Final Regulatory Impact Assessment

1. **Title of Proposal**

The Health & Personal Social Services General Dental Services (Amendment) Regulations (Northern Ireland) 2014

2. **Purpose and intended effect of measure**

(i) Objective

1. To amend the General Dental Services Regulations (NI) 1993 to introduce qualifying criteria for the provision of Health Service orthodontic care and treatment to ensure that treatment is targeted at those patients who have the greatest clinical and aesthetic need for treatment. The new system is to be introduced in April 2014 and will bring Northern Ireland into line with the rest of the United Kingdom.

(ii) Background

2. The majority of health service orthodontic care and treatment is provided in primary care by high street orthodontists, with the more complex cases being referred to hospital based orthodontists. Most treatments are provided for children in their early teenage years and as such they are exempt from Health Service fees. The terms and conditions for orthodontists are set out in the General Dental Services Regulations (Northern Ireland) 1993 (the GDS Regulations). The GDS Regulations specify that any course of treatment, likely to cost more than £280 requires prior approval from the Business Services Organisation's dental committee. As the majority of courses of orthodontic treatment will exceed the prior approval limit, most orthodontic treatment plans are required to go through this process. A typical course of orthodontic treatment to treat the upper and lower teeth costs approximately £1000. However as the GDS Regulations do not set out any qualifying criteria for orthodontic treatment and care, the vast majority of cases are approved. This means that some of the orthodontic care provided under the Health Service is demand driven by patients

(or their parents), rather than being driven by a clear clinical need. Thus the Health Service may end up providing treatment which would be deemed to be largely aesthetic or cosmetic in nature rather than focusing spending on those treatments which have oral health improvement benefits.

3. The growing demand for orthodontic treatment has had a significant impact on the budget for the provision of all General Dental Services. In 2012/13, the budget spend on treatment relating to orthodontists (i.e. all treatment costs where the patient had an item 32 code.) was £13.2m, an increase of 69% since 2007/08 The table below illustrates this trend and shows that a significant proportion of the GDS budget is spent on orthodontics, rather than treatments which have a proven oral health benefit. The Department's Oral Health Strategy[1] recognised this and recommended that "The boundaries of orthodontic treatment for health reasons and orthodontic treatment for purely cosmetic reasons should be clearly defined in the strategies for the GDS and the CDS"

Year	**2007/08**	**2008/09**	**2009/10**	**2010/11**	**2011/12**	**2012/13**
Number of patients*	18,691	19,416	19,271	22,346	24,439	28,854
Number of Orthodontists**/***	45	49	51	49	55	65
Budget spend on treatment relating to orthodontists	£7.8m	£8.3m	£8.8m	£9.9m	£11.3m	£13.2m
Total Gross Treatment Fees (including Oasis and Salaried	£50.8m	£53.0m	£55.1m	£62.3m	£65.3m	£68.3m

[1] http://www.dhsspsni.gov.uk/2007_06_25_ohs_full_7.0.pdf

dental services)						
Total Gross Treatment Fees (excluding Oasis and Salaried dental services)	£50.8m	£53.0m	£55.0m	£61.3m	£63.7m	£66.6m

*Orthodontic treatment is defined as a treatment which involves P7 item 32xx. Note these figures refer to all treatments, some of which may be ongoing.

**An orthodontist is defined as someone who has at least 30% of their claims made as orthodontic items of treatment. ***This figure refers to orthodontic individuals and not orthodontic contracts as some individuals may have more than one contract.

(iii) Rationale for Government Intervention

4. There has been a significant increase in the provision of orthodontic treatment and this continues to put pressure on the overall budget for the provision of Health Service dental care and treatment. As orthodontists are treating more and more patients, there is anecdotal evidence that many practices have had to introduce waiting lists for treatment, further lengthening the 18-24 month treatment period. This issue has arisen for a number of reasons:
   - a lack of criteria for the provision of orthodontic care and treatment; and
   - increased expectation, from both patients and parents, of treatment for all types of orthodontic conditions including those which are primarily aesthetic in nature.

