Remote supervision is here already

By Richard Schmidt, part-time locum community pharmacist and business consultant

The Pharmacists’ Defence Association and many of the candidates who have put their names forward in the Royal Pharmaceutical Society’s national pharmacy board elections are concerned that one pharmacist may soon be permitted to assume responsible pharmacist status for more than one pharmacy premises — so-called “remote supervision”.

It is, seemingly, not widely recognised that responsibility for pharmacies already been enabled by the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, albeit perhaps only during the allowable two-hour period of absence of the responsible pharmacist. This should be obvious to anyone who understands the origin and purpose of standard operating procedures.

An SOP is a document that describes what is being done, by whom and how. The SOPs that relate to responsible pharmacy are those that relate to the delivery of a safe and effective dispensary service as prescribed by the Regulations. Importantly, the Regulations have promoted the status of dispensary SOPs from professional to legal. So, it is no longer illegal for dispensary staff not to comply with their SOPs. They are, in effect, byelaws. They are an extension to the employment contracts of employed dispensary staff and to the contracts of service of self-employed locum pharmacists.

The origin of SOPs can be traced back to the mid 1970s when the requirements of good laboratory practice were put in place by the US Food and Drug Administration following its acquisition of new powers to require more robust safety and efficacy testing of pharmaceuticals after the thalidomide tragedy. They provide documentation with which lawyers can work if there is a need to prosecute an offence through the courts, and which lawyers can work if there is a need to prosecute an offence through the courts, and which lawyers can work if there is a need to prosecute an offence through the courts, and which lawyers can work if there is a need to prosecute an offence through the courts.

The Courts will in time reach their own conclusions about the meaning of these words, but in terms of a lay person's interpretation of the English, these words tell us that if a responsible pharmacist believes that named dispensary SOPs “must” be covered is the “identification of good pharmacy practice” (GPP). The history of our GPP SOPs is traceable to the 1995 Bristol babies scandal. This led the NHS to the imposition of “clinical governance” — a systematic approach to maintaining and improving the quality of care. In due course, the Health Act 1999 imposed a statutory “duty of quality” on all NHS service providers. By 1 January 1995, the Society had already made it a requirement that written protocols be followed by medicines counter staff when selling over-the-counter products or giving advice — an early example of an SOP. It was reiterated in 2002 that the implementation of dispensary SOPs in community pharmacies started as an informal good practice guideline. On 1 January 2005, dispensary SOPs became a professional requirement. On 1 October 2009, when the responsible pharmacist Regulations came into force, dispensary SOPs became a legal requirement. This was entirely predictable to any student of the history of SOPs.

So, how do our dispensary SOPs already enable remote supervision?

The phrase “by or under the supervision of a pharmacist” was not precisely defined in the Medicines Act 1968 but its meaning has over time been defined by case law. In amending the Medicines Act 1968 through the Health Act 2006, legislators have explicitly sought to defer making a change to the law relating to supervision. However, the responsible pharmacist Regulations themselves appear to effect a change in the law on this matter.

The Regulations list a range of activities that “must be covered by pharmacy procedures” then state that one of the matters that “must” be covered is the “identification of members of pharmacy staff who are, in the view of the responsible pharmacist, competent to perform certain tasks relating to the pharmacy business”. Further, the pharmacy procedures “must” specify “the arrangements which are to apply during the absence of the responsible pharmacist from the premises”. The courts will in time reach their own conclusions about the meaning of these words, but in terms of a lay person’s interpretation of