revoked.

The two new forms of contracting and the change in charging structure is provided for in the 2003 Act which implements all these changes by amending the provisions of the 1977 Act.

(iii) Rationale for Government intervention

There is a high level of discontent with the current arrangements for the provision of general dental services. Dentists tell us the remuneration system, based on payment for individual items of service, feels like a treadmill and is the main cause of dissatisfaction amongst dentists. It is thought to act as a barrier to dentists agreeing to undertake NHS dental work.

The report of the Health Committee inquiry *Access to NHS Dentistry* (19 March 2001) considered the general dental service remuneration system was at the heart of the problem. The fee structure encouraged the move of dentists out of the NHS. It also discouraged preventive dental care and the continuing maintenance of good oral health. The committee concluded the time was ripe for reform.

The 2003 Act provides a legislative framework for the implementation of recommendations in the report *NHS Dentistry: Options for Change* published in August 2002. New forms of contracting should remove existing perverse incentives for the payment system to influence the type of treatment. This will establish a better approach to patient oral healthcare based on the clinical needs and wishes of the patient. Treatment will then only be offered if it is both clinically desirable and clinically effective. Incentives in the new contracting regime will be aligned towards these ends, which implies a different approach to the issue of patient registration and payment. Clinical pathways, as are now adopted across much of medical practice, are being developed and will be applied in dentistry. They build on available evidence and best practice. Dentists will then record their clinical interventions and note the outcomes, rather than receiving a fee for each intervention.

3. Consultation

i) Within government

The Secretary of State has new powers pursuant to the amendments made to the 1977 Act by the 2003 Act to make regulations providing for general dental services contracts, arrangements under section 28C of the 1977 Act (personal medical services and personal dental services agreements) and the making and recovery of dental charges for primary dental services.

ii) Public Consultation

The British Dental Association and the British Orthodontic Society have been fully involved in the planning of local commissioning. Both sets of regulations were published in draft during the National Health Service (Dental Charges) Regulations 2005 consultation period. Stakeholders were fully consulted and amendments made to both sets of Regulations to address concerns raised.

In addition to amendments for clarification and to improve drafting, the main policy changes following consultation include:

- redefine "core hours as "normal surgery hours"
- permit electronic equivalent of paper forms
- raise under-delivery of activity tolerance from 2% to 4%
- replace requirement to complete treatment within 90 days with "within a reasonable time"
- treatment to be terminated as a result of "irrevocable breakdown of dentist/patient relationship"
- additional unit of orthodontic activity for assessment leading to a case start
- permit child and exempt only contracts where PCT agrees
- repair or replacement of restorations to generate units of activity
- extended notice period should a contractor die
- GDS contracts ongoing subject only to breach/disciplinary termination.

In February 2004 there was a wide consultation with stakeholders on a DH publication *Framework proposals for primary dental services in England from 2005.* Responses to that consultation are fully reflected in the 2005 GDS Regulations and the 2006 PDS Regulations.

4. Options

The following options were considered before the powers were taken in the 2003 Act:

Option 1 Leave things unchanged

Option 2	Introduce legislation to establish new forms of local contracting for the provisions of primary dental services to improve access to a quality NHS dental service.
Non-regulatory option	A non-regulatory option would not ensure value for tax payers' money nor proper governance of the services provided.

5. Costs and Benefits

(i) Sectors and groups affected

The 1992 Regulations and the Primary Care Act already affect:

- Patients who need dental services either under NHS or private arrangements and on whom charges impact
- dental practices providing dental services under the NHS;
- dental practice management software systems suppliers, in relation to the practice administration and charging system, and
- to a limited extent the dental laboratory industry which supplies dental appliances such as crowns and dentures.

The 2005 GDS Regulations and 2005 PDS Regulations will have a similar effect, once they are in force. They do not impact on voluntary organisations or charities.

The policy for new the new contracting regime will not have any race equality impact.

Administration of the new contracting arrangements and associated patient charging will be the responsibility of PCTs. The BSA will undertake activity monitoring and patient charge verification on behalf of all PCTs, in addition to payment functions. Both option 1 and option 2 have similar affect on administration by these public bodies.

Option 1 and option 2 have a differential affect on users of the service. The main gain under option 2 would be improved access to an NHS dental service better aligned to patients needs. Option 2 has the potential to enhance clinical effectiveness, cost effectiveness and appropriateness of oral healthcare for the patients. In addition, it is likely to lead to improved working lives for dentists and their dental teams.

