EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations establish arrangements for the introduction of "responsible officers" ("ROs") under the Medical Act 1983 ("the Act"). ROs will be appointed by health care organisations and certain other bodies, and will have responsibilities relating to the evaluation of the fitness to practise of doctors who work in the organisation. The Regulations come into force on 1st January 2011.

Part 1 of the Regulations contains general provisions: regulation 1 contains citation, commencement date and interpretation provisions; regulation 2 contains interpretation provisions for the armed forces, and regulation 3 deals with the application of the Regulations.

Part 2 of the Regulations applies to England, Scotland and Wales. This Part deals with the appointment of ROs and their responsibilities under the Act.

Regulation 4 and the Schedule specify the bodies which are "designated bodies" under the Act. These are the bodies that will be required to nominate or appoint ROs. Regulation 4(2) and Part 1 of the Schedule list bodies that are always required to have ROs, for example NHS hospitals; regulation 4(3) and Part 2 of the Schedule list bodies that will be required to have ROs only while they employ or contract with doctors, for example, Government departments. Government-owned locum agencies (NHS Professionals Ltd currently being the sole such agency in the class described in paragraph 20(a)) are designated bodies; other locum agencies in England and Wales are designated bodies only if they are on the NHS Purchasing and Supply Agency's framework agreement (paragraph 20(b) of the Schedule); this agreement can be viewed at the following website:

http://www.buyingsolutions.gov.uk/healthcms/Productsandservices/Agencystaffandoutsourcedservices/temporarystaff/Medicallocums/.

Regulation 5 sets out the duty on designated bodies to nominate or appoint ROs. A body is not required to have an RO if all the doctors who work for that body already have a connection under the Regulations with another designated body (see regulation 10).

Regulation 6 requires designated bodies to nominate or appoint an additional RO in cases where there is a conflict of interest or appearance of bias between a doctor and the original RO.

Regulation 7 sets out the conditions that must be met for a person to be nominated or appointed as an RO: the person must be a registered medical practitioner, which under current legislation means a licensed doctor; they must also have been a registered doctor for the preceding 5 years. A responsible officer must continue to be a registered medical practitioner.

Regulation 8 sets out the conditions that must be satisfied for a person to be nominated or appointed as an RO for more than one designated body: the person must be capable of carrying out the ROs' responsibilities for each body concerned, and there must be no conflict of interest.

Regulation 9 provides that the Secretary of State may nominate an RO for a designated body when the body has failed to do so, or has appointed someone unsuitable. The Secretary of State must consult the Scottish or Welsh Ministers, as applicable, before making such an appointment in respect of an NHS body in Scotland or Wales, and must consult the independent regulator (Monitor) before making such an appointment in relation to an NHS Foundation Trust.

Regulation 10 sets out the "prescribed connection" between designated bodies and doctors. When a doctor is linked to a designated body under this regulation, the RO for that body has responsibilities in respect of the doctor under regulation 11. Doctors in training in England and Wales are linked to the postgraduate deanery that is responsible for their training; doctors in training in Scotland are linked

to a Scottish training governance body (NHS Education for Scotland currently being the sole body falling within that class). Where a doctor is on the performers list of a primary care organisation, that organisation (a Primary Care Trust in England, a Health Board in Scotland or a Local Health Board in Wales) will be the designated body for the doctor, except for doctors in the armed forces who will be linked to the organisation where they do most of their work. Where the doctor is an employee of a designated body (and is not a trainee or on a performers list), the employing organisation will be the designated body for that doctor. Doctors working as locums will be linked to their locum agency if that agency is NHS Professionals Ltd, or is on an approved list (the NHS PASA framework) in England and Wales; other locums will be linked to their nearest Primary Care Trust, Health Board or Local Health Board. Where a doctor is providing services to patients in an independent hospital, the body managing that hospital will be the designated body for that doctor. Where none of the other provisions applies and the doctor is a member of one of certain designated professional bodies, the doctor will be linked to that body. A doctor who is a member of the Independent Doctors' Federation ("the IDF") will be linked to that body if none of the preceding provisions applies; the IDF is a body which represents doctors who work outside other structures, and it sought designation under the Regulations during consultations with the Department of Health. The regulation also sets out an order of priority in the event that the doctor could be connected to more than one body.

Regulation 11 sets out the responsibilities of ROs in relation to doctors who are connected with the designated body under regulation 10. ROs are required to evaluate doctors' fitness to practise. This includes ensuring that regular appraisals are carried out, developing procedures to address any concerns about doctors' fitness to practise, and reporting concerns to the General Medical Council where appropriate.

Regulation 12 sets out the prescribed connection between designated bodies and doctors who are themselves ROs. It is necessary to have special provisions in these cases because ROs cannot be responsible for evaluating themselves.

Regulation 13 makes provision similar to regulation 11 in respect of ROs' responsibilities in relation to doctors who are connected with the designated body under regulation 12.

Regulation 14 contains a requirement for designated bodies and medical practitioners to provide resources to ROs, and regulation 15 contains a duty for ROs to have regard to guidance.

Part 3 of the Regulations applies to England only. This Part contains additional responsibilities for ROs under section 120 of the Health and Social Care Act 2008.

Regulation 16 sets out the additional responsibilities for ROs in England in respect of the doctors for whom they are responsible under regulation 10; these include carrying out pre-employment checks on doctors, monitoring doctors' conduct and performance, and investigating and taking appropriate action to deal with concerns about doctors. Regulation 17 makes similar provision for ROs' responsibilities in relation to doctors for whom they are responsible under regulation 12.

Regulation 18 contains a duty for ROs to have regard to guidance, and regulation 19 concerns the requirement for designated bodies and medical practitioners to provide resources to ROs.

An impact assessment has been prepared in relation to these Regulations and is available from the Department of Health, Quarry House, Quarry Hill, Leeds LS2 7UE; see also http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Regulatoryimpactassessment.