MEDICINES MANAGEMENT POLICY AND PROCEDURE

PRIMUS PLUS HEALTHCARE

CONTACT DETAILS

Main Office Address: 603 London Road, Westcliff on Sea, Southend on Sea, Essex, SS0 9PE

Bradford Address: 1436 Leeds Road, Bradford, BD3 7AA

Phone: 01702963009

Email: care@primusplus.co.uk

REGISTERED MANAGER/ PERSON IN CHARGE

Jonas Ayitevie

Date Created: February, 2026

Next Review Date: February, 2027

Signed By: Jonas Ayitevie

1. PURPOSE

The purpose of this Medicines Management Policy and Procedure for Primus PLUS Healthcare is to establish a comprehensive, safe, and effective framework for managing medicines and associated equipment for service users in supported living without personal care arrangements. This policy is designed to ensure compliance with Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment as stipulated by the Care Quality Commission (CQC). It outlines the procedures and practices for the safe prescribing, administration, storage, and disposal of medicines, while safeguarding the well-being of adults with learning disabilities, mental health needs, and autism spectrum conditions.

The key aims of this policy are to:

1. **Ensure Safe and Effective Medicines Management**:
   This policy aims to provide a clear framework for managing medicines in a manner that protects service users, supports their health and well-being, and complies with relevant national standards and legislation. It ensures that medicines are administered safely, as per individual needs, and in line with CQC regulations and NICE guidelines.
2. **Promote the Rights and Safety of Service Users:**
   The policy ensures that individuals with learning disabilities, mental health needs, and autism spectrum conditions receive medications in a way that respects their rights, autonomy, and dignity. It provides clear guidance on how to obtain informed consent, and how to manage medication for those who may lack capacity, in accordance with the Mental Capacity Act 2005.
3. **Compliance with Relevant Legislation and Standards:**
   The policy is in line with key pieces of legislation, regulations, and guidance, including but not limited to:
   - Care Quality Commission (CQC) Regulations (specifically Regulation 12: Safe Care and Treatment, Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment).
   - Mental Capacity Act 2005, for supporting service users who may lack capacity to consent to medication.
   - The Medicines Act 1968 and the Misuse of Drugs Act 1971, for the proper storage, handling, and disposal of controlled drugs.
   - National Institute for Health and Care Excellence (NICE) guidelines, which ensure that the management of medications is in line with best practices.
   - The Autism Act 2009, which provides legal guidelines and strategies to support people with autism, ensuring they receive appropriate treatment and care.
4. **Guidance on Levels of Medication Assistance:**
   This policy defines the different levels of medication assistance provided to service users, from independent self-administration with reminders to full assistance with medication administration. It ensures that each individual's medication needs are addressed based on their capabilities and needs, promoting their independence where possible.
5. **Approach to Covert Medication, PRN Medication, Controlled Drugs, and Sharps Management:**

The policy clearly outlines the conditions under which covert medication (medication given without the individual's knowledge) may be administered, ensuring full compliance with the Mental Capacity Act 2005. It also addresses the proper procedures for managing PRN (as required) medication, controlled drugs, and sharps, which are critical in maintaining the safety and well-being of service users and staff.

6. **Safeguarding and Risk Management:**
   A key aspect of this policy is the identification and mitigation of risks related to the use of medications. This includes managing the risk of medication errors, safeguarding individuals from abuse, and ensuring that all medication-related procedures are followed to prevent harm. Regular monitoring and audits are built into the process to identify and address any medication concerns promptly.

7. **Training and Competency of Staff:**
   The policy ensures that all staff involved in medicines management receive appropriate training and are regularly assessed for their competence. This includes training on safe medication administration, recognizing side effects and adverse reactions, and knowing how to report medication errors or concerns.

8. **Collaboration and Communication with Healthcare Professionals:**
   In line with the CQC requirements, this policy facilitates collaboration between care staff, pharmacists, and healthcare professionals (including GPs and psychiatrists) to ensure safe and effective medication management. This includes ensuring that all medication decisions are made in consultation with healthcare professionals and that medication changes are communicated effectively to all relevant parties.

9. **Service User-centred Care:**
   The policy emphasizes the importance of involving service users in decisions regarding their medication where possible, and ensuring that their preferences and needs are considered. For those with communication difficulties or cognitive impairments, the policy outlines how additional support will be provided to ensure they can participate in the decision-making process.

10. **STOMP and STAMP**:
    The policy includes provisions for addressing the STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People) initiative, ensuring that medications prescribed to people with learning disabilities and autism are necessary and appropriate. It also covers the STAMP (Supporting Treatment and Appropriate Medication in Paediatrics) approach where relevant.

Key Legislation and Standards Referenced:

- Care Quality Commission (CQC) Regulations, specifically:
  - Regulation 12: Safe Care and Treatment
  - Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment
- Mental Capacity Act 2005
- The Medicines Act 1968
- Misuse of Drugs Act 1971

- National Institute for Health and Care Excellence (NICE) Guidelines
- The Autism Act 2009
- The Health and Social Care Act 2008

2. SCOPE

This Medicines Management Policy and Procedure applies to Primus PLUS Healthcare's services, specifically tailored to individuals residing in supported living without personal care arrangements. The policy ensures that medicines are managed safely, effectively, and in compliance with relevant legislation, best practice guidelines, and regulatory requirements. It covers all aspects of medication management, from assessment and consent to administration, training, and monitoring, for adults with learning disabilities, mental health needs, and autism spectrum conditions.

The scope of this policy includes:

2.1 Service Users

- Adults with Learning Disabilities: Individuals who have a significantly reduced ability to understand new or complex information, learn new skills, and cope independently, which may affect their ability to manage or administer their own medications.
- Adults with Mental Health Needs: Individuals with diagnosed mental health conditions who may require medication as part of their treatment, and whose needs and medication must be managed to prevent harm and promote well-being.
- Adults with Autism Spectrum Conditions: Individuals diagnosed with autism spectrum conditions, who may face challenges related to medication adherence, side effects, and communication difficulties regarding their medication needs.

This policy ensures that all medication management practices are tailored to meet the needs of these specific service user groups, ensuring their safety and promoting their independence wherever possible.

2.2 Staff Involved in Medicines Management

- Care Workers: Responsible for assisting with medication administration, ensuring proper storage, and observing the effects of medications.
- Healthcare Professionals: Doctors, nurses, pharmacists, and other healthcare professionals who prescribe, review, and monitor medications in line with the needs of the service users.
- Pharmacy Staff: Responsible for the accurate dispensing of medications, providing advice, and ensuring compliance with legal requirements.
- Managers: Oversee the medicines management process, ensuring compliance with this policy, relevant legislation, and regulatory standards, as well as training and staff competence.

2.3 Settings Covered by This Policy

This policy applies to all supported living without personal care services provided by Primus PLUS Healthcare, which include:

- Supported Living Arrangements: Where service users live independently in the community, but without receiving personal care. The management of their medication is integral to their independence and quality of life.
- Medication Administration in the Home: The policy outlines procedures for managing medicines when service users are in their own homes, including safe storage, assistance with self-administration, and the monitoring of medication adherence.

2.4 Types of Medication Assistance Offered

This policy covers various levels of medication assistance, in accordance with the needs and abilities of the service users:

- Level 1: Independent self-administration with support for reminders.
- Level 2: Assistance with administration by trained staff, either with or without supervision.
- Level 3: Full assistance with medication administration for individuals who cannot self-administer their medications.

2.5 Consent and Capacity Considerations

The policy applies to the management of medications for service users who are able to give informed consent, as well as for those who may lack capacity. Where individuals lack capacity to make medication decisions, Mental Capacity Act 2005 principles will be followed, and consent will be obtained from appropriate legal representatives, or through advocacy where necessary.

2.6 Special Considerations for Covert Medication and PRN Medications

This policy provides guidelines on the exceptional administration of covert medication (when medication is given without the service user's knowledge), in line with the Mental Capacity Act 2005. Additionally, it outlines protocols for the safe administration and documentation of PRN (as required) medications, particularly for those who may have fluctuating needs related to their mental health or autism spectrum conditions.

2.7 Management of Controlled Drugs, Sharps, and Gases

- The policy provides detailed instructions for the handling, storage, and administration of controlled drugs, in compliance with the Misuse of Drugs Act 1971 and other relevant guidelines.
- Sharps and Gases: The policy ensures the safe storage, handling, and disposal of sharps and gases used in medication administration, with staff trained on the appropriate safety measures.

2.8 Delegated Healthcare Tasks

If healthcare tasks (e.g., insulin administration) are delegated to staff, the policy provides clear guidance on the appropriate delegation of such tasks and ensures that all staff involved are adequately trained and competent. This ensures compliance with legal requirements and safeguarding of service users.

2.9 Medicines Management in Domiciliary Care (Home Care)

For home care (domiciliary care) agencies, this policy includes procedures to ensure that service users receive the appropriate support for their medication needs in their own homes. This includes agreeing

with the service users about medicine storage in their homes, monitoring adherence, and ensuring safety.

2.10 STOMP and STAMP

The policy ensures that STOMP (Stopping Over-medication of People with Learning Disabilities and Autistic People) and STAMP (Supporting Treatment and Appropriate Medication in Paediatrics) are reflected in the medication management process, with clear guidelines for minimizing unnecessary medication and promoting appropriate treatment plans. This applies to all service users with learning disabilities and autism.

2.11 Governance and Compliance

This policy ensures that the following governance and compliance measures are in place:

- Training and Competency Assessments: Staff involved in medication administration will undergo regular training, with competency regularly assessed and monitored to ensure the safe administration of medicines.
- Accurate and Up-to-date Medication Administration Records (MAR): The policy provides guidelines for the governance arrangements of MARs, ensuring they are complete, accurate, and reflect real-time medication administration.
- Record Keeping and Reporting: Procedures will be in place for ensuring that any medication concerns, errors, or omissions are accurately recorded and reported to the appropriate authorities, in accordance with CQC guidelines and relevant national standards.

2.12 Access to the Policy and Specialist Services for Autism and Learning Disabilities

This policy is accessible to all service users, and special consideration is given to those with autism or learning disabilities. The policy has been adapted to ensure that service users with specific needs, such as those with communication difficulties, can access and understand the guidelines. The policy also ensures that service users and their families are involved in decisions about their medication and care, in line with person-centred care principles.

2.13 Compliance with National Guidance

This policy ensures that all medicines management practices are in line with National Institute for Health and Care Excellence (NICE) guidelines, which set the standard for best practices in medication management. All procedures outlined in this policy will reflect the relevant NICE guidelines for the management of medications in individuals with learning disabilities, mental health conditions, and autism spectrum conditions.

3. POLICY STATEMENT

Primus PLUS Healthcare is committed to ensuring the safe and effective management of medicines for all service users in supported living without personal care settings. This policy outlines the procedures, roles, and responsibilities that must be followed by all staff involved in the medication management process. The aim is to protect the health and well-being of adults with learning disabilities, mental health needs, and autism spectrum conditions by adhering to the highest standards of practice, in compliance with all relevant UK legislation, national guidelines, and CQC regulations.

This policy ensures that:

1. Regulation 12: Safe Care and Treatment is met by ensuring that medication is prescribed, administered, stored, and disposed of safely, and that all medicines are appropriate for the service users' needs. The policy specifies the procedures for managing the medications of service users in a way that ensures their health, safety, and quality of life.
2. Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment is addressed by implementing safeguards to prevent abuse, errors, or misuse of medications. All medication practices are designed to prevent harm to service users, protect their dignity, and provide them with the best possible care and treatment in a safe environment.
3. Comprehensive Medication Management: The policy sets out how medication needs will be assessed, and how service users' individual requirements for medication management will be addressed. It ensures that a person-centred approach is taken for all service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. The appropriate level of medication assistance is provided, and medicines are managed to promote safety, comfort, and independence where possible.
4. Informed Consent: The policy sets clear guidelines on how informed consent for medication is obtained from service users. For individuals who lack capacity to make medication decisions, we ensure compliance with the Mental Capacity Act 2005 by using the best interest principle and involving legal representatives, family members, or advocates as appropriate. The policy also covers how consent will be documented and how individuals can express their preferences regarding medication.
5. Support for Special Medication Needs: The policy specifies the procedures for managing more complex medication-related issues, such as covert medication administration, the handling of PRN (as required) medications, and the management of controlled drugs. These protocols are designed to ensure service users receive the correct medications in the most appropriate manner for their condition, while safeguarding their rights and dignity.
6. Safe Medication Practices: Clear procedures are outlined for the safe storage, handling, and administration of medicines, including controlled drugs and sharps. These procedures ensure that medicines are stored securely, and that errors or omissions in medication administration are identified and promptly addressed.
7. Delegated Healthcare Tasks: The policy includes the delegation of certain healthcare tasks (such as insulin administration) to trained and competent staff, in accordance with best practice guidelines. This delegation ensures that medications are administered in line with prescribed instructions, and that staff are appropriately trained to handle tasks safely and effectively.
8. Training and Competency: Primus PLUS Healthcare ensures that all staff responsible for the administration of medicines are properly trained, and their competency is regularly assessed and monitored. This includes initial induction training and ongoing professional development, as well as competency checks that confirm staff are equipped to handle medications safely and in compliance with the law.
9. Record Keeping and Reporting: This policy establishes the importance of maintaining accurate and up-to-date Medication Administration Records (MAR). All medication administrations, refusals, and errors must be documented and reported in a timely manner. This ensures that CQC regulations are followed, and any issues related to medication are addressed promptly.

10. Governance Arrangements: The policy outlines how governance arrangements for medicines management will be established and maintained. This includes regular audits of medication administration and records, ensuring that any issues are identified and rectified, and that staff are held accountable for following established protocols.
11. Guidance from NICE: The policy reflects the National Institute for Health and Care Excellence (NICE) guidelines on the management of medicines, ensuring that the use of medication is evidence-based, safe, and appropriate for the needs of each individual. The guidance also includes protocols for reducing over-medication, particularly in people with learning disabilities and autism.
12. STOMP and STAMP: Primus PLUS Healthcare is committed to the principles of STOMP (Stopping Over-medication of People with Learning Disabilities and Autistic People) and STAMP (Supporting Treatment and Appropriate Medication in Paediatrics). The policy supports the reduction of unnecessary medication, promoting the use of the most appropriate treatment plans to meet the individual needs of service users with autism and learning disabilities. This is achieved through regular reviews, the use of alternative treatments where possible, and collaborative working with healthcare professionals.
13. Service User Involvement: The policy ensures that service users, particularly those with autism, learning disabilities, and mental health needs, are actively involved in decisions about their medication where possible. It promotes a person-centred approach, where service users' preferences and choices are respected, and any difficulties they may have with medication (such as swallowing tablets or understanding their treatment plan) are taken into account.
14. Access to Policy and Specialist Services: This policy ensures that all service users, particularly those with autism and learning disabilities, have access to the medicines management policy. The policy is designed to be accessible and understandable to these individuals, with additional support provided where necessary to ensure that service users can fully engage with and benefit from the procedures outlined.

