



Meeting regulatory and ethical requirements in OTP

Community Pharmacies are a key contributor to the NSW Opioid Treatment Program with more 10,000 clients receiving treatment at their local Community Pharmacy. The benefits to clients and the community are well documented and the NSW Ministry of Health provides incentive payments to pharmacies that participate in the NSW Opioid Treatment Program.

Justifiably, OTP is subject to strict regulatory requirements. In a busy Community Pharmacy it can be easy to accidentally bypass a legal requirement through taking a short cut in the QCPP OTP Procedure or by thinking, "I'll do that later".

Some common issues in regards to OTP prescriptions in Community Pharmacy are:

- Faxed or phoned prescriptions not received within 7 days
- Non-compliant prescriptions
- Prescription given to client by prescriber
- Original prescription not recorded in Dispensary software
- Prescriptions not cancelled upon expiry
- Incorrect use of Subsidiary Drug Registers (SDRs)

Let's look at each of the above issues individually:

Faxed or phoned prescriptions not received within 7 days

The legislation allows prescribers to give instructions to a pharmacist orally, by phone, email or fax for the dispensing of a Schedule 8 medicine. A prescription must be written in confirmation immediately and forwarded to the dispensing pharmacist within 24 hours. If this written prescription is not received within 7 days, the matter must be reported to the Pharmaceutical Services Unit.

What pharmacists should do when receiving this type of request from a prescriber:

- Advise the prescriber of the requirement to receive written prescription within 7 days and document this
- If prescription has not been received within 3-4 days, contact prescriber to remind them and document
- If prescription has not been received by day 7, contact prescriber and advise that you are required by law to report the issue to Pharmaceutical Services Unit

Why is this a legal requirement? Why can't the fax or email be used as the prescription? We at the NSW Branch often get asked

these questions. A prescription could potentially be faxed to more than one pharmacy and the only true confirmation can be made with the original written prescription.

What has happened is that pharmacies now accept that they won't receive the prescription within 7 days and don't have a procedure or documentation in place to ensure that the legal requirements are being met. Once standards have been eased, it is very hard to get back to where you want to be. I am suggesting that pharmacies get back to honouring the letter of the law and this may take some work with the local prescribers to ensure that legal requirements are being met. Educating local prescribers can be difficult and I would suggest meeting in an informal manner to discuss the issues at hand and the consequences of not meeting legal requirements for both the pharmacist and the prescriber.

Non-compliant prescriptions

A prescription for a Schedule 8 item must be written on separate prescription form. The prescription must be in the prescriber's handwriting (Except for computer generated prescriptions, see notes below) and include:

- Prescriber's name, designation, address and phone number
- Date of Issue
- Patient's Name and Address
- Patient's age (if less than 12 years old)
- The name and strength of the drug (for computer generated prescription must be hand written on one copy)
- The quantity to be supplied in both words and figures (for computer generated prescriptions must be hand written on one copy)
- Adequate directions for use (for computer generated prescriptions must be hand written on one copy)
- The maximum number of times the prescription may be supplied (for computer generated prescriptions must be hand written on one copy)
- Interval for repeat supply (for computer generated prescriptions must be hand written on one copy)
- Prescriber's signature

In the case of OTP prescriptions, it is essential that clear directions are given for dose and if applicable, the number of takeaway doses to be provided.

If a non-compliant prescription is received it is recommended to contact the prescriber as soon as practical to discuss and remedy the prescription. It is

also recommended to document any interaction with a prescriber regarding non-compliant prescriptions. In the event of any inspection by the Pharmaceutical Regulatory Unit or Pharmacy Council, documented evidence of discussions with prescribers demonstrate the pharmacist is ensuring compliance with the regulatory requirements.

Prescription given to client by prescriber

NSW Health has published a Protocol for OTP Pharmacists and recommends that any prescriptions for OTP medications should not be handled by a client. Prescribers should send OTP prescriptions directly to the pharmacy. The main issue here is that there is potential for the prescription to be altered by the client. For example, there has been a case where the prescriber faxed the OTP prescription to the pharmacy and handed the prescription to the client with instructions to give to the pharmacist. The client was dosed at the regular pharmacy based on the faxed prescription and then took the prescription to another pharmacy for dispensing. The client was being double dosed and/or selling take away doses. Having strong procedures in place would have prevented this from occurring. If your pharmacy has a prescriber who gives clients prescriptions for OTP, it would be useful to discuss the OTP Protocol and the potential consequences of giving clients prescriptions.

Original prescription not recorded in Dispensary software or marked as dispensed/not marked as cancelled

OTP prescriptions are subject to the same recording requirements as all Schedule 8 medications:

- Full, legible record of the prescription in an approved recording system with a unique prescription number
- Stamp or write on the prescription the pharmacy name and address, the unique prescription number and date dispensed
- Enter the transaction in the drug register
- Mark prescription as cancelled upon expiry or upon last repeat

Meeting these requirements is essential to accurate dispensing and allows pharmacists to follow up on subsequent prescriptions, especially when there is more than one pharmacist involved in the delivery of OTP.

Incorrect use of Subsidiary Drug Registers (SDRs)

Subsidiary Drug Registers are available through the Guild for Methadone/Biodone, Buprenorphine/Naloxone (Suboxone) and Buprenorphine (Subutex).

