



Europe Economics

Optical Business Regulation

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General Optical Council

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1 Introduction

The General Optical Council (GOC) is conducting a review of the current model of optical business regulation. The aim is to assess whether the current approach is balanced, proportionate, effective and cost-efficient in protecting, promoting and maintaining public health and safety. This is Europe Economics' final report to the GOC, presenting an analysis of the risks to the public arising from how businesses are run and a high-level analysis of policy options relating to optical business regulation.

1.1 Background and Focus of the Work

At present only a sub-set of optical businesses are required to be registered with the GOC. These are bodies corporate (including 'limited liability partnerships' and, in Scotland, 'partnerships') that:

- Use a protected title as defined in the Opticians Act,¹ or
- Use a name that implies registration with the GOC.

Before they can register with the GOC, bodies corporate must meet certain requirements as specified in the Opticians Act 1989 (as amended) ('the Act').

Under the current system a potentially large number of organisations providing restricted functions² are not required or eligible to be registered with the GOC. The GOC wishes to investigate whether this situation is fit for purpose, or whether changes need to be made.

Our work identifies the possible risks to public health and safety that can be caused by business practices; offers recommendations of options for business regulation that best address these risks; and provides high-level costs and benefits of these options. There are three main focuses of our work:

- **Evidence of risk** — this study goes back to first principles to assess whether there are risks arising from *any* business model that may warrant action from the GOC. This assessment does not rely on existing or preconceived ideas of GOC business regulation
- **Impacts on public health and safety** — the work is primarily concerned with problems that affect public health and safety, rather than commercial/customer service issues. However, it is possible that these may overlap
- **Regulation of businesses** — the work acknowledges existing *individual* professional regulation,³ and focuses on risks that specifically arise or are exacerbated by business practices or structures.

1.2 Structure of this Report

Chapter 2 of this report describes our methodology, including how we structured the analysis and gathered the necessary information. Chapter 3 presents the evidence we have gathered on business-related risks. Chapter 4 describes policy options and sets out a high-level analysis of these. Chapter 5 summarises our findings and sets out our conclusions. A more detailed analysis of the costs of the policy options is presented in the appendix.

¹ Defined as (registered) optometrist, (registered) dispensing optician, (registered) ophthalmic optician and (registered) optician(s).

² Restricted functions are defined as testing sight, fitting contact lenses and dispensing optical appliances to children under 16 or to the visually impaired.

³ Individual registrants at unregistered businesses are still bound by the GOC's professional *Code of Conduct*.

2 Methodology

In this chapter we present the high-level framework for risk assessment that we have developed and describe how this was used as the basis for our information gathering. The latter consisted of two elements: desk-based research and stakeholder engagement. The stakeholder engagement involved interviews with businesses and professional bodies, as well as two focus groups of GOC registrants. These are described further at 2.2 below.

2.1 Framework for Risk Assessment

Our framework for risk assessment identifies the key features of optical business practice that could be related to risks to public health and safety. The table below presents our initial framework, which was subsequently tested through interviews and focus groups. We refer to all registered optometrists and dispensing opticians as ‘registered practitioners’ or ‘practitioners’ throughout the report. Unregistered practitioners or employer/ees are specifically referred to as ‘lay practitioners’ and ‘lay employer/ees’ respectively.

Please note that each column of the table represents a separate business feature. These individual features are not intended to be linked (i.e. read down the columns, do not read across the rows).

Table 2.1: Key Features of optical care businesses

1. Ownership and management	2. Systems and processes (IT, record keeping; communication protocols; training)	3. Number of registered practitioners	4. Ratio of unregistered/unqualified employees to registered practitioners	5. Commercial considerations
Owned and managed by registered practitioner(s)	Designated systems for record keeping (e.g. IT); employee appraisal; recruitment; report and audit of clinical errors	Small practice – few practitioners in same place	High ratio of unregistered / unqualified employees (including students and assistants). Many functions delegated	Rely on individual customer satisfaction and repeat clients
Owned by registered practitioner but managed by “lay”-employee.	Systems in place for some things; others ad hoc	Large practice – many practitioners in same place	Low ratio — functions performed by registered practitioners	Can leverage from reputation of the wider group/franchise
Owned by lay-individual(s) but managed by registered practitioner	No systems in place			Financially more vulnerable
Owned and managed by “lay”-individual(s)				Commercial pressure to increase profits

In developing this framework we drew upon stylised versions of the different business models of optical businesses.⁴ These are summarised as follows:

⁴ Information for these business models was gathered through interviews with FODO and desk-based research.

- **Sole practitioner** (NHS/private/both) — owned and run by a single registered optometrist, providing services under an NHS contract and/or private services. An 'independent' business in that it is not part of a multiple or franchise. Private-only sole practitioners tend to be 'high-end' and offer premium services and products
- **Partnership/small practice** (NHS/private/both) — usually owned and run by optometrists or dispensing opticians providing services under an NHS contract and/or private services. Again, an 'independent' business in that it is not part of a multiple or franchise. Private-only, again, are generally 'high-end' and offer premium services and products
- **Franchise** — a privately-owned optical business within a wider brand (e.g. Boots' franchise). The business would be generally 100 per cent owned by the individual (usually the practice manager) with all profits and equity retained by them. The business will pay a franchising fee to the host brand as part of a franchising agreement. The business receives support from the host brand (systems and processes such as human resources, practice management and record keeping; insurance; IT; infrastructure/investment; purchasing help/cost-price stock). Usually there are conditions within the franchise agreement stipulating some operational methods. A key attraction of a franchise — at least when well-functioning — is that the owners can focus on frontline innovation rather than on the administration of running a business, and can innovate within the security of the franchise, i.e. benefitting from the scale of large business without losing the motivation of the owners. Franchise practices can offer NHS and/or private services
- **Joint venture** — similar to a franchise in that the businesses are individually owned whilst receiving support from the wider brand; the crucial difference is that ownership is held partly by the individual (director) and partly by the partnering group.⁵ A good example is the Specsavers' Joint Venture Partnership (JVP). Under the JVP model the "parent" group has greater oversight of individual practices than a franchise model, and individuals take on less risk than a franchise. To become a JVP optical partner (director) an individual must be an experienced optometrist and, in addition, demonstrate sufficient skill in running a business. To become a JVP retail partner the individual is not required to be an optometrist — these retail partner roles are often held by dispensing opticians. Under the Specsavers model there are also non-profit shareholders of the group with the right to appoint high-level Specsavers directors at the group level. These directors can remove partners who demonstrate a lack of sufficient skill⁶
- **Multiple** — a single corporation with multiple branches. The main examples of multiples are Boots (it has about 650 practices, albeit 210 of which are franchises — i.e. as would be expected, reality is more complex than our stylisation of it) and certain superstores (e.g. Tesco and Asda).

We tested this framework during the information gathering phase and have refined it to arrive at a reduced list of key features that could affect business risk (these are discussed in the next chapter). We also investigated the association of these key features with the particular business models described above. We found that on the whole this was not the case — rather, the key features were to be found across a range of different business models.

⁵ For example, in the Specsavers' model, joining a partnership means making a financial contribution rather than buying the practice outright. Shareholdings in the practices are allocated to the parent group and also to the Joint Venture Partners who run the practice day by day.

⁶ <http://businesscasestudies.co.uk/specsavers/job-roles-at-specsavers/roles-within-the-organisation.html#axzz2GpkVzZnm>

2.2 Information Gathering

We gathered information on business-related risks from the following sources:

- A literature review of medical articles and other reports
- The collation of data on risks including: GOC complaints data; Optical Consumer Complaints Service (OCCS) data; and GOC Fitness to Practise hearings data
- Interviews with professional bodies such as Federation of (Ophthalmic and Dispensing) Opticians (FODO) and the Association of Optometrists (AOP), and with individual businesses including a large domiciliary provider, a large multiple and a supermarket chain
- Focus groups with a wide range of optical professionals covering sole practitioners, employees of multiples, owners/directors of franchises and independent practices, locums and students
- Feedback from the General Optical Council.

As the purpose of the work is to provide a technical analysis of the potential health and safety risks posed by optical business practice, we have not directly sought feedback from patient or consumer groups as we felt the level of insight into health and safety risks would be limited. We understand that the GOC will obtain input from public interest and patient groups in further developing its approach to business regulation.

3 Evidence of Business Risks

This chapter presents our research findings on the type and severity of risks to public health and safety that can be linked to business features. We report on our findings from literature and discussions with the profession on the following areas:

- The role of the overall optical market
- Undermined practitioner autonomy
- Delegated functions
- Communication
- Locum practitioners
- Supervision
- Domiciliary eyecare
- Record keeping
- Under-investment in equipment.

We then present our analysis of the available data from the GOC's Fitness to Practise (FtP)⁷ cases and complaints from the OCCS. This analysis attempted to find further evidence for the prevalence and severity of business-related risks. Information from FtP cases, in the form of short case studies, is also used to provide examples of risk.

The next section examines possible mitigating factors to business-related risks, such as NHS GOS contract management and commissioning, and competition within the optical market.

The final section of this chapter presents our conclusions on the main risks to public health and safety that are influenced by business practice, as well as our conclusions on the underlying drivers.

3.1 Literature Review and Evidence from the Profession

Europe Economics' 2010 report on risks in the optical profession provides a comprehensive summary of the risks to public health and safety posed by individual practitioners (both optometrists and dispensing opticians).⁸ Although the context of this work was professional revalidation — so that the focus was on individual clinical competence — the report nevertheless identifies where professional risks might be mitigated or exacerbated by wider contextual factors, including business structures and practices.

Evidence from our report has been complemented by additional relevant research and then cross-checked through engagement with the optical profession. We present here a summary of the possible risks to public health and safety that could be influenced by business practice.

We use short case studies taken from the GOC's FtP records to illustrate some of the business risks. We emphasise that these are examples only and are not intended to highlight particular risks over others.

⁷ Strictly speaking, in the event of an FtP case against a business registrant, the GOC would allege impairment of its 'fitness to carry on business' rather than 'fitness to practise'.

⁸ http://www.optical.org/goc/filemanager/root/site_assets/revalidation/revalidation_-_risk_report.pdf

3.1.1 The optical market

We begin with a brief description of the optical market and the implications this has for optical business practice.

The impact of the economic downturn has reduced consumers' willingness to pay for new spectacles and increased switching behaviour towards cheaper choices of optical products. Indeed the market for optical goods and services shrank by five per cent between 2009 and 2011 to £2,553 million.⁹

Despite the negative economic impact, the number of optical professionals has remained steady. At the beginning of 2011 there were 12,761 optometrists and 5,821 dispensing opticians registered with the GOC in the UK, representing a slight increase since 2010 of approximately three per cent and one per cent respectively.¹⁰ The distribution of GOC registrants is concentrated in England, with just over 15,000 optometrists and dispensing opticians registered at January 2013. Scotland has around 1,500 registrants, followed by Wales and Northern Ireland with approximately 800 and 500 respectively.¹¹ The distribution of optometrists and dispensing opticians largely mirrors the distribution of the population across the four nations of the UK.¹²

Approximately 21.1 million sight tests were carried out in 2011.¹³ Patients eligible for NHS eye care are entitled to free sight tests.¹⁴ For such tests, the NHS reimburses the optical contractor a fee of £20.90 in England, Wales and Northern Ireland.¹⁵ Scotland has a different approach. Everyone is eligible for a free eye test in Scotland, with the fee paid to contractors ranging from £37 to £45, depending on the patient and the nature of the examination.¹⁶ Approximately 30 per cent of sight tests in 2011 were for private patients in England, Wales and Northern Ireland (the proportion in Scotland is almost negligible as free sight tests are available to all).¹⁷

For private tests, the estimated average charge to patients is £21.67 which is held to be less than half the actual cost of providing a sight test.¹⁸ This implies that the NHS reimbursement rate is also below cost. Whilst it may be that private test fees are implicitly capped by the NHS reimbursement fee, the private fees quoted here are anecdotally reported to be very low in comparison to actual costs.

In order to be reimbursed the NHS sight test fee under General Ophthalmic Services (GOS), optical businesses must hold a contract with the NHS (in England) or service level agreements with Health Boards to be on the Boards' Ophthalmic lists (in Wales, Scotland and Northern Ireland). It is thought that almost

⁹ YouGov (2011), 'Opticians' market report, page 37.

¹⁰ 'Optics at a Glance 2011', Optical Confederation.

¹¹ GOC registrant database 2013.

¹² Based on ONS Statistics from the 2011 population census: England has 84 per cent of the UK population and 81 per cent of GOC registrants; Scotland has eight per cent of the population and eight per cent of registrants; Wales has five per cent of each and Northern Ireland has three per cent of each (there is a balancing percentage of geographically unclassified GOC registrants).

¹³ 'Optics at a Glance 2011', Optical Confederation.

¹⁴ These include patients under 16 and over 60 years of age, those registered blind or partially blind, and those with diabetes.

¹⁵ The fee payable to GOS contractor for the year 1 April 2013 to 31 March 2014.

¹⁶ The fee paid to contractors is £37 for adults under 60, £45 for adults over 60, and the NHS supplementary eye examination fee is £21.50.

¹⁷ Feedback from stakeholders suggests there are additional eligibility allowances for free eye tests in Wales compared with England and Northern Ireland, and that therefore the actual proportion of private sight tests may be lower in Wales. However, published information on eligibility criteria implies that these are in fact the same (<http://www.nhs.uk/chq/Pages/895.aspx> and <http://www.nhsdirect.wales.nhs.uk/localservices/opticianfaq/#NHS>). However, given that the average private test fee is similar to the NHS fee it is unlikely that a small difference in the number of private tests is going to make a material difference to the income of businesses in different nations.

¹⁸ Based on the Survey of Optical Confederation members, cited in 'Optics at a Glance 2011', Optical Confederation.

all businesses hold such contracts/agreements, given the large proportion of patients that are covered by GOS.

It is a widely held view within the optical profession, in England in particular, that the reimbursed fee under GOS does not cover the actual costs of conducting a sight test. Responses from the market indicate that a typical business incurs a loss on each NHS and privately funded eye examination, with one estimate of the net cost being between £15 and £40 per test depending on different aspects of the business, such as location and rent.

Businesses are therefore required to achieve profitability through conducting additional specialist tests for private patients (which can account for a very small proportion of all eye tests done, depending on the demographics of the population which the business serves) and, in particular, through the sale of optical appliances. In 2011 spectacles (including frames, lenses and sunglasses) accounted for 76 per cent of sales, with contact lenses accounting for 16 per cent, and eye tests and care accounting for only nine per cent.¹⁹

Our stakeholder feedback suggests that the competitive pressure in the industry is high. The profit that opticians can make on the sale of spectacles and contact lenses is undermined when patients purchase these items from another supplier, hence denying the original business the opportunity to compensate for the loss on the sight test. According to the market survey by YouGov, the majority of patients in the UK purchase their prescription eyewear from the optician where they had their eyes tested (77 per cent), but a non-trivial proportion do shop around (17 per cent) or purchase spectacles online (three per cent). This trend is similar with contact lenses (82 per cent buy their lenses from the optician who tested their eyes) although the proportion of online purchasing is greater, at 12 per cent. It is likely that online purchasing, of contact lenses at least, is an increasing trend. For businesses operating at the margin, even a small diversion of trade to other suppliers or online sellers could significantly affect their profitability, increase commercial pressures and undermine investment in high-quality patient care.

Some of the focus group participants and professional bodies who contributed to this research consider that economic pressures resulting from the low profitability of sight tests could encourage sub-optimal public health and safety as businesses focus more on commercial interests than patient care. It is similarly held that the focus on the non-clinical aspect of the business has reduced the perception among the public of the importance of good optical care, thus reducing the impact of clinical excellence in attracting and retaining customers. The impact of such commercial pressure is elaborated on at a number of points in this report.

3.1.2 Undermined practitioner autonomy

‘Undermined practitioner autonomy’ refers to the situation whereby pressure that practitioners face within the business environment (such as commercial pressure) may restrict their ability to provide patient care that meets professional standards.

All optometrists and opticians performing restricted functions are registered individually with the GOC and subject to professional regulation in the form of the *Code of Conduct*²⁰, continuing education and training (CET) requirements, and the GOC’s FtP regime. These, combined with the low-risk nature of the profession (in comparison to some other healthcare professions such as medicine), suggest that the overall risks of direct harm to public health and safety posed by practitioners is very low.

However, there may be contextual factors such as the practices of businesses within which these individuals work that compromise their autonomy to carry out their activities to the best of their ability and in accordance with the requirements of their individual professional regulation. The *Code of Conduct for*

¹⁹ YouGov (2011), ‘Opticians’ market report, page 38.

²⁰ The *Code of Conduct* for individual registrants defines principles of good practice in carrying out clinical services to patients. http://www.optical.org/goc/filemanager/root/site_assets/publications/codes/codes_of_conduct.pdf

business registrants offers some guidance here.²¹ The code, for example, states that a business registrant should take reasonable and proportionate steps to ensure that its financial and commercial practices do not compromise public safety and provide the freedom for individual registrants to exercise their professional judgement in the best interests of the public. However, our focus groups suggested that practitioners could be driven by commercial targets and may not always have the freedom to take clinical actions that are most appropriate to address patients' concerns.

There are a number of potential risks related to undermined practitioner autonomy.

3.1.2.1 Eye examination times

Due to the apparent unprofitability of eye tests, some businesses may choose to shorten the duration of an eye examination to an undesirable level. Insufficient time allocated to practitioners for examinations could lead to inaccurate diagnosis and a failure to identify eye diseases which could in extremis cause irreversible damage to patients. Feedback from our focus groups suggests that practitioners can be put under significant pressure to reduce the length of eye examinations. Due to the 'case finding' nature of optics, optometrists are required to carry out a range of tests to detect the symptoms of any eye diseases. However, a practitioner working under strict time rules set by a practice may not have sufficient time to conduct an adequate eye examination that covers all area of risk.

Eye examinations play an important role in detecting glaucoma and in identifying patients from high risk groups. Our 2010 report identified risks of practitioners failing to conduct all the tests recommended for accurate diagnosis, and cited instances where this could be due to the financial cost and time constraints.²² Under the current GOS system (in England, Wales and Northern Ireland in particular), the fee provided does not cover the time and costs required to conduct all tests.

Similarly, the eye examination is crucial for identifying symptoms of retinal detachment, during which careful patient history must be elicited and a number of tests performed. Again, our 2010 report did not find substantial evidence of practitioners misdiagnosing this adverse event, but cases were identified where the examination was not conducted according to guidance and important elements were omitted.²³

It is therefore possible insufficient examination times could contribute to the risk of incomplete testing.

