Inspection decision making framework

Version 8.0

The Inspection decision-making framework is essentially a checklist of what the GPhC expects from a licensed pharmacy. To summarize the requirements the GPhC lists "Five Principles"…

Five principles
These, essentially, describe best practice arrangements for safe and effective pharmacy practice. They include the following:
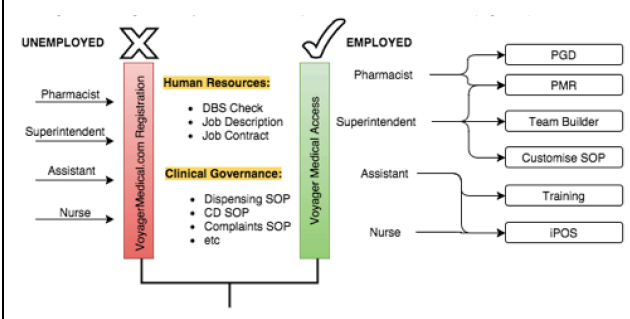
- **Principle 1** – looks at how a pharmacy identifies and manages risks.
- **Principle 2** – looks at staffing issues.
- **Principle 3** – is about the pharmacy premises.
- **Principle 4** – is about how pharmacy staff deliver services.
- **Principle 5** – is about pharmacy equipment and facilities.

These principles are then broken down further into the following checklist. Since its inception, the HubNet system has aimed to target every point on the checklist with one goal, to exceed its requirements. We do this in a number of ways, listed in the right hand column under "A HubNet Pharmacy".

Principle 1 – The governance arrangements safeguard the health, safety and wellbeing of patients and the public. (NB: the evidence for this principle will largely be drawn from that gathered under other principles – the items included below are examples only and not intended to be an exhaustive list).

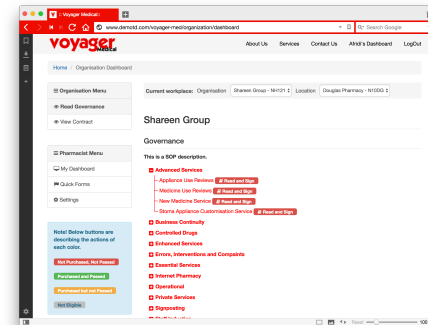| Standard 1.1 – The risks associated with providing pharmacy services are identified and managed.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**

o the pharmacy does not routinely assess key risks to patient safety from its activities and services
o there is evidence that things have gone wrong because risks to patient safety were not adequately identified and managed
o there is evidence that the same things have gone wrong more than once, with no effective action being taken to manage the risk
o there is evidence that there are risks to members of the pharmacy team, such as health and safety risks, which have not been addressed
o there is evidence that standard operating procedures (SOPS) are not being followed, and this is creating significant risk
o there are no SOPs available
	o the pharmacy team understands the key risks to patient safety presented by its activities and services and has a particular focus on the most vulnerable and high-risk patients
	o the pharmacy team members keep up to date with relevant information including national / local guidelines and best practice guidance (such as NICE, SIGN, PhE and so on) that support them in the services they provide
	o the pharmacy can demonstrate that risks are assessed before new services are introduced, and then regularly reviewed
	o the pharmacy team members can give examples of action they have taken to manage risks that have been identified
	o there are up to date standard operating procedures (SOPS) to underpin all professional services
	o SOPs are regularly reviewed to make sure they are appropriate and reflect current practice
	o SOPs are signed off by the superintendent pharmacist, or a responsible person, and dated to show when they were implemented or reviewed
	o there is evidence to show that the pharmacy team members understand the SOPS, and that they are being followed
	o business continuity planning arrangements are in place to deal with potential failure or disruption to services
		Our unique Clinical Governance module provides Standard Operating Procedure (SOP) templates to the Superintendent who can then customise and send them to every individual pharmacy team member within each pharmacy location. The system is capable of scaling from owner managers running one to five stores, to chains running 300+. Currently, we have over 150 prewritten SOPs, for this section this includes:
		• Security arrangements
		• Infection Control
		• Needlestick Injuries and Contamination
		• Storage of:
		  o CDs
		  o Cytotoxics
		  o Fridge items (cold chain maintenance)
		• Date checking
		• Working with children and vulnerable adults
		• Business continuity
		• Pharmacy Patient Safety Incident Report and Follow Up
		