5. While it is important to recognise that orthodontic treatment may have a psychological benefit to patients with severe malocclusions in terms of improving self esteem, it has been judged to have minimal direct impact on oral health improvement when compared to other treatments that are available under the Health Service and provided by General Dental Practitioners. Therefore, the Department considers that Health Service orthodontic care and treatment should be provided where there is a clear clinical need rather than provided on demand. We propose that health service orthodontic care should only be offered to those patients who have a high assessed need from both a clinical perspective and an aesthetic perspective for treatment. Such criteria exist for Health Service

orthodontic care in all other parts of the United Kingdom and the Republic of Ireland. The introduction of criteria for orthodontic treatment is consistent with the policy set out in the Department's Primary Dental Care[2] and Oral Health strategies.

6. The Department is proposing to use the Index of Orthodontic Treatment Need (IOTN) as criteria for the provision of orthodontic treatment. This Index consists of two parts; the Dental Health Component (DHC) grades patients teeth on a scale of 1-5 (1 being perfect and 5 being the worst) and the Aesthetic Component (AC) where patients' teeth are compared to a series of 10 photographs ranging from perfectly straight to very crooked. The combined score from the Index can be used to categorise prospective patients into 3 broad groups:
   - those with little need for orthodontic treatment (IOTN DHC 1 & 2);
   - those with a borderline need for orthodontic treatment (IOTN DHC 3); and
   - those with a clear and definite need for orthodontic treatment (IOTN DHC 4 & 5 and AC >6).

7. Using IOTN at a level of DHC3 with AC6 would mean that Health Service funded orthodontic treatment would be available for all those patients with a clear and definite need and many of those who have a borderline need for treatment. If IOTN at a level of DHC4 were adopted as the cut off, then those patients with a clear and definite need for treatment would receive it. There would be safeguards in place to allow patients who do not meet the IOTN criteria, but have other pressing treatment needs, to receive orthodontic treatment.

3. Options

8. The following options are considered:

Option 1 - No change to existing regulations.

Option 2(a) - Introduce legislation to establish criteria for the provision of orthodontic care and treatment at a level of IOTN with

[2] http://www.dhsspsni.gov.uk/dental_strategy_2006.pdf

a dental health component (DHC) of 3 or greater and an aesthetic component (AC) of 6 or greater (aka IOTN 3.6).

Option 2(b) - Introduce legislation to establish criteria for the provision of orthodontic care and treatment at a level of IOTN with a dental health component of 4 or greater

Option 3 - Non Regulatory Option.

9. Option 1 – The Department would not make any change to the existing regulations, there would be no criteria for the provision of orthodontic treatment and practitioners would have to apply for prior approval before commencing treatment, as with current practice and the vast majority of cases would continue to be approved.

10. Options 2(a) & (b) – The Department would amend the GDS Regulations to introduce clear criteria for the provision of Health Service funded orthodontic treatment, by requiring all practitioners to assess prospective patients against the standards set out in the IOTN. IOTN is an internationally recognised means of assessing need and eligibility of patients for Health Service orthodontic treatment on dental health grounds.

11. Under option (2a) using IOTN 3.6 would mean that all those patients with a clear and definite need for treatment and most of those patients with a borderline need for orthodontic treatment would receive it. Under option (2b), if IOTN 4 were to be adopted as the cut off, then only those patients with a clear and definite need for treatment would receive it. Under either option there would be safeguards in place to allow patients who do not meet the IOTN criteria, but have other pressing treatment needs, to receive orthodontic treatment through a prior approval system. This could include patients who have a low score on the dental health component, but a high score on the aesthetic component of the IOTN index, or where a HSC Consultant Psychiatrist certifies that orthodontic treatment would be necessary for the patient's mental health and wellbeing.

12. Northern Ireland is currently the only UK country which has not introduced a needs based system for orthodontics. The other UK countries all use IOTN as a qualifying measure and with the threshold set at IOTN 3.6. The introduction of criteria for orthodontic treatment is consistent with the policy set out in the Department's Primary Dental Care and Oral Health strategies.

