



Llywodraeth Cymru  
Welsh Government

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Regulatory Impact Assessment Document

## **A Regulatory Impact Assessment on proposals to reform the ophthalmic services delivered in primary care in Wales.**

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Mae'r ddogfen hon ar gael yn Gymraeg hefyd / This document is also available in Welsh  
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## Introduction and Guidance

Regulatory Impact Assessments (RIAs) provide Welsh Ministers, the Accounting Officer, Senedd Cymru and stakeholders with information on the likely impact of proposed legislation and can be regarded as:

- a process to help the Welsh Ministers consider the impact of proposed regulation on the interests of individuals, groups, organisations;
- a tool to enable the Welsh Ministers to weigh the costs and benefits of all options available to them before implementing a policy;
- and a means of presenting for scrutiny the relevant evidence on the positive and negative effects of such interventions.

The Welsh Government is committed to reforming the provision of ophthalmic services in Wales and this RIA provides an assessment on the likely costs, benefits and risks associated with the proposed legislative changes. Those who may have an interest in this assessment include service users, health boards, persons who provide or may wish to apply to provide NHS ophthalmic services, persons who assist in the provision of ophthalmic services or may wish to apply to assist in the provision of such services, and representative bodies.

This RIA accompanies an eight-week consultation which sets out the detail of the Welsh Government's proposals to reform the ophthalmic services delivered in primary care in Wales.

The Welsh Government has also prepared an *Integrated Impact Assessment (IIA)* alongside the consultation which has considered the main impacts of the policy delivery.

## Options

The [NHS Wales Eye Healthcare: Future Approach for Optometry Services](#) document sets out the Welsh Government's expectations for delivery of eye care services over the next decade. The focus is to improve access to eye health services, enabling patients to access services delivered by the right professional, in the right place across the entire eye care pathway of primary and community care optometry and specialist hospital eye care. Delivering on this programme requires changes to the legislation to accelerate access to eye care services in primary and secondary care.

The options are as follows:

### **Option 1 - Business as usual and leave as the status quo by retaining the existing secondary legislation as it is with no changes:**

Delivering on many of the key commitments for reform outlined in the [Programme for Government](#) and the nationally agreed *Future Approach for Optometry Services in Wales* require changes to the legal framework as the scope of services and terms of service applying to those providing ophthalmic services are set out in legislation.

Specifically, the reform requires the consolidation of two existing sets of regulations into one main set of regulations provisionally titled the National Health Service (Ophthalmic Services) (Wales) Regulations 2023. The new set of regulations will

include provisions to enable the Welsh Government to expand the types of eye care services provided in primary care.

Retaining the status quo and maintaining the legislative framework as it currently stands will not meet the demand for ophthalmic services in Wales which is predicted to increase significantly over the next 20 years linked to an increasingly elderly patient cohort and increased population. This data source is from the Royal College of Ophthalmologists, the College of Optometrists and Third Sector. A key driver for change is the need to alleviate pressure on hospital eye departments. Moving the delivery of some eye care services from hospitals to primary care optometry, where there is a skilled workforce with the capacity to meet the predicted substantial increase in demand, is the most viable and sustainable solution.

This is only achievable through amending and replacing the legislation which will enable an increase in the range of services delivered closer to home in primary care, by a trained and equipped workforce.

**Option 2 - Make no changes to the legislation and recruit more specialist eye doctors (ophthalmologists) to work in Hospital Eye Services (HES):**

Again, this option does not fulfil the obligations set out in Future Approach for Optometry Services in Wales in terms of introducing new eye care pathways to reduce the number of referrals into HES which can only be achieved through adjusting the legislation. Primary care optometry services in Wales are especially equipped to meet the challenges relating to eye health care as a result of the efforts undertaken to upskill the workforce in primary care settings over recent years. This whole pathway approach lends itself particularly well to eye care in Wales where a redistribution of the demand can be achieved with an upskilled workforce.