4. OBJECTIVES

The objectives of this Medicines Management Policy and Procedure are designed to ensure the safe, effective, and person-centred management of medicines for all service users of Primus PLUS Healthcare, particularly those in supported living without personal care settings. This policy is developed in compliance with CQC regulations, relevant UK legislation, and guidance from national bodies such as NICE, and is tailored to the specific needs of service users with learning disabilities, mental health needs, and autism spectrum conditions.

The primary objectives of this policy are as follows:

4.1 To Ensure Safe and Effective Medicines Management

- Objective: To establish clear procedures that ensure all medicines are prescribed, administered, stored, and disposed of safely and effectively. This includes the accurate documentation of all medication administrations and ensuring that all staff adhere to prescribed procedures to prevent errors and omissions in medication management.

- Regulation Compliance: In line with Regulation 12: Safe Care and Treatment of the Care Quality Commission (CQC), this objective aims to safeguard the health and safety of service users by ensuring that medication management meets required safety standards and national guidelines.

4.2 To Promote Person-centred Care in Medication Administration

- Objective: To ensure that service users are at the heart of decisions regarding their medication. This includes respecting their preferences, ensuring they understand their treatment, and actively involving them in decisions about their medication wherever possible. For those with communication challenges or who lack capacity, alternative methods of support will be provided, including involving legal representatives and advocates where necessary.
    - Regulation Compliance: This is in line with Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment as set out by the Care Quality Commission (CQC). The policy emphasizes the importance of service users' rights, dignity, and autonomy when it comes to medication management.

4.3 To Provide Clear Guidelines for Medication Assistance

- Objective: To establish a clear framework that outlines the different levels of medication assistance based on the needs and abilities of each service user. The policy ensures that medications are managed in a way that maximizes the independence of service users while ensuring safety and compliance with prescribed instructions.
    - Regulation Compliance: The policy provides a graduated approach to medication support, as required by Regulation 12: Safe Care and Treatment and NICE guidelines, ensuring service users are assisted appropriately according to their individual needs.

4.4 To Ensure Safe Handling and Administration of Medication

- Objective: To provide specific procedures for the safe administration, storage, and handling of medications, including controlled drugs, sharps, and gases. This includes the use of Medication Administration Records (MAR) to document all medication given, and clear processes for managing medication errors and omissions, as well as the safe disposal of medications.
    - Regulation Compliance: These procedures align with the Health and Social Care Act 2008, The Medicines Act 1968, and Misuse of Drugs Act 1971, and follow CQC regulations to ensure that medications are administered safely, stored correctly, and disposed of in accordance with legal and safety requirements.

4.5 To Ensure Appropriate Training and Competency of Staff

- Objective: To ensure that all staff responsible for administering medications are appropriately trained, their competency is regularly assessed, and they receive ongoing professional development. This includes initial induction training and annual updates on safe medication practices, handling medication errors, and understanding relevant laws and regulations.
    - Regulation Compliance: This objective ensures compliance with Regulation 18: Staffing (Safe Staffing) as outlined by CQC, ensuring that staff are equipped with the knowledge and skills needed to provide safe care in the management of medicines.

4.6 To Safeguard Service Users from Medication Errors and Misuse

- Objective: To establish robust systems for identifying, reporting, and addressing medication errors, including clear guidelines for responding to missed doses, adverse reactions, and medication refusals. This objective ensures that medication-related incidents are addressed promptly to protect service users' health and safety.
    - Regulation Compliance: This objective is aligned with Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment and CQC requirements, ensuring that errors or misuse are reported, investigated, and corrected in accordance with the law and best practices.

4.7 To Promote the Appropriate Use of Medications, including PRN and Covert Medication

- Objective: To ensure the appropriate use of PRN (as required) medications and covert medication administration in accordance with best practice guidelines, ethical principles, and legal frameworks such as the Mental Capacity Act 2005.
    - Regulation Compliance: This objective reflects CQC standards and Mental Capacity Act 2005 principles, ensuring that covert medication is only used in the best interest of the service user, with full compliance to legal and regulatory requirements.

4.8 To Monitor and Review Medication Practices Regularly

- Objective: To conduct regular audits and reviews of medication practices to ensure continuous improvement, compliance with regulations, and adherence to best practices. This includes monitoring the effectiveness of medicines, reviewing stock levels, and ensuring the safe and timely administration of medication.
    - Regulation Compliance: In line with Regulation 12: Safe Care and Treatment and CQC's KLOEs (Key Lines of Enquiry), this objective ensures that all medication management practices are monitored and assessed to maintain the highest standards of care and safety.

4.9 To Promote the Safe Storage of Medicines in Service Users' Homes

- Objective: To ensure that service users who manage their own medications in their homes are supported with safe storage practices. Service users will be consulted on how their medicines are stored, and guidance will be provided on how to maintain safe and secure storage, particularly for controlled drugs or high-risk medications.
    - Regulation Compliance: This reflects CQC regulations on safe storage and management of medicines, ensuring compliance with the Health and Social Care Act 2008 and NICE guidelines.

4.10 To Address the Specific Medication Needs of Service Users with Autism and Learning Disabilities

- Objective: To develop and implement a policy that addresses the unique medication management needs of individuals with autism spectrum conditions and learning disabilities. This includes ensuring that medications are prescribed and administered in a manner that is sensitive to these individuals' needs and that any over-medication is prevented through the STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People) initiative.

- Regulation Compliance: This objective ensures compliance with the Autism Act 2009, NICE guidelines, and CQC regulations, particularly in relation to the safe and appropriate use of medications for people with learning disabilities and autism.

4.11 To Ensure Full Compliance with Relevant National and International Guidelines

- Objective: To incorporate guidance from national bodies such as NICE and international best practices into medication management procedures. This includes adhering to STOMP, STAMP (Supporting Treatment and Appropriate Medication in Paediatrics), and other relevant protocols, to ensure medication is administered in the most appropriate manner for service users' specific needs.
    - Regulation Compliance: This ensures the policy complies with NICE guidelines, CQC standards, and national health policies, maintaining high-quality care and safety standards for all service users.

5. DEFINITIONS

In this section, we outline the key definitions, terms, and abbreviations used in the Medicines Management Policy and Procedure for Primus PLUS Healthcare. These terms are central to ensuring a clear and consistent understanding of the policy and its applications within supported living without personal care services, particularly for individuals with learning disabilities, mental health needs, and autism spectrum conditions.

5.1 Key Terms and Definitions

- Supported Living without Personal Care: A service model in which individuals live independently in the community but do not receive personal care services. Individuals are supported with activities of daily living (ADLs) that do not include personal care tasks such as washing, dressing, or toileting.
- Medicines Management: The process of ensuring that medicines are prescribed, administered, stored, and disposed of safely and effectively. It includes monitoring service users' response to medications and making necessary adjustments to their treatment plans to ensure their well-being.
- Service User: An individual receiving care services, specifically those with learning disabilities, mental health needs, and autism spectrum conditions. In the context of this policy, service users are individuals living in supported living without personal care, who may require assistance with their medications.
- Mental Capacity: A person's ability to make and understand decisions about their care and treatment. In cases where a service user may lack mental capacity, decisions regarding their medication and treatment may need to be made by their legal representative, family, or healthcare professional in accordance with the Mental Capacity Act 2005.
- PRN (Pro Re Nata): A Latin term meaning "as needed". PRN medication refers to medication that is taken only when required, based on symptoms or specific circumstances, such as for pain relief or anxiety. It is important that clear protocols are in place for the administration of PRN medication to ensure safe and appropriate use.

- Covert Medication: The practice of administering medication without the service user's knowledge or consent, typically in situations where the individual is unable or unwilling to take the medication, and no other reasonable alternatives are available. Covert medication should only be administered following careful ethical considerations and in accordance with the Mental Capacity Act 2005.
- Controlled Drugs: Medications that are regulated under the Misuse of Drugs Act 1971 and require special handling, storage, and documentation due to their potential for abuse or dependence. These drugs include, but are not limited to, opioids (e.g., morphine) and certain sedatives or stimulants.
- Sharps: Objects such as needles, syringes, and lancets that are capable of causing injury. The safe handling, storage, and disposal of sharps are critical to ensure the safety of service users and staff.
- Delegated Healthcare Tasks: Certain healthcare tasks, such as insulin administration or the management of catheters that may be delegated by a healthcare professional to a care worker or support staff. These tasks must be carried out in compliance with specific training, competency assessments, and clear guidelines.

5.2 Relevant Abbreviations and Acronyms

- CQC: Care Quality Commission. The independent regulator of health and social care services in England, responsible for monitoring and inspecting services to ensure they meet essential standards of care.
- NICE: National Institute for Health and Care Excellence. A UK organization that provides evidence-based guidelines to improve health and social care, including medication management in care settings.
- STOMP: Stopping Over-Medication of People with a Learning Disability, Autism, or both. An initiative aimed at reducing the use of inappropriate psychotropic medications in individuals with learning disabilities and autism.
- STAMP: Supporting Treatment and Appropriate Medication in Paediatrics. A program focusing on safe and appropriate medication use in children, including those with disabilities.
- MAR: Medication Administration Record. A document that tracks the medications administered to a service user, ensuring that the right medication is given at the right time and in the correct dosage.
- GP: General Practitioner. A healthcare professional who provides general medical care and treatment to individuals in the community. In this context, GPs are involved in prescribing medications for service users.
- PRN: Pro Re Nata, meaning "as needed". A term for medications taken only when required, rather than on a set schedule.
- COSHH: Control of Substances Hazardous to Health. A set of regulations governing the safe handling and use of hazardous substances, including medications, in care environments.

5.3 Legal and Regulatory Terminology

- Regulation 12: Safe Care and Treatment – A regulation under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, requiring providers to ensure that service users are provided with safe care, including safe and effective medication management.
- Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment – A regulation under the Health and Social Care Act 2008, focusing on protecting service users from abuse and neglect, ensuring that medications are administered appropriately and do not cause harm.
- The Mental Capacity Act 2005: Legislation that outlines the framework for making decisions on behalf of individuals who lack the capacity to make decisions for themselves. This is particularly relevant when considering consent for medication administration in service users who cannot understand the implications of their treatment.
- The Medicines Act 1968: Legislation that regulates the manufacture, supply, and distribution of medicines. It sets standards for the legal use and handling of medicines, ensuring their safe management within care settings.

5.4 Scientific and Clinical Terms

- Pharmacokinetics: The study of how the body absorbs, distributes, metabolizes, and excretes drugs. This knowledge helps determine how often medications should be administered to achieve therapeutic effects.
- Pharmacodynamics: The study of the effects of medications on the body, including their mechanism of action. This is important in determining the right medication and dosage for service users, particularly those with complex health needs.
- Side Effects: Unintended effects of medications that can range from mild to severe. Risk assessments will identify potential side effects, and monitoring will ensure they are managed effectively.
- Adverse Drug Reactions (ADRs): Harmful or unintended reactions to a medication that occur at normal doses. This includes allergic reactions, toxicity, and drug interactions.
- Medication Review: A systematic process conducted by healthcare professionals to ensure that medications are still necessary and that they are being used safely and effectively.

5.5 Service User-Specific Terms

- Learning Disabilities: A condition that affects the way a person learns new things and may impact their ability to understand and manage medications independently. This term also encompasses conditions such as Down syndrome and autism.
- Autism Spectrum Condition (ASC): A developmental disorder that affects a person's social interaction, communication, and behaviour. People with ASC may have specific needs regarding medication management, and these must be taken into account when developing care plans.
- Mental Health Needs: Conditions that affect a person's thinking, feeling, mood, or behaviour, which can impact their ability to manage medications effectively. This includes conditions such as schizophrenia, bipolar disorder, and depression.

6. LEGISLATIVE AND REGULATORY FRAMEWORK

This Medicines Management Policy and Procedure is designed to ensure compliance with all relevant UK legislation, regulations, and guidelines to provide the highest standard of care in the safe management of medicines for service users. The policy reflects the needs of adults with learning disabilities, mental health needs, and autism spectrum conditions, ensuring that all medication management is conducted in a manner that respects their rights, dignity, and health, while complying with national standards and regulations.

The Legislative and Regulatory Framework includes the following key pieces of legislation, standards, and guidelines that inform and govern this policy:

6.1 Care Quality Commission (CQC)

- Legislation: *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014*
- Key Considerations: The CQC is the independent regulator of health and social care in England. The Regulated Activities Regulations 2014, particularly Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, require that service providers ensure the safe management of medicines and protect service users from potential harm, abuse, or mistreatment.
    - Regulation 12 emphasizes the need for safe care practices, which includes the appropriate handling, storage, administration, and disposal of medicines.
    - Regulation 13 ensures that service users are safeguarded from abuse, including medication-related harm.

This policy ensures that Primus PLUS Healthcare complies with these regulations to provide safe, effective, and compassionate care to service users, particularly those with learning disabilities, mental health conditions, and autism spectrum conditions.

6.2 National Institute for Health and Care Excellence (NICE)

- Legislation/Guidelines: *NICE Guidelines on Medicines Management*
- Key Considerations: NICE provides evidence-based guidance to improve health and social care practices, including the safe use of medicines. The NICE guidelines on medicines management ensure that medications are prescribed, administered, reviewed, and disposed of in a way that prioritizes safety and efficacy.
    - The NICE guidelines cover topics such as the safe management of medicines in care settings, the use of psychotropic medications for individuals with learning disabilities and autism, and the importance of conducting regular medication reviews.

This policy follows NICE's recommendations to ensure that all medication practices for service users with complex needs (such as autism and learning disabilities) are safe, appropriate, and evidence-based.