Within the time limit set, it is possible that not all necessary tests are carried out and insufficient advice is given to patients to promote their health. Unlike the GOS system in England, eye examinations in Scotland are free for patients of all age groups and optometrists are also entitled to an NHS fee for supplementary tests.²⁴ A study comparing the eye care system in Scotland and England has found no significant differences in the number of patients with a range of ocular conditions detected during routine optometric examinations. On the other hand, the same study found that patients in Scotland were more likely to be given advice once a condition was detected and more likely to be referred — which the study's authors interpreted as suggestive of the Scottish GOS arrangements facilitating a higher level of patient care.²⁵ In another study, 23 per cent of optometrists working in Scotland felt that there were no barriers in practice to the detection of glaucoma compared with only 12 per cent of optometrists in England.²⁶ However,

²¹ The *Code of Conduct for business registrants* also only currently applies to registered businesses, a subset of all optical businesses.

http://www.optical.org/goc/filemanager/root/site_assets/publications/codes/codes_of_conduct_for_business_registrants.pdf

²² Europe Economics (2010) 'Risks in the Optical Profession' page 17.

²³ Europe Economics (2010) 'Risks in the Optical Profession' page 22.

²⁴ The number of tests an optometrist in Scotland can perform is limited to 20 eye examinations per day.

²⁵ R. Henderson et al (2012), 'A comparison of Scottish and English General Ophthalmic Services: a preliminary evaluation of the impact on patient care', *Optometry in Practice* 2012, Volume 13 Issue 4.

²⁶ Myint, J et al (2010), 'Barriers perceived by UK-based community optometrists to the detection of primary open angle glaucoma', *Ophthalmic Physiol Opt.*

there is no direct outcomes-based evidence to enable a robust comparative judgement of Scotland's standard of patient care.

However, whilst contracting issues may affect the profitability of optical businesses, the ultimate responsibility for patient care does lie with the business and the practitioners. Any practice that reduces examination times to such a degree that public health is endangered cannot legitimately pass this responsibility onto the contracting arrangements.

3.1.2.2 Ideal testing time

In a recent survey on testing times, respondents suggested that the time required for an eye exam was greater than the average time allocated, and significantly more than the "industry standard" 20 minutes. This study identified a mean allocation of 25.8 minutes (with the time allocated to testing to an optometrist ranging between 15 and 40 minutes).²⁷ The respondents to this survey, irrespective of their professional experience, raised concerns about the quality of the tests under current clinical time management and suggested that the optimal duration should be approximately 29 minutes in order to conduct an eye examination to the standards described in guidance from the College of Optometrists (with a range from 15 to 60 minutes, and 67.7 per cent suggesting 30 minutes or more were required).²⁸ A study from 1987 indicated that the 'ideal' time for optometrists to conduct a GOS sight test should on average be 26 minutes.²⁹ Although one might expect — either ideal or actual — sight test times to change over time due to increased efficiency, advances in technology, evolving clinical requirements and changing patient expectations, there is a common theme that some professionals maintain that there is a difference between actual testing times and optimal testing times and that this reflects the effects of undesirable economic pressures.

Feedback from those professionals contributing to this study refers to optometrists being affected by overrunning sight tests, whereby tests are booked for 20 minutes but regularly take 25 minutes or more. On the one hand this implies that some businesses allocate too little time to sight tests; on the other, it suggests that optometrists do generally take the time they need (i.e. they are not wholly bound by the time constraints imposed).

However, one would need to be cautious in interpreting the 'ideal' testing time since each patient has his or her own characteristics that influence examination times, and there are other factors influencing the duration of an eye test such as the experience of the practitioner, number of support staff and the use of pre-screening and other delegated tests.

Hence, there is no 'standard sight test' that could be applied to all patients and each patient should be given the sufficient time to conduct an eye test tailored to his or her characteristics and risks. Previous studies also found substantial differences between optometrists in the duration and depth of their clinical investigations, challenging the concept of a standard eye examination.

Given the lack of evidence for the validity of an 'ideal' duration for an eye test, it is imperative that practitioners should be given the flexibility in clinical investigations to ensure patients' health. This applies to tests that both require more and less time than usual.

²⁷ Optician Online (2010) 'Testing Times', accessed: <http://www.opticianonline.net/Articles/2010/07/02/25859/Testing+Times.htm?key=COMMERCIAL%20AND%20PRACTICES>

²⁸ The guidance for a routine eye examination, College of Optometrists <http://www.college-optometrists.org/en/utilities/document-summary.cfm/docid/2C06771F-5D0D-4728-825F7FF31F79D764>

²⁹ French, C (1987), 'Ideal average times for sight tests', Ophthalmic Optics Department.

3.1.2.3 Sales of optical appliances

Another area where commercial pressure may influence individual practitioners' conduct is the pressure to increase conversion rates, i.e. increase the sale of optical appliances by 'converting' more eye examinations to sales. This could be through 'pushy' sales techniques or, more seriously, through recording minor changes in prescriptions and recommending that new appliances are bought (defined here as misprescribing).³⁰ Anecdotal evidence of commercial pressures on optical staff, especially locums (e.g. remuneration linked to the supply of spectacles), can be found on informal sources such as online forums. It is not possible to judge the extent to which such pressure manifests, i.e. the proportion that is due to misprescribing rather than to sales techniques.

The risks to public health associated with misprescribing can be significant if involving children, as children's eye health and overall development is sensitive to errors in dispensing.³¹ However, our 2010 report found little evidence of misprescribing amongst children. The health risks to adults are unlikely to be serious, particularly if the effects of misprescribing are considered analogous to the adverse effects of spectacle intolerance.³²

Despite the limited evidence relating to patient harm, misprescribing nevertheless represents serious business malpractice (indeed, misprescribing is considered fraud by the NHS) and feedback from professionals suggests that this does occur in practice.

3.1.2.4 Online providers

The need for oversight of online providers of contact lenses and optical appliances is clearly a sensitive issue among practitioners, as the diversion of their patients' optical purchases to online providers restricts their ability to offset the losses induced by sight tests. If online providers do not have the characteristics that require them to register as corporate bodies then they do not have to comply with the *Code of Conduct for business registrants*. There was a feeling among practitioners to whom we spoke that there are potential risks involved with the online sale of contact lenses and appliances (the main concerns appear to be with 'illegal' practice, such as providing lenses without checking prescriptions, selling appliances to children without appropriate supervision) and that these could be addressed more easily if all businesses providing restricted functions, including online sellers, are required to register with the GOC.³³

3.1.2.5 Summary

The pressure on practitioners to meet sales and examination-time targets is a risk that is influenced by the practices of the business, and one that can occur across a range of business models. It was noted that commercial pressures are just as likely to occur in smaller independent practices as in larger multiple organisations. The key factor is the ability of the individual to act autonomously — this is less likely to be the case if he or she is an employee (at risk of losing a job if non-compliant), compared with an owner/manager of a business.

It must be noted that the influence of financial considerations on patient risks should not be considered disproportionately. All businesses are commercial undertakings and will have interests in being efficient and maximising sales of optical appliances. The use of sales targets and efficiency incentives are not a sign *per se* of inappropriate commercial practice. It is only that these factors *could* lead to a misalignment of incentives and to clinical care being compromised.

³⁰ Legitimate minor changes in prescription can have significant implications for some patients and dispensing new spectacles can be very beneficial. We refer here to the erroneous recording of prescription changes solely for the purposes of selling new spectacles.

³¹ Europe Economics (2010) 'Risks in the optical profession' page 33.

³² Europe Economics (2010) 'Risks in the optical profession' page 23.

³³ This issue is complicated by the fact that online sellers located outside the UK are not bound by the Act and would not be under the GOC's remit, regardless of the changes made to business regulation.

Feedback from the focus groups indicated that although commercial pressures are a reality for most practices, it is possible to operate a good, safe practice within the current environment, and that other drivers in addition to commercial pressure would need to be in play for a business to engage in poor practices to the extent that public health and safety was affected.

However, whilst businesses operating at the margin may not necessarily directly engage in *bad* business practices (such as pressurising employees to prioritise profits above good clinical care), there may be less scope for them to be proactive in implementing *good* practices in general. Commercial pressures are unlikely to lessen given the current situation of low sight-test fees and the trends towards online sales of optical appliances. Therefore there may be an increase in the number of businesses that are unable to improve their practices, and who may be tempted to cut corners. The extent to which this may increase risk to patients is unclear.

In terms of the impact of commercial pressures on practitioner autonomy, final consideration must be given to the fact that the ability of an individual to retain autonomy and good patient care (which also falls under the scope of their individual regulation) is significantly influenced by the nature of the individual as well as by business practice. Practitioners are ultimately responsible for patient care and if business practices are such that this care is compromised then the individual should refuse to cooperate. Unfortunately this can be difficult if this compromises the employment of the practitioner. Having a more targeted code of conduct and wider business registration might better enable employees to stand up to employers or hold them to account for poor practices.

3.1.3 Delegated functions/pre-screening

Pre-screening takes place before an eye examination and usually involves tests and assessments being delegated to optical assistants, who then report the test output to the optometrist for interpretation. It is a common practice in the industry and is a key source of time efficiency. If a function has been delegated this is recorded, although this practice varies across the profession (as does the quality of record-keeping in general).

No evidence of direct risk has been found in relation to delegated functions. The mechanics of the tests are not difficult and the quality of the results is not considered to be an issue by the profession. In addition, the registered optometrist has final responsibility for the conduct and competence of optical assistants; this is covered in the *Code of Conduct* for individual registrants.

However, the focus groups did express some concern over the training and development of optical assistants, which is the responsibility of the business. It was felt that as there is no mandatory requirement for the on-going training of assistants or for the assessment of their competence levels, the standards of assistants are left to the discretion of businesses. This may pose a risk in businesses that have poor monitoring systems, or who seek to save costs by insufficient investment in training. An example of such a risk would be staff members inventing readings for pre-screening tests because they could not get equipment to work.

Businesses have to be clear about the roles and responsibilities of optical assistants: ultimately the responsibility for the delegated functions lies with the optometrist, and this should be made clear across the practice, with support staff being appropriately supervised.

3.1.4 Communication

Communication is a key element of good clinical care. Our 2010 report highlighted the importance of communication in relation to a number of other risk areas, in particular contact lenses (e.g. hygiene advice); child care (interacting with the child and parents); spectacle non-tolerances (eliciting accurate qualitative information about lifestyle, etc.); and retinal detachments (taking comprehensive patient history); and also

features in contextual factors such as locum employment (particularly between locum and employer) and domiciliary care.

Communication between employees within practices is also crucial, and feedback from professionals suggests that there can be problems with communication that can negatively affect patient care. For example, the use of delegated functions can compromise effective communication between the optometrist and patient if the patient reveals qualitative information to the optical assistants during the tests (not realising their limited role in the assessment) which is then not repeated by the patient or passed on by the assistant to the optometrist. A business should have a good communication protocol to ensure that all necessary information is communicated to the optometrist.

Although the ultimate responsibility for the sight test is with the optometrist in charge, an appropriate supervision protocol for the business, which might include a dedicated practice manager, would increase the likelihood that the assistants are supervised effectively. Haphazard practice management can undermine the performance of assistants, in particular in relation to communication.

It was suggested that communication between practitioners and patients could be improved via internal training and guidance. Although poor communication could be due to competency of individual practitioners, it could be exacerbated by business practices such as restricted examination times, and lack of training or protocols.

3.1.5 Locum practitioners

Good communication is also vital in the employment of locums. Our 2010 report identifies a number of factors that could make locum work more risky for patients, such as the reduced accountability of locums and effectiveness of employer sanctions. An additional factor highlighted by professionals relates to the ability of locums to follow up with those patients who require further testing. This can be difficult if the locum is not regularly at the same practice. Businesses need to have in place adequate systems for follow-up in these cases, with another optometrist or support staff taking responsibility for ensuring the continuing care of the patient. Whilst it was felt that this is generally well done, having these systems in place is a key element of business practice and there is a real risk of patients being overlooked in badly organised businesses.

If a practice makes use of locums, then it is even more important for protocols and systems on record keeping, types of equipment, supervision etc. to be fully developed and in place.

Businesses also need to take extra caution to ensure the competency of the locums is of a sufficient standard and that a good level of patient care is provided. Although practices prefer to have working relationships with 'regular' locums, there are still risks that, in the absence of clear practice manuals, inadequate introductory training is given to new locums in terms of record keeping, systems and equipment, which could affect the quality of patient care. Good communication between business and locum is also required to ensure that the locum is not required to operate beyond his or her areas of competence.

There is also a possibility of poor business practice in checking the identification of a locum, which could pose a risk of an unregistered individual being allowed to practice in a business. On the other hand, examples of proper databases and systems for identification and competency checks also exist.

It was noted that a distinction should be drawn between locums that work on an ad hoc basis across businesses, and locums that work for a number of businesses on a regular basis. There are few issues with the latter as they are generally familiar with the businesses' practice and systems, and there should be adequate follow-up of patients' tests.

On the whole, although the ultimate actions of locums are overseen by the GOC through individual registration, business practice does influence the ability of locums to operate effectively. Badly managed

businesses with little oversight of employees and poor communication systems can exacerbate the effects of negligent or incompetent employees, in particular locums.

3.1.6 Supervision

As mentioned above in the context of delegated functions, optical practices often employ support staff who are not registered optometrists or dispensing opticians (e.g. GOC-registered students or unregistered optical assistants) to perform various optical functions. It is important that the roles and responsibilities of support staff are clearly set out, and that appropriate supervision systems are in place.

3.1.6.1 Students

In the optical industry, it is common practice to take on GOC-registered students to carry out non-restricted and restricted activities under the supervision of a GOC-registered professional. Whilst it is important to provide learning opportunities to trainees to develop their core competencies, it is equally important that the standard of eye care is maintained and patients are protected from any consequences due to students' inexperience through appropriate supervision.³⁴ However, in poorly managed businesses it is possible that unqualified students could be left alone to perform restricted functions and hence pose a risk to patients' health. If a business does not provide clear guidelines for supervisors then this might also compromise the effective supervision of such students. Detailed guidance on supervision is available from the Association of Optometrists and the College of Optometrists.³⁵

Analysis of FtP hearing cases over the past six years reveals some evidence of inadequate supervision. There were 29 cases involving practitioners who were either a registered student optometrist or student dispensing optician (representing just under 20 per cent of all hearings). Of these, the vast majority were related to misconduct or convictions (such as theft, drink-driving, pretending to be fully registered or failure to keep appointments with patients). Very few related to deficient performance, and only two related directly to inadequate supervision. The GOC has highlighted the importance of student supervision in the past when one large multiple was found to have failed to take reasonable measures to prevent a registered student dispensing optician from dispensing spectacles to a patient under the age of 16 without proper supervision.³⁶ However, there is no clear evidence that the inadequate supervision was caused by poor business practice or led to damage to patients' sight.

Professionals in our focus groups did not view student practitioners to pose a significant risk, and it was not felt that business practice in this area was especially deficient. They maintained the view that the supervising optometrist holds the ultimate responsibility in ensuring adequate supervision of the registered students and patients' health.

We describe below a case study from GOC FtP hearings records.

Case Study – inadequate student supervision

Description of the allegation

The Council alleged that a body corporate (a large multiple) failed to take appropriate measures for an adequate supervision arrangement for its employee, Registrant A, a registered student dispensing optician and to prevent Registrant A from dispensing spectacles to a patient under the age of 16 years without

³⁴ Under guidance from the College of Optometrists, the term 'supervision' means that the supervisor must be on the same premises as the student they are supervising, and in a position to intervene at any time.

³⁵ Supervision training videos from the College of Optometrists: <http://college-optometrists.org/en/qualifying-as-an-optometrist/supervisors/supervisor-training-videos/>

'Supervision of trainees and unregistered staff', interim advice from the Association of Optometrists: http://www.aop.org.uk/uploads/uploaded_files/In%20Practice/supervision_of_trainees_and_unregistered_staff.pdf

³⁶ http://www.optical.org/en/news_publications/news_item.cfm/GOC-highlights-importance-of-student-supervision

proper supervision by a registered practitioner in 2005. Both Registrant A and his supervisor, Registrant B, who was a registered dispensing optician, were alleged by the Council to be guilty of misconduct.

In the relevant branch of this multiple, there was only one registered optician — who was a locum — and Registrant A was assigned as a retail manager and was not qualified as a registered dispensing optician at that time. Registrant B, on the other hand, was not located at the same branch as his supervisee and the supervision was arranged remotely on most occasions.

In October 2005, a young patient was dispensed by Registrant A with an incorrect prescription; the patient returned to the practice two months later due to difficulties with the spectacles. The error was discovered but a false explanation was given to the patient to cover the internal mistake. A second pair of spectacles to the right prescription was, again, dispensed by Registrant A in the absence of any registered practitioners in the branch.

There was proven evidence for the allegations against Registrant A and Registrant B. The allegations against the body corporate on failure to prevent dispensing by Registrant A of spectacles to the patient in restricted category twice were proven but the allegation on the absence of appropriate supervision measures was not proven.

Sanction

Registrant A was found guilty of Misconduct but the Committee was satisfied that his fitness to practise was not impaired. As such, he was given a warning. Although the allegation against Registrant B was proved, he was not found guilty of misconduct given the permission he received from the training body for the unusual split in supervision and for the role he was to play as instructed by his employer.

On the other hand, the body corporate — as the employer — was found guilty of misconduct as a business corporation and was given a financial penalty of £30,000.

Evidence of poor business practice

Although Registrant A was found guilty of misconduct in dispensing spectacles to the young patient, it would also be the responsibility of his employer to maintain adequate and effective supervisory measures. The arrangement of remote supervision, for example, was found to be inadequate. Moreover, Registrant B wrongly assumed that Registrant A would be supervised, if necessary, by the locum on site, and there was no proper induction procedure given either to the locum on his supervisory role to Registrant A or any formal discussion of the supervisory obligations by the body corporate.

3.1.6.2 Scheduling

A practice's approach to the scheduling of its registered employees also has implications for risk. There might be points in the day, or days in the week, where there is no registered practitioner on the premises. Appropriate scheduling protocols could either reduce the extent to which this occurs, or identify a clear process for support staff to follow during these times.

In the absence of such protocols support staff could be left alone for undefined periods of time, and be tempted to engage in inappropriate action. For example, support staff may offer ill-formed or incorrect advice (e.g. someone complaining of pain in their eye might be told to return the next day, whereas they ought to be advised to go to another optician or even to A&E in the case of a detached retina). Other examples include spectacles being collected from a non-registrant who did not check that they matched the prescription, and an assistant who attempted to help a patient remove a contact lens (and failed, causing damage to the patient's eye).

