



CONSULTATION ON THE PROCEDURE FOR GIVING REGULATORY  
BODIES INSTRUCTIONS TO MAKE OR CHANGE RULES UNDER  
SECTION 27 OF THE NATIONAL HEALTH SERVICE REFORM AND  
HEALTH CARE PROFESSIONS ACT 2002





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# Part A: Introduction

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1. 'Learning from Bristol', the report of the Bristol Royal Infirmary Inquiry chaired by Sir Ian Kennedy in 2001, recommended that "a single body should be charged with the overall co-ordination of the various professional bodies and with integrating the various systems of regulation". This recommendation was put into effect by the NHS Reform and Health Care Professions Act 2002 ('the Act'), which also introduced recommendations from the NHS Plan for England and the consultation document 'Modernising Regulation in the Health Professions'.

We, the Council for Healthcare Regulatory Excellence (CHRE), formerly known as the Council for the Regulation of Healthcare Professionals (CRHP), started work in April 2003. Our main purpose is to promote the interests of patients and the general public by working with regulators in the health professions. We aim to stimulate good practice in regulation and to strengthen the trust that people place in healthcare professionals.

2. We oversee the regulatory work of nine organisations:

- The General Chiropractic Council;
- The General Dental Council;
- The General Medical Council;
- The General Optical Council;
- The General Osteopathic Council;
- The Health Professions Council;
- The Nursing and Midwifery Council;
- The Pharmaceutical Society of Northern Ireland; and
- The Royal Pharmaceutical Society of Great Britain.

3. Our authority extends to all parts of the United Kingdom. We are independent of the Government, and are accountable to the UK Parliament. We are funded by the Government, through the Department of Health. We are made up of a council of 19 members, including one from each of the nine regulatory bodies and 10 non-regulatory members. Our council meets regularly and has a small supporting organisation. You can get more information about our council and its meetings on our website at [www.crhp.org.uk](http://www.crhp.org.uk)

4. Our general functions are set out in section 25(2) of the Act. Broadly, these are to:

- promote the interests of patients and other members of the public by monitoring the performance of regulatory bodies;
- promote best practice by regulatory bodies;
- formulate principles for healthcare professionals to regulate themselves and to encourage regulatory bodies to follow those principles; and
- promote co-operation between regulatory bodies, and between regulatory bodies and other organisations performing related functions.

5. The Act gives us several ways to protect the public through better regulation. These include a power under section 26(1) of the Act to do anything which appears necessary to perform our functions. Powers and duties under section 26 include investigating and reporting on the performance of individual regulators, investigating how this performance compares with other regulators, and recommending changes to the way regulators perform any of their functions.
6. Section 29 of the Act allows us to refer a regulatory body's disciplinary decisions to the High Court if we think the decision was too lenient and does not protect the public. We consulted interested parties on our powers under section 29 of the Act during an earlier exercise. As well as the powers the Act gives us by law, the Act also gives regulators a legal duty to co-operate with us.
7. This consultation exercise is concerned with our power under section 27 of the Act. This section allows us to instruct a regulatory body to make or change rules if this is necessary to protect the public.
8. Section 27 only applies to rules the regulator has the power to make and which do not need a law change.
9. We will exercise our power under section 27 only after consulting the regulator concerned. We would hope to agree any new or changed rule with the regulator concerned. We would first encourage the regulator to bring about the necessary change through other routes such as changing the advice it gives on standards.
10. Under section 27(13), the Secretary of State must provide regulations for the procedure we would follow if we exercised our power under section 27. The purpose of this consultation exercise is to consider the procedure we should follow.
11. The pages which follow explain the background of section 27, describe a draft procedure we might follow to exercise our power under section 27, and set out (in annex C) the rules of each regulatory body section 27 currently applies to. We would like comments on all aspects of the proposals in this document, including some specific questions which arose while we were preparing it. While we were drawing up these proposals we held discussions with a wide range of organisations, including the regulatory bodies themselves and organisations representing patients and healthcare professionals. We are very grateful to all of them. A list of the questions we are asking for this consultation is set out at annex D.
12. When we have gathered responses to this paper, we will give the Department of Health a recommended draft procedure we should follow when deciding whether to instruct a regulator to make or change a rule. The Department of Health will draft regulations accordingly.
13. Please give us your comments on our proposals. You can send us your comments in the following ways.