13. Option 3- Under a non regulatory option, orthodontic practitioners would be encouraged to assess prospective patients using IOTN criteria and sign up to a voluntary code of practice and decide whether to offer treatment on this basis. This is a less clear cut system and leaves orthodontists open to pressure from patients with mild orthodontic conditions to provide treatment. In addition, as there would be no amendment to the GDS Regulations, the requirement to apply for prior approval would remain.

Preliminary Sift of Options

14. One of the above options has not been taken forward. The reasons for this are set out below:

- Option 3 – Non Regulatory Option – A non-regulatory option was discounted as it would not provide the necessary assurance that the criteria were being adhered to and could place undue pressure on orthodontists from patients. Without amendments to the GDS Regulations, the requirement to apply for prior approval would continue, this in turn could lead to confusion for practitioners and patients over whether or not treatment could be provided.

- Options 1, 2(a) and 2(b) were shortlisted for further assessment

4. Costs and Benefits

(i) Sector and groups affected

15. The introduction of IOTN criteria for the provision of Health Service orthodontic care and treatment will potentially have an impact on:
    - patients (who are mainly teenagers) who want orthodontic care and treatment under Health Service arrangements;
    - orthodontists and dental practitioners with a special interest in orthodontics;
    - dental practices providing orthodontic treatment under the Health Service; and
    - to a limited extent the dental laboratory and dental supplies industries that supply orthodontic appliance components.

These regulations have no impact on voluntary organisations or charities.

(ii) Analysis of costs and benefits

Option 1 – No change

16. If no changes are made to the current GDS contract i.e. it remains as it is, and the IOTN criteria are not introduced then the Health Service will continue to provide orthodontic treatment for which there is little or no clinical need. In addition the pressure on the budget for the provision of Health Service dental care and treatment will increase, as more unnecessary orthodontic treatment is provided given the current cosmetic expectations of younger people. Orthodontic practices would have to continue applying for prior approval (with the vast majority gaining approval) for orthodontic treatment which will have an administrative impact, both within practices and at the BSO. The average time taken to process a claim for prior approval by the BSO is currently 8 weeks. From the 2012/13 figures outlined below, the average spend on orthodontic care per person, in a 12 month period, is £457. These figures include all orthodontic claims including smaller claims such as would be made for repairs. No changes would be necessary to practice management software. The table below shows how demand for orthodontic treatment has increased over the past 5 years i.e. it

has grown by 49% over the five year period and the average spend on orthodontic treatment per person has grown by 7% over the same period.

	2008/09	2009/10	2010/11	2011/12	2012/13
Budget spent on treatment relating to orthodontists	£8.3m	£8.8m	£9.9m	£11.3m	£13,2m
Number of patients	19,416	19,271	22,346	24,439	28,854

17. Patients would continue to be provided treatment based on an assessment of need by the orthodontic practitioner with the dental officer in the Business Services Organisation having limited reason to decline treatment. The provision of treatment will also be based upon the assessment of individual practitioners, rather than standardised criteria, which may lead to inconsistencies in types of orthodontic treatment that is provided under the Health Service. Continuing with the current system will also mean that a proportion of the dental budget will be spent on orthodontic treatment which provides little or no oral health gain. This would impact on the ability of the HSC Board to continue to fund other treatments available under the Health Service which have a greater positive impact on the oral health of patients. No changes would be necessary to practice management software.

Option 2(a) – IOTN 3.6

18. There are approximately 65 orthodontists (an orthodontist is defined as someone who has at least 30% of their claims made as orthodontic items of treatment). This figure refers to orthodontic individuals and not orthodontic contracts as some individuals may have more than one contract) practicing in Northern Ireland, specialising in the provision of orthodontic care and treatment in a primary care setting and a smaller number of dentists with special interests who provide orthodontic care and treatment alongside GDS treatments. The introduction of a cut off for Health Service funded orthodontic care and treatment

at IOTN 3.6 should remove those orthodontic cases for which there is little clinical need from the system and would overall reduce the number of orthodontic treatments carried out every year. This will have an impact on caseloads, the gross level of fees claimed by orthodontists, and by extension, the income of those companies that manufacture and supply orthodontic appliance components.

