Executive summary
All regulation brings some cost. The challenge of good regulation is to minimise and, where possible, eliminate any unnecessary burdens.

There are opportunities for us to reduce the regulatory burden we place on others. Each of our directorates is already addressing these in their own areas of work, but there is a lack of visibility internally and externally.

We would benefit from cross-directorate coordination of these initiatives and from raising the profile of reducing regulatory burden within the organisation.

Recommendations
The Performance and Resources Board is asked to:

a. Embed consideration of reducing regulatory burdens in the business planning process, by requiring completion of a regulatory impact assessment at the project initiation stage.

b. Consider the merits of a programme board, with senior management sponsorship, and supported by the Regulation Policy team, to coordinate, promote and (where required) lead reducing burdens work across the organisation.
The issue

1. Reducing regulatory burdens is high on the political agenda. The UK governments are looking for regulators to show how we are easing the burdens we place on a hard-pressed health service. The work described in this paper focuses on reducing the burden we place on others, not the internal burden we bear. However, some of the opportunities it presents may also increase our internal efficiency.

2. Each team across the organisation is already working on projects to help us work in a more efficient and proportionate way. Not all of this work has a ‘reducing burdens’ mandate, although many workstreams will reduce burden on others (Annex A).

3. We are also improving our interactions with doctors and employers, which will lead to a reduction in burden, for example our customer service and digital media strategies (also highlighted in Annex A).

4. We do not currently have a coherent way of coordinating or articulating our work which reduces regulatory burden. This has the dual impacts of:
   a. limiting awareness, visibility and priority within the organisation; and
   b. challenging us in articulating our work externally, including to government and registered doctors.

What is ‘regulatory burden’?

5. Regulation is, by nature, burdensome for those who are regulated. It would be disingenuous to suggest that we can do away with all burden, or to claim that this would be desirable. Our role as a regulator is to protect patients. Our actions to do this need to be appropriate and proportionate.

6. We would expect to be able to describe and evaluate the intended impact of our regulatory interventions. We will define the ‘burden’ of those interventions as the extent to which the impact of any intervention exceeds its regulatory value. Sometimes this will mean a financial cost for those affected, including diversion of resources. Other times it will be less tangible, such as the anxiety generated by fear of regulatory action, the pace of change or sense of inequity.*

7. The key for reducing burden is proportionality. We must continue some of our interventions, even though they impose burden, because we would otherwise

* Business Perceptions of Regulatory Burden, University of Cumbria, May 2012
unacceptably increase the risk to patients. However, there are other parts of our work where we could improve our processes and reduce burden without additional risk.

Furthermore, as outlined above, we are pursuing opportunities to radically rethink our engagement with doctors and employers, which will have the added benefit of reducing the burden we place on them.

Discussion so far

In summer 2015, directors asked the Regulation Policy team to produce an overview of the opportunities to reduce regulatory burden across the organisation.

Directors considered the proposals at meetings in October and December 2015. Some options were dependent upon securing legislative change. Given the uncertainty around progress of the legislative reform agenda, directors asked for further exploration of opportunities which would not require legislative change.

This paper was developed through further discussion with assistant directors, heads of section and managers. It presents recommendations for taking the work forward.

Proposed solutions

Reducing burden is not new. We are already reducing burden through many of our existing projects. During a period of change for the organisation, it is important that we do not simply impose a new set of burdens on our own staff. To a significant degree, therefore, our work to reduce unnecessary burden on others should bring a discipline and internal and external profile to the things we are already doing.

To enable both of these to happen, the organisation as a whole needs to acknowledge the importance of reducing regulatory burden and of considering the burden of any interventions or actions we take.

To address internal visibility and priority, we propose that reducing regulatory burden is explicitly part of our business planning, with teams completing regulatory impact assessments during project initiation. This would include a clear assessment of the value which will derive from the project output and the possible ‘trade-offs’ in terms of whether the burden is proportionate to the risk.

We also propose that the merits of establishing a programme board, with senior management sponsorship, are considered. The board would be supported by the Regulation Policy team. It would be apprised of work across the organisation, provide an avenue for coordination of effort and communications and offer a resource for policy development where required. For the purposes of illustration, some examples of work that a programme board might wish to follow up are outlined at Annex B.
4 - Reducing regulatory burdens

Examples of work already underway

These are a selection of examples from across the organisation and do not form an exhaustive list.