		Our SOP system is unique in that it allows for tracking whether the team member has read the documents and has an embedded digital signature system to ensure legal compliance. Our Clinical Log feature includes a near miss and dispensing error recording function which logs which user (what user type pre-reg/pharmacist/nurse etc) and when the entry was made. A Superintendent, can monitor incidents and identify trends then remotely review and update procedures. In addition, our logs come with an audit function, which, allows for review summaries of incidents to be generated making a superintendents job easier than ever.

Standard 1.2 - The safety and quality of pharmacy services are regularly reviewed and monitored.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o the pharmacy team does not routinely assess the safety and quality of services provided o no evidence that records are made when things go wrong and there is no evidence of learning o the pharmacy team members do not know what they are supposed to do if things go wrong o there are no arrangements in place to learn from things that go wrong o staff are not supported to report incidents and learn from them	o the pharmacy team knows what to do, and who to tell, when things go wrong o patient safety incidents are recorded, and the records are used effectively to identify learning points and systemic weaknesses o the pharmacy team members can give recent examples of things they have learned from mistakes made o reviews (including using audits and checklists) are carried out to make sure that procedures are being properly followed and improvements in the safety and quality of services are made as a result o reviews are carried out for the full range of services provided, (including any clinical services provided), not only for dispensing and supplying, and are used to ensure that the services remain safe and improve	Our "Team Builder" module within the HubNet allows for real time updates of training and PGD status. If a staff team member is found to be lacking within two clicks the superintendent can "poke" the staff member to remind them to complete a certain module. Our Governance module, gives complete control to the Superintendent allowing them to disseminate certain SOPs to specific user types. For instance, our supervised methadone SOP would only be sent to a pharmacist, however our cleaning SOP would only go to assistants and Non-Healthcare associates.

Standard 1.3 - Pharmacy services are provided by staff with clearly defined roles and clear lines of accountability.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o the pharmacy team members do not understand their roles and responsibilities o there is evidence of errors but there are no audit trails in place to identify who was involved o there is no framework in place to define how non-pharmacist accuracy checkers operate	o the roles and responsibilities of staff are clearly documented, for example, job descriptions and SOPs make clear where responsibility lies for different pharmacy activities o people who work in the pharmacy can explain what they do, what they are responsible for, and when they might need to seek help o the pharmacy team knows what to do in the absence of a responsible pharmacist o there is a notice displayed so that the public can identify the responsible pharmacist o audit trails are in place so that the pharmacy can identify who was responsible for any professional activities o non-pharmacist accuracy checkers work within clear protocols	HubNet also includes a Human Resources module. To gain access to the pharmacy HubNet system, staff must first

		pass through the SOP Gateway followed by the Human Resources Gateway. Again our system supplies template contracts, which are freely published by the UK government.
		Our governance module includes the following SOPs: • Roles and Responsibilities of Pharmacy Staff

Standard 1.4 – Feedback and concerns about the pharmacy, services and staff can be raised by individuals and organisations, and these are taken into account and action taken where appropriate.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o there are no systems in place to deal with complaints or feedback o the pharmacy team members have failed to respond, or responded inappropriately, to complaints or feedback they have received	o there are procedures in place to deal with complaints and feedback and report back on improvements made, and these are clearly advertised o the pharmacy team encourage feedback, for example by use of customer surveys, suggestion boxes or mystery shoppers, and evidence that this is used as an improvement opportunity o the pharmacy team members can give examples of things they have done in response to external feedback they have received	HubNet includes a dedicated complaints module. Staff can enter details about the event and copy in correspondence from patients.