(ii) Analysis of costs and benefits

Costs

Option 1

Economic impacts

If the reforms did not go ahead PCTs would not have to implement the new regime which would save administrative implementation work. Dental practices would leave practice management systems as they are at present, subject to changes in the fees for treatment.

Social impacts

There is a close link between dental disease and deprivation. The current system based on payments to dentists for each item of treatment they provide ensure those patients with poor oral health get the treatment they need, but does not properly provide for a preventive approach to oral healthcare.

Environmental impacts

There are no environmental impacts from continuing with the current NHS dental services.

Option 2

Economic impacts

There are currently 8,963 dental practice addresses in England, some providing general dental services and others PDS pilots. The 2005 GDS Regulations and 2005 PDS Regulations will apply to all dental practices from 1 April 2006. Both paper and electronic changes to the practices' administrative systems will be required for the new contracting regime. Currently, as dentists' NHS fees and the related charges change each year, requiring amendments to practice administrative systems, so upgrades for April 2006 should not incur significant additional costs. The Department has been working closely with all IT suppliers and it is believed major suppliers will be upgrading most modern systems free of charge.

Dentists and practice staff will benefit from reduced bureaucracy and detailed form filling as a result of the move from over 400 different individual items of treatment to recording only course of treatment categories related to the banded patient charges.

About 30 million items of service claims are submitted to the DPB each year, 70% of which are electronic (21 million). If the simpler data to be submitted saves 1 minute per electronic claim and 1.5 minutes per paper claim then the saving at the dental practice is the equivalent of around 300 full time posts per year (assuming 40 hours a week, 45 weeks a year). There are likely to be similar time savings at the DPB and its successor body, the BSA.

It is planned to delegate the PCT administrative functions, including payments, in relation to GDS Contracts and PDS Agreements to the BSA. The BSA will verify patient charges in relation to the appropriate treatment band in order to make payments to the contractor net of patient charges. This enables the BSA to provide the PCT with regular activity monitoring information as part of its payment functions. PCTs administrative costs should not increase. Because it will be easier to track patient charge levels and contractors' activity, the BSA will also gain from the

reduced bureaucracy of the new contracting arrangements and patient charging regime.

The NICE guidance on dental recalls (*Dental recall: recall interval between routine dental examination*) advising a recall interval related to the patient's oral health risk factors means patients will typically only need to visit the dentist every 18 months as opposed to the current 6 monthly norm. This is likely to free up additional capacity at dental practices with the potential to improve access to NHS services.

Under the new contracting arrangements, dentists will agree an annual contract value to be paid to the contractor in monthly instalments. Because the total annual contract value is agreed in advance with the PCT, in future, there will be no financial incentive for dentists to unnecessarily complicate a course of treatment to maximise earnings. As now the patients' charges payable will be collected by the contract holder and the monthly contract payment will be reduced by the amount of the patient charges due.

Social impacts

Following an oral examination a dentist will set out for the patient the type and extent of dental work required and which charge band that falls into. The patient would then be entitled to, within that course of treatment, all proper and necessary dental care and treatment which the patient is willing to undergo. Since the payment is set in advance the patient knows exactly what the course of treatment will cost and can plan accordingly. Payment can be made up-front, during the course of treatment or at the end.

The new contracting regime and associated charging system may help encourage dentists to do more NHS dental work because it is simpler to operate, calculate charges and to explain to patients.

Environmental impacts

There are no environmental impacts from this measure.

Summary of Costs and Benefits

Option	**Total benefit : economic, environmental, social and administrative**	**Total cost per annum: economic, environmental, social and administrative**
Option 1 Do nothing	Some saving of any additional costs to practice administrative systems, including possible costs upgrading DOS based software, would be	Likely spend on GDS and PDS in 2006-07 of £2.2bn (including dental charges) to continue. Changes in dentists'

	avoided Possible savings upgrading DPB/BSA payment and monitoring systems	working patterns are likely to lead to a reduction in dental charge revenue in the order of £100 million in a full year. Dentists remain on the item of service treadmill with continued reduction in GDS of about 3 per annum. Administrative arrangements of BSA remain as now
Option 2 Implement new contracting regime	Predictable annual contract payments to practices improve financial stability Ongoing contracts with the NHS improve viability and "goodwill" of dental practices Reduced administrative burden on businesses More clinically effective and cost effective dental care for patients Better working lives for dentists and their teams	Additional costs for the DPB/BSA setting up new payment and monitoring systems to monitor activity and verify dental charges collected Possible costs for dental practices upgrading older software systems and practice administration
Option 3 Non-regulatory option	No implementation costs No administrative costs	Chaotic administration of the system Post-code lottery of services available to patients No accountability for NHS services provided or public funds spent

