NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical and Local Pharmaceutical Services (Prescriptions, Payments and Listings) Directions 2013

The Secretary of State for Health gives the following Directions in exercise of the powers conferred by sections 7, 8, 168A, 272(7) and 273(1) of the National Health Service Act 2006(**a**).

Citation, commencement and application

1.—(1) These Directions may be cited as the Pharmaceutical and Local Pharmaceutical Services (Prescriptions, Payments and Listings) Directions 2013 and come into force on 1st April 2013.

(2) These Directions apply in relation to England.

Interpretation

2. In these Directions—

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(**b**);

"dispensing doctor" has the same meaning as in the PLPS Regulations;

"ESP chemist" means a provider of local pharmaceutical services under a "pilot scheme" within the meaning given in section 134(2) of the NHS Act(**c**) (pilot schemes);

"LPS chemist" has the same meaning as in the PLPS Regulations;

"the NHS Act" means the NHS Act 2006(**d**);

"the NHSBSA" means the NHS Business Services Authority established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(**e**);

"NHS chemist" has the same meaning as in the PLPS Regulations;

"NHS services" means services provided as part of the health service (so includes services provided as part of the health service in pursuance of the public health functions of the Secretary of State or local authorities);

"the PLPS Regulations" means the National Health Services (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**f**); and

"the Remission of Charges Regulations" means the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003(**g**).

(**a**) 2006 c. 41. Section 7 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), section 21; section 8 has been amended by the 2012 Act, Schedule 4, paragraph 5, and Schedule 14, paragraph 3; and 168A was inserted by the 2012 Act, section 49(4). By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Directions are exercisable only in relation to England.

(**b**) S.I. 2000/620.

(**c**) Section 134(2) has been amended by the Health Act 2009 (c. 21), Schedule 1, paragraph 8, and by the Health and Social Care Act 2012, Schedule 4, paragraph 71(3).

(**d**) 2006 c. 41.

(**e**) S.I. 2005/2414.

(**f**) S.I. 2013/349.

(**g**) S.I. 2003/2382.

NHSBSA functions relating to the Drug Tariff

3.—(1) The NHSBSA is directed to compile and publish the Drug Tariff, on behalf of the Secretary of State(**a**), and to do so—

(a) in a format that is approved by the Secretary of State; and

(b) at the intervals determined by the Secretary of State.

(2) The NHSBSA is directed to distribute the Drug Tariff, as appropriate.

(3) The NHSBSA is directed—

(a) to approve, on behalf of the Secretary of State(**b**), the lists of appliances and chemical reagents which may be supplied as part of pharmaceutical services; and

(b) to determine, on behalf of the Secretary of State, the prices of the products so listed, and the basis on which the reimbursement costs that are to be payable in respect of the products so listed are to be calculated.

NHSBSA functions relating to the production of forms

4.—(1) The NHSBSA is directed to perform the functions (being functions of the Secretary of State under section 2 of the NHS Act(**c**) (general power)) mentioned in paragraphs (2) and (4).

(2) The functions mentioned in this paragraph are the production, printing and (to the extent approved by the Secretary of State) distribution of the following forms for use as part of NHS services, which are forms that need to be compatible with the arrangements for prescription charging set out in the Charges Regulations and, as appropriate, any arrangements for apportionment and reimbursement under Schedule 12A to the NHS Act (pharmaceutical remuneration)—

(a) non-electronic prescription forms;

(b) forms for non-electronic repeatable prescriptions (including batch issues);

(c) forms for the purpose of recording patient declarations in respect of electronic prescription forms;

(d) forms for the purpose of recording patient declarations in respect of electronic repeatable prescriptions;

(e) forms used for claiming the repayment of prescription charges; and

(f) forms used in respect of out of hours supply of drugs or appliances.

(3) The forms mentioned in paragraph (2) must be in a format approved by the Secretary of State, and that format must not be changed without the prior approval of the Secretary of State.

(4) The functions mentioned in this paragraph are providing information, at intervals to be determined by the Secretary of State, to the Secretary of State, the Board, NHS trusts, NHS foundation trusts, clinical commissioning groups, and local authorities about the costs of the forms mentioned in paragraph (2) and the number of those forms that the NHSBSA has available for distribution.

