

Information paper

Draft Proposed Practice Guidance for Paramedic Supplementary and Independent Prescribers.

(Draft Edition)

Please note: This document provides guidance and advice based only on the *proposed changes to legislation* that would permit Supplementary and Independent Prescribing by Paramedics. Every effort has been made to ensure that the advice in this draft guidance document is accurate for the current legislative state, and all guidance must be taken on the basis of being application only in the presence of changes to legislation.

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Proposed Practice Guidance for Paramedic Supplementary and Independent Prescribers.

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DRAFT

Proposed Practice Guidance for Paramedic Supplementary and Independent Prescribers.

Foreword

The College of Paramedics is delighted to support this Proposed Practice Guidance and the introduction of independent prescribing. We know this subject is close to the hearts and minds of many paramedics throughout the United Kingdom.

The sound and wide ranging work that has gone into producing this guidance gives a strong foundation of educational and evidenced support to all new prescribers. It will give great confidence to paramedics and ensure that patient safety and wellbeing is paramount.

Prescribing by nurses and allied health professionals is well established across the United Kingdom and there is no doubt it is a safe and effective part of the Health Care system. This guidance ensures that the role of paramedics in the patient care chain will bring the greatest benefit to patients and ensure strong governance to support the system.

The College of Paramedics congratulates everyone involved in developing a guide that will no doubt enhance the current and future care that paramedics provide.

A handwritten signature in black ink, which appears to read 'A Newton'.

*Professor Andy Newton, FCPara
Chair of the College of Paramedics*

Introduction

This Practice Guidance provides information which should underpin the decision-making and actions of paramedics who are annotated with the Health and Care Professions Council (HCPC) as supplementary and independent prescribers.

This document is 'guidance'. 'Guidance' is information which a paramedic has a duty to consider and is expected to take into account as part of their decision making process. This document provides advice on the behaviours and conduct expected of paramedics who are annotated on the HCPC register as a supplementary and independent prescriber.

Throughout this document, the use of the word 'must' indicates a legal and/or regulatory requirement and describes a mandatory action and/or behaviour. The use of the word 'should' indicates behaviours and/or actions that would be expected to occur in all normal circumstances. Each section of this guidance carries equal weight and the document is not ordered in any priority order.

If a paramedic independent prescriber deviates from the guidance in this document, the clinical judgment for so doing should be carefully recorded. You should comply with this Practice Guidance, other guidance issued by the College of Paramedics (CoP), and with any statutory requirements applicable to your prescribing practice. Failure to do so may put your HCPC registration at risk if concerns are raised about your fitness to practise. An independent paramedic prescriber will be expected to justify any decision to act outside the terms of this guidance, and in particular if the paramedic undertakes a course of action not recommended by this guidance there must be robust reasons for doing so.

The advice in this document applies to all sectors of health and social care provision in the United Kingdom where prescribing activities occur, as permitted by the prescribing laws in each of the Home Countries separately. The law may not be comparable across England, Scotland, Wales and Northern Ireland. It is up to the individual to satisfy themselves of the law in the UK country in which they work and that good governance procedures are in place in their workplace setting.

At the current time, and pending changes to UK law, prescribing is not permitted by paramedics outside of the UK and therefore a paramedic permitted to supplementary and independently prescribe in the UK cannot perform this activity outside of UK jurisdiction.

This practice guidance document focuses on prescribing primarily. There are some references to associated activities related to supply and administration, but this has been reduced to a minimum, and only where context is needed.

Supplementary Prescribing by Paramedics

Please note:

Education training programmes to prepare registered healthcare professionals to become prescribers includes training and competencies in both supplementary and independent prescribing within a single curriculum. Annotation on the HCPC register for independent prescribers also includes supplementary prescribing.

Due to the nature of paramedic practice the proposal to introduce prescribing for paramedics is focussed primarily on independent prescribing. However, subject to changes to medicines legislation, paramedics who successfully complete a HCPC approved training programme to become an independent prescriber would also be annotated on the HCPC register as a supplementary prescriber. Although supplementary prescribing does not routinely fit the practice of paramedics, due to the intended use being for on-going care rather than urgent care, it may be that supplementary prescribing, and the use of clinical management plans will be utilised in the future in settings, such as primary care where the paramedic is expected to play a greater role in the future.

Throughout this document the use of the phrase “independent prescribing” should be considered to also include supplementary prescribing. The use of “independent prescribing” is used to simplify the document and to provide consistent focus on the aspect of prescribing most relevant to paramedic practice.

Standards for prescribing

The HCPC define the standards for prescribing¹ that are required for prescribing by allied health professionals legally entitled to practice as independent or supplementary prescribers. The standards will be amended to incorporate independent prescribing by paramedics (subject to changes in legislation). The standards include the proficiencies required to prescribe safely and effectively. These proficiencies are in addition to the proficiencies that apply to non-prescribing clinical practice for all healthcare professionals.

<http://www.hcpc-uk.org/aboutregistration/standards/standardsforprescribing/>

The scope of paramedic independent prescribing

The purpose of paramedic independent prescribing is to support and enhance the delivery of urgent and emergency care for patients. This is aimed at providing high quality urgent and emergency care for patient in a way that is safe and promotes choice.

Paramedic independent prescribers will be central to supporting multi-professional working, and providing increased workforce flexibility. However, this should be done in context to core competency, and not simply to prescribe for patients to make up for short-falls in other professional prescribing groups.

Paramedic practice as a profession covers a very broad and diverse range of patients and clinical conditions, and therefore prescribing will be required by a paramedic working in any urgent and emergency care practice environment; from 999 responses to working in primary

¹ Heath and Care Professions Council (2012) *Standards for Prescribing*. London

or secondary care. Paramedics will develop specialist expertise in specific areas of clinical practice which supports urgent and emergency care. The individual activities of any given prescribing paramedic will be focused only within their competency relevant to paramedic practice. For instance, paramedics prescribing in urgent care settings will require an appropriate formulary to support this area of practice.

Paramedics are not permitted to prescribe medicines for animals.

The future scope of independent prescribing practice by paramedics will be:

“The paramedic independent prescriber may prescribe any licensed medicine from the BNF, within national and local guidelines for any condition within the practitioner’s area of expertise and competence diagnosing and treatment patients with urgent health needs.

In future, paramedics may prescribe from a restricted list of controlled drugs as set out in Regulations.”

Scope of practice and competency in prescribing

Medicines use and prescribing activity will, in the future, be fully accepted as being within the overall scope of the profession as a whole. It will be part of an individual’s scope of practice subject to appropriate education, training and competence in prescribing activities.

The post-registration educational programme in prescribing will ensure eligible paramedics are equipped with the principles of prescribing to enable them to be safe, effective and cost-effective prescribers. Paramedic independent prescribers should ensure that they are able to apply the prescribing principles to their own area of practice, bearing in mind that this may be a requirement for continuing registration.

An individual’s scope of practice must fall within the overall scope of the paramedic profession; therefore an individual’s prescribing practice must also fall within the overall prescribing scope of the profession, as defined in the College of Paramedics Scope of Practice Policy². If independent prescribing is introduced, prescribing will not be permitted by paramedics outside of the UK and therefore a paramedic permitted to independently prescribe in the UK cannot perform this activity outside of UK jurisdiction.

Prescribers must have sufficient education, training and competence to:

- Assess a patient’s clinical condition
- Undertake a thorough history, including medical history and medication history (including over-the-counter medicines and complementary therapies), and allergy status
- Diagnose where necessary
- Decide on management of the presenting condition and whether or not to prescribe and/or refer.
- Identify appropriate products of medication as required
- Advise the patient on risks, benefit and outcomes of the medication
- Prescribe if the patient agrees

² College of Paramedics (2015) *Scope of Practice Policy*. Bridgwater (unratified).

- Monitor the patient's condition, including any response to the medication prescribed
- Give lifestyle advice as appropriate
- Refer to other professionals if necessary

Prescribing is a professional skill that applies equally to all professions who undertake such responsibility. There is a unified single competency framework for all prescribers published by the National Prescribing Centre (Now part of the National Institute for Health and Care Excellence (NICE)). NB. *NICE is currently undertaking a consultation to include non-medical prescribing competencies into the Medicines Optimisation Guidance.*

http://www.npc.co.uk/improving_safety/improving_quality/resources/single_comp_framework.pdf

The College of Paramedics expects members to be able to demonstrate how they meet this competency framework.

Registration and Professional Indemnity Insurance

From July 2014, HCPC registrants must have proof of adequate indemnity to practice in order to maintain registration. This may be derived from an individual's substantive employer, or via private means. Paramedics practicing in the independent or private sector must ensure that indemnity is adequate.