6.3 The Medicines Act 1968

- Legislation: *The Medicines Act 1968*
- Key Considerations: This act is the key piece of legislation that governs the manufacture, sale, and supply of medicinal products in the UK. It covers the requirements for the storage,

handling, and dispensing of medicines, as well as the safe administration of controlled substances.

    - The policy ensures that controlled drugs (e.g., opioids and sedatives) are managed in strict compliance with the Misuse of Drugs Act 1971, and that staff are trained in safe handling procedures.

Compliance with The Medicines Act 1968 ensures that medicines are dispensed, handled, and administered according to the law, ensuring service user safety.

6.4 The Misuse of Drugs Act 1971

- Legislation: *The Misuse of Drugs Act 1971*
- Key Considerations: This act regulates the control of controlled substances (e.g., prescription medications such as opiates, sedatives, and psychotropic drugs). It establishes the legal framework for the classification and safe handling of these substances.
    - The policy outlines procedures for the storage, administration, and disposal of controlled drugs in line with the Misuse of Drugs Act 1971, ensuring that controlled substances are handled by appropriately trained staff and stored securely.

6.5 The Mental Capacity Act 2005

- Legislation: *The Mental Capacity Act 2005*
- Key Considerations: This Act provides a framework to support individuals who may lack the capacity to make decisions for themselves, including decisions about their medication. It ensures that individuals are supported in making decisions, and that decisions are made in their best interests when they are unable to do so themselves.
    - The policy follows the Mental Capacity Act 2005 to ensure that medications are prescribed and administered appropriately to individuals who may lack the capacity to consent, and that proper documentation of consent is maintained.
    - This policy ensures that service users are supported with the best interests principle and that their rights and preferences are respected throughout the medication management process.

6.6 The Autism Act 2009

- Legislation: *The Autism Act 2009*
- Key Considerations: This Act is the first UK-wide legislation aimed at improving the lives of adults with autism. It includes provisions for services to be designed to meet the needs of individuals with autism, including medication management.
    - The policy incorporates the National Autism Strategy, ensuring that medications are managed in a way that is sensitive to the needs of individuals with autism spectrum conditions.

6.7 Health and Social Care Act 2012

- Legislation: *Health and Social Care Act 2012*

- Key Considerations: The Health and Social Care Act 2012 ensures that health and social care providers are regulated, and that services comply with standards that ensure safe and effective care, including safe medicines management.
    - This policy ensures that all medication practices meet the standards for safe care and treatment as outlined by the CQC and other relevant regulatory bodies.

6.8 The Control of Substances Hazardous to Health (COSHH) Regulations 2002

- Legislation: *COSHH Regulations 2002*
- Key Considerations: These regulations govern the safe handling and storage of hazardous substances, including certain medications, to protect both staff and service users from harm.
    - The policy includes provisions for the safe handling of sharps, gases, and other potentially hazardous substances, in compliance with COSHH Regulations.

6.9 STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People)

- Guidelines/Initiative: *STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People)*
- Key Considerations: STOMP is an initiative aimed at reducing the unnecessary use of psychotropic medication in people with learning disabilities and autism. The policy ensures that medications are prescribed and reviewed carefully to prevent over-medication, promoting appropriate treatment for these service users.
    - This policy integrates STOMP principles to ensure that medication is used as part of a holistic approach to care, avoiding over-medication where possible.

6.10 Supporting Treatment and Appropriate Medication in Paediatrics (STAMP)

- Guidelines/Initiative: *STAMP (Supporting Treatment and Appropriate Medication in Paediatrics)*
- Key Considerations: STAMP focuses on ensuring that children and young people receive appropriate medication and treatment that meets their developmental and medical needs. This is relevant when considering paediatric needs within a family or care setting, especially where transition occurs for young people with learning disabilities or autism.
    - The policy ensures that children and young people transitioning to adulthood are supported by a thorough medication management plan, including the transition to supported living without personal care settings.

6.11 National Safeguarding Adults Board (NSAB)

- Guidelines: *National Safeguarding Adults Board (NSAB)*
- Key Considerations: The NSAB provides national safeguarding guidelines to protect vulnerable adults from harm, including abuse, neglect, and medication misuse.
    - The policy ensures compliance with the Safeguarding Vulnerable Adults Act 2006, providing clear safeguarding procedures related to medication management, including addressing any issues of potential abuse, misuse, or neglect in relation to medication.

6.12 Data Protection and Confidentiality Laws

- Legislation: *General Data Protection Regulation (GDPR) 2018*
- Key Considerations: This regulation governs how personal data is collected, stored, and used. It applies to all personal data related to service users' medication records.
    - This policy ensures that GDPR principles are followed when handling medication records, ensuring that service users' personal data remains confidential and is used only for the purpose of care.

6.13 Local Authority Guidelines and Local Safeguarding Protocols

- Guidelines: *Local Authority and Safeguarding Guidelines*
- Key Considerations: Local authorities have their own safeguarding frameworks that must be followed to ensure that service users' medication needs are met safely and effectively.
    - The policy aligns with local safeguarding protocols and ensures that medication practices comply with local safeguarding boards to prevent harm and abuse.

7. ROLES AND RESPONSIBILITIES

In accordance with CQC regulations, UK legislation, and national guidelines, this Medicines Management Policy and Procedure outlines the roles and responsibilities of all individuals involved in the management of medicines at Primus PLUS Healthcare. These roles are critical in ensuring that medication is prescribed, administered, stored, and disposed of safely and effectively, and that service users' needs are met in a manner that respects their rights and dignity.

The roles and responsibilities within the policy are as follows:

7.1 Care Workers

Role and Responsibilities: Care workers play a key role in assisting service users with their medication needs. This includes providing the appropriate level of support for medication administration, ensuring safe storage, and supporting service users in managing their medications.

- Assisting with Medication: Care workers assist service users in taking their medication as prescribed, ensuring that they follow the instructions provided by healthcare professionals.
- Monitoring: They observe for any side effects or adverse reactions and report these to the healthcare team immediately.
- Record Keeping: Care workers must complete Medication Administration Records (MAR) accurately, ensuring all medications are documented clearly.
- Reporting Concerns: If there is any concern about a service user's medication or health, care workers must report this promptly to the relevant healthcare professional or manager.
- Training and Competency: Care workers are required to undergo regular training and competency assessments on the safe handling and administration of medicines.

Legislative Compliance: Care workers' roles ensure compliance with Regulation 12 (Safe Care and Treatment) and Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) of

the Care Quality Commission (CQC), ensuring that service users are treated with dignity and that safe medication practices are followed.

7.2 Healthcare Professionals (Doctors, Nurses, and Pharmacists)

Role and Responsibilities: Healthcare professionals are responsible for prescribing, reviewing, and monitoring the medication of service users. They work collaboratively with care workers and managers to ensure the safe and effective management of medicines.

- Prescription and Review: Doctors or other prescribing professionals are responsible for assessing the service user's health condition and prescribing appropriate medications. They also conduct regular reviews to ensure that the medications remain appropriate for the service user's evolving needs.
- Monitoring and Adjusting Treatment: Healthcare professionals monitor the effects of prescribed medications and adjust treatment as necessary. This includes reviewing medication for side effects, effectiveness, and the potential need for adjustments.
- Guidance and Support: They provide guidance to care workers on proper medication administration and support in managing complex cases, including controlled drugs, PRN medications, and covert medication when applicable.

Legislative Compliance: Healthcare professionals' responsibilities comply with Regulation 12 of the CQC regulations and the Medicines Act 1968, ensuring medications are prescribed, monitored, and adjusted safely and effectively.

7.3 Pharmacy Professionals

Role and Responsibilities: Pharmacy professionals ensure that medicines are dispensed accurately, stored properly, and reviewed as necessary. They also support the safe handling of medicines and provide advice on the administration of medications.

- Medication Dispensing: Pharmacists are responsible for accurately dispensing prescribed medications, ensuring that the correct medication, dosage, and form are provided.
- Medicines Review: They review medications to ensure that the service user receives the correct treatment and that medications are not interacting negatively.
- Education and Advice: Pharmacists educate care workers on the safe handling of medicines, including the storage of controlled drugs and the proper handling of sharps and gases.

Legislative Compliance: Pharmacists comply with The Medicines Act 1968, the Misuse of Drugs Act 1971, and Regulation 12 of the CQC, ensuring that medication dispensing and advice adhere to legal standards and best practices.

7.4 Managers and Supervisors

Role and Responsibilities: Managers and supervisors are responsible for overseeing the overall medication management process and ensuring that all policies and procedures are followed consistently. They ensure that staff are adequately trained and supported in medication management tasks.

- Supervision and Oversight: Managers oversee all aspects of medicines management, ensuring that staff are properly trained and that the correct medication administration procedures are followed.

- Staff Training and Competency: They ensure that all staff involved in the administration of medicines are appropriately trained and assessed for competency, providing ongoing support and development.
- Monitoring and Auditing: Managers are responsible for auditing Medication Administration Records (MAR) regularly, ensuring that medications are being administered accurately and that any issues or concerns are promptly addressed.
- Reporting and Corrective Action: Managers ensure that all medication errors, issues, or concerns are reported, investigated, and that corrective actions are implemented when necessary.

Legislative Compliance: Managers' roles comply with CQC Regulations, particularly Regulation 12 (Safe Care and Treatment) and Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), ensuring the safety and well-being of service users through the correct implementation of policies and procedures.

7.5 Service Users

Role and Responsibilities: Service users have the right to be involved in decisions about their medication, where possible, and to receive medication in a manner that respects their autonomy and preferences.

- Informed Consent: Service users are provided with the necessary information to make informed decisions about their medication. If they are unable to provide consent, Mental Capacity Act 2005 procedures are followed, and best interest decisions are made in consultation with family members, carers, or legal representatives.
- Participation: Service users are encouraged to actively participate in decisions about their medication and to communicate their preferences, concerns, or challenges related to their treatment.
- Medication Management in the Home: Where service users manage their own medications at home, they are provided with guidance on safe storage and management.

Legislative Compliance: Service users' involvement in medication decisions adheres to the Mental Capacity Act 2005 and CQC Regulation 13 (Safeguarding Service Users), ensuring that their rights and preferences are respected in accordance with UK legislation.

7.6 Family Members and Legal Representatives

Role and Responsibilities: Family members or legal representatives are involved when service users are unable to make decisions about their medications. They are consulted to ensure that the service user's best interests are considered in medication decisions.

- Informed Consent and Best Interest: In cases where the service user lacks capacity, family members or legal representatives are consulted to provide input into medication decisions, ensuring that the service user's rights are protected, and that decisions are made in their best interest.
- Ongoing Communication: Family members are kept informed of any changes to medication or treatment plans, and their concerns are addressed promptly.

Legislative Compliance: This role is in line with the Mental Capacity Act 2005, ensuring that decisions about medication are made in the service user's best interests when they are unable to consent themselves.

7.7 External Healthcare Providers and Support Services

Role and Responsibilities: External healthcare providers, such as specialist mental health services, learning disability services, and autism-specific care teams, collaborate with Primus PLUS Healthcare to provide integrated care that supports service users' medication needs.

- Collaboration on Medication Management: These professionals provide guidance and expertise on managing medications for individuals with complex needs, ensuring that medications are appropriate and safe.
- Ongoing Monitoring: External providers conduct regular health reviews and offer advice on medication adjustments when necessary.

Legislative Compliance: External healthcare providers ensure that medication management is in line with NICE guidelines and CQC regulations, ensuring the safe and appropriate administration of medicines in the care setting.

8. MEDICINES MANAGEMENT PROCESS

The Medicines Management Process outlined in this policy for Primus PLUS Healthcare is designed to ensure that all aspects of medication management, from prescribing and administration to monitoring and disposal, are carried out safely and effectively in line with CQC regulations, UK legislation, and best practice guidelines. This process is crucial in ensuring that adults with learning disabilities, mental health needs, and autism spectrum conditions are provided with the safest, most effective care possible while respecting their dignity and rights.

The process is divided into several key stages: assessment, prescribing, administration, monitoring, and disposal.

8.1 Assessing Service Users' Medication Needs

Objective: To ensure that each service user's medication requirements are thoroughly assessed to determine the most appropriate treatment plan based on their individual needs.

- Individual Medication Assessment: The assessment of each service user's medication needs is carried out by healthcare professionals, including doctors, psychiatrists, and pharmacists. The assessment takes into account the individual's medical history, diagnosis, current medication regimen, and any underlying conditions that may affect medication use.
- Person-centred Care: The service user's preferences, including how they prefer to take their medication, are taken into consideration, especially for those with learning disabilities or autism. This includes accommodating any sensory or cognitive challenges related to medication administration.
- Collaborative Approach: Where appropriate, the service user's family or legal representatives are involved in the medication assessment process to ensure that all decisions are made in the best interest of the service user.

Legislative Compliance: This aligns with Regulation 12: Safe Care and Treatment of the CQC and NICE guidelines, ensuring the safe and appropriate prescribing and use of medications for each individual.

8.2 Prescribing Medication

Objective: To ensure that medication is prescribed safely, effectively, and in accordance with the service user's medical needs and preferences.

- Healthcare Professional Involvement: Medications are prescribed by qualified healthcare professionals (e.g., GPs, psychiatrists) based on the results of the medication assessment and in consultation with the service user, family members, and other relevant professionals.
- Appropriate Medication: Medications are selected that align with the individual's diagnosis, ensuring that the benefits of the medication outweigh any potential risks, especially for service users with complex needs (e.g., those with learning disabilities or mental health conditions).
- Prescription Review: All prescribed medications are regularly reviewed to ensure they remain appropriate for the service user's evolving needs. This review process includes checking for drug interactions, side effects, and the effectiveness of the medication.

Legislative Compliance: This is in compliance with the Medicines Act 1968, the Misuse of Drugs Act 1971, and Regulation 12 of the CQC, ensuring that medications are prescribed legally and appropriately.

8.3 Administering Medication

Objective: To ensure that medications are administered safely, in accordance with prescribed instructions, and in a manner that supports the service user's well-being.