Standard 1.5 - Appropriate indemnity or insurance arrangements are in place for the pharmacy services provided.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o professional indemnity insurance does not cover all services provided o professional indemnity and insurance are insufficient to meet potential claims	o there is evidence that current professional indemnity insurance is in place for all services provided and is adequate to meet potential claims	This is intentionally blank

Standard 1.6 – All necessary records for the safe provision of pharmacy services are kept and maintained.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o the pharmacy records for assuring the safety of services are incomplete, inaccurate, not available or unclear (whether the standard is failed will depend on the impact of the failings).	The pharmacy maintains legally compliant records required to support the delivery of pharmacy services. For example, legally compliant records for: • controlled drugs (CDs) running balances are recorded and regularly audited • patient returned CD's are recorded on receipt and destruction is appropriately documented and	Our "Registers" module includes the following registers: • Controlled Drugs (CD) • Private prescriptions • Emergency supplies • Extemporaneously prepared medicines • Specials

| | witnessed
• Emergency supplies include the emergency to explain what was obtained and supplied
• Private prescriptions
• PMR as backed up regularly
• Any alterations are made transparently and in accordance with legal requirements, so that it is clear what was altered when the alteration was made and who made it.
• Where a pharmacy offers a prescribing service, there is clear documentation of the consultation service, treatment prescribed and any follow up or monitoring that needs to be done. | • The Responsible Pharmacist (RP) record

All registers comply with the Medicines Act and Data Protection requirements. Our governance module includes the following SOPs:
• Equipment Maintenance
For independent prescribers, the HubNet includes a fully fledged iPMR system which can record prescribing events and create private prescriptions. |

Standard 1.7 - Information is managed to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o there is evidence confidentiality has been breached, for example the exposure of confidential information or the unauthorised sharing of confidential data o there is evidence that a previous breach of data security and confidentiality which was not dealt with appropriately o the pharmacy team members do not understand how information that identifies patients should be handled o there is evidence that confidential waste is not being adequately identified, separated and destroyed — e.g. being disposed of in the general waste	o a clear **information governance (IG) policy** is in place, reviewed regularly, read and signed by all staff and compliance monitored o a **privacy notice** is displayed and includes all of the required information o annual information governance and data security and protection toolkit submissions are made as required o people who work in the pharmacy are trained how to handle private information, and have working knowledge of data protection requirements and General Data Protection Regulation (GDPR) o the pharmacy team members can give examples to show how they protect patient confidentiality o information is made available to patients about how their data is used and how their confidentiality is maintained o evidence that where there have been breaches of confidentiality that these are documented and reported appropriately	Our governance module includes the following SOPs: • Information governance. • Data security and protection • Disposal of confidential waste The system is intuitive and easy to read, all staff need to do is read and then electronically sign each SOP.

	o appropriate procedures in place to ensure patient confidential information is not inadvertently shared by delivery drivers (use of delivery sheets) o confidential waste is identified separated and dealt with appropriately.	

Standard 1.8 - Children and vulnerable adults are safeguarded.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o there is evidence that the pharmacy team failed to act appropriately in relation to a safeguarding concern o the pharmacy team members do not demonstrate any knowledge of safeguarding there is a designated lead person for safeguarding safeguarding	o there is a designated lead person for safeguarding o safeguarding procedures are in place, with current contact details of local referral agencies available o the pharmacy team has undertaken appropriate safeguarding training, for example level 1 for non-clinical staff and level 2 for clinical staff, dementia friends training o the pharmacy team members can describe action they took or would take to safeguard vulnerable individuals, including evidence of outcomes o there is a chaperone policy in place	Applicable HubNet modules here include: • **Contact book** – which lists all the relevant signposting information. • **Governance** – Safeguarding SOP • **Complaints module** – anonymous suggestions about service, this can come from both patients and staff. • **Training –** safeguarding course

Principle 2 – Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public.