Paramedics who are full members of the College of Paramedics (COP) benefit from basic professional indemnity insurance to cover acts as a "good samaritan". Full members of the College of Paramedics also have access to cover for support with fitness-to-practise cases. For this cover to be available, members must:

- Hold current registration with the HCPC
- Hold a current FULL COP membership
- Be practising lawfully
- Be practising within the overall scope of the profession

Please note:

The College of Paramedics is currently reviewing its Professional Indemnity Insurance arrangements as part of its membership benefits. At the time of writing, the College of Paramedics advice to members, who become prescribers in future, is to obtain adequate Professional Indemnity Insurance until such time as the College of Paramedics indemnity scheme is reviewed.

Prescribing, in future, will be accepted as within the overall scope of the paramedic profession, and due to the requirement for a paramedic to be practising lawfully for professional indemnity insurance to be in force. For prescribing to be covered as part of an individual's professional indemnity insurance (regardless of where the indemnity insurance is procured from) the member must;

- Have an HCPC annotation showing their prescribing status as an supplementary and independent prescriber

In future, COP members may need to inform the COP of their prescribing status, and they must not prescribe until they are satisfied that their HCPC entry has been updated.

Paramedics must have adequate insurance or other indemnity arrangements in place for their practice. They may be personally liable for any costs if they are not adequately or appropriately insured. Many employers now expect individual health professionals to hold their own professional indemnity insurance in addition to any employer vicarious liability insurance that may be in force.

The legal requirement is for indemnity arrangements appropriate to and covering the whole of an individual's practice. Some registrants may be indemnified through their employer for example.

Please note:

The guidance in this document is draft. Changes in legislation will be necessary to enable paramedics to become supplementary and independent prescribers.

SECTION 1 – PRINCIPLES OF GOOD PRESCRIBING PRACTICE

This section provides guidance on good prescribing practice. Having achieved the competencies for prescribing, eligible paramedics are expected to follow this advice in their practice. The guidance provided in this document applies to *all* settings in which a Paramedic may prescribe – within the National Health Service (NHS) across primary, secondary and tertiary care; General Practice; independent and private health care services; Higher Education; research establishments and other fields such as armed forces, urban search and rescue, and in the offshore oil industry.

The COP considers it good practice, that where paramedics are employed, that the employing organisation signs off all protocols and procedures. Where possible paramedic independent prescribers should follow organisational-level policies and procedures and should only create local department level procedures where no national or organisational policy or procedure is in existence.

From here on, the use of the term “independent prescribing” is intended to cover supplementary and independent prescribing. The primary focus for paramedics will be independent prescribing, but will be annotated supplementary and independent prescribers. The omission of the term supplementary supports that focus and is intended to assist making the document both concise and relevant.

1. Practice Guidance 1: License to prescribe

You must only prescribe once you have successfully completed an HCPC approved prescribing programme, and had your entry on the register of the Health and Care Professions Council annotated to show your prescribing status as an independent prescriber.

You should comply with this Practice Guidance, other guidance issued by the COP, and with any statutory requirements applicable to your prescribing practice. Failure to do so may put your HCPC registration at risk if concerns are raised about your fitness to practice.

You must only prescribe within your own defined scope of practice and clinical specialty.

You must understand which legal framework you are using to prescribe medicines, and understand which types of medicine you are permitted to prescribe within that framework.

2. Practice Guidance 2: Accountability

You are professionally accountable for your own prescribing decisions, including actions and omissions. You cannot delegate this accountability to any other person nor can any other person accept accountability on your behalf for your actions. As an independent prescriber you are wholly responsible for all aspects of the prescribing process.

As a supplementary prescriber you are wholly responsible for your decision to prescribe or use the medicines listed within the written CMP. The content of a CMP is developed and agreed jointly by the doctor and supplementary prescriber (and the plan has to be agreed with the patient).

You must only prescribe within your level of education, training and competence, acting in accordance with the HCPC's Standards of Proficiency, Standard of Conduct, Performance and Ethics, Standards for Prescribing, and the College of Paramedics Career and Competency Framework³.

If you move to another area of practice you may need to undertake further training in order to establish your competency to prescribe in your new clinical specialty.

Paramedics will only prescribe according to their area of competence and the provision of ongoing evidence supporting their prescribing practice. Please refer to the College of Paramedics Career and Competency Framework (3rd Edition)⁴

You must inform anyone who needs to know about any limitations to your prescribing practice and in particular, other practitioners with dispensing responsibilities. For example, your employer may operate a specific prescribing formulary and may not allow you to prescribe outside of this formulary. This restricted formulary would only apply to your NHS practice for that employer.

You must inform the relevant authorities, such as employers and/or providers of indemnity insurance, if you have any formal regulatory restrictions which may affect your prescribing activity, for example, if the HCPC has placed a condition on your practice.

3. Practice Guidance 3: Assessment

In order to prescribe for a patient you must satisfy yourself that you have undertaken a full assessment of the patient, including a thorough history and physical assessment which leads to a point of diagnosis. This should, where possible, include accessing a full clinical record including medication and allergy history. This process may involve carers, especially if the patient has additional needs.

You should prescribe only where you have relevant knowledge of the patient's health and medical history commensurate with the prescribing decisions you are taking.

You should ensure you have considered the patient's current medication and any potential interactions with other medicines.

You should take steps to ensure that the patient is not suffering from any medical condition, allergy or receiving any other treatment, that would make the prescription of any medicine unsuitable or dangerous.

You should ensure you consider the effects of your patient's lifestyle which may affect the safety of the medicines you prescribe. This will include:

- The effects of smoking, caffeine, alcohol
- The effects of 'recreational' or 'street' drugs or those used to enhance physical or sporting performance

³ College of Paramedics. (2014) *Paramedic Career & Competency Framework (3rd Edition)* Bridgewater

⁴ College of Paramedics. (2014) *Paramedic Career & Competency Framework (3rd Edition)* Bridgewater

- The effects of over-the-counter medicines including herbal preparations

Where necessary you should have the ability to request and/or have access to the results of additional appropriate tests. These tests should be relevant to the presenting condition and/or appropriate to the prescribing decisions to be made in order to assist your prescribing decisions. These may include:

- Blood haematology
- Blood biochemistry tests e.g. liver, thyroid and/or kidney function
- Imaging investigations

You should refer to another appropriate prescriber if you do not fully understand the implications of your prescribing actions even though you may be able to take a thorough and appropriate history which leads to a diagnosis.

4. Practice Guidance 4: Clinical Need

You must only prescribe where you have assessed the patient and there is a genuine clinical need for the prescription of medicines.

You should consider the circumstances in which you may decide to withdraw medication, cease to continue prescribing a named medication or alter the prescribed dose of a medication. Patients may also wish to discuss with you withdrawal from medication. Any withdrawal from medicines needs to be planned in partnership with the patient and anyone involved with their care and take place over an agreed time period.

You should never prescribe for your own convenience, or simply because a patient demands that you do.

You should prescribe in the patient's best interests and achieve this by reaching agreement with the patient on the use of any proposed medicine where possible. The amount of information you discuss with your patient will vary according to the nature of the patient's condition, the risks and benefits of the medicine and any alternatives, and the patient's wishes, but in all circumstances will include the provision of 'sufficient information' to allow the patient to make an informed choice i.e. to give their informed consent. You should aim to:

- Establish the patient's priorities preferences and concerns
- Discuss alternative treatment options available to the patient
- Satisfy yourself that you have enough relevant information to make a prescribing decision
- Satisfy yourself that the patient understands how to take the medicine as prescribed

You should only prescribe for patients who are under your care. You should not prescribe for patients simply because you are the only prescriber available.

5. Practice Guidance 5: Consent

You should explain your role as a non-medical prescriber to the patient. You should provide your patient with 'sufficient information' relating to the risks, benefits and significant material outcomes of the medicines you are considering, as well as the comparative risks of

alternative treatment options to medication that may be considered in order that the patient can give their informed consent to treatment.

You should be aware of the variety of social, cultural and religious factors that may impact upon the choices your patient makes in agreeing prescribing decisions with you.

You should act in accordance with Department of Health, COP and employer guidance on the obtaining and documenting of consent.

The patient has the right to refuse to accept any medication you propose to prescribe for them, but if they do so you should explain the risks, benefits and outcomes of their decision.

The patient should be provided with any relevant Patient Information Leaflet (PIL) about the medicine you propose to prescribe. This would normally be provided with the medicine, but if not, the PIL or equivalent should be provided by the prescriber.