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Please provide your comments by 20 October 2004.

## Part B: Background to section 27

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1. Section 27 of the NHS Reform and Health Care Professions Act ('the Act') is one of several sections in the Act which gives us powers. We need these powers to perform our legal duties to promote the interests of patients and other members of the public. Section 27 gives us the power, after consulting the appropriate regulator and other interested parties, to instruct a regulator to make or change one or more rules if this is necessary to protect the public. Section 27 is attached at annex A. Explanatory notes to section 27 are at annex B.
2. Section 27(2) gives us the power to instruct a regulatory body to make rules for a specific purpose if we think "it would be desirable to do so for the protection of the public". This power is limited to those matters which regulators must make rules on and which need to be approved by the Privy Council. The rules needing Privy Council approval vary significantly from regulator to regulator. The rules of each regulator which currently need Privy Council approval are set out in annex C.
3. Under section 27(6) to 27(10) (and section 38(3)) any instruction we give under section 27 needs to be approved by both the House of Commons and the House of Lords, or the Northern Ireland Assembly. This requirement was added by Government after ministers emphasised that exercising our power under section 27 should be a last resort and they did not anticipate that we would need to use it. So as any instruction would need to be considered and approved by parliament, any decision to exercise our power will be taken in a meeting by our Council.
4. Under section 27(13), the Secretary of State for Health must make regulations setting out the procedure we should follow when giving a regulatory body instructions to make or change a rule or rules. The Department of Health will draft those regulations when this consultation exercise has ended.
5. In order to keep to good practice guidance (for example, the Cabinet Office's 'Enforcement Concordat') and principles relating to accountability, before we resort to giving a regulatory body instructions, as approved by Parliament, we should try to agree a satisfactory solution with the regulatory body.

# Part C: The draft procedure

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## 1 Discussion stage

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- 1.1 We will hold discussions with the regulatory body concerned. These discussions may be part of our normal contact with the regulator (for example, at a performance review meeting) or specially arranged as a result of a specific concern. If we and the regulatory body agree a solution (for example, if the regulator agrees with us that a rule needs to be changed), we do not need to follow the rest of the procedure. If we cannot reach an agreement with the regulatory body, we need to consider what to do next.

## 2 Applying the tests

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- 2.1 If, we decide that a regulatory body needs to make or change a rule or rules, and we cannot agree this with them, we will consider whether it is appropriate to issue an instruction under section 27. We can give an instruction only if the following two tests are satisfied.
- If the rule that needs to be changed or introduced needs to be approved by the Privy Council. (If not, we do not have the power to give instructions under section 27 and we would have to resort to influencing the regulatory body and their legal duty to co-operate with us.)
  - If the change is necessary to protect members of the public.
- 2.2 The decision as to whether these two tests are satisfied, and whether to exercise our power to give instructions, will be taken in a meeting by our Council.

## 3 Consulting the regulatory body about the proposed new or changed rule

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- 3.1 If the two tests above are satisfied, we will tell the regulatory body concerned that we intend to issue an instruction under section 27(2). We will explain what effect the instruction would have and the reason for it, and will ask for the regulatory body's views. We will provide a draft of our proposed instruction and the regulatory body will have a reasonable opportunity to respond. Because the regulatory body will want to consult its members, we suggest they have three months to respond.
- 3.2 By law, we only have to consult the regulatory body concerned. However, to make sure our decision-making is fair, from time to time we will ask for the views of others who might be affected by our decision. This may include consulting other regulatory bodies, and organisations representing patients and the public.