Standard 2.1 – There are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o there are not enough suitably qualified staff for the pharmacy to operate safely and effectively o staff are deployed in such a way that, for periods of time, there are not enough suitably qualified staff to operate safely and effectively	o staff are observed to safely and effectively manage the workload o the skill mix is suitable for the nature of the business o work rotas are managed to ensure staffing levels remain sufficient at all times o staffing levels are regularly reviewed to ensure they remain appropriate, particularly when new services are introduced or there are other changes to the business o staff feel able to cope and know how to get	Skill mix can be constantly monitored using our "Team Builder" module the system enables back office staff to monitor training progress.

		support if needed
	o	contingency arrangements are in place to cover staff absence	

Standard 2.2 – Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o members of staff have not been trained, or are not undergoing training appropriate for their role, in accordance with GPhC minimum training requirements o there is evidence that members of staff carry out activities for which they are not appropriately qualified or trained o pharmacy professionals (or other staff) are providing specialist services when they have not been trained or accredited to do, so for example flu vaccinations, clinical screening of chemotherapy prescriptions, MURs o there is evidence of inadequate supervisory control	o support staff are trained in accordance with GPhC minimum training requirements, appropriate to their role o pharmacists and staff have completed appropriate training for any specialist services they provide, for example flu vaccination, PGDs, and smoking cessation service, and where appropriate have a declaration of competence or certificate to prove this o pharmacists keep up to date with relevant information to support them in providing clinical services. This includes but is not limited to signing up to relevant updates, knowledge of national and local guidelines, attendance on training programmes or courses o pharmacist independent prescribers can show that they are working within their competency o supervisory arrangements are in place for those in training o the skill mix of the pharmacy team is regularly reviewed to ensure it remains appropriate, particularly when new services are introduced or there are other changes to the business o continuous learning and development are encouraged o individual learning needs are identified and addressed	Every user has the ability to access specifically tailored courses.

Standard 2.3 – Staff can comply with their own professional and legal obligations and are empowered to exercise their professional judgement in the interests of patients and the public.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o members of the pharmacy team do not feel able to exercise their professional judgement in the best interests of patients o there is evidence that excessive or inappropriate quantities of pharmacy (P) or general sales list (GSL) medicines are being sold without challenge o members of the pharmacy team say that they are pressurised to sell products or provide services inappropriately o there is evidence that medicines are sold without obtaining sufficient information to be able to assess whether they are safe and appropriate for the patient (this includes online sales)	o the pharmacy team members ask appropriate questions and provide suitable advice when they sell medicines, and know when to ask for help o the pharmacy team members are aware of the potential abuse and misuse of P or GSL medicines. Frequent purchases and requests for excessive or inappropriate quantities are challenged o the pharmacy has systems in place to identify concerns about repeat requests, patients making repeat purchases (this would include online purchases), patients asking for medicines which can be misused, are high risk, or misused in combination with other things o the pharmacy team can give examples of clinical and professional interventions o the pharmacy team can give examples of how services or interventions have benefitted patient care pharmacy professionals are comfortable making decisions and do not feel pressurised to compromise their professional judgement o the pharmacy team knows who the local accountable officer is and know how to report concerns about controlled drugs	The HubNet helps to ensure better professional conduct by hosting a range of clinical governance tools, allowing pharmacist staff to focus less on paper work and more on the patient and giving excellent customer service.
Standard 2.4 –There is a culture of openness, honesty and learning. **(NB: the evidence for this standard will largely be drawn from that gathered under other standards in this principle)**		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o there is evidence of a dysfunctional team dynamic, with a risk that patients are being disadvantaged or adversely affected o there is evidence that things have gone wrong which have been covered up	o the pharmacy team members are engaged, enthusiastic and knowledgeable about the operation of the pharmacy o there is evidence of shared learning, between members of the team, between branches and with other healthcare professionals / organisations in the	Applicable Governance modules: • Error and near miss logs The system allows for remote review by the Superintendent in real time. Applicable SOPs:

	local area where appropriate e.g. GP practices, hospitals o there is evidence that members of the team are supported and comfortable discussing their mistakes openly without fear of reprisals, and that as a result, the appropriate action is taken o members of the team understand the importance of reporting mistakes and the duty of candour o staff have periodic reviews to discuss performance and areas for development o feedback and complaints are shared with the pharmacy team and action is taken as a result	• Dealing with Dispensing Errors Witinin the hubnet there is a dedicated training tracker, a manager or superintendent can drill into each location and look at each team members training record. If something is lacking a course can be designated to a member with the click of a button.