6. Practice Guidance 6: Communication

You should communicate, using the most appropriate media, effectively with other practitioners involved in the care of the patient. This includes communication across NHS-private practice boundaries where necessary. You should refer the patient to another prescriber when it is necessary to do so.

Prescribing decisions should be made in partnership with the patient, where practicable to do so. This will include taking into account the patient's personal views and beliefs and discussing prescribing and medication decisions in relation to these. You should ensure that patients have understood what they have been told and the consequences of decisions that have been agreed.

Prescribing is not an activity that occurs in isolation. Prescribing information must be shared with other health professionals who need to know the information for the benefit of the patient, and this will include the patient's GP. You should decide the best methods of sharing this information. Where possible, you should have access to other professionals' prescribing decisions where they impact upon your own decisions. This will include communication across NHS-private practice boundaries where it is necessary to ensure that clinicians have appropriate information to inform their prescribing practice.

You must make it clear to the patient that prescribing activity cannot be undertaken in isolation. You should inform anyone else who may be in a position to prescribe for that patient of your actions to avoid prescribing errors. This is most likely to be the patient's general medical practitioner, but may also include other health and social care professionals. If the patient refuses to consent to you sharing such information you should offer an explanation of the risks of not doing so. If the patient continues to refuse to give consent, you should consider which course of action, including to not prescribing, would be in the best interests of the patient. This must be documented in their records.

You should know what medication the patient is currently taking including Over-The-Counter and herbal preparations before prescribing new medicines and you should take steps to ensure you have access to the primary source of prescribing information, which is likely to be the Summary Care Record, or equivalent.

When sending patient data, it is vital that the data is secure, and that the risk of data loss (including misdirection) is minimised. The Health & Social Care Information Centre have produced a detailed Information Governance Toolkit⁵ regarding the safe transfer of patient data which lists the most commonly used methods of communication along with the minimum standards required for safe and secure data transfer. These include:-

- Verbal Communications: The security and confidentiality of telephone and personal conversations should be considered within the organisation's policy and procedures (eg confidentiality code of practice) and included in staff training. Staff should be mindful of the need to maintain security and confidentiality when discussing personal or other sensitive information
- Telephone answering machines: This can be used where the recipient is known (i.e. GP practice) and the message will be retrieved in an appropriate manner. Best practice suggests using password protected voicemail wherever possible.
- Faxing: Patient data which is faxed should be done following the NHS IG Safe Haven principles.
- Email: Emails containing patient identifiable data should only be sent using (and receiving) NHSmail email accounts or other approved government email domains.
- Postal/Courier Services: Items must be tracked and traceable, and should include arrangements for redirected or undeliverable items
- Portable storage devices (USB Sticks): Use of these devices must only be used following an Information Risk Assessment
- Internet protocol (IP) phones (including systems such as Skype): These should only be used "point to point" within the secure N3 network. (It is accepted that clinician/patient conversations occur using this method but it is not advised for conversations about patients/clients between healthcare professionals)
- Web Based Applications: Movement of patient data within electronic systems must be encrypted and comply with the Confidentiality NHS Code of Practice.
- Short Messaging System (SMS "texting"): SMS should not be used to convey patient data due to the lack of secure transfer methods and retention of sent data.

7. Practice Guidance 7: Record Keeping

⁵Department of Health (2010) *IG Toolkit Version 8 Information Security Assurance Requirement 322 Detailed Guidance on Secure Transfers* (Online) Available at:

https://www.igt.hscic.gov.uk/KnowledgeBaseNew/DH_NHS%20IG%20-%20Detailed%20Guidance%20on%20Security%20Measures%20for%20Information%20Transfers.pdf

This practice guidance relates specifically to the record keeping of your prescribing actions. You should refer to other standards and guidance for information relating to clinical record keeping in general. Prescribing activity (e.g. writing an FP10, using a hospital based treatment/drug card or using an electronic prescribing application, or a private prescription) should occur at the time of contact with the patient in order to ensure contemporaneous activity is captured in the clinical record.

Documentation of the prescribing activity should be recorded in clinical records at the time of treatment of the patient. It is not good practice to document prescribing activity after the event e.g. at the end of the clinic session or the end of the day. Only in exceptional circumstances should documentation be delayed, but in any event the delay should not exceed 24 hours.

In supplementary prescribing, the doctor/dentist and supplementary prescriber must share access to, consult and, wherever possible, use the same common patient record.

Records must include the prescription details, together with relevant details of the consultation with the patient.

Your records should show that you have communicated with the primary healthcare record keeper (usually the GP) especially with regard to repeat, ongoing or withdrawn prescriptions. For hospital in-patients this may be in the form of the hospital discharge letter and/or clinic letter. In the pre-hospital setting, this may be in the form of an electronic or paper based clinical summary sent to the GP.

8. Practice Guidance 8: Evidence based prescribing / prescribing in the patient's best interests

You should ensure that your prescribing practice is appropriate, responsible and in the patient's best interests. Every medicine that is available to be prescribed will have an evidence base recommending its use and you should be aware of the current evidence supporting the use of a given medicine.

You should prescribe according to the available evidence base. Evidence based prescribing involves the application of the best available evidence when making prescribing decisions. Reference to the evidence base can minimise the risk of adverse drug reactions and ensure the most appropriate medicine is chosen for a patient's needs.

You should use national sources of evidence as your primary source of evidence-based prescribing. Where you can clearly demonstrate that a national source of evidence is not available, then locally agreed practice- based evidence or protocols should be followed. When supplying antibiotics you should consider antimicrobial stewardship and follow local policies for antibiotic use. The local policy is required to be based on national guidance and should be evidence-based, relevant to the local healthcare setting and take into account local antibiotic resistance patterns. They should cover diagnosis and treatment of common infections and prophylaxis of infection. As with the National Prescribing Centres (now part

of NICE) competencies for all prescribers^[1], the 2013 Public Health England / Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Antimicrobial Prescribing and Stewardship Competencies^[2] should be used by any independent prescriber to help develop their prescribing practice at any point in their professional development in relation to prescribing antimicrobials.

You should ensure your prescribing is appropriate and that patients have enough information to make an informed choice. You should consider the following factors to ensure you:

- are familiar with the current national sources of evidence for the medicine;
- are familiar with the current national sources of evidence for the condition you are treating which may also include current evidence for which medicine groups should be used, or not used, and a hierarchy of medicines use;
- have taken an appropriate assessment of the patient;
- have taken into account the patient's preferences and expressed wishes with regard to medicines use;
- have prescribed the appropriate dose for your patient's age and weight.

9. Practice Guidance 9: Delegation

You may delegate the administration of a medicine that you have prescribed to another healthcare worker or to the patient themselves. You remain accountable for your prescribing decision and you are also accountable for your decision to delegate the task of administration to someone else including the patient. This includes your assessment that the person is competent to carry out the task and has received sufficient training to carry out your instructions. You are not accountable for the outcome of an action performed by another person.

Where this information is not clearly identifiable from your written prescription then the information should be separately recorded in the patient record.

10. Practice Guidance 10: Information given to patients about their medicines

Patients, or those authorising treatment on behalf of the patient, should be given sufficient information as they require in order for them to make an informed choice with regard to prescribing decisions. You should include:

- Diagnosis giving rise to prescribing need
- Any known serious or common side effects of the proposed medicine
- How to manage any anticipated or common side-effects
- How the medicine works
- How long to take the medicine for

^[1] National Prescribing Centre provided by NICE (2012) *A Single Competency Framework for all Prescribers*. London: NICE

http://www.npc.co.uk/improving_safety/improving_quality/resources/single_comp_framework_v2.pdf

^[2] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies* <https://www.gov.uk/government/publications/antimicrobial-prescribing-and-stewardship-competencies>

- How to stop taking the medicine
- Who to contact and how to contact them in the event of a conditioning worsening

Information provided should be appropriate to the patient's levels of understanding. Any issues noted related to normal cognition, learning disability, or language barrier must be documented and a plan provided to minimise the impact of the issue.

Where practicable you should support information given to your patients in writing.

You should tell the patient that their medicine will come supplied with a manufacturer Patient Information Leaflet (PIL) which will give them additional information. In in-patient settings where the PIL is not routinely supplied, patients can request such information if they wish.

11. Practice Guidance 11: Clinical Management Plans

If you are prescribing as a supplementary prescriber, you must prescribe in accordance with a patient's individual written clinical management plan (CMP). For a CMP to be legally valid, the independent prescriber must be a medical doctor or a dentist.