3.1.6.3 Supervision of registered practitioners

A final element of supervision relates to the supervision of practitioners who are registered with the GOC, but not for all activities. For example, a dispensing optician who is not registered with a contact lens

speciality should not fit contact lenses without supervision by a registered optometrist or dispensing optician on the correct speciality register.

Case Study – unqualified fitting and supply of contact lenses

Description of the allegation

Registrant C, a registered Dispensing Optician, owned and managed a practice where he was found to supply and fit contact lenses when he was not qualified to do so. There was no clear evidence of adequate supervision by the registered optometrists on site.

Sanction

For the protection of the public, the Committee was satisfied with a proportionate order of suspension for a period of 18 months to be made to the registrant.

Evidence of poor business practice

As Registrant C was also the owner of the practice, it is difficult to identify whether the misconduct was the result of individual deficient professional performance (i.e. he should take sole responsibility) or evidence of wider poor business practice. Factors related to business practice that may have influenced the misconduct could include insufficient manpower in a busy practice or absent supervision protocols, but the records of the case do not provide such detailed evidence.

3.1.7 Elderly and domiciliary eye care

Elderly and vulnerable patients using domiciliary eye care might be more affected by poor business practices. They may lack choice or the ability to differentiate between different service qualities, or be unaware of the complaints facility available.

One risk related to domiciliary practice in residential homes is the contracting arrangements of health care. There is a possibility that the care homes will effectively take out exclusive contracts with one optical practice instead of allowing patients to choose their own providers. This is logistically easier for the homes. It could also reduce any risk of inappropriate testing, whereby a patient is tested too many times by different optometrists in the absence of good record keeping at the home. The relevant contract-holder in the NHS should be able to warn optometrists if a patient has been tested too recently (as they are informed about every visit) but this does not always happen. However, there is an obligation on the individual (part of their GOC registration) to take responsibility for appropriate testing. They need to ask the right questions and if they uncover information to suggest they should not be doing another test, then they should take action. Of course, in this context this information may not be forthcoming from the patient.

The business risk of insufficient testing time could be exacerbated by the complexity of domiciliary eye tests which usually take longer than an average on-site examination.

Domiciliary patients may be more vulnerable to “push” sales during visits and more heavily reliant on the integrity of the practitioners not to recommend inappropriate purchases (such as the sale of reading glasses to a patient with severe dementia). Complaints data include instances where the elderly were given suggestions to buy unnecessary spectacles.^{37 38} Pressure from commercial sales targets may therefore pose

³⁷ [http://www.opticianonline.net/Articles/2009/03/06/22936/Fee+earner+or+loss+leader.htm?key=COMMERCIAL AND PRESSURES](http://www.opticianonline.net/Articles/2009/03/06/22936/Fee+earner+or+loss+leader.htm?key=COMMERCIAL+AND+PRESSURES)

³⁸ We also note the regulations allow for a seven day ‘cooling off’ period for patients who have an order taken for optical appliances in their home, or in some cases workplace: ‘Cancellation of Contracts made in a Consumer’s

a greater risk here, although the ultimate responsibility for patient care remains with the individual practitioner.

However, this is a difficult area to assess risk as practitioners could differ in their opinion of what constitutes 'unnecessary': ultimately, there is little risk to adult public health from inappropriate prescribing, although it remains a serious, fraudulent and distasteful practice (arguably more so among vulnerable patients).

3.1.8 Record keeping

The importance of record keeping was highlighted in our 2010 report and is cited across the profession. Record keeping is not identified as a serious risk to public health and safety, but nevertheless is widely identified as an area that could be improved. Good record keeping has implications for both patient care and practitioner well-being. Concerns have been raised about the inconsistency and insufficient level of detail of record keeping across the profession. If records are not properly kept this could affect a patient's 'chain of care' particularly if the patient is seen by more than one practitioner or as part of a wider programme of care (e.g. interaction between optometrists and medical practitioners). As an example, if a patient's record is not kept up to date, the optometrist will be unable to tell if test readings have changed since the previous visit which could result in risks not being identified.

Although the responsibility of record keeping lies with the individual practitioner and is a requirement of professional registration with the GOC, a business' systems play an important role in facilitating this good practice.

Electronic recording systems have been adopted by many practices and they are commonplace in large multiples. However, it was felt by some focus group members that adequate training for use of the systems may not be given to the staff in a busy or badly managed practice, in particular to new recruits. There is a need for continual training to ensure good and consistent record keeping is maintained by all. A business also needs to ensure that records are stored properly and are kept confidential.

Case Study – record keeping systems

Description of the allegation

Registrant D, a registered optometrist, was alleged by the Council that her fitness to practise was impaired based on her examinations of four patients in 2007. The allegations were:

- failure to assess adequately near visual acuity
- failure to assess adequately monocular visual acuity
- failure to record adequately cup disc ratios
- failure to perform a visual field examination for one patient.

With respect to the three allegations of inadequacy of assessments and testing, there was insufficient evidence to prove the allegations by the Council and the Committee found that the tests conducted by the registrant were adequate for the needs of the patients.

However, the Committee agreed that the details of the record were inadequate but after taking into account the design of the record card and the registrant's excellent history of record keeping, the Committee judged that it was outside the registrant's responsibility.

Sanction

Based upon all the evidence available, the Committee affirmed the importance of proper record keeping but concluded that Registrant D was not guilty of deficient professional performance.

Evidence of poor business practice

The design of the record card (which was prone to record only one reading for both eyes) could be an example of poor business practice, possibly caused by insufficient knowledge on the part of the practice manager/owner or an outdated record system. The unhelpful record keeping system hindered the keeping of clear records. In this case the issue appeared to be related to the business rather than the individual practitioner.

3.1.9 Under-investment in equipment

Although there is a minimum level of equipment required to provide GOS services (for example, as set out in the GOS contract in England and GOS regulations in Scotland),^{39 40} focus group members felt that businesses may not always meet these standards and may have outdated and sub-optimal equipment, or equipment that is not regularly maintained and calibrated. Given the suggested low profitability of the industry, businesses may lack the means to make the necessary investment in equipment in the interest of patients' care. However, it was felt that there is no real risk to public health and safety from using outdated equipment, although of course patient care would be negatively affected if essential equipment was not available. This appears to be particularly relevant to equipment used in domiciliary care.

The GOS contract in England and GOS regulations in Scotland largely dictate the type and quality of equipment required.⁴¹ Under the previous system of contact management in England, primary care trust (PCT) optometric advisors would ask for equipment maintenance records and certifications of accuracy, although the frequency of inspection regimes varied considerably across PCTs. It is expected that the equipment requirements for inspections under the new NHS contract assurance system in England will be similar. This is discussed in more detail under section 3.3.1.

Case Study – insufficient equipment

Description of the allegation

Between 1980 and 2005, Registrant E, a registered optometrist, was alleged to have failed to carry out adequate tests on visual field screening, tonometry and optic disc examination during his consultations with a large number of patients. Record keeping was not up to minimum GOC standards. For instance, a patient's history, results of ocular examination and advice provided were missing in some of the records.

As a practice owner, he also did not maintain adequate equipment for the testing of glaucoma.

The deficient professional performance and poor practice environment were deemed to result in inadequate eye examinations for 53 patients, with either tonometry or visual field screening (or both) missing. Such tests should have taken place, particularly due to the additional risk factors of glaucoma of at least 27 of the patients. Failure to carry out these tests could increase the risk of missing glaucoma and delaying treatment.

Sanction

The Committee considered the seriousness of the proven allegation and determined the appropriate sanction for Registrant E was erasure from the register.

³⁹ Other equipment requirements do exist, for example under the Welsh Eye Care Service (WECS), but this service goes beyond those in the GOS and not all optometrists or optical businesses in Wales are accredited under WECS.

⁴⁰ See our discussion in Section 3.4.2 for more detail about the differences between the four nations of the UK.

⁴¹ See for example http://www.aop.org.uk/uploads/regulatory/gos_regulations_2006_with_2012_amendments.pdf

Evidence of poor business practice

The inadequate equipment provided is evidence of poor business practice. Equipment was found to be inappropriate for use in glaucoma screening for a reasonably competent optometrist by the mid-1990s.

Although poor record keeping could be caused by the deficient professional performance of the individual registrant, a clear set of internal guidelines and good record system would have helped to mitigate such risk. Given that the registrant himself was the owner of the practice, it could be argued that there were no adequate internal measures for record keeping within the business.

3.2 Complaints and Fitness to Practise Analysis

We analysed available data for evidence of business-related risks. The GOC's FtP hearings provide the most useful information for this purpose, as information from complaints to the GOC and OCCS were typically too high-level to elicit the underlying causes of the problems. In addition, the latter do not provide any insight into the severity of the complaints.

3.2.1 Fitness to Practise Hearings

We considered the GOC FtP hearings for evidence of business-related risks. These represent complaints that were deemed serious enough by the GOC's Investigation Committee to pursue through a formal hearing. They provide some information on the potential scale of business risks within the optical profession, although eliciting the full underlying factors in each case is not possible.

Building on our 2010 report, we have reviewed all hearings between 2007 and 2012 and assessed any evidence of business risks using our qualitative judgement supported by industry findings. We provide a high level statistical description of the hearings and an analysis of specific hearings that are business-related.

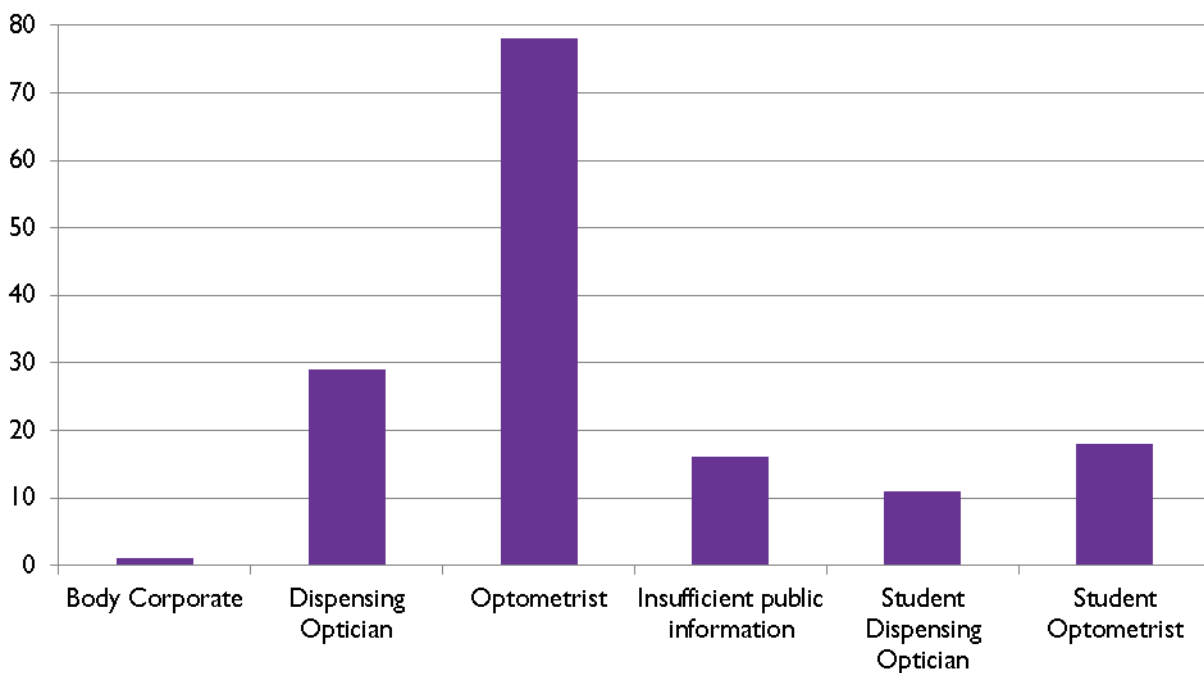
3.2.1.1 General statistics

Within the six years analysed, there were a total of 153 hearings, out of which 103 were new inquiries and 34 were interim orders (the rest were restorations or reviews of previous orders). Amongst all the hearings, the number of new inquiries and interim orders published in 2012 were 10 and 12 respectively. To avoid double-counting we only analysed new inquiries and interim orders (a total of 137), as restorations and reviews recorded in one year could reflect a hearing begun in a previous year. In addition, cases that are held under private hearing are excluded from the analysis and classified as 'Insufficient Information' due to the absence of any details of the case.

To place these figures in context, the number of sight tests conducted annually from 2006/07 until 2010/11 ranged from approximately 18.5 million to 21.1 million.⁴² The number of FtP cases obviously represents a very small proportion of eye care activity.

The chart below shows the number of professionals and businesses involved in the hearing cases analysed. As can be seen, optometrists account for the largest proportion of the hearings, followed by dispensing opticians.

⁴² Optical Confederation (2011), 'Optics at a Glance 2011'.

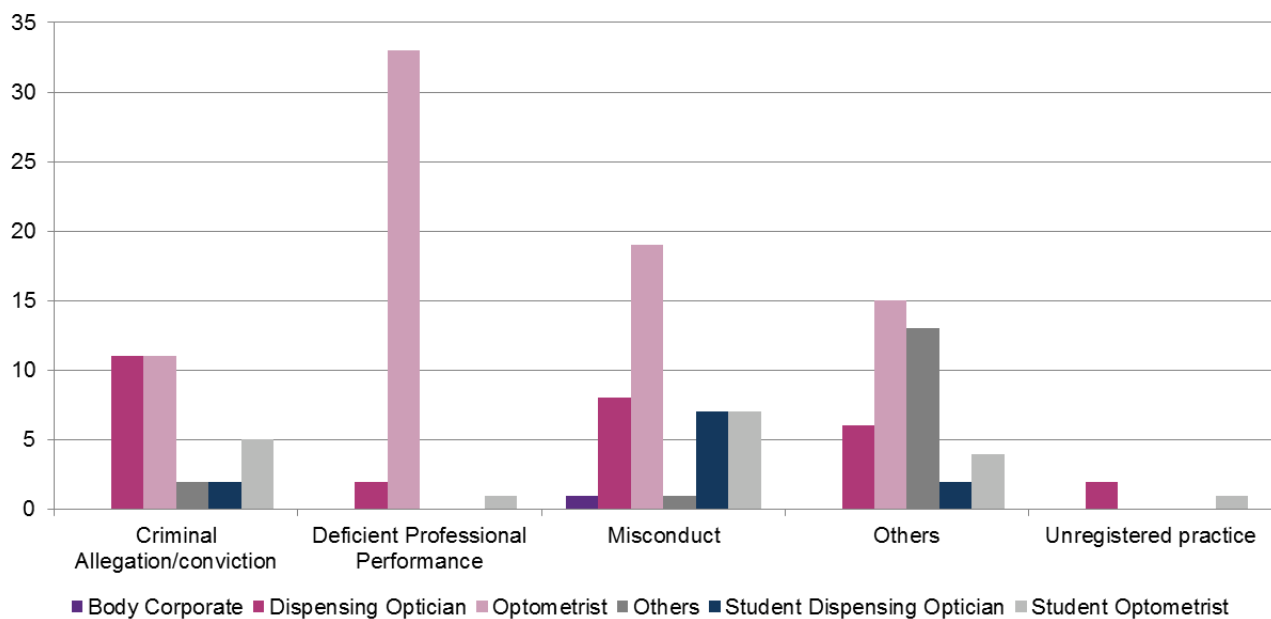
Figure 3.1: Number of Fitness to Practise hearings by professional type

Source: GOC Fitness to Practise hearings 2007 - 2012

We classified the hearings by the nature of the cases as follow:

- Criminal allegations or convictions: cases in which practitioners were alleged to have committed or been found guilty of a crime
- Deficient professional performance: complaints involving failure in providing adequate eye care to patients, such as lack of supervision and poor record keeping. This category provides the most relevant cases for the purpose of this study
- Misconduct: cases that involved improper behaviour or dishonesty in business practice.
- Unregistered practice: unqualified practitioners who carry out restricted functions and cases where the practitioners are employees of a company are of particular interest to this study
- Others: includes cases that were in breach of previous conditional registration orders, a caution from police and private hearings (private hearings will include cases where impairment was by reason of health).

There are 35 hearings classified as deficient professional performance, which accounts for nearly 26 per cent of the total. We summarise the number of cases in each category per type of professional below:

Figure 3.2: Distribution of case categories by professional type

Source: GOC Fitness to Practise hearings 2007 - 2012

Decisions of the hearings can vary from no action to erasure from the GOC register. Suspension and conditional registration are found to be the most common sanctions used in the hearings analysed. For complaints concerning deficient professional performances, 20 out of 35 cases received different degrees of sanction. The majority of the complaints concerned failures in the carrying out of testing and poor record keeping. Cases of inadequate supervision were also identified. It is difficult to judge from the decision of the FtP panel whether such failures of professional conduct are caused by poor business practice or simply a failure in professional conduct by an individual, or a mixture of both. Many of the problems relate in some way to the risk areas found through our evidence gathering as discussed above.

The cases that received sanction comprised the following complaints:

- Failure to undertake adequate examination
- Poor standard of record keeping
- Failure to refer patient for ophthalmological opinion
- Tests carried out by unqualified staff with no adequate supervision
- Inappropriate equipment for glaucoma testing
- Lack of sufficient supervision of registered students
- Cases involves criminal conviction
- Improper/dishonest behaviour of the practitioners, such as the submission of false testimonials.

3.2.1.2 Business risk

We investigated further the areas of business risks that could be related to the hearings above. Using our judgement on the hearing description, we classified the correlation of the hearings to business risks into three types — “likely”, “possible” and “unlikely”.

Out of the 137 hearings cases, we identified ten cases that were likely to be influenced by poor business practices. For example, one of the complaints involved a body corporate which was found responsible for inappropriate supervision arrangements for a registered student within its practice, while inadequate equipment for the testing of glaucoma was also found in another business practice. Other cases concerned

the employment of unqualified practitioners which is also likely to be the responsibility of the business (unless the practitioners were sole traders).

We classified a further 16 hearings as providing possible evidence of business risks. These are cases relating to poor record keeping and inadequate eye examinations which could be influenced by the commercial pressures faced by the practitioners, or by poor business systems.

The rest of the cases were unlikely to be related to any forms of business risks but mainly concerned the incompetence or improper behaviour of the practitioners themselves.

