
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the PLPS Regulations”). The PLPS Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006, for the provision of pharmaceutical and local pharmaceutical services. The PLPS Regulations include the NHS terms of service of four different types of provider: retail pharmacy businesses that are on pharmaceutical lists held by the NHS Commissioning Board (the businesses are known as “pharmacy contractors”, and the Board as NHS England and NHS Improvement – “NHSE-I”); dispensing appliance contractors; dispensing doctors; and retail pharmacy businesses that hold local pharmaceutical services contracts (known as “LPS contractors”). These Regulations also amend the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (“the Charges Regulations”), which include the charges payable for the supply of drugs and appliances as part of the NHS in England.

These Regulations contain measures that are part of the response to the coronavirus pandemic.

The Charges Regulations are amended to ensure that supplies of prescription items for or in anticipation of pandemic disease, or in other serious emergencies, either on prescription or pursuant to a patient group direction or serious shortage protocol, are free of charge – if they relate to that disease (in a pandemic situation) and arrangements have been made to that effect by the Secretary of State, or by another NHS body with the approval of the Secretary of State. Previously, this only applied to such supplies if they were supplies of drugs and, in a pandemic situation, if the supplies were in accordance with pandemic treatment protocols (“PTPs”) under regulation 247 of the Human Medicines Regulations 2012 (regulation 6).

Provision is also made so that pharmacy contractors and dispensing doctors are required to supply against a patient group direction that is approved by NHSE-I and relates to the supply of a prescription only medicine to be used for the prevention of, or as a treatment for, a disease that is, or in anticipation of it being imminently, pandemic (known as a pandemic treatment patient group direction – “PTPGD”) in the same circumstances in which they are required to supply such medicines against PTPs. Provision is made so that PTPGD or PTP supply may be triggered not only by an electronic message of a type approved by NHSE-I (the situation prior to these Regulations) but also following individual assessment of the patient’s entitlement. There are consequential amendments relating to these requirements that deal with matters such as dispensing labels (regulations 2, 3(2) to (4) and 4(2) and (3)).

Pharmacy contractors, dispensing doctors and LPS contractors may already be required by NHSE-I, in a pandemic situation, to provide a home delivery option to patients who are required to stay at home in order to assist in the management of the pandemic. These pre-existing arrangements apply to all the prescriptions that the patient receives. These Regulations allow the NHE-I additionally to require pharmacy contractors, dispensing doctors and LPS contractors to provide a home delivery option in respect of specific prescription items to eligible patients (for example, but not limited to, treatments for a disease that is pandemic). In the case of dispensing doctors and pharmacy contractors, this home delivery option is further extended to specific items supplied under a PTP or PTPGD as part of pharmaceutical services (regulations 3(5), 4(4) and 5(3)). An error in one of the existing home delivery option provisions has also been corrected (regulation 5(2)).