Where standard written CMPs are in place as a starting point, you must tailor them to reflect the individual patient's personal, medical and medicines history. The CMP must be agreed with you by a medical prescriber, and with the consent of the patient, before supplementary prescribing begins. This could be in the form of a signature, or for an electronic record, a recordable indication of agreement.

The supplementary prescriber and independent prescriber may agree to modify a CMP in the light of a patient's changing needs, and may also decide to terminate the use of a CMP if it is no longer appropriate. The supplementary prescriber must always refer back to the independent prescriber if the patient's condition changes such that the current CMP is no longer appropriate.

Within supplementary prescribing you must never prescribe medicines in the absence of a written clinical management plan which has been agreed with the independent prescriber and with the consent of the patient. The independent prescriber may agree verbally to a CMP providing that it is confirmed by fax or secure email in writing before prescribing occurs, and is formally recorded within two working days.

If you are both an independent and supplementary prescriber, you must adhere to the terms of the CMP when managing the patient's condition as a supplementary prescriber. This does not preclude you from prescribing for the patient for an unrelated condition, where you are acting as an independent prescriber and are competent to treat the condition concerned.

12. Practice Guidance 12: Transcribing

In some circumstances you may be asked to transfer medicines information from one document to another, a process known as transcribing.

Transcribing should not be a routine or regular occurrence. If you transcribe, you are accountable for your actions and omissions, and this will include any errors you make in transferring the information from one document to another.

You should satisfy yourself that transcribing is a necessary activity that cannot be eliminated by reviewing and improving the care pathway. If transcribing does occur, you should ensure that the activity meets local clinical governance requirements.

Any transcription must include:

- Patient's full name
- Date of birth
- Name of medicine
- Drug dosage, strength, timing, frequency and route of administration.

13. Practice Guidance 13: Electronic Prescribing

If you prescribe using e-Prescribing software you should also be using a compatible electronic clinical record software package that allows your prescribing activities to be referenced and cross-checked against the main electronic clinical record. The purpose of electronic prescribing is to reduce medicines errors and reduce patient morbidity and mortality; therefore the prescribing record should be linked to the clinical record.

You may prescribe via computer-generated prescriptions providing the necessary software is available.

A traceable audit trail of your prescribing actions should be maintained.

You must never print off blank prescriptions in advance and then store them for future use.

14. Practice Guidance 14: Writing NHS prescriptions

In order to write an NHS prescription, the medicine must be permitted to be prescribed at NHS expense. You should check the BNF if you are not sure if a medicine is available on the NHS. If a medicine is not available at NHS expense, it can only be prescribed against a private prescription.

Your written prescription must contain the information required by law such as:

- It must be signed in ink
- It must contain your name and workplace address
- Your prescribing designation (supplementary or independent prescriber)
- The date on which the prescription was signed by you and/or the date after which it can be dispensed
- Your profession
- The name and address of the patient
- The age of the patient if they are under 12 years old

The names of the medicines must be written clearly using approved names only. You must not use abbreviations in the name of the medicine.

A non-repeat prescription is valid for six months after the date of signing, however you should ensure that the medicines prescribed are appropriate for the patient's needs as you have assessed them, therefore the reasons for any significant delay between assessment and prescription dispensing should be documented.

You must only write prescriptions for your NHS patients on an in-patient drug chart, an in-patient hospital discharge and/or clinic letter, an in-patient To-Take-Out (TTO) form, or an FP10 for out-patients. You must only use the FP10's that has been issued specifically to you for your NHS practice and that show your name and HCPC registration number on them. All the details listed above must be included.

You must never tamper with an existing prescriber's details on a prescription form or add your own prescribing details.

You must sign your prescriptions immediately after they are produced. If this is not possible (e.g. the prescription is printed in a dispensary away from your clinic room), the unsigned prescriptions must be securely stored until you can sign them. You must sign them within 24 hours.

You must never sign a blank prescription form in advance and then store them for future use.

Subject to the required changes in legislation, if you are prescribing Controlled Drugs this must be in accordance with current provisions of the relevant Regulations.

15. Practice Guidance 15: Writing private prescriptions

You may write a private prescription for a patient who is receiving non-NHS care. When working in private practice, private prescriptions can be written for medicines that are not available on the NHS. You must not use an NHS prescription form to prescribe medicines privately. A private prescription cannot be used for NHS funded care.

A private prescription may be written on any document and it must contain the following:

- It must be signed in ink
- It must contain your name and workplace address
- The date on which the prescription was signed by you and/or the date after which it can be dispensed
- Your profession
- The name and address of the patient
- The age of the patient if they are under 12 years old

The names of the medicines must be written clearly using approved names only. You must not use abbreviations in the name of the medicine.

NHS prescription forms (FP10's) must not be used to meet the medicines needs of patients whose healthcare is being provided by the non-NHS sector. Patients receiving medicines as part of private healthcare provision are liable for the actual costs of the medicines and any private prescription charge. You must not ask the patient's GP to prescribe medicines at NHS expense which are subsequently to be administered as part of private healthcare provision.

16. Practice Guidance 16: Reviewing Prescriptions

You should review a patient's medication when you are starting a new medication, stopping a medication or changing a dose of a current medication.

17. Practice Guidance 17: Repeat Prescriptions

Repeat prescriptions are valid for six months and, unless specified in writing on the prescription otherwise, the medicine may be dispensed twice within the validity of the prescription (with the exception of contraceptives which may be dispensed six times). You should ensure that you review your patient's medication at regular intervals to ensure the prescription remains appropriate for your patient's needs.

If you issue repeat prescriptions you should ensure that you prescribe safely and responsibly. Before signing repeat prescriptions, you must be satisfied that it is safe and appropriate to do so. You should review repeat prescriptions regularly and do not issue medicines for longer than is clinically required. You must ensure the correct dose is prescribed for medicines where the dose varies according to the stage of the treatment.

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SECTION 2 – SPECIAL PRESCRIBING CIRCUMSTANCES

18. Practice Guidance 18: Family, Friends and close Colleagues.

You must not prescribe medications to treat yourself. You should be registered with your own medical and/or health practitioner who will be objective in providing you with good care.

You should wherever possible avoid prescribing for those close to you. People close to you may include your immediate family (parents, grandparents, children, grandchildren, siblings, aunts, uncles and first cousins), someone with whom you have an intimate personal relationship, your friends, and may also include colleagues with whom you regularly work. People you prescribe for should be formally under your care as your patient. If you are employed you should check your employer's policy on whether you are permitted to treat family, friends and colleagues.

You should avoid prescribing for family, friends and colleagues unless:

- No other prescriber is available to assess their clinical condition and to delay prescribing would put their life or health at risk, or cause intolerable pain
- The treatment is immediately necessary to save life, avoid serious deterioration in their health and well-being or alleviate otherwise uncontrollable pain.

Currently, and subject to any changes in legislation, you must not prescribe a controlled drug for someone close to you unless no other prescriber is available to assess the patient's clinical condition and to delay prescribing would put the patient's life or health at risk, or cause intolerable pain. Any CDs prescribed must be on the limited list of CDs available for paramedics to prescribe in the future.

You should be able to justify your decisions to prescribe for those close to you. You should record the nature of your relationship and the special circumstances that necessitated your action of prescribing for family and friends.

19. Practice Guidance 19: Children

Medicines are potent treatments and prescribing them can present significant risk to patients. This is especially so for children, whose responses may differ from adults. You must have relevant education, training and competence in treating children in order to prescribe for them. You should recognise the unique implications of prescribing for children and young people. Caution should also be taken when prescribing for pregnant and lactating women.

You should make reference to the following documents that address medicine management issues in paediatrics:

- The BNF for Children (England/Wales/Scotland) at www.bnfc.org

- Medicines Standard: National Service Framework for Children, Young People and Maternity Services at **www.dh.gov.uk** under Policy and Guidance, Health and Social Care Topics, Children Services
- Medicines Standard: National Service Framework for Children, Young People and Maternity Services (Wales)
- Royal College of Paediatrics and Child Health – information on use of licensed and unlicensed medicines at **www.rcpch.ac.uk/publications**
- Scottish Executive - *The Administration of Medicines in Schools* and *The Right Medicine: A Strategy for Pharmaceutical Care in Scotland*
- SIGN Guidance at **www.sign.ac.uk**
- DHSSPS – Medicines Management Standard
- DH – Every Child Matters (2004)

20. Practice Guidance 20: Unlicensed medicines

Medicines are classified as unlicensed if they do not hold a UK Marketing Authorisation issued by the MHRA. If you are a paramedic **supplementary prescriber** you may prescribe unlicensed medicines that are defined within a written CMP, but if you decide to do so you must:

- be satisfied that an alternative, licensed product would not meet the patient's needs
- be satisfied that there is a sufficient evidence-base for using the unlicensed medicine to demonstrate safety and efficacy
- record the medicine prescribed and the reasons for using an unlicensed product in the patient's notes
- clearly explain to a patient if you will be prescribing unlicensed medicine.

