



Health and Social Care Act 2012

2012 CHAPTER 7

PART 12

FINAL PROVISIONS

304 Regulations, orders and directions

- (1) A power to make regulations under this Act is exercisable by the Secretary of State.
- (2) Regulations under this Act, and orders by the Secretary of State, the Welsh Ministers or the Privy Council under this Act, must be made by statutory instrument.
- (3) Subject to subsections (4) to (6), a statutory instrument containing regulations under this Act, or an order by the Secretary of State or the Privy Council under this Act, is subject to annulment in pursuance of a resolution of either House of Parliament.
- (4) Subsection (3) does not apply to an order under section 306 (commencement).
- (5) A statutory instrument which contains (whether alone or with other provision) any of the following may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament—
 - ^{F1}(a)
 - (b) the first regulations under section 83 (licensing requirement: exemption regulations);
 - (c) the first order under section 86 (approval by Secretary of State of licensing criteria);
 - ^{F2}(d)
 - (e) regulations under section 105(4) (manner in which turnover to be calculated for purposes of penalty for breach of licence conditions etc.);
 - (f) regulations under section 106(3)(d) (descriptions of action for specifying in enforcement undertaking for breach of licence conditions etc.);
 - ^{F3}(g) regulations under section 114D(1)(b)(i) or (ii) (percentage to be prescribed in cases of objections to proposals for NHS payment scheme);]
 - (h) regulations under section 130 (health special administration regulations);

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- (i) an order under section 140 (maximum amount that may be raised from levy to raise funds for special administration cases);
 - ^{F4}(j)
 - ^{F5}(jb) regulations under section 277E (regulations about enforcement);
 - (k) an order under section 290(4) (addition to list of bodies subject to duty co-operate);
 - (l) an order under section 291(5) (order prohibiting bodies subject to duty to co-operate from exercising specified functions etc.);
 - (m) an order under section 303 (consequential provision) which includes provision that amends or repeals a provision of an Act of Parliament;
 - (n) regulations which, by virtue of subsection (10)(a), include provision that amends or repeals a provision of an Act of Parliament.
- (6) An order by the Privy Council under this Act that includes provision which would, if included in an Act of the Scottish Parliament, fall within the legislative competence of that Parliament is subject to the negative procedure in that Parliament (in addition to the statutory instrument containing the order being subject to annulment under subsection (3)).
- (7) Sections 28 and 31 of the Interpretation and Legislative Reform (Scotland) Act 2010 (negative procedure etc.) apply in relation to an order of the description given in subsection (6) as they apply in relation to devolved subordinate legislation (within the meaning of Part 2 of that Act) that is subject to the negative procedure, but as if references to a Scottish statutory instrument were references to a statutory instrument.
- (8) Section 32 of that Act (laying) shall apply in relation to the laying of a statutory instrument containing an order of the description given in subsection (6) before the Scottish Parliament as it applies in relation to the laying of a Scottish statutory instrument (within the meaning of Part 2 of that Act) before that Parliament.
- (9) A power to make regulations under this Act, a power of the Secretary of State, the Welsh Ministers or the Privy Council to make an order under this Act, and (subject to section 71(3)) a power to give directions under or by virtue of this Act—
- (a) may be exercised either in relation to all cases to which the power extends, or in relation to those cases subject to specified exceptions, or in relation to any specified cases or descriptions of case,
 - (b) may be exercised so as to make, as respects the cases in relation to which it is exercised—
 - (i) the full provision to which the power extends or any less provision (whether by way of exception or otherwise),
 - (ii) the same provision for all cases in relation to which the power is exercised, or different provision for different cases or different descriptions of case, or different provision as respects the same case or description of case for different purposes of this Act,
 - (iii) any such provision either unconditionally or subject to any specified condition, and
 - (c) may, in particular, make different provision for different areas.
- (10) Any such power includes—
- (a) power to make incidental, supplementary, consequential, saving, transitional or transitory provision (including, in the case of a power to make regulations, provision amending, repealing or revoking enactments), and

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- (b) power to provide for a person to exercise a discretion in dealing with any matter.
- (11) A power to give directions under or by virtue of this Act includes power to vary or revoke the directions by subsequent directions.
- (12) A direction under this Act by a Minister of the Crown (acting alone)—
- (a) must, in the case of a direction under any of the following provisions, be given by regulations or an instrument in writing—
- ^{F6}(i)
- (ii) section 234(1) (direction to NICE to prepare quality standards);
- (iii) section 245(1) (direction to NICE to perform functions);
- (iv) section 249(8) (direction to [^{F7}NHS England] to be transitional commissioner in relation to pre-commencement statements of quality standards);
- (v) section 254(1) (direction to [^{F8}NHS England] to establish information systems);
- ^{F9}(vi)
- (vii) section 260(2)(d) (direction to [^{F10}NHS England] that information of specified description is not subject to duty to publish);
- ^{F11}(viii)
- (ix) paragraph 7 of Schedule 6 (direction to [^{F12}NHS England] to exercise functions of Secretary of State relating to Primary Care Trusts), and
- (b) must, in the case of any other direction, be given by an instrument in writing.
- (13) A direction under or by virtue of this Act by any other person (or persons) must be given by an instrument in writing.