3.2.1.3 Summary

In summary, there are cases that are likely or possibly related to poor business practice — approximately 19 per cent of total cases according to our analysis. Whilst it is difficult to confirm definitively the real underlying causes of these cases, it is likely that business practice played some role. The potential areas of business risk identified in this analysis are summarised below:

- Inadequate records of sight testing
- Failure to refer patient for ophthalmological opinion
- Failure to conduct certain tests (mainly for glaucoma)
- Tests carried out by unqualified staff with no adequate supervision
- Lack of appropriate equipment for glaucoma testing
- Employment of unregistered practitioners.

Evidence from interviews with optometric advisors for different PCTs in England (some of the functions of which have now been transferred to NHS England Area Teams) suggests a wide variation in evidence of poor business practices. One PCT advisor had completed approximately 65 contract compliance checks, six of which required remedial action that, in the advisor's opinion, could have had some potential impact on public health and safety.⁴³ At face value this anecdotal evidence implies that business-related risk is a problem in practice. However, other optometric advisors reported a much lower prevalence of poor business practices, and emphasised that the main problems they came across were poor financial contract compliance and record keeping (as we have noted above, the latter makes difficult disentanglement of problems related to individual professionals or to wider business systems). Unfortunately further evidence about inspections has not been collected in a systematic way by PCTs: this means that we are unable to determine prevalence of the actual risks across the whole sector. Nor are we able to say whether these optometric advisors' experiences are at all typical.

3.2.2 Optical Consumer Complaints Service (OCCS)

The OCCS receives and handles complaints about opticians and optical practices. Since the majority of OCCS complaints are customer-service oriented, these are relevant to this study in that they may help us to understand the issues that can arise from how businesses are run. However, the detail of the complaints does not provide insight into their severity. It is worth noting that OCCS complaints would not ordinarily involve significant public harm as such complaints would normally be referred to the GOC. Analysis of OCCS' annual reports between 2007 and 2011 is summarised below.

⁴³ The majority of these six practices were independent high street practices. The most variation in business practice is thought to be found among these — both the worst and the best. Underinvestment in equipment is usually a feature of smaller, independent practices rather than of the large multiples.

3.2.2.1 General statistics

The number of cases opened in any of the five years ranges from 708 to 1007. In 2011, there were 820 complaints recorded by the OCCS and the majority of them are related to spectacle prescription and poor services or practice. Poor service or practice has become one of the largest categories of complaints since its introduction in 2010. Among all the categories,⁴⁴ some are likely to be at least partly business-related such as:

- Poor service or practice procedures
- Prescription not provided or refused
- Sight test and dispensing at separate practices
- Miscellaneous, which categorises other type of complaints.

However, it is hard to determine the risk to patients' health given the limited details of the complaints. The complaints could relate to improper behaviour of the staff or over-charging for the optical products. Hence, further information would be necessary to draw further conclusions on the complaints information.

3.2.2.2 Findings reported by the OCCS

Analysis conducted by the OCCS on its complaints data has confirmed our earlier findings. Complaints in relation to poor explanations provided by the practitioners have suggested inadequate communication between practitioners and patients. There are also complaints about sales and dispensing which could be caused by misleading marketing techniques such as 'free' eye tests, and improper training of the dispensing opticians. Additional time spent on clear explanation and internal training would help to improve customer relations and benefit the practice with repeated sales.

The OCCS also stresses that conflicts between commercial and professional interest could increase in a profit driven environment. A consumer's freedom of choice might be limited due to commercial pressure imposed on or experienced by practitioners. In some complaints, sight tests are found to be refused or a prescription not supplied unless specifically requested. OCCS also indicated a tendency for aggressive marketing of optical products that may not be in consumers' interests or even affect the standard of clinical care. The growth of online optical selling can impose additional pricing pressure on traditional business which could exacerbate the conflict between commercial performance and public health.

3.3 Mitigating Factors

We investigated whether the current situation provides any additional oversight of business practice, and whether this is likely to change in the future.

3.3.1 The GOS contract and inspections

The majority of optical businesses provide services for the NHS GOS. GOS regulations in England make the most provision for oversight of the four nations of the UK; England is also the largest nation by far in terms of optometric activity. Therefore we focus on England in this section. Further detail about the oversight in the other nations, as well as an analysis of how this affects our overall findings, is presented in section 3.4.2.

The structure of the NHS in England has undergone changes; previously GOS contracts were managed individually by PCTs. The new NHS structure has done away with PCTs and now provides for a

⁴⁴ In 2011, the categories of complaints were: eye examination, spectacle prescription, multifocal lenses, dispensing, frame, contact lenses, miscellaneous, fitness to practise, poor service/practice, no prescription given and sight test and dispensing at separate practices.

centralised system of GOS contract management, using 'NHS England Area Teams' to carry out local elements of the contract management. The procedures for contract assurance within the new system are still to be finalised (as at end of June 2013), but an overview is available from NHS England.⁴⁵

We discuss the level of oversight that the previous system provided in terms of ensuring good business practice, and comment on whether the new system is likely to represent a significant change in oversight. This discussion simplifies the overall restructure of the NHS and focusses only on those elements that are key to this study.

3.3.1.1 Contract management under PCTs

The GOS contract is very detailed and contains a number of clear requirements for businesses that relate to practice standards, including equipment requirements. PCTs were responsible for inspecting businesses (using optometric advisors) to ensure that they were compliant with contract standards, and could issue action plans for improvement where necessary. There were two types of inspection that took place: the first was general contract compliance, and the second related to the financial aspect of the contract, termed 'post-payment verification' (PPV) inspections.

It is felt by professionals (including those involved with the NHS processes of contracting and commissioning) that the role of PCTs was not widely effective in either identifying or working against poor business practice. First, the content of the inspections did not directly address many of the business issues relating to clinical governance that this study has highlighted as causes for concern, although there were some areas of overlap. The GOS contract, and corresponding PCT contract compliance inspections, focussed on issues like health and safety, infection control, information access and provision, complaints and incidents systems, and the verification of employees' GOC registration. Elements of clinical governance were included, such as:

- Record keeping (whether records are legible, up to date and securely filed, and contain all necessary information relating to a patient)
- Whether staff are properly supervised
- Whether the business ensured clinical procedures are appropriate
- Whether the business checked locums' references
- Whether equipment is appropriate and in good order.⁴⁶

However, businesses were not required to show any documented proof of their systems or protocols, for example on staff training, supervision, and scheduling (inspectors merely asked whether these systems were in place). It was also not possible to identify poor practices such as commercial pressures being placed on staff through the inspections. Feedback from the profession indicates that GOS contract requirements represented a 'bare minimum' in terms of clinical governance. The second type of inspection focussed purely on financial issues (e.g. checking that practices did not submit fraudulent claims for sight tests) and thus did not cover patient-related risks.

A second, and possibly more relevant concern, was the consistency of the contract management across PCTs. The frequency of inspections varied greatly between PCTs, with some businesses never having received a PCT inspection, and others only having had PPV inspections. Feedback from individuals involved in GOS contract management also indicates that the standards of the inspections varied greatly: inspectors were generally clinicians and had not received any formal inspection training. For example, some advisors

⁴⁵ Primary Care Commissioning 'Procedure for the assurance of General Ophthalmic Services contracts: Standard operating policies and procedures for primary care' March 2013.

http://www.loc-net.org.uk/uploaded_files/116059962410823/contractassurancegosv15docx.pdf

⁴⁶ QiO Contractor Checklist.

would undertake detailed audits of clinical records — which is held to be a very important means of identifying problems with clinical care — whilst others would simply check that the records were correctly filed and were legible.

3.3.1.2 Contract management and commissioning in the new NHS structure

The changes in the NHS are relevant in two ways.⁴⁷ First, the management of the GOS contract will be centralised, i.e. away from individual PCTs (or their successors). A system of ‘contract performance review’ will be instituted which aims to reduce inappropriate variations in optical business practice and to support improvement in the quality of the contracted services provided. Practices will be required to fill out and submit a self-declaration of their compliance with the contract’s standards. The declaration will include a checklist based on the clinical governance tool called ‘Quality in Optometry’ (QiO).⁴⁸ This is the first time a *national* quality assurance tool has been used (although QiO has been available since 2007 for contract compliance); given variations across PCTs some practices have never formally addressed the issue of quality and thus it is hoped that the formal use of this tool will provide a first step in lifting the bar for quality.

GOS contract requirements will be based on ‘Level 1’ of the QiO tool, which covers the same ground as the contract requirements under the old system managed by PCTs. As noted, it is felt that this represents only the ‘bare minimum’ of good practice management. It also does not *directly* address many of the potential risk areas identified in this report.

Although the new system will rely predominantly on self-declaration, inspections will still be carried out on a centralised basis. It is proposed that practices where a new GOS contract has been awarded will be inspected, as will practices where there are concerns about contract delivery (based on, for example, the results of the self-declaration). In addition, inspections will be conducted on a random selection of practices based on a small proportion of the total number of contracts in the Area Team (e.g. five per cent).

Given the previous variation in PCT inspections, it is not clear the extent to which the new contract inspection regime represents a change in current levels of oversight overall. In some PCTs, inspections would have been conducted on a larger sample than that proposed now (for example, one PCT advisor we spoke to thought that every contractor in her area had been inspected over a three-year period); in others the new system may represent a significant improvement.

It is also proposed that the new system will require fewer optometric advisors (clinicians) and rely more on non-clinical individuals to undertake inspections, using a more standardised inspection protocol.⁴⁹ Whilst a more formalised quality assessment regime may increase the consistency of inspections, some advisors have serious concerns about the value of such inspections. There are elements of an inspection that only a qualified optometrist can cover, such as checking whether the contents of clinical records reflect appropriate professional action.⁵⁰ Some of the optometric advisors felt that a move away from this kind of audit is a backwards step in terms of proactive regulation and represents a move towards a more reactive system. We note that whilst auditing records is an important way of identifying poor *practitioner* practice, it does not necessarily identify business-related risks.

⁴⁷ Details of the new system for optics will be released in June. We present here an overview of the proposals.

⁴⁸ QiO is a clinical governance toolkit jointly developed by the AOP, FODO, Association of British Dispensing Opticians (ABDO) and the College of Optometrists: www.qualityinoptometry.co.uk

⁴⁹ Details regarding the exact nature of inspections are still uncertain in terms of who will carry out the inspections and what they will consist of.

⁵⁰ According to one optometric advisor, auditing records is a very effective way of picking up deficient professional performance and is considered a vital part of GOS management, even though it is not possible to tell whether poor records reflect problems with individuals or the business as a whole.

The second element of the NHS changes relates to the commissioning of ophthalmic services. Clinical commissioning groups (CCGs) are increasingly looking to commission services from a single provider, particularly with regard to enhanced service pathways.⁵¹ This single provider would then be responsible for ensuring that the individual sub-contracting practices maintained good business practices and complied with all the guidelines and conditions imposed by the CCGs (which in general go over and above those required by the GOS contract). Although not all optical businesses would be part of such arrangements, it is thought that these types of arrangements, and the involvement of businesses, are growing, and that the oversight of the single providers and the CCGs will provide an increasing additional level of enforcement of good business standards.

3.3.1.3 Other examples of oversight

In the context of domiciliary practices, the Joint UK Domiciliary Eyecare Committee (an industry-led initiative) has developed a code of practice that the majority of PCTs in England encouraged practices to sign up to. It was recognised and recommended by PCTs (i.e. not mandatory but preferred). This, combined with competitive pressure, could be an effective tool for self-regulation. In addition, the GOS contract for domiciliary care has its own regulations that act as a check over practice. We have been informed by a prominent domiciliary eye care provider that practices were required to inform the PCT before a domiciliary patient was visited. In this way the PCT had prior knowledge of a patient being visited, so that if there is a problem or complaint there was already some oversight from the PCT (although, as above, the effectiveness of PCTs varied greatly). It is not yet clear how the new NHS structure will deal with domiciliary eye care.

3.3.1.4 Summary

In summary, the requirements of the GOS contract appear to provide the most visible form of regulation for business practices, although this is focused largely on financial, and health and safety issues rather than directly on aspects of good clinical governance. The regulations also represent a 'bare minimum' of quality.

The move away from PCT-based inspections in England to a more centralised system that relies on self-declaration, random inspections of contracts and fewer clinical inspectors could represent a reduction in oversight compared with the previous situation in some, more effective, PCTs. However, the extent to which this may be the case is unclear given the variation in effectiveness across PCTs, and the absence of uniform data on this. We do know that the content of inspections is likely to remain the same under the new system, and that no significant increase in scope is envisaged.

3.3.2 Competition

A second factor that might limit the extent of poor business practices is competition between optical practices on service quality.

The optical market is competitive, with downward pressure on prices through the larger corporates and online sales of appliances and contact lenses. The reimbursement of the NHS sight test fee means that businesses generally do not rely heavily on the provision of sight tests for profitability, as there is generally limited scope for pricing variability here and sight tests on their own are generally held not to be profitable.

Practices are likely to differentiate themselves on quality of services and on the sale of optical appliances in order to attract and retain patients. The introduction of more sophisticated testing techniques allows practices to gather more accurate information of patient's eye health to establish continuity of services with

⁵¹ For example, Glaucoma Referral and Children's Vision pathways. See the Local Optical Committee Support Unit for more details: <http://www.locsu.co.uk/enhanced-services-pathways/>

the patient.⁵² Loyalty and reputation are important to optical practices and where present quality competition should act as a form of oversight against very poor business.

However, public perception about what is important is a key driver of the areas on which businesses compete. Optical care customers are heterogeneous with some placing a higher value on the assurance derived from a large brand, whilst others perceive local independent opticians to provide better services than the larger companies.⁵³ Other factors such as location and the range of products are central influences on patients' choice of practice. It is likely that the public place more value on price (of all opticians' services including sight tests and appliances) than good clinical care, and thus competition is likely to be driven in large part by price.⁵⁴ On the other hand, an increasing number of businesses are attempting to differentiate on quality, e.g. delivering commissioned enhanced services. If this latter trend continues to grow and strengthen then competition could be a driver of enhanced service quality. However we would not expect competitive pressure to be a significant driver of clinical excellence per se as we consider it difficult for patients to identify this.

Further, competition may have a negative effect on businesses practice if, for example, the resulting cost pressures encourage businesses to under-invest. It is likely that this will take place in areas patients are least able to observe, such as special equipment or other clinical matters, rather than customer service or the price of optical appliances.

If there was a link between good business practice and profitability (e.g. by extending business registration such that all businesses must abide by a code of conduct in order to operate, and any costs associated with that) then this could also level the competitive playing field if all practices were bound by the same code, preventing businesses obtaining a competitive edge by undercutting clinical service.

3.4 Conclusions on Business Risk

Our research has confirmed that there are a number of areas of optical practice that are essential for good patient care and which are influenced by business practice. These are:

- A business environment that provides practitioners with autonomy to undertake their professional activities to the best of their ability and in line with professional standards
- Systems and protocols to ensure good clinical governance, including clear communication among staff; adequate supervision of assistants and students; consistent management of locums; and appropriate record keeping
- Adequate investment in equipment and training of staff to ensure that the level of care is up-to-date.

Our findings also confirm that if these factors are absent from a business, then patient care may be undermined and even damaged. Whilst evidence of actual harm is limited, there is evidence of poor business practices, as shown by our analysis of the GOC's FtP cases (where around 19 per cent of the 137 cases involving individuals are thought to contain elements symptomatic of poor business practice), feedback from a PCT inspector, and complaints collected by the OCCS.

⁵² YouGov (2011), 'Opticians' market report.

⁵³ According to YouGov (2011) market report on Opticians, 72 per cent of patients have visited a chain optician recently and only 24 per cent of patients chose local/independent opticians. Also, over 1 in 20 respondents believed that bigger brands were more reliable. On the other hand, four in ten believed that local businesses offer better service while only one in ten found that larger chain provide higher quality of service.

⁵⁴ As an example, according to a survey conducted by RNIB, 17.5 per cent of the respondents aged 60 and over who had not had an eye examination in the past two years suggested that cost of glasses was the main reason for postponing the eye test and the percentage is higher (21-26 per cent) among the lower income groups. See RNIB (2007), "Older people and eye tests".

http://www.rnib.org.uk/getinvolved/campaign/yoursight/Documents/public_oldereyesreportp.pdf

3.4.1 Drivers of poor business practice

Poor business practice could occur for a number of reasons, such as having an incompetent or uninterested owner or practice manager, or in response to commercial or economic pressures as a means of saving costs.

As noted at 3.1.1 and 3.1.2 optical businesses can be operating on tight margins with commercial pressure a real concern for some. This is caused by a number of factors, including the low NHS reimbursement fee and the ability of patients to purchase (profit-making) optical appliances and contact lenses from other suppliers. Whilst commercial pressure resulting from low NHS fees can certainly be a contributing factor to poor business practice, it does not appear to be the key driver (as there are many practices that operate to a high standard within this economic structure). However, as mentioned in 3.1.2.5, commercial pressures may well become more widespread and, although businesses may not directly engage in poor business practices as a result, the capacity or ability to undertake good practices may present a greater challenge.

In testing our analytical framework as set out in Chapter 2, we found that the number of practitioners in a practice does not appear to be a driver of business risk, as risks can be spread across a range of business types. Similarly, the ratio of registered to non-registered employees does not appear to be a key feature: the majority of businesses make use of non-registered assistants and this in itself is not a driver of risk. Rather, the way in which such assistants are managed and trained is the relevant driver.

3.4.2 Differences across the nations

Throughout the report we have made reference to differences between the four nations of the UK and how these might affect business risks. We present here an overview of the key differences and discuss how these differences impact on our overall findings.

Contract compliance

Individuals and businesses wishing to provide GOS (and receive reimbursement on sight test fees) must hold a contract with the NHS or service level agreements with Health Boards as set out below.