Furthermore, in practical terms, advanced eye health treatment and ongoing management can no longer be solely delivered in secondary care by HES, as there simply isn't the available workforce to do so, now or in the future as is highlighted in the [External Review of Eye Care Services in Wales \(rcophth.ac.uk\)](https://www.rcophth.ac.uk) September 2021 report. Capacity to provide hospital services is far below the demand for specialist eye care services, which has been exacerbated by the Covid 19 pandemic and a shortage of qualified personnel.

The Welsh Government is committed to improving health care services in Wales and improving provision for people with poor eye health is a priority. Retaining the status quo in terms of the legislation would not improve patients' access to eye health services as it would not bring into being the creation of shared care services outlined in *A Future Approach for Optometry Services*.

For these reasons, this option has been discounted.

**Option 3 - Revise the current framework within existing powers by updating the existing secondary legislation:**

With this option, the creation of shared care services will be brought into being which would expand the provision of ophthalmic services to encompass wider eye health

so that such services may be delivered in primary care. The new ophthalmic services Regulations and Directions would deliver the reform of the provision of eye care services in Wales, the focus of which is on holistic eye health care.

The new legislation will expand the services which LHBs are required to arrange when making arrangements for ophthalmic services, the scope of what constitutes as general ophthalmic services and will accelerate eye health care delivery for health professionals and citizens across Wales. The increase in clinical services delivered by optometrists, working together with hospital eye departments, will provide NHS Wales with assurance that delivery will be equitable, consistent, and timely for all citizens across Wales.

The emphasis for all eyecare services, both in hospital settings and in primary care optometry practices, must be on achieving earlier detection of eye health problems to help reduce sight loss. The changes to the legislation will increase timely access to 'sight testing', holistic eye health examinations and eye health treatment and management in primary care.

The increase in sight loss has a significant effect on the wider health and social services systems due to a number of associated factors. The effect upon patients due to a of loss of independence, trips, falls and mental health problems, including depression is far reaching from both a quality-of-life perspective and also a financial perspective, particularly for those of working age with sight loss.

#### **Welsh Government Costs:**

There will be some increase in costs due to delivery of improving services and the Welsh Ministers have agreed funding in 2022/23 of £15m, 2023/24 of £25m and £30m in 2024/25. This will be in addition to the existing budget of £43m per year to invest in and deliver the transformed NHS Wales Ophthalmic Services.

#### **Public Sector costs:**

The implementation and enforcement of these regulations will not constitute additional costs for Local Authorities. There will be minimal or no impact on the justice system and no additional costs to Police Forces in Wales.

#### **Cost to individuals**

The Welsh Ministers are required under section 129 of the NHS (Wales) Act 2006 to provide for payments to be made to help with the cost of sight tests and optical appliances (spectacles or contact lenses) for certain categories of eligible person.

Support is available to eligible patients towards the cost of optical appliances via the provision of an optical voucher which they can take to any supplier of their choice. The voucher may be used to either meet or contribute towards the cost of the patient's spectacles or contact lenses depending on the amount charged by the supplier for the relevant optical appliance and the voucher value. In return, ophthalmic practitioners / suppliers of optical appliances are able to redeem the optical voucher value from NHS Wales.

The supply of an optical appliance (through an optical voucher) is a patient benefit for the most vulnerable in our society and not a means of additional income for an optometry practice.

The proposed draft National Health Service (Optical Charges and Payments) (Amendment) (Wales) Regulations 2023 will make small amendments to the eligibility criteria to include prisoners on leave as eligible for vouchers in certain circumstances, and to provide that under 18-year-olds in care of a local authority are eligible for all optical vouchers. There will also be a change in NHS optical voucher values that assist with the cost of appliances.

Assessment of the current optical voucher system highlighted inequity for patients with higher prescription needs, as the current voucher provided to patients at the higher prescription ranges does not, in all instances, cover the cost of the optical appliance. This results in patients at greatest need, both financially and clinically, often being asked to make significant financial contributions to the cost of their spectacles, despite being eligible for financial support.

