

HEALTH AND SOCIAL CARE ACT 2008

EXPLANATORY NOTES

TERRITORIAL EXTENT

Amendments of Part 3 of Health Act 1999

Section 111: Extension of powers under s.60 of Health Act 1999

337. Section 60 of the Health Act 1999 allows Her Majesty, by Order in Council, to modify the regulation of the existing regulated healthcare professions and to bring other healthcare professions into statutory regulation. An Order made under section 60 may repeal or revoke any enactment or instrument, amend it, or replace it (subject to the restrictions in paragraphs 7 and 8 of Schedule 3 to the Health Act 1999). The Government must consult on draft Orders prior to them being laid before Parliament. The Orders are subject to the affirmative procedure. Orders which make provision for professions whose regulation is not a “reserved matter” for the purposes of the Scotland Act 1998 (in effect, those made subject to statutory regulation since 1 July 1999) are subject to affirmative procedure in the Scottish Parliament (as well as at Westminster).
338. *Section 111* brings into effect Schedule 8 which amends section 60 of, and Schedule 3 to, the Health Act 1999. The effect of the amendments is to extend the powers available under section 60.

Schedule 8: Extension of powers under s.60 of Health Act 1999

339. *Paragraph 1(2)* brings the OHPA within the scope of section 60 of the Health Act 1999. This enables changes to be made to the constitution, functions, powers and duties of the OHPA by an Order in Council so that they can be updated as approaches to regulation change and evolve and so that additional professions can be brought within the remit of the OHPA.
340. *Paragraph 1(3)* removes the reference to the ‘Pharmacy Act 1954’ (which has been repealed by the Pharmacists and Pharmacy Technicians Order 2007) from section 60(2)(a). This is replaced by section 60(2)(aa) which refers to ‘professions regulated by the Pharmacists and Pharmacy Technicians Order 2007 and the Pharmacy (Northern Ireland) Order 1976’, the first now being the relevant legislation for the regulation of pharmacists and pharmacy technicians in Great Britain and the second being the relevant legislation in respect of the regulation of pharmacists in Northern Ireland. It also inserts a new section 60(2)(ca), referring to private hearing aid dispensers. The intention is to make an Order in Council under section 60 giving the Health Professions Council responsibility for the regulation of this profession.
341. *Paragraph 1(4)* inserts a new subsection (2A) into section 60. This enables an Order in Council under this section to make provision relating to, or connected with, the specific statutory functions of the RPSGB and the PSNI. These are:
- the functions under the Medicines Act 1968 in relation to the registration and regulation of pharmacy premises, and the other inspection and enforcement functions which the RPSGB and the PSNI have under that Act;

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- the functions under the Poisons Act 1972 and the Poisons (Northern Ireland) Order 1976 in so far as they relate to persons admitted to practice, such as pharmacists, and persons carrying on a retail pharmacy business;
 - the grant of authorisations under section 28 of the Regulation of Investigatory Powers Act 2000 concerning directed surveillance.
342. The primary purpose of the inclusion of subsection (2A) is to ensure that these statutory functions, which are separate from but connected to the regulation of individual practitioners, are brought within the scope of section 60, so that changes can be made across all of the RPSGB's and the PSNI's regulatory functions where necessary. For example, this will facilitate the transfer of all of the RPSGB's and the PSNI's (subject to a decision by Northern Ireland Ministers to proceed in this way) regulatory functions under these Acts to the proposed General Pharmaceutical Council which the Government intends to create in the future by a section 60 Order. However, it is also envisaged that these powers will be used to modernise the requirements in relation to pharmacy premises in particular.
343. *Paragraphs 2, 7(3) and (4) and 8(a)* of Schedule 8 – An Order in Council under section 60 of the Health Act 1999 can amend or repeal (by virtue of paragraph 2(1) of Schedule 3 to that Act) any enactment. Paragraph 8(a) of Schedule 8 inserts a definition of “enactment” into Schedule 3. The definition includes not only Acts of the Westminster Parliament (and instruments made under them), but also Acts of the Scottish Parliament, Measures or Acts of the National Assembly for Wales and Northern Ireland legislation (and instruments made under them). Paragraph 2 amends section 62(10) of the Health Act 1999 to provide that where an Order in Council includes provision amending Scottish legislation on devolved matters but the provision is incidental to or consequential on provision about a reserved matter, the Order does not on that account require the approval of the Scottish Parliament. Paragraph 7(3) and (4) of Schedule 8 provide that, in those circumstances, Scottish Ministers are not required to consult on a draft of the Order in Council. Rather, the Secretary of State alone will consult on the draft Order (although he will have to consult the Scottish Ministers).
344. *Paragraph 4* inserts a reference to “a Northern Ireland department” into paragraph 5 of Schedule 3 to the Health Act 1999. This allows an Order in Council under section 60 of the Health Act 1999 to confer functions on or modify the functions of a Northern Ireland department. This brings the position in relation to Northern Ireland departments into line with the ability to confer functions on or modify the functions of Ministers of the Crown, as well as the Scottish Ministers and the Welsh Ministers, by means of an Order under section 60.
345. *Paragraph 5* makes amendments to paragraph 7 of Schedule 3, which specifies matters outside the scope of the Orders under section 60. *Paragraph 5(2)* replaces the existing sub-paragraph (1) of paragraph 7. New sub-paragraph (1) has the effect that those regulatory bodies to which section 60(2)(a) applies, the RPSGB, the PSNI, the Health Professions Council, the NMC, and any other regulatory body established by an Order under section 60 (such as the proposed new General Pharmaceutical Council), cannot be abolished by an Order under section 60.
346. New sub-paragraph (1A) of paragraph 7 of Schedule 3 qualifies new sub-paragraph (1) by providing that an Order in Council may establish a new regulatory body for the professions regulated by the Pharmacists and Pharmacy Technicians Order 2007 and the Pharmacy (Northern Ireland) Order 1976 and transfer to that new body regulatory functions currently exercised by the RPSGB and the PSNI. The scope of section 60 of the Health Act 1999 is confined to regulation. For that reason, the new paragraph 7(1A) of Schedule 3 to the Health Act 1999 will only enable functions relating to regulation to be transferred from the RPSGB and the PSNI to the proposed new General Pharmaceutical Council.