- **England.** Optical businesses and individuals who provide NHS services have a GOS contract with the NHS. On 1 August 2008 the provision of GOS in England was made subject to contracts between PCTs and those providers, whether professionally qualified or lay, who have met certain criteria regarding premises, equipment, good character and so on. Contracts could be for 'mandatory services', e.g. testing sight in a practice, or for 'additional services', e.g. domiciliary testing. On 1 April 2013 PCTs ceased to exist and all existing GOS contracts were transferred to NHS England (formerly the NHS Commissioning Board). The model contracts which had existed since 2008 have been updated to reflect the transfer of the contracts to NHS England.
- **Wales.** An optometrist or ophthalmic medical practitioner (OMP) can provide or perform sight tests under GOS in Wales only if he/she is on the Ophthalmic or Supplementary List of one of seven health boards. Health boards in Wales are statutory bodies responsible for securing services to meet the health needs of the people of Wales. All contractors are held on a central list, which holds the details of the contractors rather than the individual 'performers', and is effectively a list of all businesses. The Supplementary performers list identifies those working for the contractor. The NHS Shared Services Partnership (SSP) supports the seven health boards of NHS Wales. The SSP provides them with contractor services for primary care optometry including contracts and lists management, payment processing and post-payment verification.
- **Northern Ireland.** An optometrist or OMP can provide or perform sight tests under GOS in Northern Ireland only if he/she is on the Northern Ireland Ophthalmic List with a health board. Health boards in Northern Ireland are statutory bodies responsible for securing services to meet the health needs of the

people of Northern Ireland. Family Practitioner Services Ophthalmic Services are responsible for payments to practitioners for the provision of GOS and optical vouchers, and the maintenance of the statutory Ophthalmic List.⁵⁵

- **Scotland.** An optometrist can only provide, or assist in the provision of, eye examinations under GOS in an area of Scotland if he/she is on the ophthalmic list of the NHS board for that area. Scotland, uniquely, has different GOS regulations to the rest of the UK (discussed below). Optometrists offering GOS must have additional accreditation to their GOC registration.

As GOS providers in England hold contracts with the NHS, they are subject to contract compliance review, as described in section 3.3.1. GOS providers in Northern Ireland and Wales are not subject to the same contract compliance, and although the QiO toolkit has been designed for Wales as well as England, it is not used for the basis of contract compliance.

NHS Boards in Scotland are asked to inspect existing premises from which GOS are provided on a three year rolling-programme basis. Boards are also asked, before allowing an optometrist/OMP onto the Board's ophthalmic list, to inspect premises where GOS will be provided.⁵⁶ However, it appears that practice inspections do not focus on clinical governance issues: under paragraph 6 (premises and equipment) of Schedule 1 (terms of service) of the NHS GOS Scotland Regulations 2006, contractors are required to provide "proper and sufficient consulting and waiting room accommodation and suitable equipment, including required equipment", for the provision of GOS. The inspections cover: facilities; complaints procedures; essential equipment; drugs; health and safety; and record keeping.

Therefore NHS oversight is limited to GOS providers in England and, to a certain extent, Scotland.

Reimbursed fees

The key differences that relate to business practice are between Scotland and the rest of the UK. There are some differences in *professional* optical care between the nations, but these are not directly relevant to business practice.

For example, the new Wales Eye Care Service (WECS) starts from 2013, although it builds on previous initiatives, and will enable optometrists to deliver new levels of patient care through a new national enhanced service. Within the WECS the Eye Health Examination Wales (EHEW) will provide a tiered structure of eye examinations, follow-ups and further investigations. It will allow optometrists greater clinical freedom and scope to manage their patients in primary care, thereby reducing the demand on hospital eye services.

Approximately 80 per cent of optometry practices have optometrists accredited to provide the EHEW service, but there are some optometrists and practices who provide eye care under GOS only. Although the WECS will introduce an increased scope of practice over and above the GOS contract, this is at the individual professional level and neither places additional requirements on, nor implies additional monitoring of, optical businesses.⁵⁷ The reimbursement of fees under the WECS is not under GOS as the eye examinations are not sight tests and therefore fall outside GOS. Businesses need to claim costs from the NHS SSP.⁵⁸ Reimbursed costs for sight tests are the same as in England and Northern Ireland.

Scotland, however, has different GOS regulations to the rest of the UK, and a revised GOS contract was introduced in Scotland in 2006. The main aim of the new contract was to enable optometrists to serve an enhanced role in communities, providing early intervention and detection of eye disorders and reducing the burden on hospital eye services.

⁵⁵ Family Practitioner Services Ophthalmic Services is part of the wider Health and Social Care Business Services Organisation. <http://www.hscbusiness.hscni.net/services/1780.htm>

⁵⁶ See [http://www.sehd.scot.nhs.uk/pca/PCA2007\(O\)03.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2007(O)03.pdf)

⁵⁷ See <http://www.optometrywales.org.uk/wales-eye-care-service-weecs>

⁵⁸ See <http://www.bsc.wales.nhs.uk/>

The two main differences in Scotland arising from the new GOS contract are higher sight test fees and an equipment grant:

- **Higher sight test fees.** Eye examinations are free for all in Scotland (as opposed to only certain categories in the rest of the UK) and businesses are reimbursed for sight tests at fees ranging from £37 to £45 depending on the type of examination done.⁵⁹ Supplementary examination fees are £21.50
- **Equipment grant.** In 2006 and 2008 optical practices businesses in Scotland were given equipment grants of £8,000 and £10,000 respectively as part of the GOS contract. The aim was to ensure that all practices are adequately equipped to offer all the services under the GOS contract which are extended compared with the rest of the UK (a slit lamp, Volk lenses, and a full threshold field analysis).

These equipment grants imply that businesses in Scotland should be less likely to have sub-optimal equipment that could pose a risk to patients.⁶⁰ However, as discussed at 3.1.9, under-investment in equipment does not appear to be a significant driver of risk in general and therefore businesses in Scotland would not appear to be at a material advantage over those in the rest of the UK in terms of risk. In addition, part of the issue with equipment is ensuring that it is well-maintained and properly calibrated; this has managerial as well as financial implications and there is no reason why businesses in Scotland would be more or less likely to undertake this responsibility compared with the rest of the UK.

The difference in sight test fees may have more of an impact. The higher fee is likely to reduce the extent of any commercial pressure felt by optical businesses in Scotland (although it has still been noted by stakeholders that even the higher reimbursed fee does not always cover the true cost of a sight test). To the extent that financial pressures are a driver of business-related patient risks, the more favourable commercial situation in Scotland should imply a reduction in this risk driver.

Commercial pressure is not the only driver of business-related risk: businesses engage in poor practices for a number of reasons (and, similarly, there are many businesses under financial strain that still are able to provide good services). However there is likely to be a spectrum of responses to commercial pressure that includes a middle ground of businesses that might be tempted to cut corners if operating at the margin. There should be fewer of these businesses operating in Scotland who would possibly be less likely to engage in poor practices. In addition, a lighter financial strain in Scotland may enable some businesses to be more proactive in implementing good practices (even if not engaging in directly risky practices).

This spectrum may be wider across the rest of the UK. Although the actual sight test fee is the same, the extent to which this is 'below cost' is likely to vary between regions. For example, it is likely that an optical business in London makes a greater loss from NHS sight tests than a business in rural Wales, given overheads and the cost of living in London compared with Wales.

Our conclusion on this issue is that although the extent of commercial pressure is likely to differ across the UK, and be least marked in Scotland, this is not the only driver of business risk. There will be businesses that engage in risky practices regardless of their financial situation. Similarly, although NHS oversight of GOS providers is not uniform across the four nations, the available evidence does not point to any material differences in risks under the current system. We do not consider any differences in NHS oversight and remuneration great enough to warrant a different regulatory approach across the nations.⁶¹

⁵⁹ The higher fees are in part to cover the extended scope of practice, for example the £45 examination applies to over 60s where a digital photo is taken. However, even a basic examination (primary eye examination to those under 60) is reimbursed at £37 compared to £21.50 in the rest of the UK).

⁶⁰ There is of course a possible counter-argument: namely, businesses in Scotland will hold off from capital investment in anticipation of further grants being made available. Our view is that the pace of technological change in ophthalmology is not such that capital is suddenly made inadequate, and so this is highly unlikely to be a material effect.

⁶¹ Any differences in regulatory approaches between the nations would need to be fully justified and carefully thought through, otherwise there could be scope for cross-border regulatory arbitrage.

3.4.3 What are the main problems to address?

As highlighted in the Introduction to this report, our analysis must take into account existing forms of oversight. The most important form of this is individual professional regulation by the GOC whereby all registered practitioners, including those working for unregistered businesses, are bound by the GOC's *Code of Conduct*. Our 2010 risk report concluded that, from the point of view of individual practitioners, the optical profession is overall relatively low-risk compared with some other healthcare professions, and that professional integrity, regulation by the GOC and continuing education and training is sufficient to promote good public health and safety.

However, as discussed above there are some areas of optical business that affect patient care that are not directly controllable by registered practitioners, and are instead the responsibility of business owners who may not be registered practitioners. There is consensus among the associations and professionals who contributed to this work that the greater the distance between the financial ownership/legal liability of a business and the practitioners directly responsible for patient care, the greater the risk of conflicts of interest between commercial concerns and patient care. In addition, good clinical governance through appropriate systems and processes, such as good record-keeping or supervision protocols will be more consistently implemented if proper management systems are in place. Also, the individual or body with final responsibility for the practice places importance on clinical governance and patient care.

Whilst it is likely that a business owner who is also a registered practitioner will have this clinical responsibility by virtue of being an optical professional, this may not automatically be realised in practice. Poor practice management and an absence of appropriate systems may exist regardless of the nature of the owner.

Poor incentives of business owners will be exacerbated by the gaps in coverage of the current regime. If the owner/manager of the practice is not a registered optical practitioner and the practice itself is also not registered, then the GOC is not able to take action against the business practice. Depending on the facts of the case, the GOC also might not be able to take action against an individual owner who is a registrant, in relation to problems that relate to the business.

This makes it clear that individual professional registration cannot be relied upon to ensure good business practice, and that if such practice is to be overseen a form of business registration is necessary.

We summarise these two main problems using common economic terms:

- **Market failure:** a mismatch of incentives between owners with ultimate responsibility/liability for the business and the responsibility and incentives of practitioners in terms of clinical governance. There are some elements of clinical governance that rely on good business practices which cannot be implemented if the owner of the business does not adequately consider the needs of clinical governance in some way. Being directly registered with the GOC will place this professional incentive with the business
- **Regulatory failure:** a lack of comprehensive oversight of the GOC and 'levers' to issue sanctions against poor business performance or to enforce good practice.

The opinion of the profession (both individuals and associations that we interviewed) is that the current form of business regulation is not fit for purpose given such gaps in oversight and that there is more merit in increasing the scope of business regulation than scaling it back.

4 Benefits and Costs of Business Regulation

In this chapter we analyse the costs and benefits of a number of options for business registration. We first present the options we have considered, and then discuss the types of costs and benefits that the various options may give rise to, and describe some important methodological considerations. We then assess in qualitative terms each of the options in terms of its benefits, costs and wider impacts.

A more detailed analysis of the options including cost estimates is included in the appendix.

4.1 Options for Business Regulation

We list below the options for business registration that we have considered. As agreed with the GOC these are high-level and the detailed specifications of each option have not been included. In our analysis we discuss *where* such details are likely to affect the costs and benefits.

- Option 1 — Retain the current system of business registration
- Option 2 — Remove business registration
- Option 3 — Extend business registration to all businesses providing restricted functions
- Option 4 — Extend business registration and enhance code of conduct for business registrants
- Option 5 — Extend business registration and enhance code of conduct for business registrants and establish inspections of premises and audit protocols
- Option 6 — Remove business registration and introduce the registration of a dedicated “practice principal” for all business premises
- Option 7 — Voluntary self-regulation by the industry.

4.2 Understanding Costs and Benefits

In this section we present a typology of costs and benefits that might arise from the options. We also discuss the important methodological considerations that must be kept in mind when conducting a cost-benefit analysis.

4.2.1 Incremental costs and benefits

An important part of a cost-benefit analysis is identifying the extent to which the registration options will bring about *additional* costs and benefits compared with what would otherwise take place. This is achieved by developing a counterfactual, which is a benchmark situation against which to measure the impact of regulatory changes. The counterfactual seeks to take into account both the current situation and likely future developments.

We summarise the important elements of the counterfactual relevant to our analysis:

- Existing levels of business practice — there is little evidence of actual harm arising from poor business practice. The main evidence relates to *potential* risks arising from several business features

- Existing number and type of businesses already registered with the GOC — approximately 2,000 bodies corporate are already registered with the GOC. This includes all the large multiples
- NHS oversight — the changes in the NHS in England will bring about a new GOS contract management regime, which will include centralised inspections. It is not clear the extent to which this reflects an improvement or reduction in oversight compared with the current situation, given the previous variation in supervision across PCTs. There is the possibility that the clinical resources available for inspections will be reduced in the new system, and that fewer random inspections will be conducted (compared to what occurred under more effective PCTs). It is known that the *content* of NHS oversight is unlikely to change, and will remain relatively light on directly overseeing good clinical business practices
- Economic pressure — the overall short-term economic climate is likely to remain difficult. Trends towards online purchasing of contact lenses and appliances may grow, further undermining the profitability of businesses providing optical services
- Code of conduct — the GOC's current *Code of Conduct for business registrants* is relatively high-level and limited in terms of addressing specific risk areas
- Existing professional registration and legal regulation — individual registered practitioners working in unregistered businesses are bound by the GOC's *Code of Conduct* for individual registrants. All optical businesses providing restricted functions are bound by the Act.

4.2.2 Costs

The costs of the registration options relate to:

- Costs to businesses of complying with registration requirements, such as filling out forms; familiarisation with requirements; training; amending business practice
- Administrative costs to the GOC of implementing and running the registration scheme. These costs could include collecting registration submissions; fielding queries; sending reminders; and keeping the register up to date
- Fitness to practise costs to the GOC. These would include costs to the GOC of handling complaints and fitness to practise cases (including investigations and hearings) specifically related to the new businesses on the register.

The magnitude and nature of these costs will vary according to the policy options. Some cost areas will rely heavily on assumptions about the particular details of the options which have not been developed yet (for example, the exact changes to business practice that might be required), and as such will be discussed in more general terms.

The distribution of costs is an important consideration. It is likely that the costs to the GOC will be passed through to business registrants in the form of registration fees. Whilst such fees will represent a direct cost to businesses, we will not add them to the costs to the GOC as this would result in double counting.

4.2.3 Benefits

The benefits of the registration options will be the extent to which they address the specific risks identified in this study. Given the high-level nature of the policy options and the lack of concrete evidence on the scale of and harm caused by business risks, we limit our analysis to providing a clear map of the *types* of risk each option should address, and how effective this might be.

Benefits could fall into the following categories:

- Increased levels of public health and safety arising from improved business practice and removal/sanction of non-compliant businesses. This would reflect any deterrent effect that registration with the GOC may have on poor practice
- Creation of a fair and competitive environment for optical businesses by levelling the regulatory playing field
- Increased public confidence in the optical industry.

4.2.4 Wider impacts

In addition to direct costs and benefits, we also consider the wider impacts of the options. These represent wider advantages or disadvantages of the options that may occur, and include weaknesses of the policy options that may bring about indirect costs or reduce the scale of the benefits.

The types of wider impact that might occur include:

- Legal implications of changing the Act (e.g. whether it would become illegal for an optical business not to be registered with the GOC, and the implications of this for the GOC)
- Enforcement action against non-compliant businesses
- Market exit by businesses unable to meet the burden of registration.

4.3 Assessment of Options

In this section we assess each of the options in terms of benefits, costs and wider impacts. As some options build on each other, the costs and benefits will overlap to some degree. In these cases we address only the additional costs and benefits for the new option.

4.3.1 Option 1 — Retain the current system of business registration

Under this option, the existing requirements for bodies corporate to register with the GOC are retained. Sole traders, non-limited partnerships and bodies corporate not meeting the existing requirements will not be able to register, and the latter group will not be able to use protected titles. There will be no registration requirement based on the provision of restricted functions as opposed to business structure.

4.3.1.1 Benefits

We have not identified any additional benefits of the current system (although any uncertainty, risk or cost related to changing the current legal framework is avoided). Existing benefits include the low cost of this model, and the delegation of the regulation of business standards to employers, the NHS and professional associations.

4.3.1.2 Costs

We have not identified any additional compliance costs due to retaining the current system.

4.3.1.3 Wider impacts

There are a number of weaknesses to the current approach. These can be summarised under two main headings.

- Incomplete ability of GOC to take action in relation to poor business practice:
 - This stems from the incomplete coverage of businesses in the current system. Only limited companies or limited liability partnerships (or in Scotland, partnerships) can be registered with the GOC, and of these only those meeting certain requirements for ownership

- Businesses that do not wish to be registered with the GOC can either change their structure so that they are not bodies corporate, or cease using the protected title. Therefore any registered business that has received an adverse outcome following a GOC fitness to practise hearing can continue to operate under a structure/name that would not require registration
- The ownership structure requirements (that the majority of directors be registered optometrists or dispensing opticians) pose difficulties to those bodies corporate that are small, or that lose a director and cannot replace him or her with a registrant director.
- Barriers to the enforcement by the GOC of high standards in business practice:
 - The current *Code of Conduct for business registrants* is very high-level and does not provide detail on what is expected on businesses (e.g. there is no guidance on what the GOC would interpret as meeting the code)
 - The incomplete coverage of business registration means that only a small proportion of all businesses are signed up to this code.

The current system may also undermine public confidence in the role of the GOC and the optical industry if the public is not clear about the reasons why some optical businesses are registered and others not.

The current system does not address the risks and potential problems with business practice identified by this research. Given its uneven coverage and essentially voluntary nature, it may be argued that the system incurs regulatory costs whilst providing few benefits.

In addition, the changing landscape may make the current system even less fit for purpose. With the forthcoming changes to commissioning structures, PCTs will no longer be responsible for inspecting optical businesses in England. Whilst there is uncertainty about how the new system will compare to the old, given the great variation across PCTs, it is likely that in some areas the new system will result in fewer businesses being inspected. (On the other hand, the new system will impose more consistent standards.) The fundamental nature of NHS oversight will not change, however, and there will remain a gap between those areas covered by NHS contract management and those identified as risk factors in this report.

4.3.2 Option 2 — Remove business registration

Under this option the current system of business registration would be removed and no optical business would be required to register with the GOC. This would include all bodies corporate and other businesses using the protected title or providing restricted functions.

4.3.2.1 Benefits

The main benefit of this option would be the removal of an uneven regulatory system that provides little consistent benefit. This would save on the costs currently incurred through the registration of bodies corporate,⁶² although some additional GOC resources might be diverted to other supervisory activity by the GOC.

4.3.2.2 Costs

The direct costs of this option would include one-off transitional costs to the GOC, such as notification of businesses of the change in regulation and handling queries. We do not envisage these costs to be significant. As mentioned above, there should be an on-going *saving*.

⁶² These costs are incurred by the GOC but largely passed onto business registrants through fees, and thus the savings would be mainly be attributed to businesses.

4.3.2.3 *Wider impacts*

The main disadvantage of this option is that none of the risks relating to business practice would be addressed at all. The GOC would have no recourse to take action in relation to businesses for poor practice.