Amending the National Health Service (Optical Charges and Payments) Regulations 1997 (“the 1997 Regulations”) will enable the Welsh Government to provide an amended payment structure, reflecting new optical voucher values that more accurately represent the standard cost of the optical appliance across all prescription ranges.

A key intention underpinning this legislative development is to ensure continued equitable access for eligible patients across all prescription (lens strength) ranges.

To safeguard provision for eligible patients, the inclusion of a duty is proposed within the draft National Health Service (Ophthalmic Services) (Wales) Regulations 2023 which will legally oblige practitioners who provide NHS sight tests and sell spectacles to make available a basic pair of spectacles for those people who are eligible for a voucher towards the cost of spectacles.

The basic pair of spectacles must meet the specification of the individual’s prescription and be within the value of the relevant voucher to which the individual is entitled. This will ensure that an eligible person will be entitled to a basic appliance without further cost, thereby ensuring equity of access across all prescription ranges, ensuring they remain accessible for those most vulnerable.

The Regulations are not expected to alter the cost to individuals who are not eligible for an optical voucher. Those individuals currently have to pay for a sight test and for their spectacles (if required) and that will remain the case once the new service has been introduced.

#### **Cost to Opticians / Optometry Practices:**

As referred to above, proposed amendments to the 1997 Regulations include a change in NHS optical voucher values which affects the way ophthalmic practitioners / suppliers of optical appliances are paid for their services, given that they redeem the voucher values from NHS Wales.

Introducing changes to the way optometrists are paid for delivering services has been meticulously planned and prescribing updated optical voucher values helps to underpin the move towards a more clinical model of service delivery whereby optometrists are paid more appropriately for their clinical work, whilst also safeguarding continued access for eligible patients across all prescription ranges, as explained in the preceding section.

The Welsh Government is committed to leading eye care reform clinically from a patient centred perspective, and Wales is the first UK nation to fully embrace clinical services in optometry primary and community care, founded on the key principles of prudent healthcare.

The new updated optical voucher values, together with an increase to the clinical fee for providing an NHS sight test, replaces the reliance on retail sales of appliances to subsidise the cost of clinical services, and increases capacity for clinical work.

The revised voucher values have been set at a point which more than cover the cost of an appliance at each prescription strength. *Optometry practices will not therefore be negatively affected in terms of the proposed funding arrangements and will in fact experience an overall increase in payment as a result of the new voucher values combined with being paid more appropriately for their clinical work including the enhanced "sight test".*

The Welsh Government collated and analysed all current financial arrangements, including clinical and the optical vouchers, to ensure the whole system change of optometry service delivery is fit for purpose. The values of optical vouchers have been determined by a cost-plus method in which an analysis of the trade cost of supplying the optical appliance together with an additional dispensing fee has ensured that appropriate remuneration payment rates have been established for optometry practices, across all voucher values and prescription ranges.

The current optometry financial arrangement, based on the UK contract from the mid 1980's, has low financial remuneration for clinical interactions (sight tests), with higher financial remuneration for the retail element of the optical voucher (provision of an optical appliance following a sight test). This retail element subsidises the clinical interaction.

The new financial package alleviates the retail cross subsidy that has been in place since the mid 1980's and replaces it with a significant increase in remuneration for the optometry profession to deliver clinical services and to thrive in a clinical environment with appropriate remuneration. Likewise, the new clinical model enables patients to receive timely treatment when they need it and helps to support optometry practices to sustain their future business model.

These changes have been agreed through negotiation with the profession, and clinical fees and voucher values will continue to be subject to annual, tripartite negotiations between Welsh Government, NHS Wales, and Optometry Wales. This will ensure optometry practices are accurately and fairly remunerated for the work completed.

Appendix A outlines a detailed cost comparison demonstrating how the model benefits the patient, the health professional, optometry practices and NHS Wales.

### **Benefits:**

The legislative changes will support a system-wide approach for NHS Wales, to provide eye health care, where appropriate, in primary care and not just sight tests.

