

<b>Title:</b> Final Stage Impact Assessment on the proposal for the supply and administration of medicines under exemptions within the Human Medicines Regulations 2012 by dental hygienists and dental therapists across the United Kingdom  <b>IA No:</b> N/A <b>RPC Reference No:</b> <b>Lead department or agency:</b> Department of Health & Social Care  <b>Other departments or agencies:</b> Devolved administrations, professional bodies	<b>Impact Assessment (IA)</b>			
	<b>Date:</b> 24 April 2024			
	<b>Stage:</b> Final			
	<b>Source of intervention:</b> Domestic			
	<b>Type of measure:</b> Secondary legislation			
<b>Contact for enquiries:</b> <a href="mailto:medicines.mechanisms@dhsc.gov.uk">medicines.mechanisms@dhsc.gov.uk</a>				
<b>Summary: Intervention and Options</b>			<b>RPC Opinion:</b> Not applicable	

Cost of Preferred (or more likely) Option (in 2024/25 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
£860.9m	N/A	N/A	Not a regulatory provision

**What is the problem under consideration? Why is government action or intervention necessary?**

Dental hygienists and dental therapists are currently able to supply and administer medicines using patient specific directions and patient group directions. However, due to the administrative challenges associated with creating patient group directions their use is not widespread. When a patient specific direction has not been produced, dental hygienists and dental therapists are unable to supply and administer required medicines, even though they may be the first to identify the need for a medicine within a clear and established treatment pathway. This leads to unnecessary consultations with other healthcare professionals which represents an inefficient use of public money and may delay access for patients who require their skills.

**What are the policy objectives of the action or intervention and the intended effects?**

The objectives are to allow dental hygienists and therapists to work more fully in their full scope of practice in order to reduce delays in the provision of patient care, and thereby: a) reduce inefficient use of health professional time; b) improve patient experience; c) improve patient health.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

- Option 1 – Business as usual/no change
- Option 2 – Enable dental hygienists and dental therapists to supply and administer a specified list of medicines using exemptions under the Human Medicines Regulations 2012

<b>Will the policy be reviewed?</b> It will be reviewed. <b>If applicable, set review date:</b> Post-implementation				
Is this measure likely to impact on international trade and investment?		N/A		
Are any of these organisations in scope?	<b>Micro</b> No	<b>Small</b> No	<b>Medium</b> No	<b>Large</b> No
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)		<b>Traded:</b> 0	<b>Non-traded:</b> 0	

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible Minister: Andrea Leadsom Date: 24 April 2024

# Summary: Analysis & Evidence

# Policy Option 1 – Business as usual

Description:

## FULL ECONOMIC ASSESSMENT

Price Base Year 4/25	PV Base Year 2024/25	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 0	High: 0	Best Estimate: 0
<b>COSTS (£m)</b>		<b>Total Transition</b> (Constant Price) Years	<b>Average Annual</b> (excl. Transition) (Constant Price)	<b>Total Cost</b> (Present Value)	
Low					
High					
Best Estimate				0	
<b>Description and scale of key monetised costs by ‘main affected groups’</b> None, this option represents business as usual and would therefore have no monetised costs. Dental hygienists and dental therapists would retain the ability to administer and supply medicines under PSDs and PGDs.					
<b>Other key non-monetised costs by ‘main affected groups’</b> None (no change)					
<b>BENEFITS (£m)</b>		<b>Total Transition</b> (Constant Price) Years	<b>Average Annual</b> (excl. Transition) (Constant Price)	<b>Total Benefit</b> (Present Value)	
Low					
High					
Best Estimate				0	
<b>Description and scale of key monetised benefits by ‘main affected groups’</b> None, this option represents business as usual and would therefore have no monetised benefits.					
<b>Other key non-monetised benefits by ‘main affected groups’</b> None (no change)					
<b>Key assumptions/sensitivities/risks</b>				<b>Discount rate (%)</b>	1.5/3.5
None (no change)					

## BUSINESS ASSESSMENT (Option 1)

<b>Direct impact on business (Equivalent Annual) £m:</b>			<b>Score for Business Impact Target (qualifying provisions only) £m: N/A</b>
<b>Costs:</b>	N/A	<b>Benefits:</b> N/A	

# Summary: Analysis & Evidence

# Policy Option 2 – Proposed changes

Description:

## FULL ECONOMIC ASSESSMENT

Price Base Year 2024/25	PV Base Year 2024/25	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 711.6m	High: 1,010m	Best Estimate: 860.9m

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			
High			
Best Estimate			27.5

### Description and scale of key monetised costs by 'main affected groups'

Based on comparator training regimes, the cost of developing exemption training for dental hygienists and therapists who work in the NHS has been estimated to be £500,000  
 Assuming similar exemption training is developed for dental hygienists and therapists who work in the private sector, the cost of this online training is estimated to be £350 per person.  
 There is also an estimated cost for backfilling the time that hygienists and therapists spend completing the training. These costs have been based on the hourly cost (including non-wage related costs) of the professionals, and the assumption that the training will take ~2 working days to complete.

### Other key non-monetised costs by 'main affected groups'

None

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			739.2
High			1,038
Best Estimate			888.4

### Description and scale of key monetised benefits by 'main affected groups'

Reduction in inefficient search time by dental hygienist/dental therapist.  
 Reduction in number of consultations with other health professionals (i.e., dentists).  
 Improved patient experience by reducing 'inconvenience cost' due to delay or having to make additional appointments.

### Other key non-monetised benefits by 'main affected groups'

Health benefits associated with more timely access to medicines. Dental hygienists and dental therapists can identify anatomical features, recognise abnormalities, and interpret common pathology. They can carry out a clinical examination, diagnose and plan treatment within their scope of competence. Unnecessary delays in treatment could cause ongoing suffering/anxiety with the risk of a worsening in condition.