- Levels of Assistance:
    - Level 1: Independent self-administration with support for reminders (for capable individuals).
    - Level 2: Assisted administration by trained staff, with or without supervision (for individuals who need assistance but retain some independence).
    - Level 3: Full assistance with medication administration (for individuals who are unable to self-administer).
- Medication Administration Records (MARs): Every instance of medication administration is documented on a Medication Administration Record (MAR). This includes details such as the medication name, dose, time, and any observations related to the administration (e.g., refusal, side effects).
- Safe Handling: Medications are administered by appropriately trained staff, following the correct procedures to ensure the safety of the service user, including the use of gloves when necessary for handling medications such as creams or controlled drugs.
- Covert Medication: Covert medication administration (where medication is given without the service user's knowledge) will only be used in exceptional circumstances, following guidance from the Mental Capacity Act 2005 and in consultation with relevant professionals and family members. Proper documentation will be maintained for any covert administration.

- PRN (As Required) Medication: PRN medications will only be administered when necessary, with clear documentation of the reason for administration, the dose given, and the time it was administered.

Legislative Compliance: This ensures compliance with Regulation 12: Safe Care and Treatment and CQC requirements for proper medication administration and documentation.

8.4 Storing Medication Safely

Objective: To ensure that all medications are stored in accordance with legal and safety guidelines to prevent misuse, theft, and deterioration.

- Secure Storage: All medications, including controlled drugs, are stored securely in locked cabinets or other secure areas. Controlled substances are stored separately in accordance with legal requirements.
- Temperature Control: Medications that require specific temperature conditions (e.g., refrigerated medications) are stored in temperature-controlled environments to ensure their efficacy.
- Personal Medication Storage: Where appropriate, service users may store their own medications in their homes. The policy ensures that storage guidelines are clearly communicated to service users to maintain safe practices.

Legislative Compliance: This complies with COSHH regulations (Control of Substances Hazardous to Health), The Medicines Act 1968, and Misuse of Drugs Act 1971, ensuring that medications are stored safely and in accordance with legal requirements.

8.5 Managing Medication Errors and Omissions

Objective: To ensure that any medication errors, omissions, or adverse reactions are promptly identified, reported, and addressed to ensure service user safety.

- Error Reporting: Any medication errors (e.g., missed doses, incorrect dosages) or omissions are reported immediately to the relevant healthcare professional and manager. A detailed record of the error or omission is documented.
- Corrective Actions: After identifying the cause of the error or omission, corrective actions are implemented, which may include retraining staff, adjusting procedures, or conducting further assessments of the service user's medication needs.
- Adverse Reactions: Any adverse reactions to medications are documented and reported to the healthcare team. Appropriate action is taken to address any health concerns, which may include adjusting the medication regimen or referring the service user for further medical review.

Legislative Compliance: This process ensures compliance with Regulation 12: Safe Care and Treatment of the CQC, ensuring that medications are administered safely, and that any errors or issues are promptly reported and corrected.

8.6 Refusals and Safe Disposal of Medicines

Objective: To ensure that service users who refuse medications are properly supported, and that medications are disposed of in a safe and legally compliant manner.

- Medicine Refusals: If a service user refuses to take their medication, the reason for the refusal is documented and the healthcare professional is informed. If necessary, a review is conducted to address any concerns the service user may have about their medication.
- Safe Disposal: Expired or unused medications are disposed of in accordance with pharmacy guidelines and local waste disposal regulations to prevent misuse or environmental harm.

Legislative Compliance: This ensures compliance with The Medicines Act 1968, COSHH regulations, and CQC regulations, ensuring medications are disposed of in a manner that is safe, responsible, and compliant with the law.

8.7 Monitoring Medication Effectiveness and Safety

Objective: To ensure that medications remain effective and safe for the service user, and that regular reviews are conducted.

- Regular Medication Reviews: Healthcare professionals conduct periodic reviews of all medications prescribed, ensuring that the medications are still appropriate for the service user's condition and that there are no adverse effects.
- Health Monitoring: Service users' health is regularly monitored for any signs of side effects or complications resulting from their medications (e.g., monitoring vital signs, mental health status, and physical health).

Legislative Compliance: This ensures compliance with NICE guidelines and Regulation 12 of the CQC, promoting the ongoing safety and effectiveness of medications through regular monitoring and review.

8.8 Communication and Documentation

Objective: To ensure clear and accurate communication between all parties involved in the medication management process, and that accurate records are kept.

- Communication: Clear protocols are established to ensure that any changes in medication, side effects, or issues with medication administration are communicated promptly to the relevant healthcare professionals, staff, and service users.
- Record Keeping: Accurate and up-to-date Medication Administration Records (MARs) are maintained for all service users. These records document all aspects of medication management, including prescribing, administration, and any issues that arise.

Legislative Compliance: This aligns with CQC regulations and ensures compliance with GDPR for the accurate and secure handling of service users' medication data.

9. TRAINING AND COMPETENCY

At Primus PLUS Healthcare, we are committed to ensuring that all staff involved in the management and administration of medicines are properly trained and have the necessary competency to provide safe, effective care. This training and competency framework is designed to ensure compliance with CQC regulations, UK legislation, and best practice guidelines, while also addressing the specific needs of service users with learning disabilities, mental health needs, and autism spectrum conditions in supported living without personal care services.

This section outlines the training requirements, the competency assessment process, and how we ensure that our staff continue to develop their skills to maintain high standards in medicines management.

9.1 Induction Training

Objective: To ensure that all new staff involved in the administration and management of medicines receive comprehensive induction training before undertaking medication tasks.

- Content of Induction Training:
    - Overview of Medicines Management: Understanding the principles of safe medicines management, including the processes of prescribing, administering, storing, and disposing of medications.
    - Legislation and Regulatory Compliance: Staff are trained on relevant legislation and regulations, such as Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment (CQC), The Medicines Act 1968, The Misuse of Drugs Act 1971, and the Mental Capacity Act 2005.
    - Safeguarding and Risk Management: Specific training on recognizing and reporting safeguarding concerns related to medications, including abuse, neglect, and errors.
    - Service User-Specific Needs: Tailored training on how to manage medications for service users with learning disabilities, mental health conditions, and autism spectrum conditions, ensuring a person-centred approach to care.
- Competency Check: At the end of the induction training, staff will undergo an initial competency assessment to confirm that they understand key principles and can demonstrate the safe handling of medications in a controlled environment.

Legislative Compliance: The induction training is designed to comply with CQC regulations, Health and Social Care Act 2008, Regulation 12, and relevant NICE guidelines, ensuring that staff are prepared to provide safe and legal medication management.

9.2 Ongoing Training and Professional Development

Objective: To ensure that all staff maintain and enhance their skills, knowledge, and competence in managing medications through continuous professional development.

- Annual Training Updates: Staff receive annual training updates, which cover:
    - Changes to regulations or legislation related to medications (e.g., updates to CQC guidelines, The Medicines Act, or Mental Capacity Act).
    - The safe administration of covert medications, PRN medications, and controlled drugs.
    - Best practices for medication handling, error prevention, and ensuring that service users are protected from abuse or neglect.
    - Specific training on STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People) to prevent over-medication and promote the appropriate use of psychotropic medications.

- Medication Management Workshops: These workshops focus on real-world challenges faced in supported living without personal care, such as dealing with refusals of medication, understanding side effects, and ensuring that medications are appropriately tailored to the needs of individuals with autism and learning disabilities.
- Feedback and Reflection: Staff are encouraged to engage in feedback and reflective practices to continuously improve their medication administration skills.

Legislative Compliance: Continuous training is in compliance with CQC Regulation 18 (Staffing) and Regulation 12 (Safe Care and Treatment), ensuring staff remain up-to-date with legislation and best practices.

9.3 Competency Assessment

Objective: To regularly assess the competency of staff involved in the administration and management of medicines to ensure they are qualified and capable of performing their roles safely and effectively.

- Initial Competency Assessment: Upon completing the induction training, new staff are assessed through:
    - Theoretical Assessment: Staff must demonstrate their understanding of key policies, procedures, and legal requirements for managing medicines.
    - Practical Assessment: Staff must demonstrate their competence in safe medication administration, including correct dosing, use of Medication Administration Records (MAR), and safe handling of controlled substances.
- Regular Competency Reviews: Competency assessments are conducted on an ongoing basis (at least annually) to ensure that staff remain competent in their roles. This includes:
    - Observation of Medication Administration: Managers observe staff during medication administration to ensure that proper procedures are followed, and that there are no lapses in care.
    - Knowledge-based Tests: Periodic testing of staff knowledge on medication types, legislation, and medication safety practices.
    - Practical Evaluations: Ongoing practical assessments where staff demonstrate their ability to handle medications safely, including managing complex cases, such as covert medication or handling medications for service users with autism.
- Performance Feedback: After each competency review, feedback is provided to staff. If necessary, additional training or support is provided to address any gaps in knowledge or skills.

Legislative Compliance: The competency assessment process complies with CQC Regulation 18 (Staffing) and Regulation 12 (Safe Care and Treatment), ensuring that only competent staff are involved in medication administration.

9.4 Delegated Healthcare Tasks and Competency

Objective: To ensure that staff who are delegated healthcare tasks (such as administering insulin or managing controlled drugs) are adequately trained and assessed for competence.

- Delegation Protocols: Any healthcare tasks that are delegated to care staff (e.g., insulin administration, wound care, or medication management) are clearly outlined and the relevant staff members must receive targeted training.
- Competency Verification: Competency assessments are conducted before delegation and regularly thereafter. This ensures that staff have the skills and knowledge necessary to carry out delegated tasks safely.

Legislative Compliance: The delegation of healthcare tasks is in compliance with CQC Regulation 12 and the Health and Social Care Act 2008, ensuring the safe delegation of responsibilities and the competence of the staff involved.

9.5 Ensuring Staff Know Who to Contact About Medication Concerns

Objective: To ensure that staff know who to contact if they have any concerns about medication administration or if they encounter any issues, including errors, side effects, or conflicts with prescribed treatments.

- Clear Reporting Channels: Staff are provided with clear guidance on who to contact for medication-related concerns. This includes:
    - Managers or Supervisors: For immediate concerns or queries about medication practices.
    - Healthcare Professionals: For clinical concerns, such as side effects or changes to medication.
    - Pharmacists: For advice on medication interactions, contraindications, or changes to prescriptions.
- Escalation Procedures: If a concern or issue cannot be resolved at the initial level, staff are trained in the proper escalation procedures to ensure the issue is addressed promptly and in accordance with the policy.

Legislative Compliance: This ensures compliance with CQC Regulation 12 (Safe Care and Treatment), which requires clear and accessible channels for reporting and addressing medication concerns.

9.6 Evaluating and Monitoring Training and Competency

Objective: To regularly evaluate and monitor the effectiveness of training and competency assessments, ensuring continuous improvement in the medication management process.

- Annual Review of Training Programs: The effectiveness of training programs is reviewed annually. Feedback from staff and managers is used to identify areas for improvement and update training materials and protocols as needed.
- Quality Assurance Audits: Regular audits are conducted to assess whether staff are adhering to the policy and procedures, ensuring that competency standards are consistently met.
- Service User Feedback: Service users' experiences and satisfaction with medication administration are taken into account, ensuring that training and practices align with their needs and preferences.

Legislative Compliance: This process ensures ongoing compliance with CQC Regulation 12 (Safe Care and Treatment), Regulation 13 (Safeguarding Service Users), and other relevant regulatory bodies to maintain a high standard of care.

10. GOVERNANCE AND RECORD KEEPING

The Governance and Record Keeping section of this Medicines Management Policy and Procedure for Primus PLUS Healthcare ensures that there is a clear and effective structure in place for overseeing the safe and effective management of medicines. It emphasizes the importance of transparency, accountability, and compliance with CQC regulations, UK legislation, and best practice guidelines. This policy establishes procedures to ensure the proper documentation and ongoing monitoring of medication administration, while maintaining service users' safety and promoting high standards of care for adults with learning disabilities, mental health needs, and autism spectrum conditions.

10.1 Governance Arrangements

Objective: To establish robust governance frameworks that ensure the safe, consistent, and effective management of medicines across the organization.

- Responsibility for Medicines Management: The overall responsibility for medicines management lies with senior managers and designated medication leads. They are accountable for ensuring that policies are implemented effectively, and that the staff adhere to procedures, guidelines, and legislative requirements.
- Medicines Management Committee: A Medicines Management Committee (or designated team) is established, consisting of key staff members such as healthcare professionals, pharmacy staff, and managers. This committee oversees the medicines management process and ensures ongoing improvement in medication practices, including periodic reviews of medication policies, incident reports, and feedback from service users and staff.
- Regular Audits and Inspections: To maintain the highest standards of care, the policy mandates regular internal audits of medicines management practices, including:
    - Monthly or quarterly audits of Medication Administration Records (MAR).
    - Spot checks on medication storage and the administration process.
    - Reviews of prescription charts to ensure compliance with prescribed treatment plans.
- Compliance Monitoring: Managers are tasked with ensuring that audits are conducted, findings are documented, and corrective actions are implemented promptly to address any identified issues.

Legislative Compliance: The governance arrangements ensure compliance with CQC Regulation 12 (Safe Care and Treatment), Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), and Regulation 18 (Staffing), ensuring continuous monitoring and improvement of care standards.

10.2 Medication Administration Records (MARs)

Objective: To ensure that Medication Administration Records (MARs) are kept up to date, accurately reflect medication administration, and are easily accessible for auditing and review.

- Accurate Documentation: Each instance of medication administration is documented in the MAR, including the medication name, dose, time, route of administration, and any observations made (e.g., side effects, refusals, or concerns).
- MAR Access and Review: The MARs are maintained in a secure, easily accessible format, and staff involved in medication administration should have immediate access to them. These records are reviewed regularly to ensure compliance with medication prescriptions and that any discrepancies or issues are promptly addressed.
- Record Retention: MARs are retained for a minimum of five years after the date of the last entry, in accordance with legal requirements. This retention ensures that records are available for review during internal audits or external inspections.
- Updating MARs: Any errors, omissions, or changes in medication must be accurately documented and addressed, ensuring that records reflect the most up-to-date medication plan for each service user.

Legislative Compliance: This complies with Regulation 12 of the CQC regulations, ensuring that accurate and complete records are maintained for all service users' medications.

10.3 Reporting of Medication Errors and Concerns

Objective: To establish clear procedures for the timely and transparent reporting of medication errors, concerns, and adverse events.