Prevention and well-being will be further embedded across all optometry services, facilitating improved patient outcomes and reduced demand for General Practice (GP) and specialist HES, in line with prudent health care principles. Putting in place legislation encouraging the population, at the first point of contact with an optometrist, to take preventative action to avoid permanent sight loss that would have an impact on their quality of life, has obvious benefits for individual citizens and local economies. This aligns Optometry with NHS Wales General Medical Services, Dentistry and Pharmacy in terms of the wider prevention, health and well-being advice provided at primary care.

The emphasis for all eyecare services must be on achieving earlier detection of eye health problems to help reduce preventable sight loss. Estimates set out in the Welsh Government's Future Approach for Optometry Services suggest that in half of cases reported, complete sight loss could have been avoided, emphasising the importance of early intervention and prevention. It is therefore imperative to expand provision in primary care in which there already exists a skilled workforce. Optometrists are an integral part of the transformation of eye care services, with the skills to deliver 'sight testing' and 'eye health examinations' in primary care.

Sight loss has impacts across health and social services and the economy more generally. The [Time to focus report](#), which was launched by eye care charity Fight for Sight demonstrates the personal impact and wider costs of sight loss and has revealed that sight loss costs the UK economy £25.2 billion a year, as summarised below:

- There are over two million people in the UK living with sight loss, more than half of which is avoidable. This number will jump to 3.5 million by 2050.
- Sight loss costs the UK economy £25.2 billion a year, which is estimated to rise to £29.9 billion a year by 2030 and £33.5 billion a year by 2050.
- 84% of the economic costs of sight loss lie outside the health and social care system, reflecting the costs of 'informal care' by family and friends and the loss of productivity as a result of barriers to the workplace and impact on quality of life.
- The report estimates that this informal care is costing the UK economy £8.5 billion a year – a third of the total cost.
- 37% of people of working age with severe sight loss are not working due to their eye conditions. These barriers to productivity are costing the UK economy up to £7.4 billion – nearly another third of the total costs.
- The impact of sight loss on people's quality of life accounts for up to £4.6 billion – almost a fifth of the total costs.

- Compared to the UK population as a whole, people living with eye conditions reported far more problems achieving a good quality of life, with half of respondents saying they couldn't carry out usual activities.
- 41% of respondents said they experience anxiety and depression, with 30% feeling most affected by how their eye condition limits their independence and freedom to make choices.
- 70% feel some area of their life is limited by their eye condition, while 24% think their sight loss has a negative impact on their personal relationships and 21% said it limits their ability to develop personal relationships.

Assuming the UK cost associated with sight loss can be split broadly in line with population share, this suggests the cost in Wales is approximately £1.17bn per annum (based on mid-2021 population figures). Given that Wales has a larger proportion of the population in older age groups compared to the UK as a whole, this is potentially an underestimate of the cost in Wales. On this basis, it is estimated the cost of sight loss in Wales would need to fall by approximately 2% per annum for the benefit of the new service to be equal to the best estimate of the additional service delivery cost.

The evidence resoundingly supports the need to update the legislation in order to increase the range of services delivered in primary care by practitioners. By diagnosing, managing and treating more patients in primary care, using optometrists with higher qualifications, patients will have access to the appropriate care close to home.

This approach will significantly reduce the demand for ophthalmology opinion and intervention. This ensures patients who need to access HES can do so appropriately in a timely manner as a result of the increased capacity released in primary care to attend to the majority of patients' needs.

The latest publication of [Sensory Health \(eye care and hearing\) statistics April 2019 to March 2021](#) confirm that increasing demand for HES remains a challenge across Wales, wider UK nations and Europe.

In 2019-20, over 100,000 (104,233) ophthalmology referrals were made for a first outpatient appointment. This fell to around 60,000 (63,392) in 2020-21 in which eye care services had been affected by the Covid 19 pandemic with the impact reflected in the data for the financial year 2020-21.

In 2019-20, there were over 310,000 (314,054) attendances to ophthalmology outpatient appointments in Welsh hospitals. Again, this fell to less than 190,000 (186,728) in 2020-21, in view of the Covid 19 pandemic.