<b>Key assumptions/sensitivities/risks</b>	<b>Discount rate (%)</b>	1.5/3.5
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We have assumed that there is no change in risks of inappropriate administration of medicines.  
 There is uncertainty around our estimates of efficiency savings, particularly in the number of affected appointments used to estimate benefits. Therefore, adjustments have been made in a sensitivity analysis.  
 We have discounted benefits to patient health and the NHS at 1.5% per annum and all other benefits at 3.5% per annum.

## BUSINESS ASSESSMENT (Option 2)

<b>Direct impact on business (Equivalent Annual) £m:</b>			<b>Score for Business Impact Target (qualifying provisions only) £m: N/A</b>
<b>Costs:</b>	N/A	<b>Benefits:</b> N/A	
		<b>Net:</b> N/A	

# Evidence Base

## Problem under consideration and rationale for intervention

1. Over the years, responsibilities relating to the supply of medicines have been extended to certain regulated health professional groups where it has been assessed as safe, appropriate, and beneficial for to patients to do so. This supports patients to receive the medicines they require from the professional who is best qualified to help them and means they do not need to see additional professionals simply to access these medicines.
2. Medicines legislation restricts who can supply, administer, and prescribe medicines. The Human Medicines Regulations 2012 (HMRs) set out the professions that can operate under specific medicines mechanisms, which are the legal routes for supply, administration and prescribing of medicines. Clinical cases for extending a mechanism to a regulated health professional group are developed between NHS England, DHSC the healthcare professional bodies and other key stakeholders. Changes are reviewed by the Commission on Human Medicines, who consider whether proposals are safe and appropriate, and provide their advice to Ministers. Only regulated health professions are considered for medicines responsibilities; this ensures professions have appropriate governance and meet professional standards set by the regulator. This structure for medicines responsibilities and process for considering change is in place to protect patients.
3. Dental hygienists and dental therapists are separately registered dental professionals who help maintain patients' oral health by treating and preventing dental disease. Dental hygienists treat periodontal disease, deliver dental caries (decay) prevention, and promote good oral health practice. Dental therapists also treat periodontal disease and dental caries, deliver dental caries prevention, and promote good oral health practice and in addition, dental therapists may also carry out direct restorations (fillings) on primary and secondary teeth, pulpotomies (nerve treatments) on primary teeth and extract primary teeth.
4. Dental hygienists and dental therapists are currently able to supply and administer medicines using patient specific directions (PSDs), and since 2010 they have been able to supply and administer medicines using patient group directions (PGDs). A PSD is a written instruction from a prescriber to administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine. PGDs provide a framework for allowing named, authorised, and registered health professions to supply and/or administer specific medicines to a defined group of patients requiring treatment for a condition detailed in the PGD, without the need for prescription or an instruction from a prescriber. Due to the administrative challenges associated with creating PGDs in dental practices that are generally small, their use is not widespread. This means dental hygienists and dental therapists often do not have access to the required mechanism to provide patients with the medicines they need where a PSD is not available.
5. Evidence suggests there are potential efficiency gains and improvements to patient experience and health outcomes if certain healthcare professions are able to supply,

administer and/or prescribe a wider range of medicines<sup>1,2</sup>. Currently, dental hygienists and dental therapists are commonly unable to supply or administer medicines, even if they are the first to identify the need for a medicine within a clear and established treatment pathway, and they can identify from patient records if the medicine would not be suitable for the patient. This leads to unnecessary consultations with other healthcare professionals such as dentists, which represents an inefficient use of public money and may delay access for patients who require their skills. It also inconveniences patients.

6. The delay in accessing medicines may worsen health (e.g., by causing pain) for patients if it prevents them having timely access to treatment. In some interventions, both professions are placed in a position of advising a dentist, who may be less familiar with the patient's case, or the medicines required to effectively carry out the care required. This practice was highlighted as a matter of concern within the Crown report (1999)<sup>3</sup>, and most recently by the General Medical Council (GMC)<sup>4</sup>.

## Policy objective

7. The objectives of the proposed change are to allow dental hygienists and therapists to work more fully in their full scope of practice in order to reduce interruptions and delays in the provision of patient care, and thereby: a) reduce inefficient use of health professionals' time; b) improve patient experience; c) improve patient health outcomes.

## Policy change – introducing supply/administration of medicines under exemptions by dental hygienists and dental therapists

8. In 2020, NHS England (NHSE) held public consultations on proposals to extend medicines responsibilities to additional regulated health professions. This included enabling dental hygienists and dental therapists to supply and administer a number of specific medicines under exemptions. This consultation ran from 15 October to 10 December 2020 and is available to view online.

## Summary of consultation response

9. Feedback from the consultation was overwhelmingly positive, with most respondents (97% of 2,743 responses) agreeing with the proposal to amend the HMRs to allow dental hygienists and dental therapists to supply and administer medicines under exemptions. The published results of the consultation can be found here: [Proposal to enable dental hygienists and dental therapists to supply and administer specific medicines under exemptions: consultation response - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/proposal-to-enable-dental-hygienists-and-dental-therapists-to-supply-and-administer-specific-medicines-under-exemptions-consultation-response)
10. Common themes amongst respondents were that the proposal would increase autonomy, resulting in workforce empowerment. It would also be an important step towards increased effectiveness and service optimisation.

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<sup>1</sup> Carey, N., Stenner, K., Edwards, J. (2017). *Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs*. Available at: [final-report.pdf \(surrey.ac.uk\)](https://www.surrey.ac.uk/~/media/Research/Reports/2017/01/20170101-Independent-Prescribing-Review-Final-Report.pdf)

<sup>2</sup> 15 Health (2015). *Non-Medical Prescribing (NMP) – An Economic Evaluation*

<sup>3</sup> Department of Health (1999). *Review of Prescribing, supply and administration of medicines (the Crown Report)*.