6. The Small Firms' Impact Test.

The British Dental Association and Dental Laboratories Association contributed to the work of the *NHS Dentistry: Patient Charges Working Group* that was set up to review patient charges and make recommendations. Both GDS contracts and PDS agreements draw heavily on the structure of banded charging. From this, limited initial soundings did not identify any significant impact on small businesses.

Monitoring of activity under both GDS contracts and PDS agreements will be through the number of courses of treatment provided, weighted to reflect the complexity of the treatment. The weightings are derived from the relativities inherent in the banded charging system (units of dental activity). Monitoring information is therefore purely a by-product of the information submitted to charge verification.

One of the Dental Charges Regulations consultation questions asked "Do dental practice owners and managers think the banded charging system proposed will reduce the administrative burden on small businesses? Almost half of respondents expressing an opinion thought the proposed banding system will reduce the amount of administration for small dental practices. About one-third disagree (two-thirds of whom strongly disagree).

Small practices and businesses were particularly encouraged to participate in the consultation and to contribute their views.

Almost half of the 238 respondents to the consultation questionnaire expressing an opinion think that the proposed banding system will reduce the amount of administration for small dental practices. About one-third disagree, two-thirds of whom strongly disagree.

7. Competition Assessment

There is a high level of discontent with the current arrangements for the provision of general dental services. Dentists tell us the remuneration system, based on payment for individual items of service, feels like a treadmill and is the main cause of dissatisfaction amongst dentists and patients. It is regarded as being inefficient and leading to poorer quality services. It is also thought to act as a barrier to dentists agreeing to undertake NHS dental work.

Because of the nature of the NHS dentistry market, the new contracting regime is likely to have little or no impact on competition. The new Regulations will impose no additional burden on small businesses providing NHS dentistry and will have no adverse affect on competition.

The new contracting regime and associated charging system may help encourage dentists to do more NHS dental work because it is simpler to operate, calculate charges and to explain to patients.

Of the 8,963 dental practice addresses in England, some will be providing general dental services and others PDS. Some of these practices may be owned by dental corporations. A dental corporation means a body corporate which, in accordance with the provisions of the Dentists Act 1984, is entitled to carry on the business of

dentistry. It is unlikely that any dental corporation has more than 10% market share in England.

It is therefore unlikely that any costs involved in administering the new contracting regime, calculating and collecting dental charges under the 2005 GDS Regulations, 2005 PDS Regulations will have a substantially different effect on dental businesses than the 1989 Regulations and 1992 Regulations, nor are they likely to change market structure as a result. New dental practices entering the market would incur no extra penalty in operating under these regulations.

There are a limited number of relatively small companies (some subsidiaries of much larger companies) providing and maintaining dental practice software management systems. The new dataset necessary for the administration and verification of the new charging regime is a subset of the item of service codes currently submitted to the DPB for payment purposes. The Department has been working closely with all of the practice software system suppliers to ensure that the necessary upgrades to the IT software can be written with minimum disruption to their business activities and it is believed major suppliers will be upgrading most modern systems free of charge.

Administration of the new contracting arrangements and associated patient charging will be the responsibility of PCTs. The NHS BSA will undertake activity monitoring and patient charge verification as part of its payments function on behalf of all PCTs.

8. Enforcement and Monitoring

Option 1

The general dental services terms of service for dentists (Schedule 1 to the 1992 Regulations) require principal dentists to comply with their terms of service. Failure to comply would result in a breach of the terms of service. A financial withholding may be imposed on the dentist in relation to a breach.

The DPB is responsible for establishing the probity of payment claims for general dental services and PDS pilots and making payments to them for the work they have done. The DPB continually monitors dentists prescribing patterns and activity and the verification of dental charges in respect of each course of treatment provided.