Even within the context of the pandemic, the data reveals an overreliance on hospital services particularly in light of the fact that the eye care sector in Wales, supported by the Welsh Government, has evolved significantly over recent years and has the skills and qualifications to manage more patients in primary care.

The aim of the new eye care pathways enabled by the legislative changes is to reduce the number of referrals into HES by 1/3, and to increase capacity in HES by



freeing up follow up appointments through monitoring, management and treatment in primary care. Enabling Ophthalmic Primary Care services to provide, where appropriate, clinical support to patients without unnecessary onward referrals to HES represent the most clinically appropriate and cost-effective solution, increasing capacity within hospitals.

In Wales, the continued professional development of our primary care optometry workforce, ensures an appropriately skilled workforce is available to deliver the intended benefits brought forward by the necessary reform of services including the provision of eye health examinations. Over the past 5 years, increasing numbers of practitioners have gained additional post graduate qualifications in medical retina, glaucoma, and independent prescribing. This is a significant move towards a new clinical model of eye health care in Wales.

The increase in clinical services delivered by optometrists, working together with hospital eye departments provides the best outcomes for individuals, as more eye health concerns will have been detected earlier, providing assurance to NHS Wales that delivery will be equitable, consistent, and timely for all citizens across Wales.

### **Conclusion**

The Welsh Government is committed to its reform of the provision of primary care services in Wales. Therefore, to pave the way for a modern, agile and patient centred provision of ophthalmic services in Wales, the preferred option of the Welsh Government is option 3 which involves revising the current framework within existing powers by replacing and amending the existing secondary legislation.

### **Competition Assessment**

A Competition Assessment has been undertaken to assess the potential impact of making changes to the legislation. This policy is not expected to have a significant detrimental effect on competition within the industry. Optometry reform will remunerate health professionals for their clinical skills. Similarly, the new clinical model enables patients to receive timely treatment when they need it whilst also financially supporting optometry practices to sustain their future on the high street. The policy does not discriminate between premises, applying equally to all. The results of a filter test (consisting of nine yes/no questions) which support this conclusion are below, followed by evidence to support the answers.

<b>The competition filter test</b>	
<b>Question</b>	<b>Answer yes or no</b>
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	Yes
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	Yes
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	Yes
Q4: Would the costs of the regulation affect some firms substantially more than others?	No

Q5: Is the regulation likely to affect the market structure, changing the number or size of firms?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

### **Post implementation review**

We will monitor the implementation of the new service and financial model for 12 months following the date of the legislative provisions coming into force. This new model will be monitored against the targets that have been set within the Future Approach for Optometry Services. Annual interim reports and an official review assessing the impact of the legislative changes following the first five years, will be provided for publication by the Welsh Government.

## Appendix A

2019/2020

Voucher type	Vouchers reimbursed	Proportion of total
Voucher type A	208,033	0.733523032
Voucher type B	36,277	0.127912471
Voucher type C	1,522	0.005366562
Voucher type D	952	0.003356746
Voucher type E	30,734	0.108367888
Voucher type F	5,853	0.020637641
Voucher type G	138	0.000486587
Voucher type H	99	0.000349073
<b>Total vouchers reimbursed</b>	<b>283,608</b>	

EHEW Examination Type	Number of Examinations	
Band 1	119,890	
Band 2	48,052	
Band 3	33,266	
<b>Total</b>	<b>201,208</b>	

Based upon an average of 18 patients per day seen by an optometrist, with a conversion rate of 65 % (conversion of a sight test into new/changed prescription and the issue of an optical voucher). Calculations do not include new service.

### Average calculations:

#### (GOS Only)

Average sight test time 25 minutes

Average working day 7.5 hours

Average number of GOS only sight tests performed in a day 18

Average number of GOS sight tests when mixed with EHEW 14.6

(This has been calculated using the ratio of GOS to EHEW examinations as seen in 2019/20 which shows 0.8118 GOS sight tests to 0.1882 EHEW examinations.)

