



**Royal
Pharmaceutical
Society**
of Great Britain

Law and Ethics Bulletin

As a result of recent developments and changes in the way that single dispensing errors are to be dealt with the Society it is now necessary to revise and replace the Law and Ethics Bulletin issued on 26 January 2007.

Medication error logs

The maintenance of medication error logs is seen as good practice in pharmacy and, in line with clinical governance arrangements, should be included in pharmacy Standard Operating Procedures. Medication error logs are intended to be used as a risk management tool and information from the logs should be regularly reviewed, analysed and discussed within the pharmacy in order to identify risk areas associated with the dispensing and checking process. Appropriate action to review systems and procedures with a view to minimisation of future risk should be taken, where necessary.

Pharmacy owners and individuals may be apprehensive that information contained in medication error logs could be used as a basis for disciplinary action by the Society. However, the existence and regular audit and review of such logs is considered to be indicative of good practice and robust risk management. Their use is therefore encouraged.

In March 2007 the Council agreed that the criteria set out in Box 1 should be used to decide whether single dispensing errors are likely to amount to professional misconduct and warrant referral to the Investigating Committee. One of the criteria for referral to the Committee is the failure to maintain a medication error log. Single dispensing errors that do not meet the referral criteria are dealt with by the Society's inspectorate and are not referred to the Investigating Committee for consideration of further action to be taken. This is subject to the individual admitting the allegations made and accepting any advice given to them by the inspector in relation to the dispensing error made. Further information on the Council's decision can be found at <http://www.rpsgb.org/pdfs/counagen0703open.pdf>

During routine pharmacy inspections, Society inspectors may ask to see evidence that a system is in place to deal with dispensing errors, including the maintenance and use of medication error logs. However, inspectors will not usually need to ask to look at any of the actual records or any of the specific

information held within those logs. Further information on the inspection of error logs during routine visits is available at <http://www.rpsgb.org/pdfs/inspvisitschecklist.pdf>.

If the Society receives a complaint about a dispensing error, the Inspector may, as part of the investigation, ask to see the specific error log which relates to the complaint under investigation. Evidence of the maintenance of an error log by the pharmacy (where the pharmacy has been made aware of the error) can be seen as evidence of good practice. It may be particularly helpful if the error log describes any review of systems carried out at the pharmacy in light of the incident.

There may be occasions, where, as a result of concerns raised about a particular pharmacy or about the fitness to practise of an individual, it may be necessary for the pharmacy error logs to be examined. This action would only be considered in where there was genuine cause for concern about public safety.

For further information on the handling of dispensing errors please refer to the Society's website <http://www.rpsgb.org/pdfs/restooldealdisperr.pdf>

Box 1

Criteria for consideration of single dispensing errors

Single dispensing errors are not likely to be referred to the Investigating Committee **unless** one or more of the following statements are true;

- There is potential for, or evidence that, the dispensing error caused moderate or severe harm or death (the definitions of these are from the NPSA definitions for grading patient safety incidents - see Box 2).
- There is evidence that the dispensing error was a deliberate attempt to cause harm to patients or the public.
- There is evidence of ill health or substance abuse by the pharmacist.
- There is evidence that the individual departed from agreed safe protocols or standards operating procedures and in doing so took an unacceptable risk.
- There are no systems to record errors in the pharmacy (this should result in the Superintendent/Pharmacy owner being referred).
- There has been a failure to make an error log (if aware of the error).
- There are no systems to learn from errors in the pharmacy (this should result in the Superintendent/Pharmacy owner being referred).
- No attempt has been made to learn from the specific error.
- The Society's Inspector has previously given advice that would have prevented the error if it had been implemented.
- There has been an attempt to cover up the alleged dispensing error.
- There has been a failure to co-operate with an investigation carried out by the Society's Inspector or other investigatory body.
- There is evidence of other misconduct that would form the basis of a complaint.
- Failure to apologise/provide an explanation to the patient/representative (if aware of

the error).

- There is relevant history within the last 3 years.

Box 2

NPSA definitions for grading patient safety incidents

Grade of patient safety incident	Definition
No harm	<ul style="list-style-type: none">• Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care.• Incident not prevented – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.
Low harm	<p>Any patient safety incident that required extra observation or minor treatment* and caused minimal harm to one or more patients receiving NHS-funded care.</p> <p>*Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.</p>
Moderate harm	<p>Any patient safety incident that resulted in a moderate increase in treatment* and that caused significant but not permanent harm to one or more patients receiving NHS-funded care.</p> <p>*Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.</p>

Severe harm	<p>Any patient safety incident that appears to have resulted in permanent harm* to one or more patients receiving NHS-funded care.</p> <p>*Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiologic or intellectual, including removal of the wrong limb or organ or brain damage.</p>
Death	<p>Any patient safety incident that directly resulted in the death* of one or more patients receiving NHS-funded care.</p> <p>*The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.</p>