A paramedic **independent prescriber** must only prescribe licensed medicines.

21. Practice Guidance 21: Off-label use of medicines

An off-label medicine does hold a UK Marketing Authorisation issued by the MHRA, but is used in a way that is not described within the medicine's Summary of Product Characteristics (SPC).

If you are an independent and/or supplementary prescriber you may prescribe medicines for off-label use, but if you decide to do so you should:

- be satisfied that a licensed alternative is not available which includes your proposed usage within its SPC
- be satisfied that there is a sufficient evidence-base for using the medicine in an off-label way to demonstrate safety and efficacy. Where the manufacturer's information is of limited help, the necessary information should be sought from another reliable and reputable source
- record the medicine prescribed and the reasons for using an off-label product in the patient's notes
- explain to a patient in broad terms why you are using the medicine in an off-label way
- make a clear, accurate and legible record of your reasons for using a medicine in an off-label manner.

It is often necessary in paediatric practice to use licensed medicines in off-label ways. You must consult the BNF for Children or other appropriate guidelines before prescribing for children.

22. Practice Guidance 22: Mixing of Medicines

Medicines are also rendered unlicensed if they are mixed together prior to administration. The law defines 'mixing' as the combination of two or more licensed medicines together for the purposes of administering them to an individual patient. In future, if you are a paramedic independent prescriber you may mix medicines prior to administration.

Subject to changes to legislation, paramedics will be permitted to mix medicines, and must follow the guidance contained in the following document when prescribing and/or administering medicines.

Mixing of medicines prior to administration in clinical practice — responding to legislative changes. Supporting Guidance for Healthcare Providers, Practitioners and Commissioners (National Prescribing Centre, 2010)

http://www.npc.nhs.uk/improving_safety/mixing_meds/resources/mixing_of_medicines.pdf

Mixing of medicines must be done so according to best practice guidelines and be done on the basis of patient need only; never for practitioner convenience. Paramedics undertaking mixing of medicines must do so within their organisations governance framework.

23. Practice Guidance 23: Remote Prescribing

Most prescribing should occur on the basis of a face-to-face consultation with your patient. Remote prescribing occurs if you issue a prescription based on a telephone, e-mail, fax, video-link, web-based or other non-face-to-face contact with a patient and would be an exceptional circumstance. You should only remote-prescribe for your own patients or patients on your own case-load. You must ensure that you have an appropriate dialogue with your patient to:

- Establish the patient's current medication history
- Carry out an adequate assessment of the patient's condition
- Ensure there is sufficient justification to prescribe the medicines remotely, including discussing the feasibility of seeing another prescriber who can carry out a face-to-face consultation. This is particularly important when a remote-consultation does not permit an adequate assessment of the patient's condition to be undertaken.
- Ensure there are no contraindications to the proposed medicine
- Ensure arrangements are in place to provide follow-up and continuity of care
- Ensure a clear record is made of the prescribing decision and in particular the method of remote prescribing used e.g. instruction over the phone, e-mail etc.
- Ensure that the primary care record holder is informed.
- Ensure that the patient has 'sufficient information' to make an informed choice to accept your recommendation.

Where you cannot satisfy all of the conditions above, you should not use remote means to prescribe for your patient.

24. Practice Guidance 24: Prescribing on the recommendation and/or at the request of others

You should only prescribe for patients who are under your care. You must not prescribe for any patients upon whom you have not undertaken an appropriate assessment.

If you prescribe on the recommendation of another health professional who does not have prescribing rights, you must satisfy yourself that you have performed an appropriate assessment of the patient yourself in order to reach a diagnosis in order to determine if the prescription request is appropriate for the patient concerned and that the professional is competent to have recommended the medication.

25. Practice Guidance 25: Controlled Drugs

If you are a supplementary prescriber working within a written Clinical Management Plan (CMP) you may prescribe any controlled drug listed within the CMP.

If you are an independent prescriber, subject to changes to Misuse of Drugs Regulations, you may prescribe from a limited list of controlled drugs deemed necessary to ensure patients are able to access optimal and timely treatment.

The list of controlled drugs will support patients with conditions most commonly seen by paramedics in practice. This list will also follow national best practice evidence and guidance.

You must not prescribe a controlled drug for yourself.

You must not prescribe controlled drugs for someone close to you unless;

- No other prescriber is available to assess the patient's clinical condition and to delay prescribing would put the patient's life or health at risk, or cause intolerable pain.
- You must be able to justify your decisions to prescribe controlled drugs for those close to you. You must record the nature of your relationship and the special circumstances that necessitated your action of prescribing controlled drugs to those close to you.

You must know who your local pharmacist Accountable Officer (AO) is and comply with any local monitoring and/or inspection requests that the AO may make.

You must follow the Standard Operating Procedures (SOPs) that are in place within your organisation for the usage of CDs according to Regulations and SOPs must include procedures for: prescribing CDs, administering CDs, recording any adverse reactions.

If you are a supplementary and/or independent prescriber you may instruct another person to administer CDs in accordance with your valid prescription and in accordance with national guidance.

You must ensure that any prescription for a controlled drug is completed on the correct prescription form and contains all the information required commensurate with the

Schedule of the controlled drug being prescribed, which will in all cases include the patient's NHS number or other unique identifier.

You must ensure that:

- In-patient prescribing of CDs is recorded on the Medicines Administration Record (MAR) or in-patient sheet in accordance with local policies
- CDs for patients being discharged are written on locally approved To-Take-Out (TTO) sheets.
- Out-patient prescribing must be on an FP10PCD
- Out-patient prescribing by supplementary prescribers is on the relevant FP10SS form

You must only prescribe CDs at the time of clinical need and you must not prescribe more than is needed for the immediate clinical need, and in any event for no more than a 30 day supply.

You should note that the validity of prescriptions for Schedule 2, 3 and 4 CDs is 28 days.

You may use computer-generated prescriptions for controlled drugs, providing the necessary software is in place and that there is an audit trail of your prescribing practice. Your signature must be hand-written. Where patient sticky-labels are used they must be tamper evident labels and you must sign or initial over the sticky label to indicate that the sticky label relates to the patient for whom your prescription is intended.

If any part of your prescription for a CD is hand-written, you must write it yourself and not ask any other person to write all or part of the prescription for you.

All private CD prescribers require a separate 6 digit prescriber code for private CD prescriptions (this is different to your unique NHS prescriber code). This ensures that there is a clear separation between NHS and private CD prescribing and if you prescribe in both NHS and private settings you must keep your two prescriber codes separate.

26. Practice Guidance 26: Simultaneous Prescribing and Administration

Prescribing and/or supply followed by simultaneous administration of a medicine to the patient create the opportunity for errors to occur. If you prescribe for a patient, where possible a pharmacist should supply the medicine to the patient prior to administration.

Simultaneous prescribing and administration should be undertaken only in exceptional and rare circumstances and only if it is in the patient's best interests. You should ensure wherever possible that a second person checks that your prescription is what is administered to the patient. The second "checker" need not be a prescriber or registered health-professional themselves but should be able to verify that the correct medicine is being supplied to the patient.

SECTION 3 – MEDICINES GOVERNANCE

These medicines governance arrangements apply to all settings. This covers private practice settings, including where part of your home is your private practice, as well as NHS and other hospital, clinic and occupational health settings. The guidance in this section will apply alongside any organisational policies and/or procedures that the organisation may have in place.

In addition, paramedics are expected to demonstrate that they meet the Single Competency Framework for all prescribers⁶

27. Practice Guidance 27: Instructions for supplying and/or administration

If you instruct another person to supply and/or administer medicines on your behalf, you should ensure that the individual is educated, trained and competent to do so.

28. Practice Guidance 28: Dispensing

Dispensing is the preparation and supply of a medicine in accordance with the instructions contained within a prescription. Dispensing is generally performed by a pharmacist or pharmacy technician. You should ensure the separation of prescribing and dispensing of medicines whenever possible. You should not normally dispense against a prescription that you have written.

29. Practice Guidance 29: Transportation

You may transport medicines from the dispensing pharmacy to their place of use. You must display appropriate health and safety information on your vehicle if the medicine requires it e.g. medical gases.

Where medicines are left in a vehicle, appropriate security arrangements must be in place. Medicines should be in a secure container, and the vehicle itself must be locked. CDs must be within a locked container which is secured to the vehicle. The vehicle must be locked at all times.