Average conversion rate from sight tests 65%

**(GOS plus EHEW)**

Average number of Sight Tests 14.6

Average number of St's converted to voucher dispense 9.5

Average number of EHEW Examinations 3.4

Current Values		New Values		
<b>GOS Only</b>		<b>GOS Only</b>		<b>Difference</b>
Number of Sight tests performed 18 @ £21.71	£390.78	Number of Sight tests performed 18 @ £43.00	£774.00	
Average number of ST's converted to voucher dispense	11.7	Average number of ST's converted to voucher dispense	11.7	
Average voucher value	£545.23	Average voucher value	£347.10	
<b>Total Daily Value</b>	<b>£936.01</b>	<b>Total Daily Value</b>	<b>£1,121.10</b>	<b>+185.09/day</b>
<b>GOS Plus EHEW</b>				
Number of Sight tests performed 14.6 @ £21.71	£316.97	Number of Sight tests performed 14.6 @ £43.00	£627.80	
Average voucher value	£442.71	Average voucher value	£281.84	
Average EHEW value	£175.41	Average EHEW value	£199.46	
<b>Total Daily Value</b>	<b>£935.09</b>	<b>Total Daily Value</b>	<b>£1109.10</b>	<b>+£174.01/day</b>

<b>Voucher Type</b>	<b>Value (current)</b>	<b>Proportion</b>	<b>Average (11.7)</b>	<b>Value</b>	<b>Average (9.5)</b>	<b>Value</b>
A	39.1	0.733523032	8.582219474	335.5647814	6.968468804	272.4671
B	59.3	0.127912471	1.496575911	88.7469515	1.215168475	72.05949
C	86.9	0.005366562	0.062788775	5.456344582	0.050982339	4.430365
D	196	0.003356746	0.039273928	7.697689927	0.031889087	6.250261
E	67.5	0.108367888	1.26790429	85.58353955	1.029494936	69.49091
F	85.6	0.020637641	0.2414604	20.66901021	0.19605759	16.78253
G	111.2	0.000486587	0.005693068	0.63306915	0.004622577	0.514031
H	215.5	0.000349073	0.004084154	0.880135209	0.003316194	0.71464
<b>Total</b>				<b>545.2315216</b>		<b>442.7094</b>
<b>Voucher Type</b>	<b>Value (new)</b>	<b>Proportion</b>	<b>Average (11.7)</b>	<b>Value</b>	<b>Average (9.5)</b>	<b>Value</b>
1	22	0.733523032	8.582219474	188.8088284	6.968468804	153.3063
2	42	0.127912471	1.496575911	62.85618825	1.215168475	51.03708
3	155	0.005366562	0.062788775	9.732260187	0.050982339	7.902263
4	276	0.001678373	0.019636964	5.419802092	0.015944544	4.400694
5	377	0.001678373	0.019636964	7.403135466	0.015944544	6.011093
6	40	0.108367888	1.26790429	50.71617158	1.029494936	41.1798
7	77	0.020637641	0.2414604	18.59245078	0.19605759	15.09643
8	299	0.000486587	0.005693068	1.702227302	0.004622577	1.38215
9	387	0.000174537	0.002042077	0.790283818	0.001658097	0.641683
10	530	0.000174537	0.002042077	1.082300837	0.001658097	0.878791
<b>Total</b>				<b>347.1036487</b>		<b>281.8363</b>
<b>EHEW</b>	<b>Value (Current)</b>	<b>Proportion</b>	<b>Average (3.4)</b>	<b>Value</b>		

Band 1	63.68	0.59585106	2.025893604	129.0089047		
Band 2	42.46	0.238817542	0.811979643	34.47665563		
Band 3	21.22	0.165331398	0.562126753	11.9283297		
<b>Total</b>				<b>175.41389</b>		
<b>EHEW</b>	<b>Value (New)</b>	<b>Proportion</b>	<b>Average (3.4)</b>	<b>Value</b>		
Band 1	70	0.59585106	2.025893604	141.8125523		
Band 2	53	0.238817542	0.811979643	43.03492107		
Band 3	26	0.165331398	0.562126753	14.61529558		
<b>Total</b>				<b>199.4627689</b>		