If we think it is necessary to consult more people than just the regulatory body concerned, we would consider:

- giving all parties three months to respond to the consultation;
  - giving the regulatory body concerned extra time beyond the three-month consultation period so it can respond to feedback we receive; or
  - some other option (we would welcome your suggestions).
- 3.3 Depending on the responses to the consultation, we will decide whether or not to give the regulatory body instructions to make or change a rule or rules.

## 4 Instructing a regulatory body to make or change a rule

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4.1 We will send our instructions to:

- the Secretary of State for Health; or
- the Department of Health, Social Services and Public Safety in Northern Ireland (in respect of the Pharmaceutical Society of Northern Ireland).

4.2 The relevant authority publishes a draft order stating what effect it would have and when it would come into force.

4.3 The instruction is put before both Houses of Parliament (or the Northern Ireland Assembly). If it is approved, it will come into force on the date specified in the order.

4.4 The regulatory body concerned will make or change the rule or rules as set out in our instruction.

4.5 The new or changed rule is sent to the Privy Council for approval. Rarely, where the rule in question says it is necessary, the Privy Council may also put the change out for consultation before approving the rules. If the Privy Council is content it will approve the new or changed rules.

## 5 Changing and withdrawing previous instructions

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5.1 If we put forward instructions to change or withdraw earlier instructions approved after both Houses of Parliament (or the Northern Ireland Assembly) have approved them, subsections (4) to (7) of section 27 apply. These state the following.

- Our council must send a copy of our new instructions to the Secretary of State for Health or the Department of Health, Social Services and Public Safety in Northern Ireland (whichever is appropriate).
- The Secretary of State must lay before both Houses of Parliament, or the Department of Health, Social Services and Public Safety must lay before the Northern Ireland Assembly, a draft order setting out:
  - our new instructions; and
  - the date they will come into force.
- Our new instruction will not change or withdraw the previous ones until the date specified in the order made by the relevant authority.

5.2 So if we want to change or withdraw an earlier instruction that has already been considered by Parliament or the Northern Ireland Assembly, any new instruction needs to go through a fresh period of consultation before passing it to the relevant authority.

5.3 If we want to withdraw earlier instructions that have not yet been put before the Houses of Parliament (or the Northern Ireland Assembly), we simply send a copy of the new instruction to the relevant authority (after consulting on them) and the earlier instructions will be treated as though they had never been in force.

## 6 Instructions affecting more than one regulatory body

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6.1 We have described the procedure for introducing a new or changed rule involving a single regulator. If a rule change would apply to more than one regulator, the same procedure will be followed, although we will send the relevant authority separate instructions for each regulatory body. We may consult on a rule change which affects more than one regulator within a single consultation process.

# Annex A

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## Extracts from the National Health Service Reform and Health Care Professions Act 2002

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### **'Section 27 Regulatory bodies and the Council**

- (1) Each regulatory body must in the exercise of its functions co-operate with the Council.
- (2) If the Council considers that it would be desirable to do so for the protection of members of the public, it may give directions requiring a regulatory body to make rules (under any power the body has to do so) to achieve an effect which must be specified in the directions.
- (3) The Council may give such directions only in relation to rules which must be approved by the Privy Council (whether by order or not) or by the Department of Health, Social Services and Public Safety in Northern Ireland before coming into force.
- (4) The Council must send a copy of any such directions to the relevant authority.
- (5) The relevant authority is the Secretary of State or, if the regulatory body in question is the Pharmaceutical Society of Northern Ireland, the Department of Health, Social Services and Public Safety there.
- (6) The directions do not come into force until the date specified in an order made by the relevant authority.
- (7) The Secretary of State must lay before both Houses of Parliament, or (as the case may be) the Department of Health, Social Services and Public Safety must lay before the Northern Ireland Assembly, a draft of an order-
  - (a) setting out any directions he or it receives pursuant to subsection (4), and
  - (b) specifying the date on which the directions are to come into force.
- (8) Subsections (4) to (7) apply also to
  - (a) directions varying earlier directions, and
  - (b) directions revoking earlier directions, and given after
    - (i) both Houses of Parliament have resolved to approve the draft order specifying the date on which the earlier directions are to come into force, or (as the case may be)
    - (ii) the Northern Ireland Assembly has done so.
- (9) Subsections (4) and (5) apply also to directions-
  - (a) revoking earlier directions, but
  - (b) which do not fall within subsection (8)(b),but subsections (6) and (7) do not apply to such directions.