- Error Reporting Process: All medication errors (e.g., missed doses, incorrect medications, or side effects) must be immediately reported to a manager or supervisor. These errors should be documented in the MAR, along with the corrective actions taken and any follow-up care provided to the service user.
- Root Cause Analysis: When a medication error occurs, an investigation will be conducted to determine the root cause of the error. The investigation will look into staff training, procedure adherence, and the presence of systemic issues that may have contributed to the error. Corrective actions will be taken to prevent recurrence.
- Adverse Drug Reactions (ADRs): Any adverse drug reactions (ADRs) or side effects must be promptly reported and documented in the service user’s medical records. The prescribing healthcare professional should be informed so that necessary adjustments to the treatment plan can be made.
- External Reporting: Serious medication errors or ADRs may need to be reported to external bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), or other regulatory authorities, in accordance with reporting guidelines.

Legislative Compliance: This process ensures compliance with CQC Regulation 12 (Safe Care and Treatment) and the Medicines Act 1968, and follows best practice guidance for medication error reporting and prevention.

10.4 Staff Competency and Training Records

Objective: To maintain up-to-date records of staff training, competencies, and qualifications related to medicines management.

- Training Records: All staff involved in the management and administration of medications must have up-to-date training records that document the completion of induction training, ongoing training, and competency assessments. These records must be reviewed regularly to ensure compliance with training requirements.
- Competency Assessments: Staff must undergo regular competency assessments to ensure their knowledge and skills are current. These assessments should be documented and stored in individual personnel files, and any gaps identified must be addressed with further training or supervision.
- Training Completion: Staff who are new to the role or are involved in a new task (e.g., managing controlled drugs) will not be allowed to administer medication until they have completed the necessary training and demonstrated competence in that area.

Legislative Compliance: The maintenance of these records ensures compliance with CQC Regulation 18 (Staffing), ensuring that all staff are appropriately trained and competent in their medication responsibilities.

10.5 Confidentiality and Data Protection

Objective: To ensure that all medication records and service user information are stored and managed in compliance with data protection laws.

- Confidentiality: All medication records, including MARs and personal service user details, must be kept confidential. These records should only be accessible to authorized personnel involved in the service user's care.
- Data Protection: All staff must adhere to the General Data Protection Regulation (GDPR) and Data Protection Act 2018, ensuring that service users' personal data, including medication information, is securely stored and managed.
- Secure Storage: Medication records must be stored securely in both digital and paper formats, with access limited to those who are authorized to view them. Digital records must be stored within a secure system with appropriate encryption and password protection.

Legislative Compliance: This ensures compliance with GDPR, Data Protection Act 2018, and CQC regulations, safeguarding service users' privacy and ensuring the secure management of sensitive information.

10.6 Communication and Accountability

Objective: To ensure clear communication and accountability in the medicines management process.

- Communication Protocols: Clear communication channels must be established between all relevant parties involved in the medication management process, including care staff, healthcare professionals, pharmacy staff, and managers.
- Accountability: Each member of the healthcare team must be accountable for their actions and responsibilities related to medication management. This accountability ensures that errors or omissions are identified and rectified promptly.
- Feedback and Improvement: Regular meetings and feedback mechanisms should be established to discuss any concerns, errors, or challenges related to medication management.

This promotes continuous improvement and ensures that medication practices align with best practices and legal requirements.

Legislative Compliance: This ensures compliance with CQC Regulations, Regulation 12 (Safe Care and Treatment), and Regulation 18 (Staffing), ensuring proper accountability and communication within the medication management process.

10.7 Review and Evaluation of Policy and Procedure

Objective: To ensure that the medicines management policy remains up to date and effective.

- Policy Review: The medicines management policy will be reviewed annually or when there are significant changes to regulations, legislation, or operational procedures. Feedback from staff, service users, and audits will be considered as part of the review process.
- Continuous Improvement: The policy encourages ongoing evaluation to identify areas for improvement in medicines management, ensuring that care practices evolve in line with best practice guidelines and regulatory changes.

Legislative Compliance: Regular review ensures that Primus PLUS Healthcare remains compliant with CQC regulations and all relevant legislation, ensuring that our medicines management processes continually meet the highest standards.

11. SAFEGUARDING AND RISK MANAGEMENT

The Safeguarding and Risk Management section of this Medicines Management Policy and Procedure ensures that Primus PLUS Healthcare maintains a proactive approach to safeguarding service users, especially adults with learning disabilities, mental health needs, and autism spectrum conditions, in supported living without personal care services. It ensures the safety, well-being, and dignity of service users by addressing potential risks associated with medication management and taking appropriate measures to prevent abuse, neglect, and harm.

This section outlines the safeguarding principles and risk management strategies that should be followed in relation to medicines management. These are crucial to ensuring compliance with CQC regulations, UK legislation, and best practice guidelines in the care of vulnerable adults.

11.1 Safeguarding Service Users from Medication-Related Abuse and Improper Treatment

Objective: To protect service users from abuse, neglect, and improper treatment related to medication practices.

- Safeguarding Policies and Procedures: All staff are required to follow Primus PLUS Healthcare's Safeguarding Policies, which ensure that the service users are protected from medication-related abuse, such as the misuse of medication, coercion, or neglect in the administration of their treatment.
- Vigilance for Medication-Related Abuse: Staff must remain vigilant and report any concerns about potential medication abuse, such as:
    - Over-medication or under-medication that could be harmful.
    - Misuse of controlled drugs or other substances.

    - Covert medication administration without appropriate consent, especially for service users with learning disabilities or mental health needs.
- Staff Reporting: Any suspected or actual cases of medication-related abuse must be reported immediately to managers, the safeguarding lead, or an external body if necessary (e.g., local safeguarding boards or CQC).

Legislative Compliance: This policy complies with Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment of the CQC regulations, the Safeguarding Vulnerable Adults Act 2006, and the Mental Capacity Act 2005, ensuring that service users are protected from abuse, neglect, and improper treatment in all aspects of medicines management.

11.2 Risk Assessments Related to Medicines Management

Objective: To identify, assess, and mitigate risks associated with medication administration, storage, and handling to ensure service user safety.

- Risk Identification and Assessment: A comprehensive medication risk assessment is conducted for each service user to identify any risks associated with their medication management, such as:
    - Allergic reactions or adverse effects.
    - Drug interactions or contraindications.
    - Risk of overdose, especially with controlled substances or high-risk medications.
    - Risk of misuse, particularly with PRN medications or those requiring specific administration schedules.
- Risk Mitigation: Once risks are identified, strategies are developed to mitigate these risks. These strategies may include:
    - Adjustments to the medication regimen to reduce risks, including the use of alternative therapies or medications.
    - Training for staff on recognizing signs of adverse reactions, side effects, or misuse.
    - Regular monitoring of service users' health to detect any changes in their condition or medication needs.
- Medication Monitoring: Regular health checks, including assessments of vital signs (e.g., blood pressure, blood sugar), should be conducted to monitor for adverse effects and ensure that the prescribed medication remains appropriate for the service user’s condition.

Legislative Compliance: Risk assessments comply with Regulation 12: Safe Care and Treatment of the CQC, ensuring that medication practices do not pose unnecessary risks to service users' health or safety.

11.3 Ensuring Safe Handling of Medication and Reducing Risks of Medication Errors

Objective: To reduce the risk of medication errors by ensuring safe handling, storage, and administration of medications.

- Safe Medication Handling: Medication must be stored securely and handled only by trained and authorized staff. This includes ensuring that:

    - Controlled drugs are stored in secure, locked cabinets, and that only authorized personnel have access to them.
    - Sharps (e.g., needles, syringes) are disposed of safely and stored in accordance with COSHH guidelines to prevent injury and contamination.
- Minimizing Medication Errors: Steps to minimize medication errors include:
    - Double-checking medications before administration to ensure the correct medication, dose, and time.
    - MARs must be accurately completed for each service user, and any discrepancies must be reported immediately.
    - Regular audits of medication practices to ensure adherence to policies and procedures.
- Training and Competency: Staff must undergo regular training on safe medication handling practices, including:
    - Medication administration procedures.
    - The identification of medication errors and how to respond to them.
    - Safe disposal methods for unused or expired medications.

Legislative Compliance: This process ensures compliance with Regulation 12: Safe Care and Treatment and CQC requirements, minimizing medication-related risks and ensuring safe practices in line with The Medicines Act 1968 and COSHH regulations.

11.4 Preventing Over-Medication and Addressing the Risks of Polypharmacy

Objective: To prevent the over-medication of service users, particularly those with learning disabilities and autism, and to ensure that polypharmacy (the use of multiple medications) is carefully managed.

- STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People): The STOMP initiative is incorporated into the policy to reduce the unnecessary use of psychotropic medications, ensuring that these medications are prescribed only when absolutely necessary and with careful consideration of alternative treatments.
- Polypharmacy Management: Service users who are prescribed multiple medications should be regularly reviewed by healthcare professionals to ensure that the medications are still appropriate and that no adverse interactions are occurring.
- Medication Reviews: Regular reviews of the service user's medications, conducted by healthcare professionals, ensure that only necessary medications are prescribed and that there are no unnecessary or harmful medications in use.

Legislative Compliance: The policy follows the STOMP guidelines and is in line with CQC regulations and NICE guidelines, ensuring that service users receive only the medications that are in their best interest and that polypharmacy is managed safely.

11.5 Covert Medication Administration Safeguards

Objective: To ensure that covert medication administration is only used when absolutely necessary and in compliance with legal and ethical guidelines.

- Covert Medication Policy: Covert medication (administration without the service user's knowledge) will only be considered when the service user is unable to consent to treatment due to their mental capacity. This must be done in the best interest of the service user and after a careful Mental Capacity Act 2005 assessment.
- Best Interest Decision: When covert medication is considered, the Mental Capacity Act 2005 principles must be followed. The decision should be made by a team of healthcare professionals, the service user's family or advocate, and, where necessary, the local safeguarding board.
- Documentation: Any use of covert medication must be fully documented, with clear explanations of why this method was chosen, the consultation process, and the specific medication administered. The use of covert medication must be reviewed regularly to assess its continued necessity.

Legislative Compliance: This policy complies with The Mental Capacity Act 2005 and CQC Regulation 13, ensuring that covert medication is administered lawfully and ethically.

11.6 Procedures for Responding to Medication Refusals and Medicine-Related Risks

Objective: To address medication refusals in a way that respects the service user's autonomy while safeguarding their health and well-being.

- Medication Refusal Protocol: If a service user refuses medication, the following steps must be followed:
    - Identify the reason for refusal and discuss it with the service user, if possible.
    - Consult healthcare professionals to evaluate whether the medication is still necessary or if an alternative treatment may be more appropriate.
    - Document the refusal and the steps taken in the MAR and the service user's care plan.
- Addressing Risks of Medication Refusals: If the refusal poses a serious health risk (e.g., refusing a life-saving medication), the service user's family or legal representative must be informed and involved in the decision-making process.

Legislative Compliance: This aligns with Regulation 12 (Safe Care and Treatment) and CQC safeguarding regulations, ensuring that service users' rights are respected while minimizing the risks to their health.

12. STOMP (STOPPING OVER-MEDICATION OF PEOPLE WITH LEARNING DISABILITIES AND AUTISTIC PEOPLE)

The STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People) initiative is a key component of this Medicines Management Policy and Procedure at Primus PLUS Healthcare. STOMP aims to reduce the unnecessary use of psychotropic medications for people with learning disabilities and autistic people, ensuring they receive medications only when absolutely necessary, and with careful consideration of all available treatment options. This policy incorporates STOMP principles to ensure that the medications prescribed to service users are in their best interests, are carefully monitored, and are only used when appropriate.

This section of the policy is specifically designed to meet the needs of adults with learning disabilities, mental health needs, and autism spectrum conditions in supported living without personal care services. It ensures compliance with CQC regulations, NICE guidelines, and other relevant legislation to guarantee that over-medication is prevented and that service users receive the most appropriate care.

12.1 STOMP Principles

Objective: To ensure that psychotropic medication use is carefully considered, minimized when possible, and monitored to avoid over-medication.

- Psychotropic Medication Minimization: The policy emphasizes that psychotropic medications (such as antipsychotics, antidepressants, and sedatives) should only be prescribed when there is clear, evidence-based justification. Primus PLUS Healthcare will avoid the routine use of these medications unless absolutely necessary, opting for non-pharmacological interventions wherever possible.
- Holistic Care Approach: The policy advocates for a holistic care approach that includes behavioural support strategies, psychological interventions, and other forms of non-pharmacological treatment for managing challenging behaviours or mental health symptoms associated with autism or learning disabilities.
- Comprehensive Review of Medication: All medications prescribed for service users, especially psychotropic drugs, will be reviewed regularly by healthcare professionals. This review process will consider the service user's health status, medication effectiveness, and potential side effects to assess whether the medication is still required.

12.2 STOMP Implementation at Primus PLUS Healthcare

Objective: To establish a structured, evidence-based approach to reducing over-medication and ensuring that medication use is fully justified and beneficial to service users.

- Medication Reviews:
    - Regular medication reviews will be conducted for all service users who are prescribed psychotropic medications. These reviews will be carried out by a multidisciplinary team (MDT) consisting of healthcare professionals such as doctors, psychiatrists, nurses, and pharmacists.
    - The purpose of these reviews is to ensure that psychotropic medications are still necessary, that the service user is benefiting from the medication, and that there are no safer or more appropriate alternatives.
- Informed Consent and Involvement:
    - Service users and their families (where applicable) will be involved in the decision-making process when psychotropic medications are prescribed. This includes ensuring that informed consent is obtained, and that the service user understands the potential benefits and risks of the medication.
    - For service users who lack capacity, decisions about medication will be made in their best interests, following the Mental Capacity Act 2005 principles, and involving family members, advocates, and healthcare professionals as appropriate.
- Non-Pharmacological Interventions:

- Primus PLUS Healthcare will explore non-medication interventions, including person-centred behavioural strategies, autism-specific therapies, and other psychological support to manage challenging behaviours and mental health conditions.
- Staff will receive training in alternative interventions that prioritize the service user's autonomy and well-being without the use of sedative or psychotropic medications whenever possible.

12.3 STOMP Monitoring and Reporting

Objective: To ensure that the use of psychotropic medications is continuously monitored, and that any concerns regarding over-medication are addressed promptly.