(5) The NHSBSA is directed that it is able, in the manner approved and to the extent approved by the Secretary of State, to perform the function (being a function of the Secretary of State under section 2A of the NHS Act(**d**) (Secretary of State's duty as to protection of public health)) of assisting the Board and others by way of the production, printing and distribution of the

(**a**) The Secretary of State's obligation to publish the Drug Tariff is currently set out in regulation 89(1) of S.I. 2013/349.

(**b**) The approval of a list of appliances is a function of the Secretary of State under section 126(3)(d) of the National Health Service Act 2006 (c. 41), read with subsection (9) of that section. Section 126(3)(d), read with subsection (5)(b) of that section, also enables the Secretary of State to provide for the circumstances in which other medicines, drugs or appliances may be ordered under arrangements for the provision of pharmaceutical services – and for the purposes of those provisions, the chemical reagents in the list compiled by the NHS Business Services Authority (on behalf of the Secretary of State) are treated as drugs, and the list of chemical reagents is compiled for the purposes of determining the circumstances in which the chemical reagents may be ordered.

(**c**) Section 2 was substituted by the Health and Social Care Act 2012 (c. 7), Schedule 4, paragraph 1.

(**d**) Section 2A was inserted by the Health and Social Care Act 2012, section 11.

prescription forms for the purposes of private prescribing of controlled drugs that are required under the Misuse of Drugs Regulations 2001(**a**).

NHSBSA functions relating to pharmaceutical remuneration and prescription charging

5.—(1) The NHSBSA is directed to perform the functions (which are the Secretary of State's functions) that are assigned to it by the Secretary of State as part of the Secretary of State's arrangements for claiming and making of payments, and making deductions from payments, of pharmaceutical remuneration.

(2) The NHSBSA is directed that it is able—

(a) to enter into any arrangements (A1) that the Board decides to enter into with it (pursuant to section 13Z(2)(a) of the NHS Act(**b**) (exercise of functions)) for the NHSBSA to perform functions as part of the Board's arrangements for claiming and making of payments, and making deductions from payments, of pharmaceutical remuneration; and

(b) to perform the functions that it has undertaken to perform under A1.

(3) Without prejudice to the generality of paragraphs (1) and (2), the functions to be assigned to the NHSBSA by the Secretary of State, or that it may undertake to perform on behalf of the Board, may include—

(a) examining, checking, pricing and storing, for a period to be determined by the Secretary of State from time to time, of batch issues and prescriptions for drugs and appliances supplied as part of pharmaceutical or local pharmaceutical services;

(b) making payments due to NHS chemists for pharmaceutical services (including for additional pharmaceutical services);

(c) making payments due to LPS chemists for LP services(**c**) (including for those LP services which are not local pharmaceutical services, as well as for those LP services which are);

(d) making payments to practitioners suspended in accordance with Chapter 6 of Part 7 of the NHS Act (pharmaceutical services and local pharmaceutical services – disqualification), and—

(i) providing the Board with information and assistance in respect of, or

(ii) exercising the functions of the Board under,

the determinations of the Secretary of State under regulation 98 of the PLPS Regulations (payments to suspended chemists);

(e) making reward scheme payments;

(f) providing the Board with information and assistance relating to the remuneration (including product reimbursement costs) due to dispensing doctors;

(g) deducting sums to be allotted to Local Pharmaceutical Committees;

(h) recovery of overpayments, and—

(i) providing the Board with information and assistance in respect of, or

(ii) exercising the functions of the Board under,

regulation 94 of the PLPS Regulations (overpayments);

(i) deducting prescription charges;

(j) funding of prescription charge repayments and dealing with administrative matters associated with prescription charge repayments (which may include the NHSBSA providing returns, at intervals determined by the Secretary of State, of information to facilitate the monitoring of prescription charge repayments);

(**a**) S.I. 2001/3998.

(**b**) Section 13Z was inserted by the Health and Social Care Act 2012 (c. 7), section 23.