30. Practice Guidance 30: Disposal

You must dispose of used, partially used and unused medicines in accordance with current legislation and your local employer policy.

If there is no local employer policy in place, you must return all medicines to a pharmacist for safe disposal.

⁶ National Prescribing Centre provided by NICE (2012) *A Single Competency Framework for all Prescribers*. London: NICE

http://www.npc.co.uk/improving_safety/improving_quality/resources/single_comp_framework_v2.pdf

31. Practice Guidance 31: Error Reporting

If you discover that you have made an error in prescribing you must take immediate action to prevent potential harm to the patient, and you must report the error as soon as possible according to local protocols.

32. Practice Guidance 32: Reporting Unexpected Effects and Adverse Reactions

If a patient experiences an adverse reaction to any medication they have been prescribed regardless of who the prescriber is, you should record this in the patient notes, notify the prescriber (if you did not prescribe the drug) and notify the MHRA via the Yellow Card Scheme immediately. Yellow cards are found in the back of the British National Formulary and also online at www.yellowcard.gov.uk.

You may also inform the patient that they can report adverse reactions independently to the Yellow Card Scheme.

You can also report adverse reactions via the Medicines and Healthcare Products Regulatory Agency (MHRA) website at www.mhra.gov.uk and serious incidents for investigation (previously known as Serious Untoward Incidents/SUIs) to the National Reporting and Learning Service (which includes, the National Patient Safety Agency (NPSA) using National Framework for Reporting and Learning from Serious Incidents Requiring Investigation <http://www.nrls.npsa.nhs.uk/home/>). The NPSA is now part of NHS England.

33. Practice Guidance 33: Complementary, Herbal and Homeopathic products.

Complementary, herbal and homeopathic products may interact with other medicinal products and/or laboratory tests. You should ensure you obtain, and record, information from the patient as to whether they are using any such products. Where there is evidence that you should do so, you may need to advise that your patient stops using a complementary, herbal or homeopathic product prior to starting taking a conventional medicinal product or undergoing a medical and/or surgical procedure.

Some herbal and homeopathic preparations are classed as medicines and are classified as POM, P or GSL depending on their action and route of administration. You may only prescribe and/or supply and administer these products in accordance with an appropriate prescribing and/or supply and administration framework.

The MHRA regulates other herbal products under the Traditional Herbal Registration (THR) scheme and other homeopathic products under the National Rules Scheme (NRS). Other products may not be subject to regulation of their quality, safety or efficacy. You should only recommend these products if you have suitable education, training and experience to do so.

The MHRA holds a list of complementary, herbal and homeopathic products that are known to, or may have, interactions with medicinal products and you should be aware of these before recommending that a patient takes a complementary product in addition to, or as a substitute for, any currently prescribed medicine. Some herbal preparations are prohibited

or restricted in their use in humans due to known toxic and/or harmful effects, and you should not recommend these products to your patients.

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SECTION 4 – CLINICAL GOVERNANCE

Patient safety is of paramount importance within all aspects of prescribing and medicines management. Paramedics must practise within the law, to a high professional standard, and ensure that they strive continuously to improve the quality of care that they offer to patients. Poor professional performance needs to be identified and rectified at an early stage. The guidance in this section will apply alongside any organisational policies and/or procedures that the organisation may have in place.

34. Practice Guidance 34: Governance Structures

If you are employed you must follow the governance arrangement that are in place. Arrangements should be in place for:

- clear lines of responsibility and accountability for overall quality of clinical care;
- development of quality improvement programmes such as clinical audit, supporting evidence-based practice, implementation of clinical standards, monitoring of clinical care, access to appropriate CPD programmes;
- management of risk;
- procedures to identify and remedy poor performance;
- Competency frameworks for prescribing.

35. Practice Guidance 35: Clinical Audit

Clinical audit is an important part of clinical governance. If you are both an independent and supplementary prescriber, you should audit independent and supplementary prescribing activities separately.

If you are a supplementary prescriber you should ensure that you participate in regular (normally at least annually) meetings with your medical independent prescriber.

You should audit how many of the patients for whom you have prescribed medication have required medical follow-up, and how many have been successfully treated. You should also audit those patients for whom you took an active decision not to prescribe for.

You should monitor how patients respond to treatment and how many follow-up visits are taking place (planned or unplanned representations to the same or another health provider). Systems should be put in place to ensure that patients who do not attend ('DNA') for their follow-up appointments with services the patient is referred to are followed up (e.g. by telephone, letter, text message or email).

If you are a supplementary prescriber you should audit your practice to ensure that the patient's CMP is being followed.

You should ensure that the prescriptions you write are clear and legible. You should audit how many times a pharmacist contacts you to query what was written.

You should seek your patients' experiences of your prescribing where possible.

36. Practice Guidance 36: Prescribing Analysis

You should ensure that you have information about national guidelines (e.g. NICE guidelines, NICE), local guidelines, local agreements and formularies to ensure you make the best prescribing decision for your patients.

If you are prescribing within the NHS, your activity should be included in the reports on the quality of clinical care to local Medicines Management Committees (or their equivalent).

37. Practice Guidance 37: Learning from incidents and errors

You should record all incidents and/or errors with your local reporting systems to facilitate national reporting where required.

You should review incidents within your local team and/or medicines management committee (or equivalent) to enable learning and where necessary change practice.

38. Practice Guidance 38: Risk Management

You should ensure that you have an appropriate Risk Management programme in place. This should include clinical risk management and patient safety (including the National Reporting and Learning Service <http://www.nrls.npsa.nhs.uk>), confidentiality, safety of prescription pads and a system for handling errors and complaints.

39. Practice Guidance 39: Continuing Professional Development

You must remain up-to-date with appropriate knowledge and skills to enable you to prescribe competently and safely within your scope of practice.

You should ensure that your prescribing CPD is in line with your current or future practice, including your role as a prescriber.

You should record your CPD in a format that easily enable you to demonstrate your fitness to practise as a prescriber.

You should ensure that you set aside sufficient time to access programmes and resources to meet your prescribing CPD needs. This may include Peer Review sessions. You should include reflective learning in your CPD portfolio and feedback from multiple sources and professions. Paramedics must follow the guidance provided by the HCPC on the standards required for continuing professional development.

<http://www.hcpc-uk.org.uk/registrants/cpd/standards/>

40. Practice Guidance 40: Poor Performance

You should be aware of the procedures in place for identifying poor prescribing practice.

41. Practice Guidance 41: Safety of NHS Prescription Pads

NHS FP10's are classed as secure stationery. Each prescription has a serial number, and has specific anti-theft and anti-forgery features. Prescription pads will be ordered by the Trusts via a secure ordering system and supplied to the named professional they relate to. You are responsible for the safety of your named prescription pad. You must take all reasonable and responsible steps to prevent its loss or inappropriate use. You should only use one prescription pad at a time.

You should keep a record of the first and last serial number of the prescriptions in the pads issued to you. If a whole prescription pad is lost or stolen you must report the serial numbers of the missing prescriptions.

At the end of each working day you should record the serial number of the first remaining prescription in your current pad. If your current pad is lost or stolen after you last used it, the relevant serial number of unused prescriptions must be reported.

Prescription pads should be stored in locked areas when not in use. You should not store prescription pads away from your place of work. In particular you should not store pads at home or in your vehicle except when travelling between places of work.

42. Practice Guidance 42: Links with Pharmaceutical Companies / Conflict of interest

If you have a commercial or financial interest in any pharmaceutical product or company then you should ensure that your patients have access to this information where relevant, and you should ensure that your interest does not affect your ability to prescribe in the patient's best interest alone.

You must not allow your own, or your employer's (if applicable) commercial or financial interests in a pharmaceutical company or product influence the way you advise your patients.

You must declare any conflict of interest in a 'register of interests' either within your personal portfolio, or within your employers Hospitality Register which should be produced on request for audit purposes.

43. Practice Guidance 43: Gifts and Benefits

Your prescribing choice for your patient must be based solely on clinical suitability and cost effectiveness, working within any local formulary that you may be obliged to follow.

The advertising and promotion of medicines is strictly regulated. You must not accept personal gifts that are given to influence your prescribing activity nor must you solicit or accept a gift or inducement to influence your prescribing patterns.

You may accept hospitality for a professional or scientific meeting, but such hospitality must be reasonable in level, and subordinate to, the main purpose of the meeting.

You may accept awards and/or grants to attend educational events offered by pharmaceutical companies that enable you to undertake CPD relevant to your practice.