Fitness to practise changes

1. Between 2010-2013, over 83% of the investigations opened resulted in no action being taken against the doctor. To reduce unnecessary investigations, in November 2014, we piloted provisional enquiries. These are limited enquiries we make at the first stage of the FtP process to help us decide whether to open an investigation. Of 103 enquiries completed in the pilot, 72 (70%) were closed. It is estimated that we can avoid between 176-247 unnecessary investigations per year through this process.

2. Provisional enquiries were rolled out as business as usual from September 2015. This alleviates a number of burdens:

   a. Resolve complaints more quickly – reducing impact on doctors and complainants.

   b. Reduced cost – an investigation officer would be able to complete 117 provisional enquiries each year, compared with 30-50 cases per year for a full investigation.

3. From 2016 (after changes to the Medical Act and our rules come into force), we are no longer required to inform employers about provisional enquiries (though we may choose to do so in some cases). This will streamline the provisional enquiry process and reduce the regulatory burden on employers.

4. In phase two of the provisional enquiries process, we will pilot an extension of the process to include single clinical incidents – we estimate that single clinical incidents comprise 15-20% of all Stream 1 cases. Over 90% of single clinical incidents are closed without any further action being taken. This change will be supported by enhanced triage guidance that the ELS will use to support giving advice for concerns to be dealt with locally where appropriate.
Meetings with doctors have also reduced the number of hearings and has a significant impact on regulatory burdens, particularly where employers may be called to give evidence.

**Research into the experience of doctors subject to warnings and restrictions on their practice**

6 We recently commissioned research into the impact of restrictions on a doctor’s practice with a small sample of doctors who either received a warning or were subject to other restrictions (mainly conditions and undertakings) between 2006 and 2013.

7 The initial findings suggest that insight by the doctor is an important factor for successful remediation. Employer’s reactions to both warnings and restrictions can vary and are dependent on a number of factor’s including: the doctor’s prior relationship with the employer; the nature of the case; and the risk to organisational reputation.

8 The findings also suggested that, though the intention of restrictions may be to assist a doctor in remediating and returning to practice, for example, working under supervision for a period of time, in reality, they may be prevented from doing so because the required supervision cannot be provided by the employer.

9 The full report was published in 2016. The findings of the report will help us to reflect on the impact of our actions and help us in developing a clear pathway to remediation for doctors where this is appropriate.

**New standards in education and training**

10 We recently launched our new standards in education and training, *Promoting excellence*. For the first time, there is one single document outlining the standards for both undergraduate and postgraduate education. This makes our standards clearer and easier to use for both internal teams and external organisations, reducing the number of criteria and requirements from 230 to 76. While education providers don’t need to do less, the document is less repetitive, higher level and less prescriptive, allowing more leeway for providers to choose the right methods for their students and environments.

11 The new standards were developed with the support of an expert advisory group (with key stakeholders represented). After extensive engagement, a consultation was held on the draft standards, which received positive feedback.

12 The new standards went into force from January 2016, and we will be reviewing their impact at a later date.

**Registration and revalidation projects**

13 We are undertaking a project to review the acceptable criteria for overseas primary medical qualifications. We currently require all applicants to meet all seven criteria. The
review will consider whether we are asking for information which is helpful in making an assessment and will increase transparency about what information we are asking for and why. This should make clear to all doctors whether or not their qualification will meet our requirements before they apply, and what information we will require from them. A paper recommending changes to streamline the criteria will be presented to Strategy and Policy Board in December 2016.

14 We are engaging with external stakeholders to look at the revalidation guidance produced for doctors to improve the consistency of the messaging. This will help us to be clearer about the information which doctors need to provide for revalidation and reduce mixed messaged about our requirements, which cause unnecessary burden on doctors providing evidence.

15 We are also undertaking a project to streamline and improve our voluntary erasure and registration and licensing restoration and relinquishment processes. Voluntary erasure is a process which doctors feel is unnecessarily distressing. We will be looking to develop a more customer-friendly approach. We will require legislative change for much of the reforms required.
4 - Annex B

Illustrations of cross-directorate proposals for consideration

The following examples illustrate opportunities to reduce burden which do not relate to a specific function and would require a level of cross-directorate coordination.