- (10) If the Council gives directions which fall within subsection (9), the earlier directions which those directions revoke shall be treated as if subsections (6) and (7) had never applied to them, and as never in force.
- (11) A regulatory body must comply with directions given under subsection (2) which have come into force and have not been revoked.
- (12) A regulatory body is not to be taken to have failed to comply with such directions merely because a court determines that the rules made pursuant to the directions are to be construed in such a way that the effect referred to in subsection (2) is not achieved.
- (13) The Secretary of State shall make provision in regulations as to the procedure to be followed in relation to the giving of directions under subsection (2).
- (14) The regulations must, in particular, make provision requiring the Council to consult a regulatory body before giving directions relating to it under subsection (2).
- (15) In this section-
  - (a) "making" rules includes amending or revoking rules, and
  - (b) "rules" includes regulations, byelaws and schemes.

### **Section 38 Regulations and orders**

- (3) A statutory instrument containing regulations under section 28 or an order under section 36, or an order of the Secretary of State under section 27, shall not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.
- (4) No order shall be made by the Department of Health, Social Services and Public Safety in Northern Ireland under section 27 unless a draft of the order has been laid before, and approved by resolution of, the Northern Ireland Assembly.'

# Annex B

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## Extract from the explanatory notes to the National Health Service Reform and Health Care Professions Act 2002

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### **'Section 27: Regulatory bodies and the Council**

155. Section 27 provides underpinning powers for the Council and duties on the regulatory bodies, in order to ensure that the Council can do its work effectively.
156. Subsection (2) provides the Council with a reserve power to direct a regulatory body to make rules for a particular purpose. One situation in which it is envisaged that this power might be used is where the Council felt that consistency between the fitness to practise rules of all regulators was essential for the protection of members of the public.
157. Subsection (3) limits the effect of this section to the more important types of rules which regulatory bodies can make, those where the rule-making powers created in their different enactments require the permission of the Privy Council before they come into force (or in the case of the Pharmaceutical Society of Northern Ireland, require the permission of the Department of Health, Social Services and Public Safety in Northern Ireland). These mostly have to do with the maintenance of the professional register and fitness to practise issues.
158. Subsections (4) to (10) (read in conjunction with section 38(3) and (4)) provide for control over the Council's use of directions by stating that if a direction is made, it does not come into force until both Houses of Parliament (or, in the case of the Pharmaceutical Society of Northern Ireland, the Northern Ireland Assembly) have approved an Order laid before them setting a date for it to come into force.
159. Subsection (11) places a regulatory body under a duty to comply with directions which have come into force. If a regulator refused to comply with a direction made under this section, it would be open to the Council to seek, by way of judicial review, an appropriate declaration or order from the Court.
160. Subsection (12) ensures that a regulatory body is not in breach of the obligation to comply under subsection (11) merely because a court has interpreted the rules (made to comply with a direction) in a manner which means that the rules did not in fact give effect to that direction.
161. Subsections (13) and (14) require the Secretary of State to make regulations concerning the procedure to make a direction and providing that such regulations must include provision that a direction may only be made after consultation with the regulatory body in question.'