<sup>4</sup> Avery, T., Barber, N., Ghaleb, M. et al (2012). *Investigating the prevalence and causes of prescribing errors in general practice*.

11. We also consulted on measures to regulate the use of exemptions, which received strong support from respondents. We proposed that, rather than the GDC keeping an annotated register of all dental hygienists and dental therapists who have completed additional training to be able to use exemptions, dental practitioners and their employer would be responsible for ensuring exemptions were only used by those who had completed the training. Regulation of exemptions would therefore be captured in the ongoing requirements of registration with the GDC. 84% of respondents agreed with this proposal for regulating the use of exemptions, 11% stated that they didn't know and 5% disagreed.

## Description of options considered

### Option 1 – Business as usual/no change

12. Dental hygienists and dental therapists retain the ability to administer and supply medicines under PSDs and PGDs.

### Option 2 - Enable dental hygienists and dental therapists to supply and administer a specified list of medicines using exemptions within the Human Medicines Regulations

13. Currently dental hygienists and dental therapists are unable to administer a required medicine when a PSD or PGD is not in place, and must rely on a dentist, which is likely to cause a delay, both to the professionals and to the patient receiving the medicine. The proposed change would allow dental hygienists and dental therapists to use exemptions, which would give them the ability to administer and supply specific medicines without the need for a PSD or PGD, enabling clinicians to make more full use of the skills already within their scope of practice. This would improve the timeliness of treatment procedures, which has the following intended benefits:

- a. **Efficient use of health professional time** – Currently where a PGD is not in place and a medicine is required there is a burden on the dental hygienist/dental therapist who has to seek out and organise a PSD, and a dentist who has to see the patient and provide this. Removing this burden by allowing the dental hygienists/dental therapists to supply/administer the medicine using exemptions releases time that could be better used for more complex patient care.
- b. **Better patient experience** – Reducing delays in accessing the medicines required could improve patient convenience and satisfaction. Patients would no longer have to wait for health professionals during this time, or arrange, travel to and attend another appointment.
- c. **Improved patient health** – More timely access to treatment may reduce the risk of patients' conditions deteriorating. It may also reduce the risk that the dental hygienist or dental therapist is put in a position of advising an independent prescriber on what medicines are required to undertake specific treatments.

## Costs

14. Dental hygienists and dental therapists would be required to train to use exemptions. Given that 97% of those who responded to the consultation were in favour of the proposals, we anticipate seeing a strong demand for training to use exemptions as

dental services seek to implement the reform to the benefit of their practice and patients. Expert opinion of representatives from the professional bodies estimates that, within 5 years, 75% of the profession will be trained and then this will be the 'steady state' for this model. It is possible that this could be an under- or over-estimate of how many hygienists/therapists would undergo training, however, other than the initial costs to develop the training, the effects on the costs and benefits would increase or decrease relative to each other, for example a higher proportion of professionals undergoing training would incur a higher cost however this would also increase the benefit.

15. A draft Outline Curriculum Framework to prepare dental hygienists and dental therapists to use exemptions is being developed by NHS England in conjunction with key stakeholders, including the professional bodies and the General Dental Council. This framework will support education programmes to be developed at pace following legislation changes.
16. Based on the Outline Curriculum Framework, it is expected that the exemptions training will be delivered through online courses that dental hygienists and therapists will have access to. The duration of the training is expected to be about 2 days, and it is likely that separate training will be developed on different training systems for professionals who work in public vs. private practices.
17. We estimate that there are currently 10,810 dental hygienists and dental therapists (combined) in the UK, according to the General Dental Council<sup>5</sup>. We also assume that the number of people employed will increase by 2% per year. Using survey data on the proportion of professionals that work in public vs. private practices (See [Annex A](#)) we estimate that 40% of dental hygienists and therapists work mostly in the NHS, while 60% work mostly in private practice.

### **Professionals working in the NHS**

18. Based on comparator training regimes, the cost to develop the training delivered to professionals who work in the NHS, is expected to be between £450,000 and £500,000. In order to give a conservative estimate of the costs, we have used the upper limit of this range in our modelling, assuming that development of the training will cost £500,000. It is expected that the NHS will cover these costs, with no cost implication for the 40% of learners who work in NHS practices.
19. We also estimate the backfilling cost for learners, which we have based on the unit cost (including on-costs) of the professional estimated at £42.28 per hour<sup>6</sup>. The hourly cost of staff covering colleagues' absence is assumed to be the same as there are no (or marginal) capital or management costs associated with the additional cost of staff backfill. Multiplying the unit cost by the duration of the training (assumed to be 15 hours) gives a backfilling cost of £634 per professional being trained.
20. Those working in the NHS will mostly work as subcontractors, and so will likely bear the costs of the time required to train themselves. However, in order to avoid risks of understating the costs to the NHS, we assume that the cost to backfill the professional are passed on to NHS providers. We have therefore calculated the backfill costs that will accrue to the NHS, based on the assumption that 40% of learners will work in NHS practices.

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<sup>5</sup> General Dental Council (2024) Registration Report – April 2024

<sup>6</sup> Based on the mid-point of the annual salary range according to the National Careers Service for [dental hygienists](#) and [dental therapists](#), with additional on-costs estimated using dentist (provider-only) unit costs from the [PSSRU](#) (excluding direct staff employee expenses which may include the cost of employing dental hygienist/therapists).