19. There has been little research published on the potential impact/costs of IOTN on orthodontic practices in Northern Ireland. The different contractual arrangements in England, Wales and Scotland and the proposed legislative framework for Northern Ireland, limit the value of research carried out in those jurisdictions. A published audit of patients treated in a specialist orthodontic practice in Northern Ireland, indicates that 84% of referred patients would meet the proposed criteria of IOTN 3.6 and would therefore be eligible for treatment without prior approval. There would be an additional cohort of patients, with exceptional needs, who do not meet IOTN 3.6 but whose treatment is approved by BSO through the prior approval process as described at paragraph 12. While it is not possible to be definitive about the number of patients whose treatment will be approved, we have estimated that no more that 5% of current patients would fail to meet IOTN 3.6 but still have their treatment approved by the BSO because they have other pressing treatment needs.

20. Using the figures from the published audit of the Northern Ireland practice as an example and 2012/13 budget and activity figures, the number of patients having treatments that would be assessed as IOTN 3.6 + would be 24,237 a further 5% or 231 patients may be eligible for treatment after seeking the prior approval of the BSO. This would lead to a spend of approximately £11.2m per year. Comparing this to the 2012/13 budget spend of £13.2m on orthodontic treatments it shows the introduction of IOTN 3.6 would lead to a saving of £2.0m per year from the GDS budget (Due to the length of time for completing a course of orthodontic treatment, this would be realised over an 18 to 24 month period). This is based on an average spend of £457 per person in a 12 month period.

These figures include all orthodontic claims including smaller claims such as would be made for repairs.

21. Practice administration systems may need to change in order to accommodate and record the assessment of patients against IOTN criteria. However, practices will no longer have to routinely apply for prior approval of treatment and will also be able to submit claims for treatment electronically, if they wish to do so, which would ease administration in practices and at the BSO and provide a more seamless system for patients.

22. Training and calibration in IOTN was offered by the HSC Board to all specialist orthodontists to ensure that the new criteria could be implemented and applied consistently across Northern Ireland. Many specialist orthodontists have taken up this training. The HSC Board will also carry out post treatment checks to ensure that practitioners are complying with the criteria and doing so in a consistent and fair manner and with good clinical outcomes.

23. Under this option there will now be clear criteria for the provision of Health Service orthodontics. This would mean that patients and their general dental practitioners will have a much better idea of who will be eligible for Health Service orthodontic treatment without going through a potentially lengthy referral process. By introducing clear criteria for treatment, some of the pressure on orthodontists to provide treatment purely for aesthetic reasons, as a result of patient/parent expectation will be removed. This should, in turn reduce waiting times for those patients who do meet the criteria for treatment.

24. There will however, be some patients who, when assessed against IOTN criteria, are no longer eligible for Health Service orthodontic treatment. If they do not reach 3.6 on the IOTN scale, but the orthodontist still feels that the patient has pressing oral health needs, such as a high score on the aesthetic component of the IOTN index, or where a HSC Consultant Psychiatrist certifies that orthodontic

treatment would be necessary for the patient's mental health and wellbeing, then they could apply to the BSO for approval of the treatment.

25. The Department contends that those patients, who do not meet IOTN 3.6 or have their treatment approved by the BSO, do not have sufficient aesthetic or oral health needs for publically funded orthodontic treatment.

Option 2(b) – IOTN 4

26. The introduction of a cut off for Health Service funded orthodontic care and treatment at IOTN 4 would reduce the number of orthodontic treatments carried out every year. This would represent a higher threshold for entry to Health Service orthodontic care than IOTN 3.6.