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347. Under the current provisions in section 60 of, and Schedule 3 to, the Health Act 1999, an Order in Council cannot require a majority of the members of a regulatory body to be lay members. *Paragraph 5(3)* removes this restriction through the removal of paragraph 7(2) of Schedule 3 to the Health Act 1999.
348. *Paragraph 5(4)* removes a restriction that has prevented Orders under section 60 from being used to make provisions allowing functions conferred on the Privy Council in relation to some of the regulated professions to be exercised by another person. The professions affected are pharmacists, doctors, optometrists, dispensing opticians, osteopaths, chiropractors, dentists and the other professions regulated, or to be regulated, under the Dentists Act 1984. In practice, it is anticipated that once this restriction has been removed the extended section 60 power will generally be used to transfer functions from the Privy Council to the regulatory bodies for the affected professions rather than to third parties.
349. *Paragraph 6* makes amendments to paragraph 8 of Schedule 3 to the Health Act 1999, which specifies other matters that are outside the scope of an Order under section 60. *Paragraph 6(2) and (3)* allow the fitness to practise functions of the regulatory bodies to be transferred to the OHPA by a section 60 Order. They also ensure that the regulatory functions currently exercised by the RPSGB, the PSNI and the Hearing Aid Council can be transferred to a new regulatory body, using an Order under section 60, which would otherwise be prohibited as regards certain protected functions.
350. *Paragraph 7* makes amendments to paragraph 9 of Schedule 3 to the Health Act 1999, which specifies the preliminary procedures for making an Order under section 60. *Paragraph 7(2)* makes changes to clarify that where an Order under section 60 deals with more than one profession (for example, pharmacists and pharmacy technicians, or doctors and dentists), representations on the published draft Order should be invited from people considered appropriate to represent any profession covered by the Order. Representations should also be invited from people considered appropriate to represent the users of the services provided by any profession covered by the Order.
351. *Paragraph 7(3) and (4)*: see the explanation in relation to paragraph 2 above.
352. *Paragraph 8(a)*: see the explanation in relation to paragraph 2 above.
353. *Paragraph 9* amends paragraph 11 of Schedule 3 to the Health Act 1999, by replacing references to the National Health Service Act 1977 with references to the NHS Act 2006 and the NHS (Wales) Act 2006 (which consolidated NHS legislation in England and Wales respectively).
354. *Paragraph 10* repeals paragraph 12 of Schedule 3 to the Health Act 1999, which contains limitations on the extent to which changes can be made under section 60 in relation to the regulation of the pharmacy profession in Northern Ireland. This will allow for changes to the PSNI through an Order under section 60, specifically for the regulatory functions of the PSNI to be transferred to a new General Pharmaceutical Council (subject to a decision by Northern Ireland Ministers to proceed in this way).

Section 112: Standard of proof in fitness to practise proceedings

355. Currently, the application of the standard of proof in fitness to practise proceedings by regulatory bodies is not consistent. At present, all except two of the health regulatory bodies (the GOC and the NMC) use the civil standard of proof rather than the criminal standard of proof in fitness to practise proceedings.
356. *Section 112* inserts a new section 60A into the Health Act 1999. This new section imposes a requirement for all the regulatory bodies and the new OHPA to use the civil standard of proof in fitness to practise proceedings. A restriction is included in *subsection (4)*, the effect of which is that an Order under section 60 of the Health Act 1999 may not amend this new section or make any provision which is inconsistent with the imposition of the civil standard of proof.