Option 2

There are contractual requirements on those holding contracts for the provision of primary dental services including a PCT, NHS trust or NHS foundation trust and their employees, including to collect NHS dental charges only in accordance with the new regulations. Failure to comply with the regulations may amount to a breach of contract or the employee’s terms and conditions of service. PCTs have sanctions, under the terms of the contract, including the issue of remedial notices and breach notices, to contractors who breach the requirements in relation to charges. A breach of contract could mean the contractor can no longer provide primary dental services because his contract is terminated.

Contract holders will be required to submit to the BSA data for activity monitoring and patient charge verification. Data from this process will be provided regularly to

both PCT and the provider of the service. Information in relation to the annual review (and mid-year review where there is evidence of significant under provision) will be derived from this data.

The Department of Health is planning a public communications campaign in the run-up to April 2006. This will explain to patients what the changes will mean for them, how to access the service, how their future care will be provided and how the new charges system will work. This is likely to include an information leaflet for practices to give to patients.

9. Post-implementation review

Once the new arrangements both for contracting and dental charging are in place data will be submitted by contractors on the courses of treatment provided and the persons to whom services have been provided. Weightings to reflect complexity of the course of treatment derived from the charges bandings will be applied by the BSA for contract monitoring purposes.

For 2006-07, contract values and activity levels for dentists transferring from the general dental services will be based on their most recent gross earnings. The financial and activity values between 1 October 2004 and 30 September 2005 will provide this information. Contract values will be protected, providing the contractor maintains NHS commitment for three years until March 2008. Activity will be monitored during the period so that future levels of activity can be determined in relation to units of dental activity and the level of charges in future years. NHS charges, including dental charges, are usually reviewed and uprated annually in April.

Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed: Rosie Winterton

Date: 6th December 2005

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Annex

Implementation and delivery plan

Option 1
The National Health Service (General Dental Services) Regulations 1992 would remain in place. Revisions to the Statement of Dental Remuneration would be required to implement the new fee scale following recommendations of the Doctors' and Dentists' Review Body with effect from 1 April 2006. Changes to the narrative of the SDR would also be required to update various rules under which dental treatment is provided in line with current best practice. For example restrictions on the use of composite resin fillings (tooth coloured fillings) on molar teeth are no longer in line with current teaching.

Activity monitoring arrangements for personal dental services would need to be put in place as the current mechanisms in relation to the number of patients registered with the contractor, patient contacts or courses of treatment (unweighted) are inefficient and unreliable.

Option 2
Following approval of the National Health Service (Dental Charges) Regulations 2005, by a resolution of each House of Parliament, they will be published on the Department of Health website http://www.dh.gov.uk and the NHS Primary care Contracting website http://www.primarycarecontracting.nhs.uk for the information of stakeholders. It is hoped that the Regulations will have been approved by both Houses and made by the end of December. The Regulations will come into force on 1 April 2006, which will amount to more than a 3 month period in which preparations can be undertaken for implementation.

The NHS (General Dental Services Contracts) Regulations 2005, and the NHS (Personal Dental Services Agreements) Regulations 2005 are both constructed on the basis of the provision of courses of treatment weighted by complexity. The categories of course of treatment and weightings, to be known as units of activity, are derived from the banded charging regime. These Regulations will come into force early in January 2006 for the purpose of agreeing contracts and for provision of services from April 2006. This provides a three month preparatory period.

Publication of the finalised NHS (Dental Charges) Regulations 2005 will enable the DPB to provide definitive information to dentists on their contract values for 2006-07 and the number of units of dental activity (UDAs), and where appropriate, the number of units of orthodontic activity (UOAs) they are to provide in relation to the contract value. This will be sent to dentists and their PCTs early in December 2005 to enable contracts for 2006-07 to be finalised

Publication of the NHS (Dental Charges) Regulations 2005 will also enable the DPB to finalise new payment systems for payments to contractors and the validation of patient charges raised for dental services provided under contracts. Similarly the dental software systems suppliers will finalise the dental practice based software systems to run the new contracting arrangements. The Department has worked

closely both with the DPB and the dental systems suppliers to ensure a smooth transition from the current arrangements to the new regime.

The implementation timetable for option 2 is:

Information for dentists, PCTs, system suppliers	end November 2005
GDS Contracts regulations	laid December 2005 in force January 2006
PDS Agreements Regulations	laid December 2005 In force January 2006
Statement of Financial Entitlements	December 2005
Transitional Provisions Order	December 2005
Performers Lists Regulations	January 2006

Option 3

For the reasons stated above, a non-regulatory option is unworkable and so no implementation plans have been developed for this option.