Whilst there is not significant evidence of poor business practice resulting in patient harm, there are FtP cases that involve elements of business practice (and the anecdotal evidence from some PCT optometric advisors is also suggestive of this). Further, the *potential* risks associated with business practice would remain (e.g. those relating to systems and protocols) and could increasingly result in patient harm.

The GOC would also lack the means of promoting good standards in business practice through its *Code of Conduct for business registrants* (of course, the *Code of Conduct* for individual registrants would remain in place). What benefit there is in the current system would be lost.

An unintended consequence might be that increased pressure is placed on individual registrants as the only parties the GOC can hold to account in cases of poor patient care, even if the underlying causes are related to business practice.

4.3.3 Option 3 — Extend business registration to all businesses providing restricted functions

Under this option, all businesses providing restricted functions would be required to register with the GOC. This would include all bodies corporate, partnerships and sole traders, regardless of their use of protected title. The registration would therefore protect restricted functions rather than titles.

A possible sub-option would be to exempt sole-traders from registering both as an individual practitioner and as a business owner. This would rely on the ability of the GOC to sanction the individual for problems relating to the business.

There might also need to be a specific exemption for the provision of restricted functions by other registered practitioners, such as GPs and ophthalmologists, who are already registered with the General Medical Council.

We note that if all optical businesses are required to be registered, the requirements for registration would have to change from their current state, in particular the requirement for the majority of directors to be registered optometrists or dispensing opticians.

We also note that under this option only registered businesses would be allowed to use protected titles. This would increase the ability of the GOC to identify which businesses should be registered (although would not address the problem of identifying businesses providing restricted functions without using a protected title).

4.3.3.1 *Benefits*

Mechanism for sanction

The main benefit of this option is that the GOC would have the ability to take action against any business providing restricted functions in the event of sub-optimal care resulting from poor business practice. Given that the potential risks arising from business practice are more certain than evidence of harm arising from these risks, it would appear to be most appropriate to have a regulatory regime that provides a mechanism for taking action in the event of harm occurring rather than anything more interventionist such as an inspection model. Businesses would not be able to avoid possible sanction by restructuring or changing their business/trading names. This would address the regulatory failure of incomplete and unequal scope of regulation.

This would in turn have benefits for public health and safety as business owners, regardless of their commercial incentives, would have a responsibility towards patient care by dint of being held accountable for clinical governance. This would address the market failure of a misalignment between patient care incentives and final liability/responsibility for business practices.

Regulating the provision of restricted functions through the GOC would also imply a regulatory, rather than legal, route for resolution of patient safety issues. At present concerns about any businesses (outside of the scope of the GOC) can only be addressed through a legal criminal prosecution, which is expensive and entails a significant standard of proof, or through an individual pursuing compensation through civil proceedings.

Improve practice through deterrence

This option implies a more reactive than proactive regulatory approach. As this option includes no change to the code of conduct the likely benefit in relation to improving practice in specific risk areas may be limited. However, the possibility of action by the GOC might encourage businesses to improve their clinical governance arrangements, or at least deter them from neglecting these.

Responsibility for wider professional standards

Registration of all businesses with the GOC would also improve their knowledge of the role of the GOC and the standards of the optical profession. As suggested by industry feedback, an employer would be more likely to report deficient performance or misconduct of a registered employee if the employer (via the business) is also registered with the GOC, rather than just dismissing the employee as may happen in a purely commercially-run practice.

In addition, registered employees may be encouraged to withstand commercial pressure or act against poor business practices knowing that their employers are also accountable to the GOC.

Flexibility in compliance

This option would not stipulate how owners are to ensure good clinical governance; flexibility would be given to businesses to determine how to address this. No significant compliance costs are therefore envisaged beyond the payment of any registration fee.

Level playing field

Requiring all businesses that provide restricted functions to register with the GOC would place them all under the same obligation to maintain standards. This would prevent unregistered businesses from making cost savings by cutting corners in patient care.

Simplification

This option would simplify the current system by removing the requirement for businesses to be registered dependent on business titles, ownership structure and/or management structure. Both businesses and the GOC would be spared the time and effort involved in checking/explaining whether registration is necessary, and of changing registered status if the nature of the business changed.

Signalling

If all businesses that provide restricted functions are registered with the GOC, this may improve public confidence in the optical industry through the businesses' public commitment to a published code of conduct. This in turn may discourage patients from attending unregistered businesses which would further act to reduce the risks posed by poor practice.

A key benefit perceived by the optical profession, at least, is that the GOC could use business registration to promote to the public the value of eye care and the importance of attending registered practices.

According to market statistics, only a quarter of parents have their children's eyes tested as a matter of routine and the major cause for delaying an eye test is a lack of knowledge about the importance of eye

care.⁶³ Stakeholder feedback indicates a belief in the scope for improvement in public awareness about the need of proper eye services. The profession feels that the GOC could usefully address this. Suggestions from the profession included publishing educational materials on the importance of eye care or improving public access to the register of bodies corporate published on the GOC website. This would also further act to reinforce business registration as businesses would have a commercial incentive to register with the GOC if this affected the public's perception of that business (through a regulatory badging effect). But it is unclear the extent to which consumers value the registered status of optical businesses or professionals.

4.3.3.2 Costs

The costs of this option relate almost entirely to those incurred by the GOC, namely:

- Administrative costs
- FtP costs
- Management costs of queries relating to standards and requirements.

Given that this option does not include any specific performance requirements for businesses, we assume that compliance costs are low. We also assume that the administrative requirements for businesses would be minimal, although this would depend on how the GOC implemented the registration process.

Administrative costs

The GOC would incur one-off and on-going administrative costs of registering a large number of additional businesses. Although there are no available statistics on the number of optical businesses providing restricted functions, we estimate that there could be around 4,200 *additional* optical businesses that will join the register.⁶⁴ There are likely to be economies of scale in adding to an existing system, but nevertheless the costs to the GOC are likely to be significantly higher than at present.

The GOC envisage that one-off costs would include eight registration officers for three months to cover the additions to the register.⁶⁵ There may also be one-off costs to the GOC of drafting the rule changes, equivalent to half a year of a legal officer.

Approximately two full time registration officers would be required on an on-going basis to maintain the register, with an additional two temporary officers to deal with retention issues for three months each year.

The registration fee for business registrants could be spread differentially across businesses (possibly according to the number of employees) such that larger businesses would pay either up to or more than the current fee, and small businesses would pay less.

Fitness to practise costs

The costs associated with dealing with complaints may increase if the public begins to make specific complaints regarding businesses where they would not have done so before. We do not think this increase would be material in practice. If consumers are aware of businesses having a different registration to individual practitioners, then the *subject* of the complaint may shift from individual practitioners to the business, but unless the cases worthy of complaint increase it is unlikely that the GOC will have to deal with an increase in the number of complaints.

⁶³ YouGov (2011), 'Opticians'. From consumers' survey responses, the most common reason given for delaying an eye test is the consumers' belief that they do not need one.

⁶⁴ This estimate is based on information on the total number of registered optometrists and the current number and size of registered businesses. See the appendix for more details.

⁶⁵ The costs would of course depend on the way in which the GOC phased in registration. Higher upfront costs would be expected if registration was to be completed within a short time frame.

Indeed, under the more comprehensive registration system it may be that — at least in the longer term — complaints related to business practice decrease.

Fitness to practise costs may also increase if the number of investigations and hearings relating to businesses increases. It is likely that among the large number of new business registrants there will be those that do not abide by the *Code of Conduct for business registrants* as set out by the GOC. Whistle-blowing on the part of registered employees and other registrants may bring these issues to the GOC's attention and result in FtP investigations and/or hearings (although an effective whistle-blowing strategy can be difficult to implement in practice).

It is unlikely that the number of investigations and, more so, hearings would increase significantly above the current level. Cases that are deemed serious enough to warrant a hearing would almost certainly involve an individual registrant as well as businesses, and individual cases are already dealt with by the GOC (there may be more changes in the overall decisions about who should bear the responsibility and be sanctioned, rather than in the absolute number of cases).

We estimate the increased FtP costs by using information on the current FtP costs relating to business registrants and uplifting this to account for the expected increase in the number of business registrants under this option. We do not apply a full pro-rata increase as it is likely that some of the new business-related FtP cases would have been classified as individual cases in the past and thus would not qualify as truly additional cases.

Together, the on-going administrative costs and FtP costs associated with the options are estimated to be at a low level, with low one-off costs.

4.3.3.3 Wider impacts

A potential disadvantage of this option is that there may be a limit on the GOC's ability to enforce the registration regime. As the new regime would be based on function, rather than title, it could be challenging for the GOC to judge whether any particular unregistered business was providing restricted functions. The requirement that only registered businesses can use protected titles helps the GOC identify which businesses should be registered. However, non-compliant businesses not using a protected title would only be identified by discovery.

A possible unintended consequence of this option would be to increase the number of illegal practices: those providing restricted functions without being registered with the GOC. This would place a greater burden on the GOC's illegal practice function, and may reduce public and professional confidence in the GOC if it is unable to pursue all cases of illegal practice. The only recourse the GOC has for dealing with illegal practice is to pursue a criminal prosecution, for which the standard of proof is greater than that required to levy a sanction under its fitness to practise regime. A possible mitigating strategy could be to make as a matter of professional conduct that individual registrants should not work for any unregistered businesses.

4.3.4 Option 4 — Extend business registration with an enhanced code of conduct for business registrants

This option would broadly follow Option 3, except that an enhanced code of conduct would be developed. Businesses would continue to be required to sign up to this code as a condition of registration. The code could include guidance or requirements for how businesses should address specific areas identified in our risk assessment (e.g. how the training of assistants should take place; how locums should be managed; the use of a dedicated practice manager for large businesses; the need for written protocols, etc.). The code would be kept live through on-going improvement and still allow businesses flexibility in how the guidelines are implemented.

In our view the GOC's role should be to enforce standards that minimise public health and safety risks. This might mean that the guidance captures what is considered to be 'safe and effective practice', rather than 'best practice'. The role for issuing best practice guidance would be retained by professional bodies and academic organisations.

4.3.4.1 Benefits

In addition to the benefits of comprehensive registration under Option 3, this option carries the additional benefit of more targeted requirements and guidance for good business practice through an enhanced code of conduct. Specific risk areas identified in our assessment (such as the training of optical assistants, communication and supervision protocols, and the management of locums) could be targeted, which would serve to maintain good practice standards across the industry. Particularly as some new business registrants will not be owned by registered professionals, a more detailed code would provide valuable guidance.

All businesses could benefit from a 'badging' effect. Feedback from businesses and professionals highlights that the GOC badge is an important perceived benefit of regulation by the GOC.

4.3.4.2 Costs

The GOC would incur one-off costs in developing an enhanced code of conduct. We estimate that this would entail half a year of a policy manager, including overheads — with a lower on-going contribution to keep the guidance "live" — and potentially interaction with registrants concerned over its interpretation. We have assumed dissemination would be on-line.

Businesses would incur costs of complying with the new code insofar as the requirements of the code are over and above their current levels of practice. As the code would aim to maintain 'safe and effective practice' standards it is likely that the vast majority of businesses would already be meeting these. Businesses falling below these standards would entail some compliance costs. It is also likely that in bringing their standards up to those laid out in the code these businesses would be improving the quality of care provided to patients which may at least partly offset the compliance costs. However, all new business registrants would incur some costs in ensuring their systems and practices complied with the new code of conduct.

The estimated on-going costs for this option are above those for Option 3, with a low one-off cost, and low on-going costs.

4.3.4.3 Wider impacts

The main possible issue with this approach is again the ability of the GOC to enforce the registration requirement and adherence to the new code.

4.3.5 Option 5 — Extend business registration, enhance code of conduct for business registrants and establish inspections of premises and audit protocols

This option builds on Options 3 and 4 by adding the capability of the GOC to inspect the premises of optical businesses and to audit the protocols used by businesses to ensure good clinical governance.

4.3.5.1 Benefits

The inspection of premises would enable the GOC to maintain direct oversight of registered businesses and to ensure that the practices met the standards of the enhanced code. This would include checking that equipment was up-to-date and all necessary systems were in place.

The benefit of the GOC's inspection powers could increase in light of the potential scaling back of inspections in England compared with the previous system under PCTs, and the lack of such inspections in

Wales and Northern Ireland. More importantly, such inspections could be more closely targeted at elements of business practice most linked to patient risk.

However, given the lack of evidence of actual harm caused by business practice, it is unlikely that a more interventionist regulatory approach would bring significant benefits in terms of reduced harm to patients, i.e. such an intrusive approach could not be proportionate. There may also be overlap in scope (i.e. the businesses covered), if not content, of inspections with the new NHS contract management regime in England, particularly if the GOC adopted a sampling approach to its inspections.

The benefit of the GOC auditing businesses' protocols would increase the effectiveness of the enhanced code of conduct. The threat of audit or inspection (even if this was undertaken at random) would incentivise businesses to meet the standards of the code in terms of documenting good business practice protocols.

However, any audit of documents will not necessarily ensure that businesses adopt the protocols and systems in practice, as this could become merely a 'box-ticking' exercise on the part of businesses. This system could create a greater administrative burden for both the GOC and businesses, with no real link to actual practice. On the other hand, the audit of protocols could give the GOC more leverage to act if subsequent problems were found within businesses.

4.3.5.2 Costs

The costs of this option would depend largely on the way it is executed. The costs of inspections to the GOC would include the one-off costs of training inspectors and the on-going costs of the inspectors and inspections themselves, which would include time at the inspection, preparation and follow-up, and travel time. There may also be increased data capture and analysis costs if the GOC were to monitor more closely the performance of business registrants. Costs to businesses would include preparing for the inspections, as well as ensuring their systems complied with the new code of conduct (as in Option 4). It is also possible that the GOC would incur FtP costs over and above the additional costs described in Option 3, if inspections uncovered a greater number of FtP cases.

We benchmark the inspection costs against the General Pharmaceutical Council's costs, and assume that the GOC would conduct inspections on a three-year rolling basis. The estimated cost to the GOC of these inspections is high. Costs would be reduced if the GOC undertook inspection on a sample-basis, although this could imply additional sampling costs if this was to be risk-based.

GOC would incur one-off costs of setting up the inspection regime (i.e. this would entail the creation of a new department), including the recruitment and training of inspectors. Depending on the number of inspectors the recruitment costs would likely be relatively low.

We apply an indicative 10 per cent increase in additional FtP costs attributed to Option 3 to represent the additional costs the GOC may incur through uncovering new cases through inspections.

Costs to businesses of preparing for inspections are uncertain. If we assume that compliant businesses will spend a day of a registrant's time per premise preparing for the inspection and being present at the inspection, the total annual on-going cost would be a medium-level cost.

Costs of auditing business protocols could be analogous to the GOC's costs incurred in reviewing individual registrants' applications for exceptional circumstances (to excuse non-compliance with CET requirements),⁶⁶ although dependent on the number of documents each business would submit and the

⁶⁶ Information regarding the costs to the GOC of reviewing exceptional circumstances was obtained for Europe Economics' previous work for the GOC on the costs and benefits of revalidation (2012).

nature of the documents the costs could be higher.⁶⁷ The estimated costs of auditing businesses' documents on a three-yearly rolling basis are expected to be low.

The total on-going costs of this option to both businesses and the GOC (including the costs under Option 4) are high, with relatively low one-off costs. On-going costs would be lower (although still high) if inspections and audits were conducted on a five-year rolling basis.

4.3.5.3 Wider impacts

The main disadvantages of this option is the level of cost and the interventionist approach that are unwarranted by the low evidence of actual business-related risk in the optical sector. A proportionate and reactive approach may be more appropriate.

Having an inspection regime based on the code of conduct would require this code to be both detailed and prescriptive, meaning increased compliance costs compared with Options 3 and 4.

4.3.6 Option 6 — Remove business registration and introduce registration of a dedicated “practice principal” for all business premises

This option would remove the requirement for businesses to be registered with the GOC on an ownership basis, and instead require that each business must register a dedicated practice principal for each of its premises. Similar to models adopted in other areas of the health sector, like the “practice principal” model in dentistry and “superintendent” model in pharmaceutical industry, the practice principal would be a registered optometrist or dispensing optician and would be responsible for ensuring that good clinical governance was in place.⁶⁸ The practice principal would be accountable for patient safety problems linked with business practice and should ensure that good patient care would not be affected by commercial interests.

4.3.6.1 Benefits

The benefit of this option is that clinical governance would be directly overseen by a registered optical professional. The professional would be well aware of the requirements for good patient care (unlike a lay-owner) and could be advised on how to implement appropriate systems and protocols to avoid business-related risks.

The principal would be accountable to the GOC's professional and business codes of conduct.

This option would save on the administrative costs of holding a separate business and professional register, as all principals would already be individually registered with the GOC. An additional field could be added to the register to indicate whether the individual was also a practice principal.

4.3.6.2 Costs

The costs of this option to the GOC would be limited, and in fact savings could be made from removing the business register. Practice principals would already be registered on an individual basis with the GOC.

However, there could be significant costs to businesses. Registrants becoming practice principals may have to undergo basic managerial and business training. We estimate that this may require a day of a registrant's time per premise, which equates to a high one-off cost.

Businesses would also incur on-going costs arising from time spent by practice principals in ensuring good clinical governance throughout the practice (e.g. checking that correct procedures were carried out,

⁶⁷ For example, if clinical input is needed in assessing the document.

⁶⁸ Although we note that in the dentistry model a practice principal can be a non-registrant, which differs from our envisaged model.

carrying out clinical audits, etc.). We estimate that principals would spend approximately four days a year on this role, which results in a very high cost across all premises.

A significant, but unquantifiable cost, would be the recruitment of such practice principals, at least in some businesses. This approach implies a major change in the way registrants work, and practitioners may not wish to bear the additional levels of responsibility or accountability, particularly as they would not necessarily be appropriately remunerated (as an owner would be who adopted the same responsibility). If a practice principal is required for every premise, this suggests that 8,000 of the 18,000 registered professionals (40 per cent) would need to be willing to take on this role. It may be difficult for businesses to assign one of their existing practitioners to this role, or to hire one that is willing to take it on.

4.3.6.3 Wider impacts

The main disadvantage of this option is that it fails to address the main market failure identified in this research, namely that the individual/body with ultimate responsibility for the business (legally and financially) may be less focussed on patient care or within the remit of the GOC. Whilst a dedicated practice principal would seek to ensure good business standards are upheld and would bear responsibility for this, he or she may still not be able to affect significant change if the business owner remains outside the remit of the GOC. This would particularly be the case where any investment is concerned, such as equipment or training or record-keeping (although we have noted that underinvestment in equipment is not a serious risk).