- Monitoring Psychotropic Medication Use:
  - Service users who are prescribed psychotropic medications will be closely monitored for potential side effects, including sedation, weight gain, metabolic issues, and cognitive effects. Monitoring will include regular health checks and screenings for conditions that are commonly associated with psychotropic drug use.
- Audit of Medication Practices:
  - An audit process will be implemented to ensure that psychotropic medications are prescribed in line with STOMP principles. The audit will review medication usage patterns, the necessity of psychotropic drugs, and the effectiveness of non-pharmacological interventions.
  - The results of the audit will inform training and policy revisions as necessary to improve the medication management process and reduce the risk of over-medication.
- Reporting Concerns:
  - Any concerns regarding over-medication or inappropriate prescribing practices will be reported through the organization's incident reporting system. These concerns will be investigated promptly, and actions will be taken to address any identified issues.
  - The findings from medication audits, concerns about over-medication, and feedback from service users and staff will be reviewed regularly by the Medicines Management Committee or relevant oversight body.

Legislative Compliance: These monitoring and reporting practices comply with Regulation 12 (Safe Care and Treatment) and Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) of the CQC regulations, ensuring that medication practices are transparent and that service users are protected from over-medication and its potential harms.

12.4 STOMP and STAMP: Implementing Guidelines for Specific Populations

Objective: To ensure that STOMP is implemented in a way that considers the unique needs of individuals with autism spectrum conditions and learning disabilities in supported living settings.

- Targeted Approaches for Autism and Learning Disabilities:
  - Special attention will be given to service users with autism spectrum conditions and learning disabilities, as these individuals are more likely to be prescribed psychotropic medications due to communication difficulties and behavioural challenges.

- The policy will prioritize person-centred care for individuals with autism or learning disabilities, focusing on the individual's strengths and using therapeutic methods such as speech therapy, occupational therapy, and applied behaviour analysis (ABA) as alternatives to medication.

- STAMP (Supporting Treatment and Appropriate Medication in Paediatrics):
    - STAMP guidelines will be followed in cases where younger service users transition into adult services or require specialized paediatric care for autism or learning disabilities.
    - Medication decisions will be made with a clear understanding of the individual's developmental needs, and the least restrictive options will be pursued to support positive behaviour management.

12.5 STOMP and Service User Empowerment

Objective: To empower service users to have a say in their treatment plans and medication use, ensuring that their rights are respected and that they are fully informed about their care.

- Involvement in Treatment Decisions:
    - Service users will be encouraged and supported to take an active role in decisions regarding their medications, particularly for those who are capable of understanding the implications of their treatment.
    - Service users with learning disabilities or autism may require additional support, such as easy-read formats, visual aids, or advocacy services, to help them understand their treatment options and make informed choices.
- Service User Preferences:
    - Service users' preferences regarding medication, including whether they prefer oral medication, the timing of doses, or alternatives to medication, will be documented in their care plans and considered during medication reviews.

12.6 Training and Awareness for Staff on STOMP

Objective: To ensure that all staff involved in medicines management are fully trained on STOMP principles and the appropriate management of psychotropic medications.

- STOMP Training:
    - Staff will receive training on the STOMP initiative, which includes understanding the risks of over-medication, the importance of exploring non-pharmacological treatments, and how to involve service users and their families in decision-making.
    - Training will include the Mental Capacity Act 2005, best practices in behavioural support, and how to implement alternative therapies effectively.
- Competency Monitoring:
    - Staff will undergo regular assessments to ensure that they understand STOMP principles and can apply them in practice, ensuring that service users receive the least restrictive treatment options.

13. SPECIAL CONSIDERATIONS FOR SERVICE USERS WITH SPECIFIC NEEDS

In compliance with CQC regulations, UK legislation, and best practice guidelines, Primus PLUS Healthcare recognizes that service users with specific needs, including those with learning disabilities, mental health needs, and autism spectrum conditions, require personalized, compassionate, and legally compliant care in the management and administration of medications. This section of the Medicines Management Policy and Procedure outlines the special considerations that must be taken into account when providing medication-related services to these vulnerable populations.

We aim to provide care that respects each individual's unique needs, supports their autonomy, and ensures that they receive safe and effective treatments in line with Regulation 12: Safe Care and Treatment, Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, and other relevant UK legislation.

13.1 Service Users with Learning Disabilities

Objective: To ensure that service users with learning disabilities receive medication in a manner that is safe, appropriate, and sensitive to their specific cognitive and communication needs.

- Person-centred Care Approach: Each service user with learning disabilities will have an individual care plan that incorporates their preferences, cognitive abilities, and communication methods for medication administration.
    - Care plans must specify the level of assistance needed (e.g., reminders, support with administration, or full assistance).
    - Strategies will be put in place to ensure the service user understands their medication regimen as much as possible. This may involve the use of easy-read formats, visual aids, or pictures to support understanding.
- Informed Consent: In cases where the service user can communicate their wishes, informed consent will be obtained regarding their medication. For those who cannot give consent, decisions will be made in line with the Mental Capacity Act 2005, ensuring that decisions about medication are made in their best interests, with the involvement of family members or advocates where appropriate.
- Behavioural Support: Non-pharmacological interventions will be prioritized for managing behaviours associated with learning disabilities, such as speech therapy, behavioural therapy, and environmental modifications to reduce the need for psychotropic medications.
- Regular Medication Reviews: Medications prescribed to service users with learning disabilities will be reviewed regularly by healthcare professionals to ensure their continued appropriateness, particularly when managing conditions such as attention deficit hyperactivity disorder (ADHD) or challenging behaviour.

Legislative Compliance: This approach complies with CQC Regulation 12 (Safe Care and Treatment), Mental Capacity Act 2005, and relevant NICE guidelines, ensuring that medications are administered safely, with full consideration for the service user’s cognitive abilities.

13.2 Service Users with Mental Health Needs

Objective: To provide a safe and supportive environment for service users with mental health conditions, ensuring that their medication is managed in a way that promotes recovery, well-being, and autonomy.

- Psychotropic Medication Management: Service users with mental health needs, including those with depression, bipolar disorder, or schizophrenia, may require medications such as antidepressants, antipsychotics, or mood stabilizers. These medications will be prescribed and managed with great care, following appropriate guidelines.
    - Minimizing Over-Medication: In line with STOMP (Stopping Over-Medication of People with Learning Disabilities and Autistic People), efforts will be made to minimize the use of psychotropic medications and ensure they are prescribed only when necessary. When psychotropic medication is prescribed, regular reviews will be conducted to assess its effectiveness and minimize unnecessary or prolonged use.
- Monitoring for Side Effects: Service users on psychotropic medications will be monitored for potential side effects, including weight gain, sedation, or movement disorders (e.g., tremors). These side effects will be documented in the service user's care plan, and any adverse effects will be reported to a healthcare professional immediately.
- Mental Health Crisis Management: Clear protocols will be in place to manage any mental health crises, ensuring that service users receive appropriate interventions if they experience worsening symptoms or if they refuse medication due to side effects or other concerns.
- Psychosocial Support: A comprehensive approach to mental health will be adopted, including counselling, therapy, and peer support, alongside pharmacological treatments. This ensures that service users receive holistic care, addressing both their medical and emotional needs.

Legislative Compliance: This policy adheres to CQC Regulation 12 (Safe Care and Treatment) and Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), as well as Mental Health Act 1983 (Amended 2007), ensuring that service users with mental health conditions receive care that is appropriate, effective, and respectful.

13.3 Service Users with Autism Spectrum Conditions

Objective: To ensure that service users with autism spectrum conditions (ASC) receive medications that are necessary, safe, and beneficial for managing both physical and behavioural health.

- Individualized Medication Plans: Service users with autism often have specific and complex needs regarding medications. Medication plans will be personalized, considering the individual’s sensory sensitivities, communication challenges, and any other co-occurring conditions such as ADHD or epilepsy.
    - Medications will be prescribed based on the individual's sensory profile and communication style, ensuring that they are comfortable with the medication process and that their preferences are respected.
- Behavioural and Sensory Supports: Non-medication treatments, such as sensory integration therapy, structured routines, and positive behaviour support plans, will be emphasized before psychotropic medications are prescribed. These approaches help minimize reliance on medications to manage behavioural challenges associated with autism.

- Communication and Consent: For individuals who may struggle with communication, alternative methods of ensuring informed consent will be employed, including the use of visual aids, communication boards, or assistive technologies to help convey information about their medication regimen.
- Medication Sensitivity: Special care will be taken to assess and monitor how service users with autism react to medications, particularly regarding side effects related to sensory overload or gastrointestinal distress. Adjustments will be made to the medication regimen to minimize any negative impact on the service user's well-being.

Legislative Compliance: This approach complies with CQC Regulation 12 (Safe Care and Treatment), Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), The Autism Act 2009, and the National Autism Strategy, ensuring that service users with autism receive individualized and appropriate care.

13.4 Service Users with Multiple and Complex Needs

Objective: To provide safe and effective medication management for service users with multiple and complex needs, including those who have combinations of learning disabilities, mental health needs, and autism spectrum conditions.

- Holistic Medication Review: Service users with multiple and complex needs will have regular holistic medication reviews, which include input from a range of healthcare professionals (e.g., GPs, psychiatrists, occupational therapists, and specialists in learning disabilities and autism). This ensures that the service user's medication plan is comprehensive and fully reflects their complex needs.
- Coordinated Care: A multidisciplinary team (MDT) approach will be adopted to ensure that all aspects of the service user's care are integrated, particularly when multiple medications are prescribed. This approach ensures that there are no dangerous drug interactions, and that the service user's mental, emotional, and physical health are all considered.
- Customizing Medication Delivery: Medication regimens may need to be adjusted based on service user preferences, and certain individuals may benefit from medication blister packs, liquid formulations, or other customized delivery systems to accommodate physical or sensory challenges.

Legislative Compliance: The holistic approach to care for individuals with multiple and complex needs is compliant with CQC regulations, Regulation 12 (Safe Care and Treatment), and Mental Capacity Act 2005, ensuring that all aspects of care are considered in the medication management process.

13.5 Ensuring Access to Medicines for All Service Users

Objective: To ensure that service users with specific needs are able to access and use their medication safely and effectively.

- Access to Medicines: Service users will be supported to access their medications in a way that meets their specific needs, ensuring that all service users, including those with learning disabilities, mental health needs, and autism spectrum conditions, receive medications in the safest manner possible, with appropriate assistance if needed.

- Medicines Storage in the Home: For service users who manage their medications in their homes, clear guidelines will be established in collaboration with the service user about how to safely store their medicines to prevent misuse, loss, or injury.
- Involvement of Family and Carers: Where applicable, family members or carers will be involved in the medication management process to ensure that medications are stored, administered, and monitored correctly at home, and that service users have the necessary support to manage their treatment.

Legislative Compliance: This policy ensures compliance with CQC Regulation 12 (Safe Care and Treatment) and NICE guidelines, guaranteeing that all service users, regardless of their specific needs, are supported in the safe management of their medications.

14. PROCEDURES FOR MEDICINE REFUSALS AND SAFE DISPOSAL METHODS

At Primus PLUS Healthcare, we are committed to ensuring the safe and effective management of medicines in line with CQC regulations, relevant UK legislation, and best practices. This section of the Medicines Management Policy and Procedure outlines the procedures for handling medicine refusals and safe disposal methods, ensuring that service users receive the best care, while their rights and safety are respected. These procedures are particularly important for service users with learning disabilities, mental health needs, and autism spectrum conditions, and are designed to ensure compliance with Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment.

14.1 Procedures for Medicine Refusals

Objective: To provide clear and compassionate guidance on how to handle medicine refusals in a way that respects the service user's autonomy while safeguarding their health and well-being.

- Understanding the Reason for Refusal:
    - When a service user refuses medication, it is important to first understand the reason for refusal. This may include concerns about side effects, taste, or the perceived need for the medication. In some cases, refusals may be linked to underlying mental health or autism spectrum conditions.
    - Staff should gently encourage open communication, offering reassurance and support to understand the service user's concerns and try to resolve them in a way that respects their dignity and preferences.
- Assessing Capacity to Refuse Medication:
    - If the service user is able to communicate and has capacity to make decisions, their refusal should be respected, following the Mental Capacity Act 2005 principles.
    - If the service user lacks capacity to make an informed decision regarding the refusal (e.g., due to mental health conditions or learning disabilities), the decision will be made in their best interests. This will involve consultation with healthcare professionals, family members, and legal representatives if necessary, to ensure the appropriate decision is made.

- Immediate Actions Following Refusal:
    - If the refusal is minor (e.g., refusing one dose of medication), staff should:
        - Document the refusal in the Medication Administration Record (MAR).
        - Assess the need for further intervention: This may involve offering the medication again or consulting healthcare professionals for alternative treatment options.
    - If the refusal may pose a serious health risk (e.g., life-threatening medication or required for a chronic condition), the healthcare team should be informed, and a reassessment of the care plan will be conducted to explore alternatives.
    - If the refusal is persistent or if the service user refuses critical medication, staff should:
        - Seek advice from healthcare professionals, and
        - Review the care plan to assess whether medication adjustments are needed.
- Recording and Reporting Refusals:
    - All refusals must be recorded in the MAR with detailed explanations of the reasons for refusal and actions taken in response.
    - Refusals that may impact the service user's health should be escalated to relevant healthcare professionals and documented clearly in care records.

Legislative Compliance: This procedure complies with CQC Regulation 12 (Safe Care and Treatment) and Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), as well as the Mental Capacity Act 2005, ensuring that medication refusals are handled ethically and in the best interest of the service user.

14.2 Safe Disposal of Medicines

Objective: To ensure the safe and compliant disposal of medicines, protecting both service users and staff from harm, and ensuring that environmental regulations are met.

- Expired or Unused Medicines:
    - Any medications that are expired, unused, or no longer required for the service user should be disposed of promptly in a safe and environmentally responsible manner. Medicines should never be flushed down toilets, thrown away in regular waste bins, or left to accumulate.
    - Controlled substances (e.g., opioids, sedatives) and high-risk medications (e.g., cytotoxic drugs) must be handled with particular care due to the potential risks they pose to individuals and the environment.
- Disposal Procedures:
    - Medication Disposal System: All unused or expired medicines must be disposed of through an authorized licensed waste disposal provider. Primus PLUS Healthcare will ensure that the provider follows legal and environmental regulations, including the Environmental Protection Act 1990 and The Waste (England and Wales) Regulations 2011.

- Sharps Disposal: Any sharps used for medication administration (e.g., needles, syringes) must be disposed of in puncture-resistant, sealed containers. These containers must be kept securely and collected by authorized waste disposal services.
- Controlled Drugs: Specific procedures will be followed for the disposal of controlled drugs in compliance with The Misuse of Drugs Act 1971. Controlled drugs must be destroyed in the presence of two authorized personnel, and a formal disposal record must be signed and maintained.