21. Combining the costs to develop the training for NHS colleagues, and the costs to backfill their learning time, the total undiscounted training cost over 5 years to reach the 'steady state' is estimated to be £2.4m. The total undiscounted training cost over 10 years is estimated to be £2.6m.
22. In line with department impact assessment guidance, the opportunity cost of the training that accrues to the NHS has been calculated based on the estimated values that the value of a Quality Adjusted Life Year (QALY) is £70,000, and the NHS funds that can be used to generate a QALY is £15,000 at the margin, due to budget constraints on providers. This relationship suggests that the total opportunity cost of costs accruing to the NHS, over the 10 year appraisal period, is £13.6m. In accordance with the discounting rates recommended in the Green Book<sup>7</sup>, discounting NHS costs at 1.5% per annum and non-NHS costs at 3.5% per annum, we estimate a present value cost of £13.1m

### **Professionals working in private practices**

23. For professionals who work in private practices, it is assumed that external education providers will also develop online training courses similarly based on the Outline Curriculum Framework. Based on comparator online training courses, we estimate the cost of training will be £325 per professional<sup>8</sup>. The costs to attend this training is expected to fall to learners.
24. As with professionals who work in NHS practices, we also estimate the backfilling cost for learners, which we have based on the unit cost (including on-costs) of the professional estimated at £42.28 per hour<sup>9</sup>. The hourly cost of staff covering colleagues' absence is assumed to be the same as there are no (or marginal) capital or management costs associated with the additional cost of staff backfill. Multiplying the unit cost by the duration of the training (assumed to be 15 hours) gives a backfilling cost of £634 per professional being trained.
25. The undiscounted total cost to train professionals working in private practice, including both the assumed training cost and the cost to backfill, is estimated to be £17.5m. In accordance with the discounting rates recommended in the Green Book<sup>10</sup>, discounting NHS costs at 1.5% per annum and non-NHS costs at 3.5% per annum, we estimate a present value cost of £14.4m.

### **Combined costs**

26. The undiscounted combined cost of training professionals who work both in the NHS, and in private practices, including opportunity costs, is £31.1m. The discounted cost is estimated to be £27.5m.

### **Unquantified costs**

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<sup>7</sup> [The Green Book \(2022\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/106503/green-book-2022.pdf)

<sup>8</sup> Based on comparative online training courses, uplifted to be equivalent to a 15-hour course e.g., [ONLINE - NHS Dentistry - Practising Within the Rules, Regulations & Dental Assurance Framework - LonDEC](https://www.nhs.uk/online-learning/online-learning-for-dentists/)

<sup>9</sup> Based on the mid-point of the annual salary range according to the National Careers Service for [dental hygienists](https://www.nhs.uk/online-learning/online-learning-for-dentists/) and [dental therapists](https://www.nhs.uk/online-learning/online-learning-for-dentists/), with additional on-costs estimated using dentist (provider-only) unit costs from the [PSSRU](https://www.pssru.ac.uk/) (excluding direct staff employee expenses which may include the cost of employing dental hygienist/therapists).

<sup>10</sup> [The Green Book \(2022\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/106503/green-book-2022.pdf)



27. It is expected that exemption training will also be added to the undergraduate curriculum for training dental hygienists and therapists. This would mean that, in the future, new graduates would not need to complete the online exemption training looking to be developed here. Future overseas graduates would still likely be required to undertake the training. The additional costs to incorporate this training into undergraduate training have not been considered here, however we would expect a similar level of benefit for each professional as considered below.

## **Risk of inappropriate administration of medicines**

28. If dental hygienists and dental therapists are able to supply and administer medicines to a patient under exemptions, there is the potential that they will mistakenly supply or administer a medicine that is unsuitable for the patient. If this becomes more likely than in current practice, there will be an associated net health cost. In the 2023 consultation, the training and qualifications that registered dental hygienists and dental therapists must obtain was raised by respondents. It was suggested that practitioners are trained to use the medicines and understand the risks involved.

29. There is little published information testing differences in inappropriate medicines usage or medicines error resulting from expansions in medicines responsibilities. The most extensive relevant study finds no difference between nurse prescribers and consultant doctors, and that nurses outperform junior doctors<sup>11,12</sup>. Previous evaluations do not find any evidence of increased risk of medicines errors<sup>13</sup>.

30. The Commission on Human Medicines determined that while there was a lack of evidence of the benefits and risks involved in the use of the medicines, commissioners agreed the risks were low. This is because hygienists and therapists would be working in the context of a dental practice led by a dentist and the proposed list of medications was modest. On balance, we conclude that there is unlikely to be an increase in the risk of inappropriate administration and supply of medicines. We discuss this further in paragraphs 53-56.

## **Benefits**

### **Method**

31. We estimate the benefits per average affected appointment, and scale this up to the total number of appointments per year for the whole workforce in order to estimate the total benefits. In our calculations of averages, we only include the appointments where the process would be affected by the change. The BSDHT conducted a member survey in 2015<sup>14</sup> (unpublished) and the data has been used here (n=721), which is presented in Annex A, with questions asked in the survey available in Annex B.

32. The survey data required a significant amount of interpretation. In this process we were purposefully conservative in our interpretation of the frequency of affected appointments

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<sup>11</sup> Ashcroft, D., Lewis, P., Tully, M. (2015). Prevalence, Nature, Severity and Risk Factors for Prescribing Errors in Hospital Inpatients: Prospective Study in 20 UK Hospitals. *Drug Safety*, 38:833-843

<sup>12</sup> Seden, K., Kirkham, J., Kennedy, T., Lloyd, M., James, S., Mcmanus, A., Ritchings, A., Simpson, J., Thornton, D., Gill, A., Coleman, C., Thorpe, B., Khoo, S. (2012). Cross-sectional study of prescribing errors in patients admitted to nine hospitals across North West England | *BMJ Open*

<sup>13</sup> Carey, N., Stenner, K., Edwards, J. (2017). Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs. Available at: [final-report.pdf \(surrey.ac.uk\)](https://www.surrey.ac.uk/final-report.pdf)

<sup>14</sup> BSDHT (2015) Member survey: Prescription only medicines in use – Not published

(e.g. if someone reported that most of their appointments were affected, and that they had 30-39 appointments a week, then we assumed that 15 were affected, or if someone said “rarely”, we assumed that in an average week none were affected). We also model an additional, more conservative sensitivity analysis, which is described in paragraphs 47-48.