(**c**) *See* paragraph 1(7) of Schedule 12 to the National Health Service Act 2006 (c. 41), which defines "LP services" for these purposes. LP services are all the services provided under an LPS scheme (as defined in paragraph 1(2) of that Schedule), which may, or may not, be limited to local pharmaceutical services.

(k) exercising functions of the Secretary of State under the Charges Regulations (in particular under regulations 8, 9 and 10(2)(c)(**a**) (which relate to certificates of exemption, pre-payment certificates and repayment of charges));

(l) exercising functions of the Secretary of State under the Remission of Charges Regulations (but not under regulation 12(1)(c)(**b**) (repayments));

(m) exercising functions of the Board under direction 7;

(n) exercising functions of the Board under section 165A of the NHS Act(**c**) (pharmaceutical remuneration – further provision); and

(o) arrangements for auditing, monitoring or analysing the making of payments of pharmaceutical remuneration (including of product reimbursement costs), which may include—

(i) providing, promptly and regularly, information requested by the Secretary of State on the costs and trends of prescribing as part of NHS services, and

(ii) carrying out (agreed) exercises to establish trends in prescribing in respect of prescriptions dispensed in the community.

(4) The NHSBSA is directed that it is able to exercise any of the functions of the Board under Schedule 12A of the NHS Act(**d**) (pharmaceutical remuneration) that it is directed by the Board, with the consent of the Secretary of State, under paragraph 4(a) of that Schedule to exercise.

(5) The NHSBSA is directed to perform the following functions (being functions of the Secretary of State under section 2 of the NHS Act(**e**) (general power))—

(a) publicising the arrangements for claiming remission or repayment of charges under the Remission of Charges Regulations;

(b) publicising the arrangements for claiming the travel expenses payable under the Remission of Charges Regulations;

(c) publicising the exemptions from, and the arrangements for claiming exemptions from, charges under the Charges Regulations; and

(d) publicising the arrangements for the provision of pre-payment certificates under the Charges Regulations,

but before any publicity material is published by the NHSBSA pursuant to this paragraph, that publicity material must be approved by the Secretary of State.

NHSBSA functions in respect of other remuneration of NHS chemists and LPS chemists

6. —(1) The NHSBSA is directed to perform the functions (which are the Secretary of State's functions) that are assigned to it by the Secretary of State as part of the Secretary of State's arrangements for claiming and making of payments, and making deductions from payments, of remuneration payable to NHS chemists or LPS chemists in respect of NHS services arranged by the Secretary of State.

(2) The NHSBSA is directed that it is able—

(a) to enter into any arrangements (A2) that the Board decides to enter into with it (pursuant section 13Z(2)(a) of the NHS Act(**f**) (exercise of functions)) for the NHSBSA to perform functions as part of the Board's arrangements for claiming and making of payments, and making deductions from payments, of remuneration payable to NHS chemists or LPS chemists in respect of NHS services—

(**a**) Regulation 8 has been amended by S.I. 2002/2352, 2005/578 and 2009/29. Regulation 9 was substituted by S.I. 2007/1510 and has been amended by S.I. 2009/411, 2011/518 and 2013/475. Regulation 10(2) has been amended by S.I. 2000/3189 and 2002/2352.
(**b**) Regulation 12(1) has been amended by S.I. 2004/696 and 2013/475.
(**c**) Section 165A was inserted by the Health and Social Care Act2012 (c. 7), section 51(1).
(**d**) Schedule 12A was inserted by the Health and Social Care Act 2012, Schedule 3.
(**e**) Section 2 was substituted by the Health and Social Care Act 2012, Schedule 4, paragraph 1.
(**f**) Section 13Z was inserted by the Health and Social Care Act 2012, section 23.