Standard 2.5 –Staff are empowered to provide feedback and raise concerns about meeting these standards and other aspects of pharmacy services.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o there is evidence that no action, or insufficient action, has been taken when individuals in the pharmacy team have raised legitimate concerns o there is evidence of threats or the fear of reprisals preventing concerns from being raised	o members of the pharmacy team know how to raise concerns and who they can tell o there is a whistle blowing policy in place which is regularly reviewed o members of the pharmacy team feel comfortable raising concerns and making suggestions o regular team meetings provide an opportunity to discuss feedback or concerns o there is evidence, over a period of time, of concerns that have been raised, with records to show what was done o staff have direct access to the superintendent pharmacist, head office, or pharmacy owner(s) if they need it	Our complaint module is anonymised so that both pharmacy staff and patients can use the system. Complaints are directly referred to the Superintendent and Pharmacist on duty.
Standard 2.6 – Incentives or targets do not compromise the health, safety or wellbeing of patients and the public, or the professional judgement of staff.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o there is evidence that the interests of patients have been compromised by targets and incentives in place 'Met' examples include when: o there are incentives in place that encourage the inappropriate sale of medicines or take up of services for instance a 'buy one get one free on codeine containing products' promotion o there is evidence of undue pressure to meet targets that has an adverse effect on patient care o incentivised services do not optimise the health and wellbeing of patients and are carried out as a 'tick box' activity for financial reward	o the pharmacy team members can explain how their approach to meeting targets serves the best interest of patients o targets are applied reasonably so that the pharmacy team can exercise discretion o targets and incentives are chosen and applied so that patients and the public will benefit if they are met o targets and incentives are regularly reviewed to ensure they remain appropriate o incentivised services such as MURs, which are provided by the pharmacy, are meaningful and lead to positive outcomes	The governance module contains the following SOPs: • Meeting targets responsibly

Principle 3 – The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public.

3.1 - Premises are safe, clean, properly maintained and suitable for the pharmacy services provided.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
- there are dirty or untidy areas of the pharmacy that are detrimental to the safe provision of services - there are areas of structural damage or dampness that present a significant risk to the safe operation of the pharmacy - there is excessive clutter that presents a significant hazard or risk - there are significant health and safety risks (for instance completely blocked fire exits, dangerous electrics, or significant tripping hazards) • there is evidence that the premises are unsuitable for the pharmacy services provided, for example. where they are clearly too small for the volume of work - medicines are sold via a pharmacy website that does not display the MHRA logo	- the pharmacy premises are clean, tidy and in a good state of repair - there is sufficient floor space and desk or worktop space to work safely and effectively - the pharmacy team members know what to do if repairs or maintenance are needed - any necessary urgent works are undertaken - the design and layout of the pharmacy is suitable for the nature of the activities - work areas and public areas are well organised, separated and uncluttered - the pharmacy website prominently displays the pharmacy's name, owner, address, registration and superintendent (if applicable)	The governance module contains the following SOPs: - Cleaning - Medicine assembly - Delivery of medicines - Delivery of Controlled drugs - Business continuity Quick forms includes: - Cleaning rota "Keep area clear" poster The contact book can also be used to list up to date an appropriate sign posting.
3.2 - Premises protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
- there is evidence that staff are not able to overcome any limitations in the structure, design or layout of the premises — for example, conversations in the dispensary can be clearly heard by patients in the retail area - the facilities for private and confidential consultations and examinations, etc are not sufficient to protect dignity and confidentiality - pharmacy websites are not secure - the website used to access services does not make it clear which pharmacy is supplying the medicines and when third parties are involved	- there is a consultation room or private area that can be used for confidential conversations, consultations or examinations, and so on - the consultation room is suitably constructed and equipped for the purpose it serves - the dispensary is screened to provide privacy for the dispensing operation - there is a screened area of the medicines counter to provide greater privacy for routine activities - pharmacy websites have appropriate security safeguards in place	The governance module contains the following SOPs: - Patient confidentiality - Privacy Officer - Safeguarding