33. The survey data collected suggests that in 9 of the 50 appointments that dental hygienists and dental therapists have per week they come up against the issue of being unable to supply and administer the medicines that their patients need. We assume that all of these could be resolved by the ability to administer/supply under exemptions, based on the expert opinion of representatives from the professional body.

### **Efficiency**

34. There are two sources of efficiency benefits. The first area of inefficiency in current practice is the time wasted by the dental hygienists/dental therapists in trying to locate a dentist to prescribe the required medicines, which results in delayed treatment. In the survey used, dental hygienists and dental therapists were asked about the delays resulting from this barrier to supply and administration, and the frequency of these delays. There were responses where the reported delays were inconsistent with the reported number of incidences that the barrier was faced (for example, if the barrier was reported to be faced 10 times, and more than 10 delays were reported). For the main analysis, we took the delays reported at face value, assuming that any errors would be balanced out and negligible over the whole sample. In sensitivity analysis in paragraphs 47-48, we adjust for over-counting by reducing the number of delays.
35. Of the 9 delayed appointments per week, the survey data suggested that 5 resulted in a minor (0-10 minute) delay, 3 resulted in a major (10+ minute) delay, and 1 resulted in a rearranged appointment. We assume that these delays represent inefficient search time by the dental hygienist/dental therapist. Assuming a minor delay wastes an average of 5 minutes of dental hygienist/dental therapist time, and both a major delay and rearranged appointment waste an average of 15 minutes of dental hygienist/dental therapist time, we estimate that when the required mechanism is not in place, the average wasted dental hygienist/dental therapist time is 9.4 minutes per affected appointment. Using the unit costs of the dental hygienist/dental therapist (£42.28, including on-costs), this gives an average estimated cost of £6.62 per appointment, which would be removed by the proposed option.
36. The second source of efficiency benefit represents the savings to other professional's time. Once a dentist has been located, there is another source of inefficiency in that the dentist has to prescribe the required medicines that could have been competently supplied and/or administered by the dental hygienist/dental therapist, thus wasting the dentist's time. Generally, when the patient's dentist is in the same practice, a reassessment is not necessary. The survey data suggests this happens 6.5 of the 9 times, and it uses 3.6 minutes of dentist time. When a reassessment is needed, this requires more of the dentist's time; the survey data suggests that this happens in 2.5 of the 9 appointments and takes 5.6 minutes of dentist time. We therefore estimate that the average wasted dentist time when the required mechanism is not available is 4.2 minutes. Using the unit cost of a dentist estimated at £123.21 (based on the hourly cost including on-costs for performer only

dentists<sup>15</sup>), this is a cost of £8.54 per appointment that would be removed by the proposed option.

### Patient Experience

37. We consider the impact on patients to be an ‘inconvenience cost’ due to delay or having to make additional appointments. Firstly, as described in paragraph 23, there is an average delay of 9.4 minutes per affected appointment. Secondly, approximately 1 in 9 affected appointments are estimated to result in a rearranged appointment. We assume that this requires an additional 45 minutes of patient time, which takes into account the hassle of rearranging the new appointment, attending including travel. This suggests an average 16.1 minutes wasted patient time per appointment that is affected by current restrictions.
38. The Department of Transport published research in 2015 on the value of ‘delayed travel time’. They estimate that for all modes/distances that travellers would be willing to pay (workers and non-workers) on average £11.21 in order to save one hour of travel time<sup>16</sup>. To bring this figure into 2024/25 pricing we have updated this in line with GDP inflation to £14.32. We consider this as the cost of wasted patient time, and an indication of patient dissatisfaction resulting from delays, although this is likely to underestimate the anxiety and inconvenience for patients.
39. Using the average wasted time of 16.1 minutes per affected appointment; we estimate that a current cost of £3.84 per affected appointment could be avoided as a result of the proposed changes.

### Health benefits

40. Dental hygienists and dental therapists can identify anatomical features, recognise abnormalities, and interpret common pathology. They can carry out a clinical examination, diagnose and plan treatment within their scope of competence. Unnecessary delays in treatment could cause ongoing suffering/anxiety with the risk of a worsening in condition. A delay in treatment may cause ongoing suffering/anxiety, and there is a risk of escalation of conditions. Neither of these effects is quantified, as we have insufficient data to attempt to scale it.

### Total benefits

41. This gives a total benefit of £19.00 per appointment affected, or £7,673 per professional per year. These assumptions and resulting benefits are expressed in Table 1.

Table 1. Lost Time and Unit Cost for two professions and patients.