Each supply of any of the above must be recorded in the SDR or approved electronic drug register showing the following:

- Client's name
- Prescription number
- Prescriber's name
- The amount of methadone or buprenorphine supplied

- Date of supply
- For take-away doses, the date for the dose to be taken and the amount of each dose

If a pharmacy is dispensing both Methadone Syrup and Biodone, separate SDRs must be kept for each. Methadone/Biodone doses should be recorded in mls. Bottles of Methadone and Biodone have a slight "overage" to allow for small losses in the dispensing process. Any variance in what is on hand and what is in the drug register should be reported to the Pharmaceutical Services Unit.

A common error for Buprenorphine SDR records is that doses are recorded in mg. This does not allow tracking of what has been dispensed. There are two strengths of both Subutex and Suboxone (2mg and 8mg) and the number of each used should be recorded in the SDR. For example, a dose of 16mg could be recorded as 2 x 8mg or 1 x 8mg & 4 x 2mg or 8 x 2mg.

While it is a requirement to carry out a Schedule 8 stocktake every March and September, for OTP Pharmacies more frequent stocktakes are recommended, for example monthly. Again, any discrepancies should be reported to the Pharmaceutical Services Unit.

Meeting ethical and professional obligations

Pharmacies participating in OTP should have ready access to the following resources:

- NSW Poisons & Therapeutic Goods Regulation 2008
- NSW Opioid Treatment Program Community Pharmacy Dosing Point Protocol
- NSW Clinical Guideline: Treatment of Opioid Dependence

All pharmacists who deliver OTP to clients should read the above resources to ensure they have a good understanding of both the legislative requirements and the clinical background to OTP.

Polypharmacy is a major issue in OTP clients and one that is largely ignored by both prescribers and pharmacists. Pharmacists have a professional and ethical obligation to ensure that medicines dispensed are appropriate for the patient and ensure the medicine is safe. Away from OTP, it is not unusual for a pharmacist to contact a prescriber to discuss a potential interaction/side effect/dose change, yet this rarely happens in OTP cases.

A combination of sedating medicine, such as a benzodiazepine, and OTP can have a major effect on a client and their fitness to drive or operate machinery. Often multiple prescribers are involved and a pharmacist can intervene by providing clear advice (to both the client and the prescriber) on the risks associated with concurrent prescribing of sedating medications. If a client presents as intoxicated, dosing should be refused and the prescriber contacted.

Continued page 14

Pharmacists may be aware that the Pharmaceutical Regulatory Unit is currently undertaking audits of OTP Pharmacies. The Self Audit form for OTP Community Pharmacies is available on the NSW Guild website and will assist pharmacies in meeting their regulatory and professional obligations. It is important to note that documentation is essential in meeting these requirements.

For example written QCPP Procedures, recording of patient interactions around safety and dosing protocols, recording of discussions with prescribers, e.g. intoxicated patient, missed doses, takeaways.

The Guild is always available to provide support and advice to pharmacies providing OTP.

Needle Syringe Program and the Pharmacy Fitpack Scheme

Guest Columnist: Deb Woodbridge



The Pharmacy Guild Fitpack Scheme has been running for many years now, and functions as a complementary service to the Needle Syringe Programs (NSP) in preventing the spread of blood borne viruses such as HIV and Hepatitis C among people who inject drugs and the wider community.

In metropolitan areas it is reasonably easy to get your hands on a Fitpack if you are an injector. It's 7pm on a Wednesday night, the drugs have finally come through, you can jump on the bus up to the local late night pharmacy and buy a pack. However in rural areas it's not that easy. Due to this (and other rural specific issues) we have the highest rates of receptive syringe sharing (RSS) in NSW. While NSP's have worked tirelessly to introduce many and varied NSP distribution sites, access still remains an issue for many. The "tyranny of distance" may sound like a catch cry from the hard done by rural brothers and sisters, but it does remain a very real issue for many.

That's where you guys come in...there isn't an NSP in every town or village, nor is there an Emergency Department or even a vending machine...but there is a Pharmacy.

Two Pharmacies that are participants of the Fitpack Scheme have been interviewed for this article, one of them has been a member since the early days of the Guilds introduction of the Fitpack Scheme in the late 1980's, or early 1990's. Michael Hermann is a Pharmacist from Southside Pharmacy in Lismore in Northern NSW. Michael said that one of the positives about being in the Scheme is "having played a part in Australia's success in holding back the blood born disease epidemic and the associated misery and cost to the community". He went on to say that "remuneration of course" was another positive.

Michael said that "once the staff became comfortable with the service there has been very few negatives". He said that the NSP over the years has provided support in a number of ways, notably around disposal assistance and information, resources such as posters and leaflets, and useful tips on how to provide a discreet service. He went on to discuss the importance of "delivering the program with a level of empathy that is respected by the clients, and in a manner that satisfied both the staff, and left general customers largely unaware of the transaction".

Tenzin Willow, a Naturopath at McDonalds Pharmacy in Casino in the Northern NSW area said that "so far they have had no issues, and the clients have been respectful". Furthermore "participating in the Fitpack Scheme, apart from making it safer for the clients and the community, has provided another point of contact with the community, and enabled them to discuss other health issues assisting the Pharmacy in providing a more holistic service".

In addition to playing your part in preventing the spread of blood borne viruses such as HIV and Hepatitis B/C, when you sign up to be part of the Fitpack Scheme you will receive free Fitpacks for sale or exchange; access to a sharps disposal service; and you may also be eligible to receive incentives including an initial one off \$350 plus GST payment. To register, go to www.guild.org.au/guild-branches/nsw/professional-services/nsp/register-to-participate.

Deb Woodbridge is a Harm Reduction Officer/Needle and Syringe Program based in Lismore, and covers the Mid North Coast and Northern NSW Local Health Districts.