Whilst individual registrants would register themselves as practice principals, it would be difficult for the GOC to ensure that each business employed a dedicated practice principal because it would not have register of all businesses. Therefore the oversight of the GOC may not be increased substantially under this option.

4.3.7 Option 7 — Voluntary self-regulation by the industry

This option would also entail a move away from the regulation of businesses by the GOC. Businesses would instead participate in self-regulation. Rees (1988)⁶⁹ identifies three types of self-regulation:

- ‘Pure’ voluntary self-regulation, whereby rule making and enforcement are both carried out privately by the industry itself, independent of direct government involvement
- Mandated full self-regulation, driven by the industry but officially sanctioned by the government, which monitors the programme, and if necessary, will take steps to ensure its effectiveness and
- Mandated partial self-regulation, whereby the government has some direct role and the system entails either public enforcement of privately written rules, or governmentally mandated internal enforcement of publicly written rules.

Such that this option represents an alternative to the other options, we discuss it in terms of voluntary self-regulation. However, there would certainly be scope for the GOC or the Department of Health to have a greater role.

The way in which self-regulation would be implemented would, by definition, be left up to the optical industry, although the GOC might engage in a dialogue with industry to give guidance on the system’s shape and design. A self-regulation system could consist of the following elements:

- An independent body to oversee the regulation and to accredit and/or sanction businesses. Such a body would be set up by the optical industry through, for example, the professional bodies

⁶⁹ Rees, J. (1988) ‘Reforming the Workplace: A Study of Self-Regulation in Occupational Safety’. Philadelphia: Univ. of Pennsylvania Press, cited in Gunningham and Rees (1997) ‘Industry Self-Regulation: An Institutional Perspective’ *Law and Policy*, Vol. 19, No. 4, October 1997.

- A code of practice that details the quality level of business practice necessary for good clinical care. Such a code could focus on the potential risk areas identified in this report. It could build on the existing QiO resource used as a basis for the management of the GOS contract
- Businesses would sign up to the code, and could be asked to demonstrate that they are compliant through a self-declaration. They would then be accredited by the industry body (e.g. provided with a certificate or membership). The body would have the power to withhold or remove accreditation from non-compliant businesses
- A range of badging options could be used, i.e. businesses that are accredited could display a logo, business holding NHS contracts could stipulate accreditation etc.
- A public awareness programme could be undertaken to raise the profile of accredited businesses over and above non-accredited ones.

There are a number of general advantages and disadvantages of self-regulation, which we discuss here before moving onto the specific costs and benefits for such a system in the optical industry.^{70 71}

- Self-regulation offers a degree of flexibility, both in terms of targeting regulation to meet the specific requirements of the industry and in terms of adapting to developments in the industry and in the types of risks involved. It avoids the need to use Parliamentary time
- Self-regulation is driven by the industry itself (i.e. those having the expertise and technical knowledge to identify the most appropriate ways to minimise the scope for risks occurring) and can thus be a very targeted form of regulation
- The costs associated with voluntary self-regulation for the public authorities are likely to be relatively modest.⁷² Voluntary self-regulation incurs costs primarily for the businesses signing up to it
- A disadvantage of introducing voluntary regulation is that there may be private interests motivating behaviour (in contrast to statutory public regulation that clearly aims to work in the public interest).⁷³ Standards are driven by the organisation or the profession rather than necessarily what would be in the public interest, and while the standards themselves may be well defined, quality assurance systems may not be in place
- In addition, the effectiveness of any self-regulation relies largely on the scope for enforcement. Not only may there not exist an independent official complaint process in voluntary self-regulation models (or an industry body capable of monitoring and identifying non-compliant businesses), but even where such quality assurance procedures do exist, when businesses are found not to meet the set standards there are limited sanctions available to punish them aside from “naming and shaming” or excluding them from membership. The credibility of this action would depend on the effectiveness of commercial sanctions exercised through public awareness of the benefits of the regulation. Under a voluntary self-regulation approach an organisation that does not comply can still operate as there is no mechanism to

⁷⁰ Gunningham and Rees (1997) ‘Industry Self-Regulation: An Institutional Perspective’ *Law and Policy*, Vol. 19, No. 4, October 1997.

⁷¹ Lenox and Nash (2003) ‘Industry self-regulation and adverse selection: a comparison across four trade association programs’ *Business Strategy and the Environment* Vol 12, Issue 6, pages 343–356.

⁷² One example of where such costs to the authorities may be more significant would be a framework of voluntary regulation with statutory underpinning, for example in the field of medicines the trade association (ABPI) runs a committee of its members that designs and keeps up to date a code of practice; it rebukes member companies whose publicity seems to step over the mark from “information provision” to “advertising to patients” and occasionally suspends them from membership (including famously Merck a year or so ago, for breaching another part of the ABPI code of conduct). If any fines or other sanctions requiring the authority of law are needed the Medicines and Healthcare products Regulatory Agency (MHRA) would intervene.

⁷³ As observed by Kay (1988) “with self-regulation, regulatory capture is there from the outset”. Kay (1988), ‘The Forms of Regulation’, in A. Sclدون (ed), *Financial Regulation—or Over-Regulation* (1988), 34.

withdraw their practice rights (indeed, it can be argued that businesses could have an incentive to free-ride).

4.3.7.1 Benefits

The benefit of this option is that it provides a form of regulation that is in line with the relatively low levels of risk in the optical industry compared with some other healthcare professions such as medicine. It is reasonable to assume that, given its professional expertise, the industry should be able to design a code of practice that effectively targets the relevant areas of business risk and that remains up to date with the development of these risks (e.g. risks associated with online sales might increase in the future). Optical professional and industry bodies have already collaborated extensively over a number of issues, most relevantly the collaborative work on QiO which is to be used as the basis for the new GOS contract assurance system.⁷⁴ This could be adapted and broadened to include specific elements of good clinical governance.

Businesses could benefit from a 'badging' effect, provided sufficient effort was undertaken to inform the public of the benefits of attending an optical practice covered by the self-regulation system. Informing the public would probably be essential as at present being "GOC approved" is likely to be a stronger badge, and businesses would miss out on this if registration with the GOC ceased. Feedback from businesses and professionals highlights that the GOC badge is an important perceived benefit of regulation by the GOC.

4.3.7.2 Costs

Costs to the GOC would be minimal, and could involve little more than assisting the industry body in setting up the system. Compared to the current situation, this option would represent a saving as the GOC would no longer be responsible for registering bodies corporate.

Costs would be incurred largely by businesses through fees to the industry body, and any changes in business practice necessary to meet the new guidelines (to the extent to which this is over and above their current standards). We assume that the industry body would be based within one of the existing professional bodies and thus one-off costs of physical set up would be minimal.

Costs to the industry would depend on the exact form that the self-regulation system takes. At a minimum, there would be one-off costs of developing the new code of practice. We have assumed these costs would be somewhat higher than the costs of developing the new code of conduct incurred by the GOC under Option 4, as there are likely to be more stakeholders involved and the process is likely to take longer.⁷⁵

On-going costs would also be incurred by the industry body of overseeing the accreditation of compliant businesses. These would be largely administration costs. We assume that these would be less than the administrative costs incurred by the GOC in maintaining a business register as there would be less activity associated with the monitoring and removal of businesses.

If the industry body were to monitor and investigate non-compliant businesses, then resources for this would be needed. Similarly, if businesses were to submit self-declarations on how they complied with the new code of practice they would incur limited administrative costs. Other costs could also include public awareness campaigns (which would most likely be essential for the effectiveness of any sanction).

However, these costs would depend on the design of the self-regulation system which at this stage we are not in a position to predict.

⁷⁴ <http://www.qualityinoptometry.co.uk/>

⁷⁵ In particular, stakeholders from all four nations of the UK would need to be involved.

4.3.7.3 *Wider impacts*

Although the direct costs of this option for industry and the GOC are likely to be relatively low, there could be negative wider impacts. Given the different interest groups within the optical profession, each with different ways of conducting business (e.g. sole practitioners; independents; multiples; online providers) it might be difficult practically for agreement to be reached on what constitutes good business practice, particularly relating to issues such as practitioner autonomy. Further, without full acceptance by the whole industry any self-regulation model would lack credibility and become ineffective. This raises the risk that businesses (particularly large ones) might hold the system hostage by refusing to cooperate unless their specific interests were met. There could also be the risk that a self-regulation regime is captured by one group and used against others. A possible example of this could be traditional brick and mortar practices agreeing to criteria that undermine online suppliers.

Even without any such disagreements or regulatory capture, enforcement of self-regulation would probably be difficult. First, some mechanism would be needed to identify non-compliant businesses.⁷⁶ Complaints and whistle-blowing might have a role, although our discussions with registrants suggest that whistle blowing, particularly in smaller practices, is rare.

Second, non-compliant businesses would need to be disciplined in some way. Disciplinary tools could include peer pressure, 'naming and shaming' by the industry body, or denial of accreditation or membership. Peer pressure may be weak in relation to rural or isolated practices where business owners and managers have little contact with their peers or little need to cooperate with other businesses. Denial of accreditation and public shaming would only incentivise businesses to comply if they were unable to profitably operate outside of the system. There is no evidence to suggest that the public would attach much value to the regulatory status of an optical business, particularly as this is currently not required.

Difficulties with enforcement would mean that a system of self-regulation would be unable to address one of the key shortcomings of the current system of bodies corporate registration — the lack of complete oversight. A voluntary system would have little power over businesses that chose to be non-compliant, and there would be no means of holding them accountable.

Other self-regulation models might be more effective in terms of enforcement. For example, the industry could sign up to a charter giving sanctioning powers to a public body such as the GOC. This would reflect a co-regulatory strategy whereby the system is given legitimacy by law. However, issues may still remain in relation to identifying non-compliant businesses. It is also not clear how a system of co-regulation would be very different to one overseen fully by the GOC, such as Option 4.⁷⁷

⁷⁶ We refer here to businesses that do not adhere to the code once signed up to it. As this option is *voluntary* self-regulation, a business that did not sign up to the code in the first place would not be considered 'non-compliant'. The self-regulation system would need to be designed in such a way as to incentivise businesses to sign up to the code (e.g. through positive regulatory badging).

⁷⁷ This would particularly be the case if the implementation of Option 4 drew significantly on the industry in designing the new code of practice.

5 Summary and Conclusions

Our research into business risks has identified a number of factors that are very important to good patient care and that are influenced by the practices of the business and not just by individual practitioners. These are:

- A business environment that provides practitioners with autonomy to undertake their professional activities to the best of their ability and in line with professional standards
- Systems and protocols to ensure good clinical governance, including clear communication among staff; adequate supervision of assistants and students; consistent management of locums; and appropriate record keeping
- Adequate investment in equipment and training of staff to ensure that the level of care is up-to-date.

Whilst there is little direct evidence of patient harm arising from failures in these areas, there is evidence of poor business practice in the optical industry that could pose a risk to public health and safety. These potential risks could be exacerbated by increasing economic pressure arising from the downturn and patient trends towards buying profit-making optical appliances and contact lenses from alternative suppliers. The changes in the management of the GOS contract by the NHS might also lead to a reduction in oversight (even if minimal).

The nature of optical businesses and the current business registration system give rise to two main problems in relation to these risk factors:

- Market failure: a mismatch of incentives between the owners with ultimate responsibility/liability for the business and the responsibility and incentives of practitioners in terms of clinical governance. There are some elements of clinical governance that rely on good business practices which cannot be implemented if the owner of the business does not adequately consider the needs of clinical governance in some way. Being directly registered with the GOC will place this professional incentive with the business
- Regulatory failure: a lack of comprehensive oversight of the GOC and 'levers' to issue sanctions against poor business performance, and inability to enforce good practice.

Whilst the risks relating to business practice are not significantly high, it is clear that the current incomplete system is not ideal, and there is enough evidence to suggest that a proportionate yet comprehensive system of business registration would be desirable.

We have considered seven business regulation options. These are summarised in the table below, along with our assessment of the relative benefits of each in relation to key risk areas, and the relative (qualitative) costs.

In the table, the ticks indicate where an option mitigates a particular risk over and above current experience; the crosses indicate where the option would exacerbate a risk, and the zeros indicate where the option would have no impact.

Figure 5.1: Summary of the costs and benefits of regulatory options

	1. Retain current system	2. Remove all business registration	3. Extend registration	4. Extend registration and enhance Code of Conduct	5. Additional inspection and audit powers	6. Dedicated practice principal per premise	7. Self-regulation
Incomplete oversight of optical businesses	o	x	✓	✓	✓	o / ✓	o/ x
Undermined practitioner autonomy from commercial pressure	x	x	o / ✓	✓	✓	o	x
Inadequate systems for clinical governance (e.g. training or assistants; communication and supervision protocols)	x	x	✓	✓✓	✓✓	✓	o
Underinvestment in equipment	x	x	o	✓	✓✓	o	o
Unlevel competitive playing field	o	o	✓	✓	✓✓	✓	o
Additional costs (on-going)	Negligible	Low saving	Low	Low	High	High	Very low saving
Additional cost (one-off)	Negligible	Negligible	Low	Low	Low	High	Low

Option 1 does not change the current incomplete oversight or the un-level playing field and, given the possible reduction in oversight by the NHS and increasing economic pressure, may in fact increase the risks associated with inadequate systems, undermined practitioner autonomy and underinvestment in equipment.

Option 2 exacerbates the existing problems even more.

Option 3 provides some benefit across all elements due to the increased coverage of registration and the deterrent effect this could have against poor business practice. This is most effective in dealing with the problems resulting from incomplete oversight by the GOC and an un-level playing field. The benefits are relatively limited in encouraging better clinical governance as this option still encompasses the limited code of conduct.

Option 4 scores highly in terms of relative benefits, in particular in improving clinical governance, and is among the lower cost estimates.

Option 5 scores highest, notably on improving clinical governance and levelling the playing field (inspections would enforce the obligation on all businesses to adhere to the same standards) but is also costly to implement. Also, given that the risks identified consisted mostly of potential risks rather than direct evidence of harm, it is unclear that such an interventionist approach would be proportionate.

Option 6 would have little impact on the incentive problem as represented by undermined practitioner autonomy and underinvestment in equipment, as these areas would still be liable to influence by the practice owner who would not necessarily be registered with the GOC. As it would also be difficult for the GOC to identify which businesses were employing a dedicated manager or not, oversight may be incomplete. This option is the most costly, with both one-off and on-going compliance costs incurred mainly by businesses.

Option 7 is unlikely to provide complete oversight of optical businesses and, to the extent that businesses choose not to participate in the system, might even represent a decrease in oversight from the current system. The relatively low benefits of this option are largely due to likely difficulties in enforcement of a voluntary code of practice. The GOC would also not have any visibility of business compliance save that which it obtained from the self-regulatory industry body. We have assumed that voluntary self-regulation would not materially change the standards of business practice, at least in the short- to medium-term. Whilst a more detailed and targeted code of practice could lead to improved standards, difficulties in enforcing the code would most likely mean that those businesses currently engaged in poor practices (for any reasons other than well-meaning ignorance) would not change their behaviour. Indeed, cases of

undermined practitioner autonomy might increase compared to the current situation as a result of increasing commercial pressures.

Our analysis of the seven options suggests that Option 4 is the most appropriate, as it targets the key problems identified whilst being proportionate to the risks involved. The system could be implemented in such a way as to place as little burden as possible on businesses, especially small ones.

6 Appendix: Cost Estimates for Regulation Options

In this appendix we present our cost estimates for the options for business regulation, as presented in Section 4 of this report. We begin with our approach to estimating the total number of optical businesses that might be subject to registration, and then describe our estimates of the costs for the various options. We note that the figures presented in this appendix are estimates only, and subject to uncertainty in a number of areas, in particular the overall number of optical businesses and the exact costs associated with the various options.

6.1 Estimating the Number of Optical Businesses

We have sought to obtain data on the total number of optical businesses providing restricted functions. However, this information is not available. Below we set out how we have estimated this number, using information available on the number of registered optometrists and dispensing opticians, the number of registered bodies corporate, and the number of large multiple practices whose employee numbers are known. Our overall aim is to estimate the number of optical businesses, based on the total number of optometrists and the estimated average number of optometrists working in each business. We have assumed that all optical businesses providing restricted functions employ at least one optometrist.^{78,79}

We begin by describing the following information on the number of GOC registrants:⁸⁰

Table 6.1: GOC registrants 2013

Registrant type	Number
Optometrists	13,616
Dispensing opticians	6,182
Bodies corporate	2,181

Source: GOC statistics, 18 March 2013

Of the optometrists registered with the GOC, the vast majority are registered with the NHS for the GOS contract (estimated at just under 12,000 in 2013).⁸¹ We assume that of those *not* registered with the NHS (approximately 1,600), half provide optical services on a purely private basis, and half are directly employed by hospitals and therefore are not relevant to our estimation of optical businesses.

The figures used in table 6.1 for bodies corporate are from March 2013, which included a forecast figure to take into account the individual registration of all Specsavers outlets. The registration process is now complete but the figures have not been updated.

⁷⁸ We assume that dispensing opticians are unlikely to work in a business without an optometrist.

⁷⁹ This does not take into account locum optometrists who may work for more than one business, and therefore are not associated with just one business: we do not have sufficiently detailed information on the number of locums or the number of businesses for which they work. This implies that the final number of optical businesses will be a slight over-estimate. However, this might be offset to some extent by the fact that some practices might only use locum optometrists.

⁸⁰ Information obtained from the GOC register, 18 March 2013.

⁸¹ Information obtained from NHS Workforce Statistics 2011, uplifted to 2013.

Our next step is to estimate the number of large corporates currently registered with the GOC (this includes multiples, joint venture companies and individual franchises). The table below presents the results of our research into the largest corporations. Information has been gathered from the websites of the corporations and from the GOC.

Table 6.2: Large corporations registered as bodies corporate

Large corporate	Number of Outlets	Notes	Number of GOC registrations
Boots Opticians multiple	480	All practices under 1 registration	1
Boots Opticians franchise	183	Registered individually	92
D&A franchise	27	Registered individually	27
Tesco Opticians	170	All practices under 1 registration	1
Galaxy Opticians	10	All practices under 1 registration	1
Specsavers franchises / joint venture companies	621 ⁸²	Registered individually	621
Asda Opticians	95	All practices under 1 registration	1
Vision Express multiple	320	All practices under 1 registration	1
Vision Express franchise	21	Registered individually	21
Optical Express	232	All practices under 3 registrations	3
Scrivens Opticians	140	All practices under 1 registration	1
Total	2,299		770

Sources: GOC for the number of registrations, March 2013. Individual businesses' websites for the number of outlets, confirmed June 2013, and interviews. We note that D&A (Dollond & Aitchison) has now merged with Boots.