Dental hygienists/ Dental therapists		Dentist		Patient		Total
(£42.28 per hour)		(£123.21 per hour)		(£14.32per hour)		
Time lost	Cost (£)	Time lost	Cost (£)	Time lost	Cost (£)	Cost (£)

<sup>15</sup> PSSRU, Unit Costs Database of Health and Social Care Professionals, 2020/21, available at: [Unit Costs of Health and Social Care / PSSRU](#)

<sup>16</sup> Department of Transport (2015). *Provision of market research for value of travel time savings and reliability*

	(mins)		(mins)		(mins)		
Average per affected appointment	9.4	£6.62	4.2	£8.54	16.09	£3.84	£19.00
Total per professional per year	3,800	£2,673	1,700	£3,449	6,500	£1,551	£7,673

42. Based on the modelling of the number of professionals, this approximates to an undiscounted benefit over 10 years of £543.9m. Using survey data on the proportion of professionals that work in public vs. private practices and excluding the patient wellbeing benefits, we estimate benefits to the NHS of £2,449 per professional per year, or £173.6m (undiscounted) over 10 years.
43. In line with department impact assessment guidance, the opportunity cost of the training that accrues to the NHS has been calculated based on the estimated values that the value of a Quality Adjusted Life Year (QALY) is £70,000, and the NHS funds that can be used to generate a QALY is £15,000 at the margin, due to budget constraints on providers. Taking account of this relationship, we estimate an undiscounted £810.0m of benefits from NHS savings. This relationship does not hold true for individuals and private practices, as they do not face the same budget constraints, and so there is assumed to be no difference between the cost of producing a QALY and the value of a QALY. Adding the adjusted NHS benefits (£894.8m) and the non-adjusted other benefits (£370.3m) gives the total undiscounted benefits of £1,180m. Discounting NHS benefits at 1.5% per annum and non-NHS (private practice and patient) benefits at 3.5% per annum, we estimate a present value benefit of £1,021m.

### Sensitivity analysis

44. We made an adjustment to our assumptions in a sensitivity analysis, based on limitations of the survey data. As discussed in paragraph 22, there were issues where responses on the number and nature of delays were inconsistent with the number of incidences that the barrier was faced (for example, where the barrier was reported to be faced 10 times, but more than 10 delays were reported). For those who reported a higher number of delayed appointments than the total number of appointments affected, there was a total excess of 1900 appointments (across the 721 respondents). This indicated an average of 2.6 excess delays per professional, and we adjusted down the number of delays to account for this (from 9 to 6).
45. We assumed that distribution of the nature of these excess delays (i.e. split of minor, major and rearranged appointment) was the same as the distribution of total reported delays. For example, 60% of reported delays across the sample were minor, and so 60% of the excess was assumed to be over-reporting of minor delays. The result is that the sensitivity analysis does not change the average benefit per affected appointment but does change the annual benefit per professional. Table 2 expresses the assumptions and resulting benefits used in the sensitivity analysis.

Table 2. Lost Time and Unit Cost for two professions and patents, sensitivity analysis

	<b>Dental hygienists/ Dental therapists</b>		<b>Dentist</b>		<b>Patient</b>		<b>Total</b>
	<b>(£42.28 per hour)</b>		<b>(£123.21 per hour)</b>		<b>(£14.32 per hour)</b>		
	Time lost (mins)	Cost (£)	Time lost (mins)	Cost (£)	Time lost (mins)	Cost (£)	Cost (£)
Average per affected appointment	9.4	£6.62	4.2	£8.54	16.1	£3.84	£19.00
Total per professional per year	2,700	£1,904	1,200	£2,457	4,600	£1,105	£5,466

46. Making these adjustments resulted in a present value benefit of £840.8m, with a discounted benefit of £739.2m. If we consider the central estimate as the mid-point of the sensitivity analysis and our main analysis estimate of £1,011m, giving a total discounted benefit £888.4m.

### Net Benefits

47. Net benefits are the difference between the total benefits and the total costs. The discounted net present value is estimated to be £1,010m for the main analysis. Using the sensitivity analysis, we estimate a net present value of £711.6m. Considering the best estimate as the mid-point of the main analysis and the sensitivity analysis gives a total net present value of £860.9m. Table 3 below provides a summary over 10 years, with this table provided for lower and upper estimates in Annex C.

Table 3. Summary of 10-year costs and benefits, central estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	1.9	14.5	12.6
Year 2	1.5	29.6	28.1
Year 3	1.5	45.2	43.7
Year 4	0.8	53.8	53.0
Year 5	0.5	58.8	58.3
Year 6	0.2	60.4	60.2
Year 7	0.1	61.2	61.1
Year 8	0.1	62.4	62.3
Year 9	0.1	63.7	63.5
Year 10	0.1	64.9	64.8
<i>Total (undiscounted)</i>	6.6	465.6	459.1
<i>Total (discounted)</i>	6.3	424.7	418.4
<b>Total with opportunity costs (undiscounted)</b>	<b>31.1</b>	<b>1,010</b>	<b>979.4</b>
<b>Total with opportunity costs (discounted)</b>	<b>27.5</b>	<b>888.4</b>	<b>860.9</b>

## Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

48. Research by the University of Surrey is looking into the impact of supplementary prescribing by dietitians and independent prescribing by radiographers. This research may provide learnings more broadly for the introduction of medicines mechanisms by regulated health professionals<sup>17</sup>. There is not a significant amount of data available on the possible impacts of these changes, and so using survey responses from the BSDHT, reality checked by the Chief Professions Officers' Medicines Mechanism (CPOMM) programme: exemptions working group (which includes professional bodies, regulators and staff from NHS England) and interpreted cautiously by analysts is appropriate.

### Risks and assumptions:

49. We believe our estimates of the monetised value of the benefits of this change are reasonable. The areas of greatest uncertainty are the frequency of affected appointments. We have tried to account for these uncertainties by including a sensitivity analysis around the frequency of affected appointments.

### Risks of inappropriate administration of medicines

50. In our main analysis, we have not attempted to quantify any risks of the potential harm to patients (health loss) that might occur if inappropriate supply or administration of medicines is more likely as a result of the proposed changes.

51. Although the evidence suggests this is unlikely, we have attempted to conduct a break-even analysis to understand the scale of this risk. We try to estimate how much the rate of medicines errors would need to increase to offset the benefits.