27. The published audit of patients treated in a specialist orthodontic practice in Northern Ireland indicates that 75% of patients currently accessing orthodontic treatment would meet the proposed criteria, of IOTN 4 or above, and would therefore be eligible for treatment without seeking prior approval. There would be an additional cohort of patients who do not meet IOTN 4 but whose treatment is approved by BSO through the exceptional prior approval process. While it is not possible to be definitive about the number of patients whose treatment would be approved, it has been estimated that no more that 5% of current patients would fail to meet IOTN 4 but still have their treatment approved by the BSO.

28. Using this practice as an example, the number of patients having treatments that would be assessed as IOTN 4 would be 21,640 a further 5% or 361 patients may be eligible for treatment after seeking the prior approval of the BSO. This would mean that 22,001 patients would be eligible for treatment. This would lead to a spend of approximately £10.0m per year, a saving of up to £3.1m per year against the current spend. This is based on an average spend of £457 per person, per year. These figures include all orthodontic claims including smaller claims such as would be made for repairs.

29. Practice administration systems would need to change in order to accommodate and record the assessment of patients against IOTN criteria. However, practices will no longer have to routinely apply for prior approval of treatment. Practices would also be able to submit claims for treatment electronically, if they wish to do so, which would ease administration in practices and at the BSO.

30. Training and calibration in IOTN was been offered by the HSC Board to all specialist orthodontists to ensure that the new criteria could be implemented and applied consistently across Northern Ireland. Many specialist orthodontists have taken up this training. The HSC Board will also carry out post treatment checks to ensure that practitioners are complying with the criteria and doing so in a consistent and fair manner and with good clinical outcomes

31. Under this option there will now be clear criteria for the provision of Health Service orthodontics. This will mean that patients and their general dental practitioners will have a much better idea of who will be eligible for Health Service orthodontic treatment without going through a potentially lengthy referral process. By introducing clear criteria for treatment, some of the pressure on orthodontists to provide treatment purely for aesthetic reasons, as a result of patient/parent expectation will be removed. This should, in turn reduce waiting times for those patients who do meet the criteria for treatment.

32. There will however, be some patients who, when assessed against IOTN criteria, are no longer eligible for Health Service dental treatment. If they do not reach 4 on the IOTN scale, but the orthodontist still feels that the patient has pressing oral health needs, such as a high score on the aesthetic component of the IOTN index, or where a HSC Consultant psychiatrist certifies that orthodontic treatment would have a beneficial impact on a patient’s mental health and wellbeing, then they could apply for approval of the treatment.

5. Impact on the Orthodontic Industry

33. The Department is aware that the introduction of IOTN criteria will impact on the number of Health Service treatments provided by orthodontists and therefore the fees that they can claim. Nevertheless, the Department considers that, at a time when the overall HSC budget is under pressure, it is appropriate to focus spending on those treatments which have the greatest oral health benefits, rather than orthodontics which provides primarily aesthetic benefits. This also brings Northern Ireland into line with the rest of the UK.

34. Most, if not all, orthodontic practices in Northern Ireland are small businesses and therefore should all be impacted to the same degree. If IOTN 3.6 is recommended and taking the information from the published audit as an example, approximately 4,386 patients would no longer receive Health Service funded orthodontic treatment. This would mean an overall reduction in fees of £2.0m from Health Service funded orthodontic treatment for orthodontists in Northern Ireland, or approximately £30,830 per orthodontist. Due to the length of time for completing a course of orthodontic treatment, this would be realised over an 18 to 24 month period. In 2012/13 the average Health Service gross earnings per orthodontist were £288,300. Therefore, the loss of funding works out on average as approximately 10% of individual orthodontist's gross earnings. A proportion of this might be offset by patients opting to receive orthodontic treatment privately.

35. There have been discussions with the Dental Practice Committee of the BDA NI over the proposal to introduce IOTN as part of a new contract for orthodontists and in relation to the need to address the pressure on the GDS budget. As a result, changes have been incorporated which remove the requirement for prior approval in routine cases. This should reduce the administrative burden on orthodontic practices and produce savings for these practices. The HSC Board offered and funded training for specialist orthodontists in primary care practices on IOTN, to ensure that it is understood and implemented consistently by orthodontists across NI.