# Annex C

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## Rules currently needing approval from the Privy Council

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### **The General Chiropractic Council**

#### **Rules relating to the following.**

- Appeals against the decisions of the Registrar
- The constitution and procedures
- Continuing professional development (CPD)
- Electing members of the council
- The functions of legal assessors
- The functions of medical assessors
- Health appeal tribunals
- The Health Committee
- The Investigating Committee
- The period of provisional registration
- The Professional Conduct Committee
- Professional indemnity insurance
- Referring matters for a preliminary investigation
- Registration after a transitional period
- Registration during a transitional period
- Registration with foreign qualifications
- Restoring conditional registrations

### **The General Dental Council**

#### **Rules relating to the following.**

- Assessing dentists who qualified overseas
- Registers and fees
- Continuing professional development (CPD) for registered dentists
- Procedure for enforcing continuing professional development (CPD) requirements

- Continuing professional development (CPD) requirements for those applying to go back on the dentists' register
- Procedure for dealing with applications to go back on the dentists' register
- Dental auxiliaries
- Electing dental members of the Council
- Electing the president of the Council
- Council and committee proceedings
- Evidence and procedure in Professional Conduct Committee and Health Committee hearings
- Evidence and procedure in Continuing Professional Development (CPD) Committee hearings

## **The General Medical Council**

### **Rules relating to the following.**

- Removing and suspending members (the Removal and Suspension of Members rule – expected to come into force on 1 March 2004)
- Assessing professionals who qualified overseas (the Review Board for Overseas Qualified Practitioners Rules Order 1979)
- Voluntary removals from the register, and going back on the register after a voluntary removal (the Voluntary Erasure and Restoration following Voluntary Erasure Regulations 2003 and the Restoration and Registration Fees Amendment Regulations 2003)
- Registration fees (the Restoration and Registration Fees Amendment Regulations 2003 and the Medical Practitioners Registration (Fees) Regulations 1985)
- Fitness to practise committee (the constitution of Fitness to Practise Committees (Transitional Arrangements) Rules 2003)
- Electing members (the Election of Members Scheme)
- The Preliminary Proceedings Committee and Professional Conduct Committee (the Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988 and the Professional Conduct Committee (EC Practitioners) (Procedure) Rules 1989)
- Professional performance (the Professional Performance Rules 1997)
- The Health Committee (the Health Committee (Procedure) Rules 1987)
- The Interim Orders Committee (the Constitution of Interim Orders Committee Rules 2000 and the Interim Orders Committee (Procedure) Rules 2000)
- Fraud or mistakes (the Fraud or Error Rules 1980)

## **The General Optical Council**

### **Rules relating to the following.**

- The Investigating Committee (the Investigating Committee Rules 1960)
- Registration and enrolment (the Registration and Enrolment Rules 1976)
- Publicity (the Rules on Publicity 1985)
- Contact lenses (the Rules on the Fitting of Contact Lenses 1985, the Contact Lens (Qualifications etc.) Rules 1988, and the Contact Lens (Specification) Rules 1989)
- The Disciplinary Committee (the GOC Disciplinary Committee (Procedure) Rules 1985)
- Eye tests (the Testing of Sight by Persons Training as Ophthalmic Opticians Rules 1993) and the Sight Testing (Examination and prescription (No. 2) Regulations 1989 – made by the Secretary of State)
- The Companies Committee (the Companies Committee Rules 1993)
- The Disciplinary Committee (the Disciplinary Committee (Constitution) Rules 1998)
- The Education Committee (the Education Committee Rules 1999)
- Eye diseases or injuries (the Rules relating to Injury or Disease of the Eye 1999)
- Working under names other than those under which professionals are registered or enrolled (no current rule)
- Registered opticians practising orthoptics (no current rule)
- Opticians administering drugs (no current rule)
- The Disciplinary Committee (the GOC Disciplinary Committee (Legal Assessor) Rules 1961 - made by the Lord Chancellor)
- Selling glasses and lenses (the Sale of Optical Appliances Order of Council 1984 - made by the Privy Council)
- Punishments (the GOC (Maximum Penalty) Order of Council 1994 - made by the Privy Council)