(i) arranged by the Board (other than pharmaceutical or local pharmaceutical services, which are covered by direction 5), or

(ii) arranged by a clinical commissioning group, but—

(aa) the Board is providing resources to the clinical commissioning group in respect of those services, pursuant to section 14Z10 of the NHS Act(**a**) (power of Board to provide assistance or support), and

(bb) those resources include support in respect of the claiming and making of payments, and making deductions from payments, of remuneration in respect of those services; and

(b) to enter into arrangements (A3), with the consent of the Secretary of State, with—

(i) a clinical commissioning group which provide for the making of payments to NHS chemists or LPS chemists of amounts determined by the clinical commissioning group to be payable in respect of NHS services provided by those chemists under arrangements for the provision of those NHS services made between those chemists and the clinical commissioning group, or

(ii) a local authority which provide for the making of payments to NHS chemists or LPS chemists of amounts determined by the local authority to be payable in respect of NHS services provided by those chemists under arrangements for the provision of those NHS services made between those chemists and the local authority; and

(c) to perform the functions that it has undertaken to perform under A2 or A3.

Examination of prescription forms and payment data by representative bodies

7.—(1) Subject to paragraph (2), the Board must afford, in response to a reasonable request from—

(a) an ESP chemist or NHS chemist (C);

(b) a Local Pharmaceutical Committee that represents C; or

(c) an organisation that the Board considers to be representative of ESP chemists or NHS chemists and that represents C,

reasonable facilities for examining prescriptions (whether electronic or non-electronic) on which drugs or appliances provided by C were ordered, any associated patient declarations or batch issues, and particulars of the amounts calculated to be payable to C in respect of the drugs or appliances.

(2) For these purposes—

(a) facilities afforded for examining non-electronic repeatable prescriptions are to be considered reasonable if the Board determines that only access to the associated batch issues is to be afforded; and

(b) particulars of the amounts calculated includes particulars of individual elements in the calculation but does not include particulars relating to the underlying process by which the amounts are calculated.

(3) Pursuant to paragraph (1), in the case of providing facilities for examining—

(a) electronic prescriptions, the Board may provide related non-electronic patient declarations (for as long as non-electronic patient declarations continue to be used in relation to electronic prescriptions), or information from them, in a paper or electronic format; and

(b) prescriptions, batch issues or patient declarations, if the facilities are being provided by any Special Health Authority ("SpHA") (including the NHSBSA) exercising functions on the Board's behalf, the arrangements that the SpHA makes to exercise those functions must have the approval of the Secretary of State.

(**a**) Section 14Z10 was inserted by the Health and Social Care Act 2012, section 26.

(4) In the case of facilities afforded to a representative organisation or Local Pharmaceutical Committee, the Board need only afford those facilities if it is satisfied that the representative organisation or Local Pharmaceutical Committee—

(a) will handle or process any information obtained as a consequence of being afforded those facilities in such manner as the Board may reasonably specify; and

(b) will only permit access to any information obtained as a consequence of being afforded those facilities to persons who fully understand the confidential nature of the information and the purposes for which they are being permitted access to it.

(5) In the case of a SpHA (including the NHSBSA) exercising functions on the Board's behalf under paragraph (1), the arrangements that the SpHA makes to exercise those functions must provide that the SpHA is to refuse to comply with any request under paragraph (1) if complying with that request would, in the opinion of the Secretary of State, involve disproportionate expense on the part of the SpHA.

(6) In determining what would, at any time, involve disproportionate expense, the Secretary of State—

(a) may have regard to the volume of requests that the SpHA is receiving under paragraph (1) at that time; but

(b) is to exercise the power in a manner that does not prejudice the rights that C has in relation to receiving the correct amounts payable to C in respect of pharmaceutical or local pharmaceutical services.

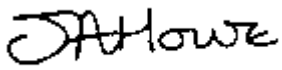
Ceasing of effect of the National Health Service (Pharmaceutical Services) Directions 2005

8. For the avoidance of doubt, the National Health Service (Pharmaceutical Services) Directions 2005(**a**) have ceased to have effect.

Amendment of the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) Directions 2006

9. In the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) Directions 2006(**b**), omit direction 15 and Schedule 4 (which relate to functions of the authority in relation to pharmaceutical claims processing and pharmaceutical services).

Signed by authority of the Secretary of State for Health



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27th March 2013

(**a**) Signed on 1st December 2005.
(**b**) These Directions came into force on 1st April 2006.