You must follow your employer's policy on receiving gifts and hospitality. If you do not have an employer you must consider whether it is appropriate to accept gifts or hospitality in response to your prescribing activities.

44. Practice Guidance 44: NHS/ Private Practice Prescribing boundaries

You must not ask the patient's GP to prescribe medicines at NHS expense which are subsequently to be administered as part of private healthcare provision. If you do ask a GP to do this, they are within their rights to refuse to do this.

45. Practice Guidance 45: Checking Registrations and Annotations

You must provide evidence of your valid registration as a paramedic with the HCPC to your employer / those using your prescribing services.

You should provide evidence of your valid status as an independent prescriber annually to your employer / those using your prescribing services.

You must only prescribe in accordance with the type of annotation awarded to you.

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Glossary

Administration	Process by which a medicine is introduced into, or applied onto, the patient's body.
Advice	The act of giving information to service users pertaining to aspects of the condition for which they are seeking intervention. The information given may be an opinion or recommendation relating to suggested future intervention or actions. The information may include guidance to seek the opinion of another health professional. The information is given to the service user to consider, and the service user may choose whether to act on the advice given or not.
Appropriate practitioner	Registered professional defined within medicines legislation as being authorised to issue prescriptions for POM class medicines and/or to receive bulk supplies of POM class medicines.
Black-triangle drugs	New licensed medicines under intensive monitoring by the MHRA and subject to special adverse incident reporting requirements. The MHRA issues a monthly list of medicines subject to Black Triangle status.
Clinical Governance	Quality assured activities which ensure that pre-determined clinical standards that have been set, are maintained by practitioners, and are evident within health care settings.
Clinical Management Plan (CMP)	<p>A written plan (which may be amended from time to time) relating to the treatment of an individual patient which is agreed by the patient, the independent prescriber (a doctor or dentist only) and the supplementary prescriber who is to prescribe medicines under the plan.</p> <p>Licensed medicines including off-label and black triangle products, unlicensed medicines and controlled drugs may be included in a CMP. A CMP may be for a named medicine or a group of medicines e.g. non-specified NSAIDs.</p>
Commissioner	Person or organisation that requests and/or funds a service or activity.
Competence	The ability of an individual to demonstrate their capability in a certain skill area at a defined level of ability at a set point in time.
Competencies	The component skills that describe and define the actions and activities required in order to demonstrate competence in a skill area.
Controlled drug	A medicine subject to control by the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

CoP	The College of Paramedics
Dispensing	To label from stock. The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used, or supplied directly to the patient.
Disposal	The removal and disposal of medicines that are no longer required or are no longer suitable for their intended use and /or the removal of unwanted medicines or waste materials from the clinical site.
GSL	General Sales List. A medicine for which all active ingredients are listed in the relevant Human Medicines Regulations schedule, or are so classified in their marketing authorisation.
Guidance	Document containing recommendations for the use of a particular treatment and/or modality; the circumstances when it should be used and the population/patient groups who should receive it. Health professionals have a duty to take guidance fully into account where it is published, but they are not bound by its contents and may deviate from it where there is a clear indication to do so. A guidance document may impose a duty on a health provider to fund the treatment and/or intervention.
Guideline	A wide-ranging recommendation dealing with the management of a disease condition. A guideline document does not impose a duty on a health provider to fund the treatment of the disease condition.
HCPC	Health and Care Professions Council
Independent prescriber (IP)	A professional who is registered on the appropriate statutory register for their professional group and (for non-doctors) against whose name is recorded an annotation signifying that they are qualified to prescribe, supply and administer medicines as an independent prescriber. A person responsible for the assessment of patients with undiagnosed conditions, and for decisions about the clinical management required including prescribing. They assume full accountability for the prescribing decisions they make. They may instruct another person to administer the medicines under the terms of a Patient Specific Direction (PSD). An independent prescriber may be a medical prescriber (doctor/dentist only) or a non-medical independent prescriber (nurse, pharmacist, optometrist, physiotherapist, podiatrist, and subject to legislative changes, radiographers and paramedics). The non-medical independent prescribing professions

	between them do <u>not</u> have the same rights with regard to the use of mixed medicines, unlicensed medicines, and controlled drugs. Medical prescribers have different rights to all non-medical prescribers together.
KSF	Knowledge and Skills Framework
Licensed medicine	A medicine with a valid marketing authorisation (product licence) in the UK.
Marketing authorisation (MA)	Formal approval by the MHRA to place a medicinal product on the UK market, formerly known as 'product licence'. Defines the terms, conditions and/or patient groups that the product may be used for. Use of a medicine outside of the terms of the MA is known as 'off-label' use of the product.
Medical device	All products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. Examples include x-ray and other imaging equipment, pacemakers, artificial joints, anaesthetic equipment, infusion equipment, beds, wheelchairs, and surgical dressings.
Medical prescriber	A doctor or dentist who can independently prescribe both licensed and unlicensed medicines, and who may instruct another health professional to administer such medicines to patients under the terms of a PSD.
Medicinal product	Any substance or article (but not instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported, for use wholly or mainly in either or both of the following ways: <ul style="list-style-type: none"> • administration to one or more human beings (or animals) for a medicinal purpose • used as an ingredient, by a practitioner, pharmacy or hospital, in the preparation of a substance or article this is to be administered to one of more human beings for a medicinal purpose.
Medicinal purpose	Any one or more of: <ul style="list-style-type: none"> • treating or preventing disease • diagnosing disease or ascertaining the existence, degree or extent of a physiological condition • contraception • inducing anaesthesia • otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and

	whether by terminating, reducing, postponing, increasing or accelerating the operation of that function, or in any other way.
Medicine	A substance that claims to, or has the actual function of, treating or preventing disease in humans or animals.
Mixing	The combining of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient. Mixed medicines are unlicensed.
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NHS prescription charge	Tax paid by patients for medicines or other treatments prescribed for them by an NHS 'appropriate practitioner' and supplied at NHS expense. Some patients are exempt from paying prescription charges and receive the medicines free of charge. Prescription charges are set by the Government and do not directly reflect the production costs and/or retail prices of the medicine.
Non-medical prescriber (NMP)	A nurse, pharmacist and some allied-health professional groups who are registered on the appropriate statutory register for their professional group, and against whose name is recorded an annotation signifying they are permitted by the relevant law to prescribe, supply and administer medicines as either an independent and/or supplementary prescriber. The limits of their prescribing rights is determined by law and not be the same for each professional group especially with regard to mixing medicines and controlled drugs.
NPSA	National Patient Safety Agency (Now part of NHS England)
Off-label drugs	Use of a medicine outside its licensed indications (as contained within the SPC). Off-label use only applies to medicines that are already licensed i.e. hold a valid Marketing Authorisation.
Over-the-counter (OTC)	Description of a medicine that can be supplied without a written prescription from a variety of outlets, including self-selection without supervision, by a patient.
P	Pharmacy Only
Patient Group Direction (PGD)	A written instruction for the supply or administration of a named medicine in a defined clinical situation to groups of patients who may not have been identified before presenting for treatment. In order to be valid,

	<p>a PGD must meet specific legal criteria. This includes the requirements that only licensed medicines are included in a PGD, that the health professional [paramedic] named on the PGD is registered with the appropriate statutory regulator [HCPC], and that the supply and administration of the drugs listed in the PGD is not delegated to anyone else. PGDs tend to be used in hospital and primary care settings but are also valid in other non-NHS clinical settings. PGDs can include medicinal products for use outside their licensed indications ("off-label") if their use is exceptional and justified by best clinical practice. Off-label use only applies to medicines that are already licensed. PGDs cannot be used for the administration of unlicensed products not for the use of pharmacy-prepared products as these are not fully licensed.</p>
Paramedic	<p>A person who is registered on the HCPC register under article 5 of the Health Professions Order 2001 and entitled to practise using the protected title of 'paramedic'.</p>
Patient Specific Direction (PSD)	<p>A prescription from a doctor, dentist or other independent/ supplementary prescriber for a medicine to be administered to a named patient by another health professional. The patient must be individually identified on the PSD. The prescription must be signed and dated by the doctor/dentist or other independent/ supplementary prescriber. Unlicensed medicines may be administered under a PSD provided it has originated from a doctor or dentist. A PSD is not a standard proforma that is drawn up by a [paramedic] for a doctor to sign. This may be one way of indicating the desired prescription, but the doctor is free to amend or alter this in any way as they see fit as they will have accountability for any medicines prescribed.</p>
Prescribe	<p><u>LEGAL</u>: to request in writing, in the appropriate manner, the supply and administration of a Prescription Only Medicine for use by a named patient. Only 'appropriate practitioners' may prescribe. The Human Medicines Regulations 2012 define the professional groups classed as 'appropriate practitioners'. Paramedics are authorised as independent prescribers.</p> <p><u>GENERAL</u>: to authorise in writing, in the appropriate manner, the supply and administration of any medicinal product(s), for use by a named patient, at public expense.</p> <p><u>LAY</u>: to advise on the use of a product, especially</p>