- a. A medicine error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient. The frequencies of medication errors are not known with any precision either in general or in specific settings, but limited data below reveals they are quite common but that they do not always result in noticeable harm. A UK hospital study of 36,200 medication orders found that a prescribing error was identified in 1.5% of cases and a serious error occurred in 0.4% of cases<sup>18</sup>. We take this 1.5% as the baseline medicines error rate<sup>19</sup>.
- b. We estimate the cost of a medicines error based on a study on the costs and benefits of reducing prescription errors<sup>20</sup>. They identify six medicines<sup>21</sup> where errors are clinically important and estimate the QALY difference between prescriptions with and without errors using parameters from the literature. Using these estimates, and the relative frequency of these, we estimate that prescription errors cost an average of 0.08 QALYs. Given that the medicines considered were chosen based on the known clinical effect, we assume that this represents the 0.4% of serious errors and assume that the rest of the errors

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<sup>17</sup> Evaluation of supplementary prescribing by dietitians and independent prescribing by radiographers | University of Surrey

<sup>18</sup> Dean B, Schachter M, Vincent C, Barber N. (2002) Prescribing errors in hospital inpatients: their incidence and clinical significance, *Qual Saf Health Care*, vol. 11 (pg. 340-4)]

<sup>19</sup> This error rate is based on a higher number of medications compared to the list in the proposed option and is therefore indicative. The true rate is likely to be lower.

<sup>20</sup> Elliott, R.A., Putman, K.D., Franklin, M. *et al.* Cost Effectiveness of a Pharmacist-Led Information Technology Intervention for Reducing Rates of Clinically Important Errors in Medicines Management in General Practices (PINCER). (2014) *PharmacoEconomics* **32**, 573–590

<sup>21</sup> NSAIDs, Beta blockers, ACEIs, Methotrexate, Lithium, Amiodarone

have no effect. This results in a QALY cost per error of 0.02. Valuing a QALY at £70,000<sup>22</sup>, this suggests an economic cost per medicine error of £1,500.

- c. Given this cost per medicines error, we estimate that the net benefits would only be offset if the error rate were more than 10 times higher than the current error rate. This suggests that the conclusion that we would not expect these changes to be very sensitive to the theoretical risk of increased inappropriate supply or administration of medicines.
- d. Note that this analysis is highly uncertain; we have taken a conservative approach to estimating the value of risk in QALYs using a study on six medicines that are a higher risk than the medicines considered in the proposed option. We believe the error rate is likely to be an overestimate. It is also not clear that the rate of prescription error would be the same rate of administration or supply error, the estimated costs are not likely to be representative of a dental hygienist's / dental therapist's practice, and it is a simplification to assume that an error rate is attributable to a single professional or factor.

52. The likelihood of any increased risk in inappropriate administration of medicines is considered to be low. This is for four main reasons:

- e. Eligible dental hygienists and dental therapists wishing to access exemptions would be required to gain entry to and successfully complete an approved training programme. They would also be required to undertake appropriate steps to maintain their skills and competence in keeping with the GDC Standards for the dental team.
- f. The use of exemptions will be limited to medicines that dental hygienists/dental therapists are already competent in administering. This reduces risks of selecting the wrong medicines.
- g. The dental hygienist/dental therapist will have access to the patient's notes, and so would be in a position to understand if they have any contraindication, allergies or previous adverse reactions to the medicine required.
- h. Due to their proximity to the patient, the dental hygienist/dental therapist may have a better understanding of their history and situation than a dentist who has not previously met them. They may therefore be in a better position to understand the patient's suitability for the medication.

53. Although we think any increased risk in inappropriate administration of medicines is unlikely, there are a number of processes in place that mitigate any risks:

- i. Practice guidance to be published will advise regarding ongoing training and supervision, adherence to local formularies and working within scope of practice and competence.
- j. If an error in supply or administration occurs whilst using exemptions, dental hygienists and dental therapists must take immediate action to manage the effects on the patient, prevent potential side effects to the patient and must

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<sup>22</sup> Green Book (2022) [The Green Book \(2022\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/106422/green-book-2022.pdf)

report the error as soon as possible according to local protocols. The reporting of errors must be in an open and transparent way, in order that anything learned from the incident is shared as appropriate.

- k. If a patient experiences an adverse reaction to a medication: once the required treatment has been undertaken, this should be recorded in the patient's notes and, if indicated, the Medicines and Healthcare products Regulatory Agency should be notified via the Yellow Card Scheme. Dental hygienists and dental therapists are expected to be able to recognise common side effects and adverse reactions to the medicines they administer, and to know when there is a potential risk of an interaction.
- l. Lack of compliance with standards would lead to action from the GDC which could include removal from the professional register.

### **Private sector impact**

- 54. The change in legislation will have an impact in any setting in which dental hygienists and dental therapists work, including the independent sector. Dental hygienists and dental therapists undertaking private practice will be able to utilise the exemptions in the course of their work and within their scope of practice and competence if the relevant training is completed.
- 55. In addition, employers outside the NHS have the same roles and responsibilities as those within the NHS to implement the same standard of local governance arrangements related to the safe storage, supply, and administration of medicines. The requirement for good medicines governance is unchanged in private practice and dental hygienists and dental therapists operating in this way must follow all required safe custody and governance processes.

### **Effects of inflation**

- 56. To capture the impact of inflation, the GDP Deflator Index has been used. As per the GDP Deflator Index, inflation between financial years 2021/22 and 2022/23 rose by 6.74%<sup>23</sup>. Between the financial years 2022/23 to 2024/25 this is further projected to rise by 7.34%<sup>19</sup>. Further sensitivity analysis, however, taking the increase in inflation into account has not been carried out for this impact assessment. The proposed policy would enable dental hygienists/therapists to undergo training to supply and administer a wider range of medicines under exemptions to free up dentists' time. Training to use exemptions is optional and it would be for practices to determine whether it would be beneficial for their area. The costs of training are likely to be borne by the professionals who undergo the training and therefore the proposed policy does not commit to spending.
- 57. By freeing up dentists' time, this creates a cost saving when comparing hourly pay rates for dentists and dental hygienists/therapists and therefore elements of the IA modelling are based on unit costs of dental professionals' time. This element has not been modelled as dental professionals pay is negotiated individually on an annual basis, so there is a large amount of uncertainty in terms of future wage levels.