## **The General Osteopathic Council**

### **Rules relating to the following.**

- Registration (the Transitional Period (Application for Registration and Fees), the Conditional Registration Rules and the Registration Rules)
- Registration Rules SI 1328 1998
- Professional indemnity insurance rules (the Professional Indemnity Insurance Rules)
- Medical assessors (the Medical Assessors Rules)
- Investigating complaints (the Investigation of Complaints Procedure Rules SI 1847 1998)

- Legal assessors (the Legal Assessors Rules SI 1848 1998)
- Going back on the register of conditionally registered osteopaths (the Restoration to the Register of Conditionally Registered Osteopaths Rules SI 1037 2000)
- Fraud or mistakes (the Fraud or Error and Appeals Rules SI 1846 1999)
- Appeals (the Health Committee Appeals Rules SI 243 2000)
- Professional conduct (the Professional Conduct Committee Procedure Rules SI 241 2000)
- The Health Committee (the Health Committee Rules SI 242 2000)
- Qualifications (the Recognition of Qualification SI 1281 2000)
- Registering fees (the Application for Registration of Fees SI 1038 2000)
- Electing members and a chairman (the Election of Members and Chairman of Council Rules SI 15 2001 and the Election of Members and Chairman of Council Rules SI 827 2002)

## **The Health Professions Council**

All of the Health Professions Council's rules need Privy Council approval.

## **The Nursing and Midwifery Council**

### **Rules relating to the following.**

- Registration, the register, and paying fees
- Appeals against the registrar's decisions
- The procedure to be followed by the Investigating Committee, the Conduct and Competence Committee and the Health Committee when considering any allegation made against a registrant
- The practice of midwifery and standards for local supervising authorities
- Electing members
- The constitution and the procedure for the Practice Committees

All the Nursing and Midwifery Council's rules need Privy Council approval, as do any fees they charge in connection with their work.

## **The Royal Pharmaceutical Society of Great Britain**

### **Rules relating to the following.**

- All byelaws and regulations made under their charter or by law (including registration and retention fees) need Privy Council approval
- Any changes to their charter
- Putting any pharmacist previously removed from the register by order of the Statutory (Disciplinary) Committee under the Pharmacy Act 1954 back on the register
- Appointing examiners under the Pharmacy Act 1954
- Appointing pharmacy inspectors under the Poisons Act 1972

## **The Pharmaceutical Society of Northern Ireland**

All of the rules of the Pharmaceutical Society of Northern Ireland need to be approved by the Department of Health, Social Services and Public Safety.

# Annex D

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## Questions for consultation

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1. What criteria should we use to decide whether a rule change is needed to protect members of the public?
2. How long should the consultation period be for getting feedback on a proposed instruction? Although it is normally good practice to have a consultation period of three months, a shorter period might be sufficient if the consultation is on a single issue and is justified in order to protect the public as quickly as possible. However, any instruction we make under section 27 is likely to be controversial, otherwise the regulatory body would act voluntarily. In these circumstances, the regulatory body would almost certainly want to consult its own members and the consultation period needs to allow for this.
3. How widely should we consult on a proposed instruction?
4. If it is appropriate for us to consult more widely on a proposed rule change, which of the options explained in this document is best?
5. Should the regulations specify who we should consult? One view would be that this should be up to us. An alternative is the model used in, for example, the Nursing and Midwifery Council Order 2001. This includes:

'Before establishing any standards or giving any guidance under this Order the Council shall consult representatives of any group of persons it considers appropriate including, as it sees fit, representatives of -

- (a) registrants or classes of registrant;
- (b) employers of registrants;
- (c) users of the services of registrants; and
- (d) persons providing, assessing or funding education or training for registrants or prospective registrants.' (Art 3(14))

6. Do you think that the process outlined is the appropriate way to proceed with rule changes affecting more than one regulatory body that we feel are necessary to protect the public?

Please give us your comments on our proposals. You can send us your comments in the following ways.

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Please provide your comments by 20 October 2004.