	by an authorised person or to recommend especially as a benefit.
Prescribing	Issuing prescriptions for the medical treatment of a single individual by an 'appropriate practitioner'. A pharmacist is legally required to be involved in the sale and/or supply of the medicine identified within a written prescription. Therefore 'prescribing' is a process by which medicines are supplied to a patient involving at least two separate persons – the prescriber and the pharmacist.
Prescription	<u>LEGAL</u> : a written instruction by an appropriate practitioner for the supply and administration of the medicinal products listed within it. A written tool against which POM's may be supplied. A prescription is issued by an 'appropriate practitioner' under or by virtue of the National Health Service Act 1977 (England) / the National Health Service (Scotland) Act 1978 / the Health and Personal Social Services (Northern Ireland) Order 1972.
Prescription Only Medicine (POM)	Prescription Only Medicine. Such medicines may only be supplied and administered against a valid written 'prescription'.
Product Licence (PL)	Formal approval by the MHRA to place a medicinal product on the UK market. Now known as a 'marketing authorisation.' Defines the terms, conditions and/ or patient groups that the product may be used for. Use of a medicine outside of the terms of the PL is known as 'off-label' use of the product.
Repeat Prescribing	A partnership between a patient and a prescriber that allows the prescriber to issue duplicate prescriptions at agreed intervals without the patient having to consult the prescriber at each issue.
Repeatable Prescription	A prescription which authorises a pharmacist to issue a medicine more than once (e.g supply X medicine every month for six months).
Standard	A statement on the level of proficiency expected to be demonstrated by a person professing to hold a certain skill or ability. The standards for prescribing are set and regulated by the HCPC.
Summary of product characteristics	(Previously known as the Data Sheet): Information available for individual licensed medicines, forming an integral part of the marketing authorisation (licence). It provides information for health professionals on how to use the medicinal product safely and effectively.
Supplementary prescriber (SP)	A professional who is registered on the appropriate statutory register for their professional group and

	against whose name is recorded an annotation signifying that they are qualified to prescribe, supply and administer medicines as a supplementary prescriber. A person responsible for the continuing care of patients who have been clinically diagnosed by an independent prescriber.
Supply	The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used, or supplied directly to the patient.
Traditional Herbal Registration (THR) number	MHRA registration scheme for herbal preparations that have been assured for safety, efficacy and quality, i.e. licensing for herbal preparations. Equivalent to a Product Licence for medicines.
Unlicensed medicine	A medicine that does not have a UK marketing authorisation.

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Appendix 1: Background

Key Legislation and definition of terminology

Medicines use in the UK is controlled by the terms of the Human Medicines Regulations 2012 which provide the legislative framework for medicines use in the UK. Paramedic prescribers must understand the various medicines frameworks available to them.

Administration framework

The Patient Specific Direction (PSD) – A PSD is a written or electronic instruction from a prescriber for a medicine to be administered to a named patient. It relates to the relationship between the prescriber and another professional. A paramedic must only administer the medicine in accordance with the instructions that are written by the prescriber. Instructions should be written, although in a genuine life threatening emergency an oral instruction may be given.

Supply and administration frameworks

The Patient Group Direction (PGD) – This is not a prescribing tool for the paramedic. A senior doctor and a senior pharmacist, in conjunction with the paramedics who will use the tool, define in writing the named medicines that may be supplied and/or administered to groups of patients who may, or may not, have been individually identified prior to treatment. The PGD must be drawn up in a specific way in order to be legally valid. The paramedic, who must be named in the PGD, must supply and administer the medicine in accordance with the instructions that are written within the PGD. PGDs are not valid in all healthcare delivery settings.

Exemptions - This is not a prescribing tool. Specific pieces of law allow certain listed medicines to be supplied and administered to patients by certain health professional groups without the need for another appropriate prescribing or supply/administration framework. There are Exemptions that apply specifically to paramedics.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribing-sellingandsupplying-of-medicines/ExemptionsfromMedicinesActrestrictions/Paramedics/>

Prescribing frameworks

Supplementary prescribing - This allows a paramedic to prescribe in partnership with a doctor or dentist. The medicines to be used must be defined in writing within a Clinical Management Plan (CMP) and be appropriate to the needs of the named patient. Supplementary prescribing requires the involvement of a doctor or dentist, the supplementary prescriber and the patient. The terms of use and definition of "Clinical Management Plan" are defined in law. For a CMP to be legally valid, the independent prescriber must be a doctor or a dentist. Supplementary prescribing can be used to prescribe licensed medicines, unlicensed medicines, mixed medicines and all controlled drugs.

Independent prescribing - This allows a paramedic to autonomously prescribe, as well as supply and administer medicines to individual named patients appropriate to the needs of the named patient. Whilst the principles of prescribing are the same, non-medical independent prescribers are different from medical prescribers in terms of restrictions and context within which they prescribe, therefore doctors and non-medical independent prescribers are not directly comparable with each other in their activities.

Categories of medicine

General Sales List medicines (GSL)

These products can be sold with reasonable safety without the supervision or advice of a doctor or pharmacist, and may be obtained through a variety of outlets. All GSL medicines must hold a valid UK product license and all the active ingredients must be listed in the product. Regulations restrict the pack sizes and quantities of the medicine that may be sold without supervision. Larger volumes may only be sold under supervision (P class) or prescription (POM class). An example of this would be paracetamol that is limited to 16 tablets under GSL terms, but may be supplied in larger quantities under P or POM terms.

Pharmacy sale medicines (P)

These products can be sold with reasonable safety from premises that are under the supervision of a pharmacist but without the need for a written prescription. The products may be available for self-selection by the general public but a pharmacist is aware of the purchase at the point of sale.

Both GSL and P class medicines are known as “over-the-counter” (OTC) medicines as they can be sold and supplied (in some cases only at certain low volumes) without a written prescription for supply.

Prescription only medicines (POM)

The Human Medicines Regulations 2012 define those medicines that must be classed as POM and include those that:

- contain certain listed substances
- are controlled drugs
- are for parenteral (i.e. injection) administration (with the exception of insulin)
- emit radiation
- come under other listed criteria

POMs may only be sold, supplied and administered in accordance with a written prescription by an appropriate practitioner and dispensed from a registered pharmacy or dispensing doctor's practice.

The Human Medicines Regulations 2012 defines “appropriate practitioner” for the purposes of issuing written prescriptions as:

- doctor, dentist, vet
- independent nurse prescriber
- independent pharmacist prescriber

- independent optometrist prescriber
- independent physiotherapist prescriber
- independent podiatrist prescriber
- supplementary prescriber acting under a written Clinical Management Plan (CMP) - nurse, pharmacist, podiatrist, physiotherapist, radiographer, optometrist.

A paramedic who is annotated on the Health and Care Professions Council (HCPC) register as a Supplementary Prescriber may only prescribe POMs under a written Clinical Management Plan (CMP). Those annotated as both an independent and supplementary prescriber may use both frameworks. Regulations require that POMs may not be advertised to the general public, only marketed to health professionals, and there is blanket ban on the advertising to the public of certain treatments for certain specified medical conditions such as cancer.

Controlled Drugs

The Misuse of Drugs Act 1971 controls certain types of drugs that may be liable to misuse and abuse because of their effects on users. Schedule 2 of this Act lists the drugs subject to these specific controls and it categorises the drugs into one of three classes: Class A, Class B and Class C. The term “controlled drug” is used to refer to drugs within these three categories.

The Misuse of Drugs Regulations 2001 permits the use of controlled drugs in healthcare and further classifies controlled drugs as one of five Schedules that reflect the differing levels of control required for use of each category of drug. Controlled drugs are also subject to specific regulations pertaining to the storage and documentation required for their use.

Further changes to home office regulations will be required for paramedics to independently prescribe controlled drugs.

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- Good Medical Practice in Prescribing Medicines (2006). *General Medical Council*. London.
- Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers in the safe use of medicines (2nd Edition) <http://www.csp.org.uk/publications/practice-guidance-physiotherapist-supplementary-andor-independent-prescribers-safe-use->
- Good Practice in Prescribing and Medicines Management for Podiatrists. <http://www.scpod.org/EasySiteWeb/GatewayLink.aspx?alId=36739>
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