- Documentation of Disposal:
  - All medication disposals must be recorded in the Controlled Drugs Register, if applicable, or in the MAR, specifying the medication, quantity disposed of, the method of disposal, and the name and signature of staff involved.
  - Records of disposal should be reviewed regularly to ensure compliance with internal procedures and regulatory requirements.
- Staff Training on Disposal Procedures:
  - All staff involved in the handling and disposal of medicines will receive training in safe disposal methods. This includes training on the safe handling of controlled drugs, sharps disposal, and the legal and environmental responsibilities of proper medication disposal.

Legislative Compliance: The disposal process complies with CQC Regulation 12 (Safe Care and Treatment), the Health and Safety at Work Act 1974, COSHH Regulations 2002, and environmental laws governing the disposal of hazardous waste, ensuring the safe and lawful disposal of medications.

14.3 Disposal of Medicines in Supported Living without Personal Care

Objective: To ensure the safe disposal of medicines for service users who reside in supported living without personal care, ensuring their safety and compliance with medication disposal laws.

- Agreement with Service Users on Medicine Storage and Disposal:
  - In supported living settings, service users are often responsible for the storage and disposal of their own medications. Primus PLUS Healthcare will work with service users to develop individualized care plans that include specific agreements on how and where medications will be stored, and how unused or expired medicines will be disposed of safely.
  - The service user's family or carers will be involved in the disposal process when appropriate, ensuring that service users who may not have the capacity to manage their own medications receive assistance with safe disposal.
- Regular Inspections and Guidance:
  - Staff will regularly inspect the medications stored in the service user's home to ensure that they are being stored properly and that any unused or expired medications are promptly disposed of in accordance with guidelines.
  - Service users will be reminded periodically about the importance of safe medication storage and disposal, and clear guidance will be provided on how to dispose of unwanted medications correctly.

14.4 Safe Disposal and Environmental Responsibility

Objective: To protect the environment and ensure that medication disposal complies with all legal and environmental standards.

- Environmental Impact: Primus PLUS Healthcare ensures that the disposal of medicines follows environmentally responsible practices. We will not encourage the disposal of medicines via household waste or toilets, and will ensure that unused or expired medicines are disposed of through professional, licensed disposal services.
- Legal and Ethical Compliance:
    - The safe and legal disposal of medications will follow all relevant UK regulations, including the Environmental Protection Act 1990, Waste (England and Wales) Regulations 2011, and The Medicines (Human and Veterinary) Regulations 2012, which mandate the correct disposal of medicines.
- Staff Awareness and Accountability:
    - All staff will receive training on the environmental impact of improper disposal and the legal responsibilities associated with medication disposal. This ensures that all medicines, including controlled drugs, are disposed of securely and responsibly, preventing any risk to the environment or public health.

15. SPECIAL MEDICATION CONSIDERATIONS

At Primus PLUS Healthcare, we understand that service users with learning disabilities, mental health needs, and autism spectrum conditions may have unique requirements when it comes to the management and administration of medicines. Special considerations must be made to ensure that medications are used safely, effectively, and with respect for the individual's preferences and rights. This section of the Medicines Management Policy and Procedure outlines the special medication considerations that must be taken into account to comply with CQC regulations, UK legislation, and best practices.

This policy is designed to ensure that service users in supported living without personal care services receive medications that are tailored to their specific needs, supporting their independence, well-being, and safety.

15.1 Medication for Service Users with Learning Disabilities

Objective: To ensure that individuals with learning disabilities receive medications in a manner that is accessible, understandable, and appropriate for their cognitive needs.

- Individualized Care Plans:
    - Service users with learning disabilities will have individualized medication care plans that take into account their cognitive abilities, understanding of their treatment, and communication needs. The care plan will be designed to meet the specific requirements of the service user, ensuring they understand their medication regimen as much as possible.

- Where applicable, visual aids or easy-read materials will be used to help the service user understand the medication instructions.

- Informed Consent:
  - Informed consent will be obtained where possible, with service users being given information in a way they can understand. For those unable to provide consent due to their learning disability, decisions about medication will be made in the best interests of the service user, in line with the Mental Capacity Act 2005. Family members, legal guardians, and advocates will be involved in the decision-making process as needed.

- Behavioural and Psychological Support:
  - For service users with learning disabilities, non-pharmacological treatments, including behavioural therapy, speech therapy, and environmental modifications, will be prioritized before the use of psychotropic medications to address behavioural challenges.

- Medication Reviews:
  - Medications, especially those that manage behavioural issues or mental health conditions, will be reviewed regularly by healthcare professionals to assess their ongoing appropriateness and to explore alternative treatments when necessary.

Legislative Compliance: This approach ensures compliance with CQC Regulation 12: Safe Care and Treatment, Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, and the Mental Capacity Act 2005, promoting safe, individualized medication care for service users with learning disabilities.

15.2 Medication for Service Users with Mental Health Needs

Objective: To ensure the appropriate use of medications in managing mental health conditions while supporting the mental well-being and autonomy of service users.

- Psychotropic Medication Use:
  - For service users with mental health conditions such as depression, anxiety, schizophrenia, and bipolar disorder, medications such as antidepressants, antipsychotics, and mood stabilizers may be prescribed. However, these will be carefully monitored to ensure they are used appropriately and only when necessary, in line with STOMP (Stopping Over-medication of People with Learning Disabilities and Autistic People).

- Non-Pharmacological Alternatives:
  - Non-medication treatments, including cognitive behavioural therapy (CBT), psychotherapy, and mindfulness, will be utilized as alternative approaches to managing mental health conditions when possible. Medication will be seen as a last resort after exhausting other therapeutic options.

- Side Effects and Monitoring:
  - Service users receiving mental health medications will be closely monitored for potential side effects, such as sedation, weight gain, and movement disorders. Any

adverse effects will be reported and the medication regimen will be adjusted accordingly.

- Informed Consent and Advocacy:
    - Service users will be involved in decision-making regarding their mental health medications as much as possible. If a service user lacks capacity to make informed decisions, decisions will be made in their best interests, and family members, advocates, and healthcare professionals will be consulted.

Legislative Compliance: This policy ensures compliance with CQC Regulation 12 (Safe Care and Treatment), Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), The Mental Health Act 1983 (amended 2007), and NICE guidelines, ensuring that mental health medications are administered safely and effectively.

15.3 Medication for Service Users with Autism Spectrum Conditions

Objective: To ensure that service users with autism spectrum conditions (ASC) receive medications that are suitable and effective for their unique needs.

- Person-centred Medication Plans:
    - Each service user with autism spectrum conditions (ASC) will have a person-centred medication plan that takes into account their individual preferences, sensory sensitivities, and any co-occurring conditions (e.g., ADHD or anxiety disorders). The medication plan will also reflect any non-pharmacological strategies such as structured routines, sensory integration therapy, and visual supports to minimize the need for medications.
- Medication Sensitivity:
    - People with autism may have heightened sensory sensitivities to medications or may experience side effects differently. Careful monitoring will be conducted to ensure the medication does not worsen any sensory challenges, and adjustments will be made where necessary.
- Behavioural Support:
    - Before resorting to medication, behavioural support strategies will be explored, including applied behaviour analysis (ABA) and social skills training to address specific behaviours. Medications will be considered only when non-pharmacological interventions have not been effective.
- Covert Medication:
    - In rare cases where service users with autism are unable to take medications voluntarily, covert medication may be considered. However, this will only occur after careful assessment of mental capacity and after consultation with the service user's family, legal representatives, and healthcare professionals. The decision will be made in the best interests of the service user, as per the Mental Capacity Act 2005.

Legislative Compliance: This policy complies with CQC Regulation 12 (Safe Care and Treatment), Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), The Autism Act

2009, and NICE guidelines, ensuring that service users with autism are provided with safe and appropriate medication care.

15.4 Medication for Service Users with Multiple and Complex Needs

Objective: To ensure that service users with multiple and complex needs, including combinations of learning disabilities, mental health needs, and autism, receive medications that are tailored to their complex conditions and individual requirements.

- Comprehensive Medication Reviews:
    - Service users with multiple and complex needs will receive regular and comprehensive medication reviews. These reviews will involve a multidisciplinary team (MDT), including healthcare professionals such as doctors, nurses, psychiatrists, and pharmacists, to ensure that medications are appropriate and effective for the service user's unique combination of needs.
- Holistic and Coordinated Care:
    - The medication plan for individuals with complex needs will be holistic, ensuring that all aspects of their health are considered, including physical, emotional, and behavioural health. The care plan will outline all treatments, therapies, and interventions, including both pharmacological and non-pharmacological approaches.
- Monitoring and Adjustment:
    - Service users with complex needs will be closely monitored for side effects, drug interactions, and effectiveness. Adjustments to medications will be made based on the outcomes of these reviews to ensure the service user's overall health and well-being.
- Communication and Coordination:
    - Clear communication will be maintained among all professionals involved in the service user's care to ensure a coordinated approach to medication management. This includes regular communication with the service user's family, legal representatives, and other key stakeholders.

Legislative Compliance: This approach complies with CQC Regulation 12 (Safe Care and Treatment), Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), and NICE guidelines, ensuring that service users with multiple and complex needs receive safe and integrated care.

15.5 Addressing Medication for Vulnerable Populations

Objective: To ensure that the needs of vulnerable service users are fully considered in the prescribing and administration of medication.

- Vulnerable Service User Protection:
    - Service users who are particularly vulnerable due to age, cognitive limitations, or mental health challenges will have their medication prescribed and managed with heightened care. This includes ensuring that all medication decisions are made in their best interests, considering their cognitive, emotional, and physical health needs.
- Safeguarding and Abuse Prevention:

- To prevent abuse and improper treatment, all medication practices will be closely monitored, and any concerns about the misuse of medication will be reported and addressed promptly. This is especially important for vulnerable individuals who may have difficulty reporting abuse or understanding their rights.

Legislative Compliance: This section ensures compliance with CQC Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) and Regulation 12 (Safe Care and Treatment), guaranteeing that vulnerable service users receive medication in a way that is respectful, safe, and in line with their best interests.

16. MONITORING AND COMPLIANCE

The Monitoring and Compliance section of the Medicines Management Policy and Procedure at Primus PLUS Healthcare outlines the procedures to ensure that all medicines management practices are effectively monitored, compliant with CQC regulations, and meet the legal requirements set forth by relevant national bodies. This section is crucial to ensure the safe and effective administration of medicines, safeguarding service users, and maintaining the integrity of the medication administration process in supported living without personal care settings.

The goal of monitoring and compliance is to assess whether the policy and its procedures are being implemented correctly, and to take corrective action when necessary to improve the standards of care for service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. This process will also ensure that Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment are consistently met.

16.1 Monitoring the Medicines Management Process

Objective: To ensure that all medicines management practices adhere to established guidelines and are monitored regularly for quality and safety.

- Regular Audits:
  - Regular internal audits will be conducted to review medication administration records (MARs), the appropriateness of prescribed medications, and adherence to medication protocols.
  - Audits will focus on key areas, including:
    - Medication errors and omissions
    - Adherence to prescribed medication regimens
    - Documentation accuracy
    - Storage and handling of medicines, particularly controlled substances and sharps.
  - Audits will be performed at least quarterly and findings will be used to drive improvements.
- Medication Review:

    - A systematic medication review will take place regularly for each service user, particularly for those with learning disabilities, mental health needs, and autism spectrum conditions. This review will be conducted by a multidisciplinary team (MDT), including healthcare professionals such as GPs, psychiatrists, and pharmacists. The reviews will assess the continuing appropriateness of medications and make necessary adjustments to minimize the risk of over-medication or inappropriate prescribing.

- Continuous Monitoring for Adverse Reactions:
    - Service users will be closely monitored for adverse reactions to medications, and any issues identified will be addressed immediately. All reactions will be documented, and appropriate adjustments to the medication regimen will be made. Incident reports will be filed, and corrective actions will be taken in cases of significant issues.

Legislative Compliance: These practices comply with CQC Regulation 12 (Safe Care and Treatment) and Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) by ensuring safe, effective, and properly documented medicines management.

16.2 Staff Competency and Training

Objective: To ensure that all staff involved in the medicines management process are trained, competent, and regularly assessed on their medication administration responsibilities.

- Induction and Ongoing Training:
    - All staff who handle or administer medicines will undergo comprehensive induction training, which includes understanding medication protocols, safe storage and handling of medicines, and recognizing and managing medication errors.
    - Ongoing training will be provided to all staff at least annually, with specific focus on new medications, changes in best practice, and updated guidelines from relevant bodies such as NICE and CQC.
- Competency Assessment:
    - Staff competency will be assessed regularly, including practical evaluations and knowledge-based tests on medication administration procedures.
    - Assessments will include the use of medication records, the correct administration techniques, and the ability to identify and manage adverse drug reactions.
- Supervision and Support:
    - Regular supervision and support will be provided to staff, ensuring that they feel confident and capable in their medication-related duties.
    - Staff will be encouraged to report any concerns about medication management practices, and those concerns will be addressed promptly by a senior staff member.

Legislative Compliance: This approach adheres to CQC Regulation 12 (Safe Care and Treatment) by ensuring staff are adequately trained, assessed, and supported in the safe administration of medications.

16.3 Governance of Medicines Administration Records (MAR)

Objective: To ensure that Medication Administration Records (MAR) are accurate, up-to-date, and properly maintained to ensure safety and accountability in medication management.

- MAR Record Audits:
    - Regular audits of MARs will be conducted to ensure they are complete, accurate, and up-to-date. This will include verifying that medications have been administered as prescribed and that any discrepancies or omissions are promptly addressed.
    - Audits will also assess the accuracy of documentation and ensure that any changes to a service user's medication regimen are properly recorded.
- Electronic MAR (eMAR):
    - If applicable, electronic medication administration records (eMAR) systems will be used to streamline documentation, minimize errors, and improve access to up-to-date medication information. These systems will be regularly monitored for compliance.
- Documentation of Medication Errors and Concerns:
    - All medication errors or concerns raised by staff or service users will be thoroughly investigated and recorded in the incident report system. This process ensures that corrective actions are implemented to prevent recurrence.
    - Regular feedback on audit findings and errors will be provided to staff to support continuous improvement.