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<sup>23</sup> GDP deflators at market prices, and money GDP March 2024 (Quarterly National Accounts) - GOV.UK ([www.gov.uk](http://www.gov.uk))



## Monitoring and Evaluation

58. We will engage with the sector regularly to understand the impact of the regulation changes. The Department has no separate plans to formally evaluate the policy because local monitoring of the changes will be undertaken through the clinical governance schemes that already exist in the practices where the exemptions are utilised.
59. Under existing legislation all registered dental hygienists and dental therapists are regulated and accountable to the General Dental Council (GDC).
60. Section 46 of the Medicines and Medical Devices Act 2021 (MMDA) requires the Secretary of State to lay a report before Parliament every two years on the operation of regulations made under section 2(1) (and other powers under the Act) with the next reporting period concluding in July 2025. Consequently, the instrument does not include a bespoke statutory review clause. In line with the requirements of the Small Business, Enterprise and Employment Act 2015, Minister Andrea Leadsom has made the following statement:

*“It is not appropriate in the circumstances to make provision for review in this instrument. This is because there is already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months”.*

## Annex A

### Survey Data

(Survey conducted by the British Society of Dental Hygiene and Therapy)

In the last week...	Main analysis	Sensitivity analysis
Number of appointments	50	50
Number where prescription barrier faced	8.8	6.3
5 minute delay	4.9	3.5
15 minute delay	2.5	1.8
Rearranged appointment	1.3	0.9
Time wasted for patient	16.1	16.1
Time wasted for professional	9.4	9.4
Supporting data	Frequency	Time to prescribe
No reassessment	6.4	3.6
Other dentist	2.4	5.6
Average		4.2

Practice

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NHS 40%

Private 60%

## Annex B

### Questions asked in the BSDHT survey

How many patients do you see in a week?

- 0-9
- 10-19
- 20-29
- 30-39
- 40-49
- 50-59
- 60+

What length is your average appointment time?

- 15 mins
- 20 mins
- 30 mins
- 1 hour
- Other

How many times this week did you have to deal with a patient where there wasn't an appropriate PSD/PGD in place?

Of these, how many resulted in a minor delay to treatment? (0-10 minutes)

Of these, how many resulted in a significant delay to treatment? (10+ minutes, not including rearrangement)

Of these, how many resulted in rearranging an appointment?

When there wasn't an appropriate PSD/PGD in place (in a typical week), and you had to get a prescription from another professional which professional usually provides the prescription? (drop down list of possible professionals)

- The patient's dentist
- Any dentist on the premises
- Principle dentist
- Patient's doctor
- Other (please specify)

How many times did it require a reassessment of the patient?

When it did not require a reassessment of the patient, how much of another professional's time does it typically take? (minutes)

- 1-2 mins
- 3-5 mins
- 5+ mins

How long would a reassessment take?

- 0-2 mins
- 3-5 mins
- 6-10 mins
- 10+ mins

How would you describe your practice?

- Private
- Mixed but mainly private
- Mixed but mainly NHS
- NHS

To have an accurate picture of money lost it would be helpful to understand how much the running costs for your surgery per hour are. Could you please provide the following information?

(This information will be anonymised and typical surgery running costs will be factored into this)

What is your daily rate, assuming normal practice hours, to the dental practice?

What is the daily total of patient's payment (NHS/Private) to the practice for your services?

Do you have nursing support?

## Annex C

### Summary of 10 year costs and benefits, lower estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	1.9	12.1	10.2
Year 2	1.5	24.6	23.1
Year 3	1.5	37.6	36.1
Year 4	0.8	44.8	43.9
Year 5	0.5	48.9	48.4
Year 6	0.2	50.2	50.1
Year 7	0.1	50.9	50.8
Year 8	0.1	51.9	51.8
Year 9	0.1	53.0	52.8
Year 10	0.1	54.0	53.9
<i>Total (undiscounted)</i>	<i>6.6</i>	<i>387.47</i>	<i>380.9</i>
<i>Total (discounted)</i>	<i>6.3</i>	<i>353.4</i>	<i>347.1</i>
<b>Total with opportunity costs (undiscounted)</b>	<b>31.1</b>	<b>840.8</b>	<b>809.7</b>
<b>Total with opportunity costs (discounted)</b>	<b>27.5</b>	<b>739.2</b>	<b>711.6</b>

### Summary of 10 year costs, upper estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	1.9	16.9	15.0
Year 2	1.5	34.5	33.1
Year 3	1.5	52.8	51.3
Year 4	0.8	62.8	62.0
Year 5	0.5	68.7	68.2
Year 6	0.2	70.5	70.4
Year 7	0.1	71.5	71.4
Year 8	0.1	72.9	72.8
Year 9	0.1	74.3	74.2
Year 10	0.1	75.8	75.7
<i>Total (undiscounted)</i>	<i>6.6</i>	<i>543.9</i>	<i>537.3</i>
<i>Total (discounted)</i>	<i>6.3</i>	<i>496.1</i>	<i>489.8</i>
<b>Total with opportunity costs (undiscounted)</b>	<b>31.1</b>	<b>1,180</b>	<b>1,149</b>
<b>Total with opportunity costs (discounted)</b>	<b>27.5</b>	<b>1,038</b>	<b>1,010</b>