Textual Amendments

- F1** S. 304(5)(a) omitted (1.7.2022) by virtue of Health and Care Act 2022 (c. 31), s. 186(6), **Sch. 5 para. 99(2)**; S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- F2** S. 304(5)(d) omitted (1.7.2022) by virtue of Health and Care Act 2022 (c. 31), **ss. 85(8)**, 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- F3** S. 304(5)(g) substituted (1.7.2022 for specified purposes, 1.4.2023 in so far as not already in force) by Health and Care Act 2022 (c. 31), s. 186(6), **Sch. 10 para. 4**; S.I. 2022/734, reg. 2(b) (with regs. 13, 29, 30); S.I. 2023/371, reg. 2(d)
- F4** S. 304(5)(j) omitted (1.7.2022) by virtue of Health and Care Act 2022 (c. 31), **ss. 85(8)**, 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- F5** S. 304(5)(jb) inserted (1.10.2022) by Health and Care Act 2022 (c. 31), **ss. 100(3)**, 186(6); S.I. 2022/1003, reg. 2(c)
- F6** S. 304(12)(a)(i) omitted (1.7.2022) by virtue of Health and Care Act 2022 (c. 31), s. 186(6), **Sch. 5 para. 99(3)**; S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- F7** Words in s. 304(12)(a)(iv) substituted (1.7.2022) by Health and Care Act 2022 (c. 31), s. 186(6), **Sch. 1 para. 22**; S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- F8** Words in s. 304(12)(a)(v) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 17(30)(a)** (with reg. 3)
- F9** S. 304(12)(a)(vi) omitted (1.2.2023) by virtue of The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 17(30)(b)** (with reg. 3)

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- F10** Words in s. 304(12)(a)(vii) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 17(30)(c)** (with reg. 3)
- F11** S. 304(12)(a)(viii) omitted (1.2.2023) by virtue of The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 17(30)(d)** (with reg. 3)
- F12** Words in s. 304(12)(a)(ix) substituted (1.7.2022) by Health and Care Act 2022 (c. 31), s. 186(6), **Sch. 1 para. 22**; S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)

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Changes and effects yet to be applied to :

- specified provision(s) amendment to earlier commencing SI 2012/1831 art. 10 by [S.I. 2012/2657 art. 15](#)

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- Pt. 9 Ch. 1B inserted by [2022 c. 31 s. 96](#)
- s. 102(4)(ba) inserted by S.I. 2019/93, Sch. 1 para. 13(3) (as substituted) by [S.I. 2019/1245 reg. 28](#) (This amendment not applied to legislation.gov.uk. The affecting statutory instrument has no legal effect. It was made under a procedure which meant that it ceased to have effect 28 days after signing unless it was debated and approved in Parliament within that time. It was not debated and approved within 28 days, so it has expired with no effect.)
- s. 105(3A)(3B) inserted by [2013 c. 24 Sch. 14 para. 21](#)
- s. 106(3A)(3B) inserted by [2013 c. 24 Sch. 14 para. 22](#)
- s. 250(2)-(2B) substituted for s. 250(2) by [2022 c. 31 s. 95\(2\)\(a\)](#)
- s. 250(6)-(6D) substituted for s. 250(6) by [2022 c. 31 s. 95\(2\)\(d\)](#)
- s. 251251ZA substituted for s. 251 by [2022 c. 31 s. 95\(3\)](#)
- s. 251C(6A) inserted by [2022 c. 31 s. 95\(4\)\(a\)](#)
- s. 259(1)(aa)(b) substituted for s. 259(1)(b) by [2022 c. 31 s. 98\(b\)](#)
- s. 259(1)(aa) words substituted by [S.I. 2023/98 Sch. para. 17\(11\)\(a\)\(iii\)](#) (This amendment comes in force at the same time as 2022 c. 31, s. 98 comes into force)
- s. 259(10A)(10B) inserted by [2022 c. 31 s. 98\(h\)](#)
- s. 304(5)(ja) inserted by [2022 c. 31 s. 95\(5\)](#)