3.3 - Premises are maintained to a level of hygiene appropriate to the pharmacy services provided.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o there is inadequate hygiene and infection control for the safe provision of services (for example vaccination services and diagnostic testing) including the facilities for hand-washing or cleaning equipment o the uncleanliness of work areas is such that it may represent a risk of infection to patients or staff or risk of contamination to medicines, medical devices or equipment 'Met' examples include when: o medicines, or medical devices are stored in the toilet	o there are suitable sinks in the dispensary, staff room and toilets which have hot and cold water, soap and hand drying facilities available o toilet facilities are clean and well maintained o work areas are hygienically cleaned o there are suitable hygiene and infection control arrangements in place for specialist services, (for example vaccination services and diagnostics tests this includes gloves and sterile wipes.	The governance module contains the following SOPs: • Ensuring clinical hygiene • Cleaning

3.4 - Premises are secure and safeguarded from unauthorised access.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o there is evidence that the premises are not secure (for example a lock doesn't work, broken window, hole in wall) o the pharmacy is within a shared use premises and access to the pharmacy by other users of the property is not adequately restricted o the pharmacy has failed to respond to advice from the police following break-ins, particularly where there have been repeated incidents	o the pharmacy premises are lockable and vulnerable entry points are appropriately constructed or protected o other security measures are utilised as appropriate, e.g. swipe card access, alarm systems, CCTV, panic buttons, security guards o there is a physical barrier to prevent unauthorised access to restricted areas	The governance module contains the following SOPs: • Ensuring premises security

3.5 - Pharmacy services are provided in an environment that is appropriate for the provision of healthcare.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o there is insufficient lighting for staff to be able to work safely o temperature extremes within the pharmacy adversely affect the staff or medicines o products are offered for sale that are not considered compatible with a healthcare environment (for example tobacco products)	o all areas of the pharmacy are well lit and ventilated o room temperatures are appropriately maintained to keep staff comfortable and are suitable for the storage of medicines o the pharmacy layout allows effective supervision of staff and pharmacy activities o the appearance reflects a professional healthcare provider o areas where patients receive clinical services and may need to wait, for instance in a consultation	Quick forms contains: • Consultation room confidentiality notice. The governance module contains the following SOPs: • Influenza vaccine service provision • Travel clinic service provision

	room for ten minutes following a flu vaccination, are appropriate, suitable and safe	

Principle 4 – The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public.

4.1 – The pharmacy services provided are accessible to patients and the public.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
- there are barriers to accessing pharmacy services which prejudice the care of patients - there is evidence that the pharmacy has not made any reasonable adjustments or alternative arrangements to facilitate access to services for patients with specific needs, such as not making any provision for patients in wheelchairs or patients with visual impairment	- the pharmacy provides information to promote services offered, and signposts people who need services they do not offer - the pharmacy provides a range of services and takes steps to make sure people can use them, for example wheelchair access arrangements, hearing loops and large print labels ***a pharmacy providing services at a distance makes their contact details clear to patients, including the ability to check when a delivery is due***	Contact book contains up to date sign posting information. Our clinical logs module contains a clinical diary so that pharmacists can better communicate between shifts. Our iPMR system allows for the electronic recoding of Risk Assessment forms enabling the better provision of influenza and travel clinics. Our Quick Forms module contains how to guides for DMR, weight loss, smoking cessation and repeats. Our governance module contains SOP for: - Operating in the Absence of a Responsible Pharmacist - Repeat Dispensing - Setting up a distance selling pharmacy