As the total number of bodies corporate registered with the GOC is 2,181, there are 1,411 registered bodies corporate that are not included in our 'large corporation' registrations number.⁸³ We do not know the size distribution of these firms, but classify them as 'smaller independents'.

We have made assumptions about the average number of optometrists employed in different types of businesses in order to estimate the total number of businesses (i.e. not just those registered as bodies corporate). We assume that all dispensing opticians work with at least one optometrist; therefore, only optometrists are relevant to estimating the number of businesses. We assume that the number of optometrists working as sole traders is 2,000.⁸⁴ This is based on an estimate from the AOP that just over 1,000 of its members describe themselves as sole traders: since not all members list their mode of practice, we include an uplift to account for this. All our assumptions are presented in the table below.

⁸² At the time when these figures were calculated, the Specsavers registration process had not been completed and so this was based on an estimated figure. As at 1 April 2013, there were 651 Specsaver outlets registered with the GOC.

⁸³ $2,181 - 770 = 1,411$.

⁸⁴ This represents approximately 15 per cent of all optometrists.

Table 6.3: Assumptions used in estimating the number of businesses

Assumption	Value
Average number of optometrists employed per multiple outlet	2.5
Average number of optometrists employed per franchise / joint venture outlet	2
Average number of optometrists employed per smaller independent	1.5
Number of optometrists employed directly in hospitals	813
Number of optometrists working as sole traders	2,000

Note: although 'smaller independent' excludes sole traders, we set the average number of optometrists at 1.5 to allow for the fact that some optometrists may work at more than one practice, even for more than one employer.

Note: as discussed above, we assume that half of the optometrists not contracted with PCTs for GOS contracts are employed directly in hospitals. We assume the other half work solely in the private sector.

We estimate the number of registered optometrists that are employed by multiples and franchises by summing the number of outlets and multiplying by our assumptions about employment, as set out in Table 6.3 above.

Table 6.4: Estimated number of optometrists employed by large corporates

Large corporate	Multiple outlets	Franchise outlets	Total
Boots Opticians multiple	480		
Boots Opticians franchise		183	
D&A franchise		27	
Tesco Opticians	170		
Galaxy Opticians	10		
Specsavers franchises / joint venture companies		621	
Asda Opticians	95		
Vision Express multiple	320		
Vision Express franchise		21	
Optical Express	232		
Scrivens Opticians	140		
<i>Total number of outlets</i>	<i>1,447</i>	<i>852</i>	<i>2,299</i>
Average number of optometrists per outlet	2.5	2	
Estimated number of optometrists employed	3,618	1,704	5,322

Source: Individual businesses' websites, confirmed June 2013, and interviews.

We now total the optometrists accounted for by large corporations, sole traders and hospital optometrists.

Table 6.5: Optometrists accounted for by large corporations, sole traders and hospital employment

Employment type	Estimated number
Optometrists employed in multiples	3,618
Optometrists employed in franchises / joint ventures	1,704
Optometrists employed in hospitals	813
Optometrists working as sole traders	2,000
Sub-total: Optometrists accounted for	8,134

We then subtract this sub-total from the total number of optometrists to arrive at the remaining number of optometrists. We assume that these remaining optometrists are employed by smaller independent practices, at an average of 1.5 optometrists per business. This gives an estimated number of other independent businesses of 3,655 as shown in the table below.

Table 6.6: Estimation of the number of smaller independent businesses

Category of optometrists	Number
Total number of optometrists	13,616
Less the number of optometrists accounted for by corporations, sole traders and hospital employment	8,134
Remaining optometrists	5,482
Number of smaller independent businesses (5,482/1.5)	3,655

We then add the number of large corporations registered with the GOC, plus the number of sole traders, plus the estimated number of smaller independent businesses to arrive at the total estimated number of optical businesses, as shown in the table below.

Table 6.7: Estimated number of optical businesses

Business type	Estimated number of businesses
Registered large corporations	770
Sole trader optometrists	2,000
Other independent businesses	3,655
Total businesses	6,425

The number of currently *unregistered* businesses is then calculated by subtracting the number of body corporate registrations from this figure of total businesses. This is shown in the table below.

Table 6.8: Estimated number of unregistered businesses

Businesses registration status	Estimated number of businesses
Total number of businesses	6,425
Number of businesses currently registered	2,181
Number of unregistered businesses	4,244

Therefore the total number of currently unregistered optical businesses is estimated at 4,244.

6.2 Estimating the Costs of Regulation Options

This section sets out how we have estimated the additional costs arising from the registration options. The estimated number of businesses, as calculated above, enters into some but not all of the cost calculations.

6.2.1 Option 1: Retain the current system of business registration

This option does not involve any additional costs.

6.2.2 Option 2: Remove business registration

This option would entail an on-going saving to the GOC of approximately £470,000. This is the GOC's estimated cost of currently maintaining the body corporate register based on an estimation of the proportion of time spent by each department on matters relating to body corporates.

6.2.3 Option 3: Extend business registration to all businesses providing restricted functions

The costs of this option relate almost entirely to those incurred by the GOC, namely:

- Administrative costs, including the costs of managing queries relating to standards and requirements (any staff costs relating to the GOC include overheads)
- Fitness to Practise (FtP) costs.

6.2.3.1 Administrative costs

The GOC would incur one-off costs of registering the additional businesses (estimated to be around 4,240) and drafting the legislative changes, and on-going costs of maintaining the register.

The GOC estimates that one-off costs would entail the resources of eight additional registration officers for a three month period (i.e. equal to two full time equivalents (FTEs) and half a year of a legal officer's time to draft GOC rule changes. The one-off administrative costs are therefore estimated at £120,000.

The GOC envisages that on-going costs of maintaining the register will include two full time registration officers, and two temporary officers to cover the retention process for three months a year. This equates to 2.5 FTE, at an estimated total cost of £100,000.

6.2.3.2 Fitness to practise (FtP) costs

We assume that there could be some increase in FtP costs as more businesses would be under the GOC's FtP remit. We do not know precisely how FtP costs relating to businesses would increase, and have estimated the increase in the following way. It is estimated that approximately 10 per cent of current costs are currently attributed to businesses (which equates to approximately £150,000). Increasing this by the same proportion of increased business registrants gives an additional FtP cost of around £290,000. However, it is likely that some proportion of the additional business-related FtP cases would have previously been brought against individual registrants (we estimate 40 per cent) and therefore the truly additional FtP costs are estimated to be around £175,000.

Combining the administrative and FtP costs, the total additional on-going costs of Option 3 are estimated at approximately £275,000, with one-off costs of £120,000.

Table 6.9: Cost estimates of Option 3

Cost item	On-going	One-off
Administrative costs to GOC		
One-off costs		£120,000
On-going costs	£100,000	
Fitness to practise costs to GOC		
FtP costs for business registrants (current)	£150,000	
Pro-rata increase due to extended business registration	£291,860	
Proportion of additional costs already accounted for by previous individual cases	40%	
Additional FtP costs due to extended business registration	£175,116	
Total costs	£275,116	£120,000

Note: the cost to the GOC of updating and maintaining the register may be subject to review, and will depend on the registration requirements and the length of time required to include the additional businesses. The costs do not account for the need to find space for the additional employees.

6.2.4 Option 4: Extend business registration and enhance code of conduct for business registrants

In addition to the costs of registering additional businesses, the GOC would incur one-off costs in developing an enhanced code of conduct. We estimate that this would cost approximately £40,000. There will also be a lower on-going contribution to keep the guidance “live” — and potentially interaction with registrants concerned over its interpretation. We estimate this to be approximately £20,000 a year.

There may also be compliance costs for businesses in ensuring their practices complied with the code of conduct. These costs would depend on the extent to which businesses currently fall short of the standards of the code, although there would be a minimum cost to businesses of at least reviewing their practices and systems. We have estimated that this would be a quarter of a day averaged across currently unregistered businesses, approximately £160,000 in foregone earnings.

The total on-going cost for Option 4, which includes the registration costs of Option 3, is therefore approximately £320,000. One-off costs are estimated at £160,000. The table below summarises the cost estimates.

Table 6.10: Option 4 cost estimates

	On-going	One-off
GOC administrative costs		
As Option 3	£275,116	£120,000
Develop code of conduct - GOC		
Developing code		£40,000
On-going guidance	£20,000	
Business compliance costs		
Foregone earnings		£159,137
Total costs of Option 4	£295,116	£319,137

6.2.5 Option 5: Extend business registration, enhance code of conduct for business registrants and establish inspections of premises and audit protocols

The costs of this option would depend largely on the way in which it is executed. The costs of inspections to the GOC would include the one-off costs of training inspectors and the on-going costs of the inspectors

and inspections themselves, which would include time at the inspection, preparation and follow-up, and travel time. There may also be increased data capture and analysis costs if the GOC were to monitor more closely the performance of business registrants. There may also be additional FtP costs (over and above those of Options 4 and 5) arising from cases discovered through the inspection process. Costs to businesses would include preparing for the inspections, as well as ensuring their practices comply with the code of conduct (as in Option 4).

6.2.5.1 Cost of inspections - GOC

As well as the costs applicable to the GOC in Option 4, we have drawn on the inspection costs against the General Pharmaceutical Council's (GPhC) inspection costs to underpin our assumptions about the GOC.⁸⁵ The GPhC conducts inspections on a three-year rolling basis and incurs approximately £410 per inspection.⁸⁶ With an estimated 8,000 optical premises, this implies an annual cost to the GOC of just over £1 million.⁸⁷

This estimate is on the basis of an inspection of each premise every three years: costs would be reduced if the GOC undertook inspection on a sample-basis (although this could imply additional sampling costs if this was to be risk-based). Similarly, if the GOC conducted inspections on a five-year basis, this would reduce the cost to approximately £650,000 per year.

We also assume that the GOC would incur one-off costs in setting up the inspection department of £80,000, and a one-off cost of recruiting and training inspectors of approximately £8,000. The latter figure is calculated by estimating the length of each inspection (around 1.2 days) and therefore the number of inspectors needed per year to cover 8,000 premises every three years (about 14).⁸⁸ We assume the inspectors would be part time, such that 28 individuals would be required. We assume the cost of training would be equivalent to the daily forgone earnings of optometrists (£150) and that two days of training would be needed, i.e. there would be no external training cost.⁸⁹

6.2.5.2 FtP costs for the GOC

It is unknown how many additional FtP cases would be discovered through inspections. Whilst it is likely that there would be some additional cases, it is also possible (and indeed, is the purpose of extended regulation) that business practices would improve such that the number of FtP cases would in time decline. We have included an indicative figure for increased FtP costs based on 10 per cent of the estimated additional FtP costs described in Option 3, around £17,000.

6.2.5.3 Cost of inspections - businesses

Costs to businesses of preparing for inspections are uncertain. If we assume that compliant businesses will spend a day of a registrant's time per premise preparing for the inspection and being present at the inspection, the total annual on-going cost across all businesses would be £400,000 (£1.2 million over three years to cover all premises). If the GOC conducted inspections on a five-year basis, annual costs across all businesses would be £240,000.

6.2.5.4 Costs of auditing protocols - GOC

Costs of auditing business protocols could be analogous to the GOC's costs incurred in reviewing individual registrants' applications for exceptional circumstances as an excuse for CET non-compliance (£30

⁸⁵ General Pharmaceutical Council Annual Report 2012:

<http://www.pharmacyregulation.org/sites/default/files/GPhC%20Annual%20Report%202011-12.pdf>

⁸⁶ Calculated as total annual inspection costs (£1.89 million) divided by the number of pharmaceutical businesses on a three-year basis (13,850/3).

⁸⁷ The number of premises is estimated from the 2007 NHS statistics, with an uplift for 2013.

⁸⁸ This works from the assumption of 225 working days a year.

⁸⁹ The daily forgone earnings of optometrists is taken from our 2012 study for the GOC on CET options. This figure is based on feedback from the optical profession, and represents the lower bound of responses.

per business), although the cost could be higher dependent on the number of documents each business would submit and the nature of the documents.⁹⁰ This would be a new requirement for all businesses (including those already registered with the GOC), estimated at just under 6,000. If we assume the GOC would audit protocols on a three-year rolling basis, the annual cost would be approximately £60,000. If audits were on a five-year cycle, on-going costs would be approximately £40,000 a year.

The table below summarises all the costs of Option 5.

Table 6.11: Option 5 cost estimates

	On-going	One-off
Option 4 costs		
Extend registration and enhance code of conduct	£295,116	£319,137
Cost of inspections - GOC		
Set up department		£80,000
Cost per inspection	£409	
Number of premises per year for 3-year basis (5-year)	2,667 (1,600)	
Cost of inspections per year for 3-year basis (5-year)	£1,091,697 (£655,018)	£80,000
Cost of increased FtP cases - GOC		
	£17,512	
Training and recruitment of inspectors		
Number of inspectors (part time)		28
Recruitment and training cost per inspector (two days)		£300
Costs of recruitment and training		£8,188
Costs of inspections - businesses		
Costs of preparation and inspection time per premise	£150	
Additional costs to businesses per year for 3-year basis (5-year)	£400,000 (£240,000)	
Costs of audit - GOC		
Cost per business	£30	
Number of total businesses	6,425	
Additional costs for 3-year basis (5-year)	£64,247 (£38,548)	
Total additional costs (3-year basis)	£ 1,868,571	£ 407,325
Total additional costs (5-year basis)	£ 1,246,194	£ 407,325

6.2.6 Option 6: Remove business registration and introduce registration of a dedicated “practice principal” for all business premises

The costs of this option to the GOC would be limited, and in fact savings could be made from removing the business register (estimated, as above, at £470,000 per year). Practice principals would already be registered on an individual basis with the GOC, and a small adjustment could record the fact that they were also practice principals.

However, there could be significant costs to businesses. Registrants becoming practice principals may have to undergo basic managerial and business training. We estimate that this may require a day of a registrant’s time per premise, which equates to a one-off cost across all businesses of £1.2 million (approximately £150 per premise).

⁹⁰ For example, if clinical input is needed in assessing the document.

Businesses would also incur on-going costs arising from time spent by practice principals in ensuring good clinical governance throughout the practice (e.g. checking that correct procedures were carried out, carrying out clinical audits, etc.). We estimate that principals would spend approximately two extra days a year on this role, which results in a very high cost across all businesses - approximately £2.4 million (approximately £300 per premise). The table below summarises the costs elements.

Table 6.12: Option 6 cost estimates

	On-going	One-off
Cost savings for GOC from removal of business register	(£470,000)	
Costs to businesses of training		£1,200,000
Additional cost of principals to ensure good governance	£2,400,000	
Total cost of Option 6	£1,930,000	£1,200,000

6.2.7 Option 7: Voluntary self-regulation by the industry

Costs to the GOC of a system of voluntary self-regulation should be minimal, and could involve little more than providing guidance to the industry in setting up the system. Compared to the current situation, this would represent a saving to the GOC as it would no longer be responsible for registering bodies corporate (estimated, as with Option 6, at £470,000 per year).

Costs would be incurred largely by businesses through fees payable to the industry body, and any changes in business practice necessary to meet the practice standards of the new code of conduct (to the extent to which this is over and above their current standards). We assume that the industry body would be based within one of the existing professional bodies and thus one-off costs of physical set up would be minimal.

Costs to the industry would depend largely on the exact form that the self-regulation system would take. At a minimum, there would be one-off costs of developing the new code of conduct. We have assumed these costs would be somewhat higher than the costs of developing the new code of conduct incurred by the GOC under Option 4, as there are likely to be more stakeholders involved and the process is likely to take longer.⁹¹ We estimate that the process will take a year of two FTEs — £160,000. On-going costs of keeping the code and related guidance 'live' is estimated at £40,000 a year.

On-going costs would also be incurred by the industry body of overseeing the accreditation of compliant firms. These would be largely administration costs. We assume that these would be less than the administrative costs incurred by the GOC in maintaining a business register as there would be less activity associated with the monitoring and removal of firms. We estimate that on-going costs would be 60 per cent of the costs to the GOC of maintaining the register (see Table 6.9) — £318,000 a year, being 60 per cent of (£470,000 plus £100,000).

If the industry body were to monitor and investigate non-compliant firms, then resources for this would be needed. Similarly, if firms were to submit self-declarations on how they complied with the new code of conduct they would incur limited administrative costs. Other costs could also include public awareness campaigns. However, these costs would depend on the design of the self-regulation system which at this stage we are not in a position to predict.

The table below summarises the cost elements of Option 7.

⁹¹ In particular, stakeholders from all four nations of the UK would need to be involved.

Table 6.13: Option 7 cost estimates

	On-going	One-off
Cost savings for GOC from removal of business register	(£470,000)	
One-off costs of developing code of conduct		£160,000
On-going guidance	£40,000	
On-going maintenance of self-regulatory industry body	£342,000	
Total cost of Option 6	(£88,000)	£160,000

6.3 Summary Table

We include the cost benefit summary table below with the cost estimates. As before, the ticks indicate where an option mitigates a particular risk over and above current experience, the crosses indicate where the option would exacerbate a risk, and the zeros indicate where the option would have no impact.

Table 6.14: Cost-benefit summary

	1. Retain current system	2. Remove all business registration	3. Extend registration	4. Extend registration and enhance Code of Conduct	5. Additional inspection and audit powers	6. Dedicated practice principal per premise	7. Self-regulation
Incomplete oversight of optical businesses	o	x	✓	✓	✓	o / ✓	o/ x
Undermined practitioner autonomy from commercial pressure	x	x	o / ✓	✓	✓	o	x
Inadequate systems for clinical governance (e.g. training or assistants; communication and supervision protocols)	x	x	✓	✓✓	✓✓	✓	o
Underinvestment in equipment	x	x	o	✓	✓✓	o	o
Unlevel competitive playing field	o	o	✓	✓	✓✓	✓	o
Additional costs (on-going)	Negligible	(£470,000)	£275,116	£295,116	£1,868,571	£1,930,000	(£88,000)
Additional cost (one-off)	Negligible	Negligible	£120,000	£319,137	£407,325	£1,200,000	£160,000

The cost key we used in the qualitative cost-benefit analysis is presented below.

Table 6.15: Cost key for qualitative cost-benefit analysis

Qualitative cost	Cost estimate
Negligible	around zero
Very low	< £100,000
Low	< £500,000
Medium	< £1,000,000
High	> £1,000,000