36. Primary Care Orthodontists are all self employed independent Health Service contractors. There are no corporate bodies providing orthodontic care and treatment in Northern Ireland. Therefore, the Department does not consider that these proposals would have a disproportionate impact on smaller businesses. The Department understands that most orthodontic practices are clustered around urban areas or large regional towns and that therefore there should be no impact on rural businesses from the introduction of criteria for orthodontic treatment.

37. There could also be an impact on the dental supplies industry that provides appliance components to orthodontists. The Department has not been able to quantify this impact, but we would stress that this system is already operational across all other UK countries.

6. Competition Assessment

38. These regulations seek to introduce clear qualification criteria for the provision of HS orthodontics and will apply equally to specialist orthodontists, dentists with a special interest in orthodontics and General Dental Practitioners. Most orthodontic practices receive patients on referral from General Dental Practitioners practising in the surrounding area. The Department does not foresee that the introduction of these criteria will alter this arrangement. The new regulations are not expected to have any adverse affect on competition.

7. Enforcement and Post Implementation Review

39. Option 1- The current arrangements, whereby all proposed courses of orthodontic treatment are subject to prior approval by the BSO before treatment can commence, would continue.

40. Option 2(a) and (b) These regulations would amend the General Dental Services terms of service. A failure to assess and record the IOTN score for prospective patients would be considered a breach of a practitioner's terms of service. This could in turn lead to the imposition of a financial penalty or a requirement to submit claims for prior approval for a defined period. The HSC Board will also carry out checks to verify that orthodontists are applying the criteria correctly through a programme of practice visits and post payment verification checks.

41. The Department and HSC Board have regular meetings with the British Dental Association and these would continue after the implementation of the new procedures for assessing need for orthodontic treatment. The HSC Board and BSO will monitor levels of orthodontic treatment through the payments process and by monitoring the treatments submitted for prior approval.

8. Consultation

42. The NI Dental Practice Committee of the BDA has been involved in discussions with DHSSPS and the HSC Board over the introduction of the IOTN criteria. The Department will continue to meet with the BDA to discuss the implementation of these changes. The draft Regulations were issued for consultation, along with supporting papers, between 7 January and 3 April 2013. The consultation asked "Do you agree that funding for Health Service orthodontic treatment should be prioritised for patients with a clinical need and that the threshold is set at IOTN 3,6, as is the case in the rest of the United Kingdom?" Of the 209 responses to this question, 191 (91%) agreed and 18 (9%) disagreed.

43. As indicated by the breakdown in responses, there was broad support for using IOTN criteria to prioritise those patients with a clinical need for orthodontic treatment. There were some suggestions that orthodontic treatment should remain available without any restrictions or alternatively more stringent criteria could be introduced to release greater levels of savings. However, after considering all the responses and the analysis outlined in the partial Regulatory Impact Assessment that accompanied the consultation, it has been decided that IOTN 3.6 will be used as the cut off for Health Service funded orthodontic treatment in Northern Ireland.

44. A summary of the responses to the consultation and subsequent analysis by the Department has been published at: http://www.dhsspsni.gov.uk/showconsultations?txtid=60987

Recommendation

45. The Department considers that as there are pressures on all Health and Social Care budgets, including that for GDS, it is sensible and appropriate to focus spending on those treatments which have oral health improvement benefits. However, whilst seeking to introduce criteria for the provision of Health Service funded orthodontic treatment, the Department is mindful that Option 2(a) – IOTN 3.6 rather than 2(b) – IOTN 4 would have a lesser impact on orthodontic practitioners and prospective patients and is consistent with the criteria in use in the rest of the UK. The Department considers therefore, that IOTN 3.6 is an appropriate point at which to begin providing free Health Service orthodontic treatment and care. The savings from the introduction of this measure will help the HSC Board to address the pressures on the GDS budget.

Declaration

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

Signed: ....

Date:

Edwin Poots MLA

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