PHARMACY GUILD OF NEW ZEALAND

# Pharmacy Quality Audits

## Medicines Control (a regulatory team within Medsafe) undertakes Pharmacy Quality Audits (PQA), under the Pharmacy Quality Audit Framework, on behalf of the Districts to ensure pharmacy services to the public meet the required standards.

Their primary focus of these audits is to check that pharmacies meet the requirements of the legislation, the Health and Disability Services Pharmacy Services Standard, Integrated Community Pharmacy Services Agreement (ICPSA), Code of Ethics and other relevant codes and practice guidelines.

While some elements of the ICPSA are audited, funding and payment issues are not part of this type of audit. Another team at Te Whatu Ora, the Health Payments Integrity Team (HPIT) are responsible for financial auditing, as well as fraud investigation.

Here are some tips for a smooth, stress-free PQA audit:

- Keep the controlled drug safe locked at all times – it is a legal requirement that the safe is kept locked unless in immediate use.
- Ensure the stock on hand of a controlled drug is exactly what is recorded in the controlled drug register. An easy way to keep on top of this is to incorporate into the pharmacy's SOP for the dispensing of controlled drugs that the stock on hand in the safe of a particular controlled drug after a dispensing matches what is recorded in the controlled drug register and to tick the column in the register to show that this has been counted and checked. If this is done regularly, it is easy to sort out any discrepancies or missed entries and will also provide an additional check when dispensing a controlled drug.
- Ensure codeine, DHC Continuous and other Class C2 controlled drugs are stored in the controlled drug safe at all times.
- Methadone must be stored in the controlled drug safe until the patient collects it.
- Undertake regular stocktakes of liquid controlled drugs, including methadone, to account for the overage.
- Ensure the twice yearly stocktakes on 30 June and 31 December each year have been completed, which includes a physical controlled drug stocktake and a quantity stock account of each controlled drug.
- Emergency supplies of prescription medicines must meet the legal requirements and only be for a genuine emergency, comprising of a maximum of 72 hours' worth of a regular medicine and a record made under the patient's name in the PMS (Toniq/RxOne). The legislation does not allow a pharmacist to make a "loan in advance" or lend a regular medicine to a known patient.
- It is a requirement under Section 51(1)(e) of the Medicines Act that a pharmacy maintains an up-to-date set of reference resources. Guild membership allows free access to a number of the required reference resources.
- Ensure the pharmacy has access to legislation updates via the Guild member app or an RSS web feed set up for the relevant New Zealand legislation.
- Have up to date standard operating procedures (SOPs) and ensure all the staff know how to access these. The SOPs should be personalised for the pharmacy and reflect the processes and procedures that

are carried out in the pharmacy. The Guild offers an SOP platform, GuildLink, which provides a complete set of template standard operating procedures, with regular automatic updates.

- Evidence of the qualifications of pharmacists and technicians must be held in the pharmacy to prove that all staff are qualified to provide pharmacy services. This includes additional pharmacist training, such as ECP, sildenafil, vaccination, etc.
- Monitor the dispensary refrigerator temperatures on a regular basis (at least weekly) and ensure that there is a record made of these temperatures.
- Monitor ambient temperatures regularly and keep a record of this monitoring.
- Data-loggers and e-loggers used in temperature monitoring must be validated for accuracy (at least on a quarterly basis), ideally against a mercury max-min thermometer.
- Record and review near-miss events and dispensary errors. If there is a need to provide evidence in the case of a Health and Disability enquiry, it is very difficult to remember details of an event several months down the track.
- Ensure customers know how to make a complaint by displaying this information and have a documented process for handling customer complaints.
- Ensure that the Medicines Classification Database on the Medsafe website is consulted to check whether a medicine can be repacked for over-the-counter (OTC) sale to a patient and in what quantity.
- Medicines repacked for OTC sales must be labelled with the patient's name and pharmacist's name as the prescriber, not just under "patient OTC" in the computer.
- Check that your electronic record of pharmacist-only medicine sales correctly records the name of the pharmacist who has undertaken the sale. It is acceptable to record pharmacist-only sales using a paper-based system.
- Ensure all stock, including compounding materials, have had a recent expiry date check and there is a robust system for prompting this to happen on a regular basis.
- Job sheets for each individual compounded products are completed in full and filed for the required numbers of years.
- Repackaging of bulk medicines, e.g., packs of 100 paracetamol tablets, packs of 90 aspirin EC tablets, is documented and this documentation is retained by the pharmacy.
- For compliance packaging, a current prescription or a copy of a signed current chart must have been received before the packing is initiated.