Illustration 1: organisational acceptance of a distributed model of regulation

1. Responsible officers (ROs) have a duty to raise appropriate fitness to practise concerns with us. They are not employed by the GMC, but they have a statutory duty to engage with us, and they have a relationship with their Employer Liaison Adviser which includes regular face-to-face meetings. We have mechanisms to raise concerns about ROs via escalation to their Higher Level RO through the ELS.

2. Similarly, we work closely with deaneries and LETBs and request information in the form of dean’s reports and assurance around enhanced monitoring progress.

3. We are not consistent about whether we consider assurance from an RO to be sufficient for us in determining fitness to practise or revalidation concerns. A policy decision on acceptance of a more distributed model would allow us to reduce our requests for information from ROs.

Illustration 2: coordinate the development of an operating model for future relations with system regulators

4. We have an interim lead for our operational relationship with CQC and our devolved offices support engagement with their respective equivalents. However, we don’t have an overarching strategy outlining how we want to develop how we work with systems regulators in the future. This limits our ability to maximise the opportunities to reduce regulatory burden on the system through information sharing and joint working.

5. To fully realise the benefits of joint working, we need a policy decision on our strategic approach and committed resource empowered to develop relationships in accordance with this strategy. We also need to build our understanding of the relevance of external data, for example through initiatives such as the Statement of Intent with NHS England and CQC regarding data and regulatory requests in primary care.
Illustration 3: coordinate a new approach to what information can be shared internally

6 Each directorate uses a separate part of Siebel. This restricts information internally and individuals need to liaise with others or, in some cases, may not be aware other relevant information exists. Some information is confidential and access must be limited eg regarding an ongoing fitness to practise investigation. However, other information may not be considered internally confidential.

7 A GMC-wide decision on what can and cannot be shared internally would prevent us from duplicating work and reduce inconsistencies, particularly when teams are engaging externally. We should bear in mind that external parties are engaging with us as an organisation and would expect us to interact with them in a joined-up way.

Illustration 4: unified and coordinated communications across functions

8 Our communications with doctors have developed significantly over recent years. This work continues with our customer service strategy. We still recognise the challenge of improving the coordination of our communications and making best use of opportunities to engage doctors at key contact points eg registration.

9 These key contact points often take place in processes we have so far seen as purely transactional and operational. By reframing our thinking and considering the opportunities which these interactions offer, we can improve our consistency of messaging, our reach to doctors and our ‘value add’ to a doctor’s practice and career.

10 Furthermore, our coordination of communications can be improved, particularly with regard to managing our routine communication with doctors in FtP procedures. The investigation officer can act as a gateway for communication these doctors. This will ensure that, for example, a doctor who is under investigation is not contacted separately about unrelated matters, and any communication from us is contextualised. This links to our response to the December 2014 Horsfall report.

Illustration 5: potential function-specific policy work

11 This includes:

   a  Registration to consider whether the questions we ask at the point of registration are proportionate. We may find opportunities to reduce burden on individual doctors.

   b  Linked to proposal 1, Fitness to Practise to consider its approach to reviewing all never event reports with ROs.
Illustration 6: Understanding regulatory burdens through engagement

12 We only have anecdotal evidence for our identification of burdens eg through the liaison services or comments which teams receive. Before pursuing a full programme of work, we need a stronger and more robust evidence base.

13 We have included a question in this year’s tracking survey related to burdens. We ask respondents whether they agree that the requirements the GMC places on their organisation are reasonable and proportionate, and if they disagree, why. We expect the results from the survey to be available in late 2016.

14 For more detailed feedback, we can engage the RO reference group to ask what they feel is unnecessarily burdensome. This group is an appropriate method for engagement as they are representative of ROs across the country. They are already engaged with the GMC and we anticipate would be constructive and receptive to the request for feedback.

15 But, there is a challenge in terms of managing expectations. We won’t be able to address all the behaviours which ROs find burdensome eg if we are restricted by legislation, or if we feel that the balance of risk requires the intervention. Additionally, we are undertaking work in Fitness to Practise to pass concerns which do not reach our threshold for action to appropriate local systems at an earlier stage. Any engagement would need to be clear that this work will continue.

16 We would need to design careful engagement which is open about the scope of our request and the reasons for the potential limitations in our response. We will also need to provide timely updates to the group on progress and outcomes.

17 This would be a significant step for us in maturing our relationship with the RO reference group beyond issues directly related to their functions.