4.2 - Pharmacy services are managed and delivered safely and effectively.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o there is evidence that pharmacy services are provided in a way that puts patient safety at risk o services are provided without reliable audit trails being in place o there is evidence of inappropriate medicines being supplied to patients when the pharmacist missed an opportunity for clinical intervention o medicines are left unsealed or unlabelled for extended periods of time during dispensing o there is evidence of pharmacy (P) medicine sales, or handing out prescriptions, in the absence of the responsible pharmacist o the pharmacy delivers medicines without adequate control (posted through letter boxes without adequate risk assessment or safeguards, for example) o there is evidence of medicines being supplied unlawfully, for example invalid prescriptions, or expired patient group directions (PGDs) o the pharmacy provides a vaccination service without having appropriate anaphylaxis resources in place	o pharmacy services are effectively managed to make sure they are provided safely advice. o controls are in place to reduce the risk of picking and dispensing errors, for example, regular use of dispensing aids to actively manage risks, for example stickers, information notes, baskets o there are effective audit trails to demonstrate that professional services are effectively managed and these identify the individuals involved at each stage o a documented owing system is in use when medicines cannot be immediately supplied which ensures the service is properly managed o there is evidence that delivery services are effectively managed to ensure medicines are supplied safely (see the GPhC guidance for registered pharmacies providing pharmacy services at a distance, including on the internet) o compliance aid dispensing is well organised to ensure patients receive their medicines on time and can use them safely o substance misuse services are effectively managed to provide assurance that clients receive appropriate care o appropriate clinical checks are carried out (for example for high risk medicines including valproate, warfarin, methotrexate and lithium) o all services are supported by appropriate equipment, resources, emergency procedures, training and up to date guidance, for example vaccination services, prescribing services and emergency hormonal contraceptive services o patient group direction (PGD) services are provided in accordance with appropriate documentation o internet services have appropriate safeguards against misuse o hub and spoke arrangements are managed safely and effectively o pharmacies that are associated with online prescribing services can provide evidence that all online prescribers have appropriate authority to prescribe	The governance module contains the following SOPs for dispensing the following items: • Methotrexate • Controlled drugs • Cytotoxics • Insulin • Supply of Oral Anticoagulant Medication • Supply of Paraffin Based Skin Products • Supply of Veterinary Medicines • Supplying of Oral Anti-Cancer Medicines In addition, other SOP templates include: • Date checking • Stock rotation • Blood Glucose Monitoring • Blood Pressure Monitoring

	o a pharmacy providing services at a distance has reliable systems in place to confirm the age and identity of patients requesting medicines	

4.3 - Medicines and medical devices are: obtained from a reputable source, safe and fit for purpose, stored securely, safeguarded from unauthorised access, supplied to the patient safely, disposed of safely and securely		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o the safety of medicines and medical devices is compromised by inadequate management arrangements o there is evidence of patient returned medicines being re-used, being stored with current stock medicines or not being disposed of safely o out of date medicines are present in stock and there are no effective arrangements in place for identification and removal of the expired medicines in stock o there is evidence that date expired medicines have been supplied o stock medicines are not appropriately packaged or labelled o there are counterfeit medicines or unlicensed imported medicines present in stock controlled drugs are not stored in accordance with safe custody requirements o there is evidence that medicines that require refrigeration are not stored in appropriate conditions, including during delivery o medicines are stored in areas where there is a significant risk of unauthorised access o medicines or medical devices that are not fit for purpose have not been appropriately quarantined	o the pharmacy has appropriate management arrangements in place, that it can provide assurance that medicines and medical devices are fit for purpose o all medicines as obtained from licensed wholesalers o the pharmacy complies with the requirements of FMD o all stock medicines are kept in the original manufacturers packaging o there is evidence that stock medicines are regularly checked to make sure they are fit for purpose all medicines are in date and short dated medicines are highlighted o there is evidence of regular fridge temperature checks, demonstrating that appropriate storage conditions have been maintained o controlled drugs are stored in accordance with safe custody requirements o possession of CD cabinet keys is restricted o the pharmacy team members make appropriate checks when they hand out medicines, to make sure they are supplied correctly o the delivery service has arrangements in place to protect thermolabile (temperature sensitive) medicines and controlled drugs o there are arrangements in place to identify high risk medicines such as valproate, warfarin, methotrexate and lithium and evidence that patients are suitably counselled o pharmacy medicines are displayed in restricted areas to avoid self- selection o patient returned medicines are segregated and disposed of appropriately controlled drugs are rendered unusable before disposal o the pharmacy has appropriate arrangements in place to	The governance module contains a whole folder dedicated to Controlled Drugs, SOP include: • Balance Check and Record Keeping • Delivering Controlled Drugs • Destruction of Controlled Drugs • Dispensing Codeine And Dihydrocodeine • Dispensing of Controlled Drugs • Dispensing Methadone • Extemporaneous preparation of methadone • Instalment dispensing of Controlled Drugs • Recording Concerns over CD management • Security and Storage of Controlled Drugs • Supervised Controlled Drugs • Supply of Sativex

	handle and dispose of hazardous waste including sharps and cytotoxic medicines	

4.4 - Concerns are raised when it is suspected that medicines or medical devices are not fit for purpose.

"Not met" examples include when…	"Met" examples include…	A HubNet Pharmacy
o there is evidence that patient safety has been compromised by failure to act or raise concerns about medicines and medical devices which are not fit for purpose o the pharmacy does not receive drug alerts or does not have a system to deal with them o there is evidence that black triangle or yellow safety card reporting incidents are not dealt with o there is evidence that patient level recalls have not been actioned (where stock affected has been held)	o the pharmacy has arrangements in place to deal with any concerns about medicines o the pharmacy receives drug alerts and recalls from MHRA and other authorities and takes the action required o the pharmacy team members can explain how drug alerts are received and checked o the pharmacy team members can show how they have dealt with drug alerts that have been received o the pharmacy team members know what to do if they receive damaged stock, or if a patient returns a faulty medicine o the pharmacy team knows what to do if patients report unexpected side effects from their medicines o there is evidence that all affected patients have been contacted and given appropriate advice in response to a patient level recall	Our complaints module allows for anonymous suggestions about service, this can come from both patients and staff.

Principle 5 – The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public.

5.1 - Equipment and facilities needed to provide pharmacy services are readily available.		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o there is evidence that patient safety is compromised by a lack of appropriate equipment and facilities o there is no access to appropriate or up to date reference material	o the pharmacy uses appropriate equipment and facilities for the services provided o all resources required for the services offered are available e.g. consultation room, measuring or monitoring equipment, reference sources, equipment for extemporaneous dispensing o contingency arrangements are in place to manage failure of equipment that is essential for safe service provision	The governance module include SOPs for: • Blood Glucose Monitoring • Blood Cholesterol Monitoring

5.2 - Equipment and facilities are: obtained from a reputable source, safe to use and fit for purpose, stored securely, safeguarded from unauthorised access, appropriately maintained		
"Not met" examples include when…	**"Met" examples include…**	**A HubNet Pharmacy**
o there is evidence of a negative outcome for a patient, because of equipment or facilities Inspection decision making framework o there is evidence that measuring equipment in use is not fit for purpose o there is evidence that equipment or test strips are used after their expiry date or without appropriate calibration o there is evidence that multiple use finger prickers are used o there is evidence that the safety of pharmacy services is compromised by the inadequate management of equipment or facilities	o the pharmacy has appropriate management arrangements in place, so that it can provide assurance that equipment and facilities are fit for purpose o equipment is obtained from reputable suppliers o all measures are stamped (crown, British Standard [BSI, ISO or CE) o the pharmacy team can demonstrate that equipment is regularly cleaned, calibrated, tested and serviced o the pharmacy team members know how to use equipment and facilities, and know what to do if anything does not seem to be working properly	The governance module include SOPs for: • Cleaning • Pharmacist Locum Induction

5.3 - Equipment and facilities are used in a way that protects the privacy and dignity of the patients and the public who receive pharmacy services.		
"Not met" examples include when…	**Met" examples include…**	**A HubNet Pharmacy**
o there is evidence that the privacy and dignity of patients using pharmacy services is compromised by inappropriate use Of equipment and facilities o confidential material is stored where there is a significant risk of unauthorised access or where it can be seen by the public	o access to patient medication records (PMR) or IT is controlled through passwords which are secure and changed frequently o computer screens are positioned so they are not visible to the public o the pharmacy team takes appropriate precautions when making private phone calls or talking about confidential	This is intentionally blank

	matters	
	o the consultation room is used for private consultations and conversations and protects the dignity Of patients	
	o there is appropriate use of NHS smart cards, and access of summary care records	
	o there is evidence that confidential information is kept secure, e.g. consultation room kept locked, items awaiting collection not visible from retail area, secure retention of records	