Legislative Compliance: This policy meets the requirements of CQC Regulation 12 (Safe Care and Treatment) by ensuring accurate documentation, which is essential for safe and effective medication management.

16.4 Feedback and Service User Involvement

Objective: To ensure that service users and their families or carers have an opportunity to provide feedback about their medication experience and that this feedback is used to improve care.

- Service User Feedback:
    - Service users will be encouraged to share their thoughts and feedback on the medication management process. Feedback will be gathered through regular care reviews, service user meetings, and direct consultations.
    - Service users will be asked about their satisfaction with their medication regimen, including whether they experience side effects, have any concerns, or feel involved in the decision-making process.
- Involvement of Family or Carers:
    - For service users who lack capacity, family members or legal guardians will be included in the decision-making process regarding medication. Regular communication with family members will ensure that they are aware of their loved one's medication needs and any changes to the care plan.

Legislative Compliance: This section complies with CQC Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) and Regulation 12 (Safe Care and Treatment), ensuring that the medication process remains transparent and inclusive.

16.5 Reporting and Addressing Medication Concerns

Objective: To ensure that any concerns or issues related to medication are reported promptly, investigated, and resolved in a timely and transparent manner.

- Reporting Procedures:
    - All staff will be trained to recognize medication concerns and report them promptly to senior staff or management. Concerns may include issues such as medication errors, missing doses, or side effects.
    - A clear reporting system will be in place for staff to report incidents or concerns regarding the safety or effectiveness of medication administration, including any concerns about the handling and storage of medicines.
- Investigation and Corrective Actions:
    - All reported medication concerns will be thoroughly investigated, and corrective actions will be implemented. This could include staff retraining, adjustments to medication regimens, or procedural changes to prevent similar issues in the future.
- Transparency and Follow-Up:
    - The outcomes of investigations and corrective actions will be communicated to relevant staff members and service users, ensuring transparency and accountability.

Legislative Compliance: This approach ensures compliance with CQC Regulation 12 (Safe Care and Treatment) and Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment), ensuring that medication concerns are promptly addressed and resolved.

16.6 Compliance with National Guidelines and Legislation

Objective: To ensure that Primus PLUS Healthcare continuously meets the standards set by relevant national bodies and complies with applicable UK legislation in relation to the management of medications.

- Compliance with NICE Guidelines:
    - The policy will reflect the latest NICE guidelines on the safe and effective management of medicines, particularly in relation to service users with learning disabilities, mental health needs, and autism spectrum conditions. Regular updates will be made to ensure that practices are in line with the most current guidance.
- Legislation Compliance:
    - The Medicines Management Policy is designed to meet the requirements of UK laws, including the Health and Social Care Act 2008, the Medicines Act 1968, and the Mental Health Act 1983 (amended). Regular audits and reviews will be conducted to ensure ongoing compliance.

17. MAKING THE POLICY ACCESSIBLE FOR SERVICE USERS (SPECIALIST SERVICE)

At Primus PLUS Healthcare, we are committed to ensuring that the Medicines Management Policy and Procedure is not only comprehensive but also accessible to all service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. We believe that a clear understanding of their rights and care plans is essential for service users to actively participate in their medication management and treatment. Therefore, this section outlines the steps we will take to make the policy accessible and understandable, aligning with CQC regulations, relevant UK legislation, and best practices.

This section will ensure that our medicines management procedures align with the principles of person-centred care while being in compliance with Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment.

17.1 Understanding Service User Needs

Objective: To provide an accessible, clear, and inclusive approach to the Medicines Management Policy, tailored to the needs of service users with different cognitive abilities and communication preferences.

- Individualized Communication:
    - Every service user will have a personalized communication plan that takes into account their cognitive abilities, sensory preferences, and communication style (e.g., verbal, visual, non-verbal). This ensures that the Medicines Management Policy is presented in a way that is understandable to each individual.
    - For service users with learning disabilities or autism spectrum conditions, visual aids, easy-read formats, and sign language interpreters (if necessary) will be used to convey the policy's contents.
- Assessing Capacity for Understanding:
    - The service user's ability to understand and make decisions regarding their medications will be assessed. If the service user has the capacity to engage with the policy, efforts will be made to involve them in decision-making about their care, including agreeing to their medication regimen.
    - For service users with limited capacity, decisions will be made in their best interests, following Mental Capacity Act 2005 guidelines. Family members, advocates, or legal representatives will be involved as needed to ensure that service users' preferences are respected and that they are provided with appropriate support.

17.2 Adapting the Policy for Service Users with Learning Disabilities

Objective: To make the Medicines Management Policy accessible to service users with learning disabilities by simplifying the language and using supportive communication techniques.

- Easy-Read Versions:
    - An easy-read version of the Medicines Management Policy will be provided, using simple language and pictures to explain key concepts such as medication administration, refusal procedures, and the roles of care staff.
    - Service users will be encouraged to ask questions and seek clarification about any aspect of the policy, with staff available to provide further explanation if needed.

- Person-centred Care:
    - Service users with learning disabilities will have individual care plans that specify the level of assistance required for medication management. These plans will be reviewed regularly to ensure they remain relevant and to incorporate any changes in the service user's needs.
    - Efforts will be made to involve the service user in decisions about their medications, whenever possible. This includes ensuring that their care plan reflects their preferences regarding medication, such as when and how they want to take it.

Legislative Compliance: This approach adheres to CQC Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, ensuring that individuals with learning disabilities receive care that is tailored to their abilities and preferences.

17.3 Adapting the Policy for Service Users with Autism Spectrum Conditions (ASC)

Objective: To ensure the Medicines Management Policy is accessible to service users with autism spectrum conditions (ASC), accounting for sensory sensitivities, communication difficulties, and individual needs.

- Sensory-Friendly Materials:
    - The Medicines Management Policy will be provided in formats that take into account the sensory sensitivities of service users with autism. For example, the font size, color, and paper texture will be selected to minimize discomfort or overstimulation.
    - Visual materials, including charts, pictures, and timelines, will be used to help service users with ASC better understand medication administration routines and expectations.
- Clear Communication and Support:
    - Service users with ASC often have specific communication preferences (e.g., visual communication, pictures, or gestures). The policy will be adapted to these needs by providing visual support or by having staff guide the service user through the medication management process in a calm, predictable, and structured manner.
    - Staff will be trained to recognize and support the sensory and communication needs of service users with autism, ensuring they are given clear, structured, and consistent information.

Legislative Compliance: This approach ensures compliance with CQC Regulation 12: Safe Care and Treatment, Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, and The Autism Act 2009, ensuring that service users with autism have access to clear and personalized medication-related information.

17.4 Making the Policy Accessible for Service Users with Mental Health Needs

Objective: To ensure that service users with mental health needs understand and are involved in the Medicines Management Policy, taking into account any communication challenges or cognitive impairments related to their condition.

- Clear and Supportive Communication:

- The Medicines Management Policy will be explained in plain language and in a non-judgmental, empathetic manner to service users with mental health conditions. For example, service users with depression or anxiety may need more time or reassurance when discussing their medication needs.
- Counselling or therapeutic support may be provided if a service user expresses anxiety or concerns about their medication, ensuring that they feel heard and supported in making medication decisions.

- Collaborative Decision Making:
  - Service users with mental health needs will be included in medication decisions where possible, with their input considered alongside healthcare professionals' advice. Service users will be encouraged to share their preferences or concerns regarding their medications, such as side effects or concerns about their treatment regimen.
  - For service users experiencing difficulties with decision-making capacity, the Mental Capacity Act 2005 will be followed, and decisions will be made in the best interests of the service user, with family, carers, or advocates involved where appropriate.

Legislative Compliance: This ensures compliance with CQC Regulation 12: Safe Care and Treatment, Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, The Mental Health Act 1983, and the Mental Capacity Act 2005, promoting a person-centred approach for service users with mental health needs.

17.5 Ensuring Service User Access to Information and Involvement

Objective: To ensure that service users, regardless of their condition, are actively involved in their medication care plans and that the Medicines Management Policy is available and understandable to them.

- Providing Information in Multiple Formats:
  - The Medicines Management Policy will be made available in a variety of formats, including easy-read versions, audio recordings, and visual formats, to meet the diverse needs of service users.
  - Staff will assist service users in accessing and understanding the policy, ensuring that all service users have the opportunity to be informed and engaged in their care.
- Family and Carer Involvement:
  - For service users who may need additional support (e.g., those with limited capacity), family members or carers will be actively involved in the medication management process. This may include assisting in medication administration, discussions about treatment options, and participation in regular medication reviews.
- Empowering Service Users:
  - Primus PLUS Healthcare will support service users in expressing their preferences and taking an active role in decisions related to their medication. The policy will be structured to encourage service users to ask questions, raise concerns, and engage in discussions about their treatment in a safe and supportive environment.

18. EMERGENCY PROCEDURES

At Primus PLUS Healthcare, we prioritize the safety and well-being of our service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. This section of the Medicines Management Policy and Procedure outlines the necessary procedures to follow in the event of a medication-related emergency, ensuring that we are prepared to respond effectively and safely to incidents such as overdose, adverse reactions, or medication errors. These procedures align with CQC regulations, relevant UK legislation, and the needs of our service users in supported living without personal care services.

This section ensures compliance with Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, and aims to provide clear guidance for managing emergencies that may arise in the medication administration process.

18.1 Recognizing Medication Emergencies

Objective: To ensure that staff can recognize and respond promptly to medication-related emergencies, ensuring the service user's health and safety are prioritized.

- Types of Medication Emergencies:
    - Overdose: A situation where a service user has consumed more than the prescribed amount of a medication.
    - Adverse Reactions: An unexpected, harmful reaction to a medication, such as allergic reactions, severe side effects, or toxicity.
    - Medication Errors: Mistakes in medication administration, such as administering the wrong medication or incorrect dosage.
    - Serious Side Effects: Severe or life-threatening side effects such as respiratory distress, anaphylaxis, or cardiovascular complications.
    - Severe Reactions to Covert Medication: Adverse reactions resulting from the administration of covert medication without the service user's knowledge or consent.
- Signs and Symptoms to Monitor:
    - Symptoms such as difficulty breathing, swelling, unusual drowsiness, rash, vomiting, or confusion may indicate a medication emergency.
    - Monitoring for signs of overdose or medication error (e.g., missed doses or incorrect medication) is also essential.

18.2 Immediate Actions in Case of a Medication Emergency

Objective: To outline the immediate actions that staff should take when a medication-related emergency occurs, ensuring a swift and appropriate response.

- Overdose or Serious Side Effects:
    - Call for Medical Assistance: In the event of an overdose or serious adverse reaction, staff should immediately contact emergency medical services (e.g., 999 for an ambulance) to ensure that the service user receives urgent medical attention.

- Administer First Aid: If appropriate, staff should provide basic first aid measures while awaiting emergency services, such as performing CPR (if trained) or ensuring the service user is in a safe position (e.g., laying them on their side if unconscious).
- Provide Medication Information: If known, provide emergency responders with detailed information about the medication(s) involved, including the name of the drug, dosage, and time of administration.

- Adverse Reactions:
  - Monitor and Stabilize: Staff should monitor the service user's condition closely. If symptoms worsen, contact emergency services immediately.
  - Medication Review: If the adverse reaction is suspected to be linked to a recent medication change, contact the prescribing healthcare professional for advice on how to proceed.
- Medication Error:
  - Assess the Situation: If a medication error occurs, the staff member should immediately assess the situation to determine whether the error poses a risk to the service user's health.
  - Corrective Action: If the wrong medication has been administered or the wrong dose has been given, the staff should seek advice from a healthcare professional on how to proceed, including whether any corrective medication or action is necessary.
  - Notify Management: The error must be reported immediately to the line manager and documented in the incident reporting system. A thorough investigation will follow to prevent future errors.
- Covert Medication:
  - If covert medication has been administered and the service user shows signs of an adverse reaction, staff should immediately stop further administration and follow the emergency procedure for adverse reactions, contacting emergency services as needed.
  - A review of the use of covert medication will be conducted immediately to assess whether it was necessary and if it can continue.

18.3 Reporting and Documentation of Medication Emergencies

Objective: To ensure that all medication-related emergencies are documented accurately and thoroughly for follow-up action and compliance.

- Incident Report:
  - An incident report must be completed for any medication-related emergency. The report should include:
    - Details of the incident, including the type of emergency (e.g., overdose, adverse reaction).
    - Actions taken, including any first aid administered, emergency services contacted, and any medication adjustments made.

        - Outcome of the emergency, including whether the service user was stabilized, transferred to a hospital, or monitored further.
        - Follow-up actions, including any changes to the service user's medication regimen or care plan.
    - The report will be reviewed by the management team, and any necessary corrective actions or procedural changes will be implemented.
- Healthcare Provider Notification:
    - In cases of medication errors or serious incidents, the prescribing healthcare provider must be notified immediately to ensure appropriate follow-up care for the service user.
    - If the service user is taken to the hospital or emergency care, relevant hospital staff will be informed of the medication emergency and any action taken by care staff.
- Review of the Incident:
    - After any medication-related emergency, a review of the incident will be conducted. This will include identifying whether the incident could have been prevented, reviewing the procedures involved, and taking corrective actions as needed.
    - The medication management process will be updated if necessary, and additional staff training or protocol revisions may be implemented.

18.4 Communication and Coordination during Emergencies

Objective: To ensure effective communication and coordination between staff, service users, healthcare professionals, and emergency services during medication emergencies.

- Clear Communication:
    - In the event of a medication emergency, staff should ensure clear, concise communication with emergency services, healthcare professionals, and management teams.
    - Staff should be trained to provide accurate information regarding the medication, dosage, time of administration, and the condition of the service user.
- Coordination of Care:
    - Primus PLUS Healthcare will coordinate with external healthcare providers, such as general practitioners (GPs) or specialist services, to ensure that the service user receives appropriate follow-up care after an emergency.
    - The service user’s family or carers will be notified, with their consent, if necessary, to ensure that they are informed and involved in the ongoing care of the service user.

Legislative Compliance: This emergency procedure aligns with CQC Regulation 12 (Safe Care and Treatment), ensuring that staff respond promptly and appropriately to medication-related emergencies. It also complies with Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) by ensuring that emergency procedures are in place to protect service users from potential harm.

18.5 Training and Preparedness

Objective: To ensure that all staff are adequately trained to handle medication-related emergencies and that appropriate procedures are in place to respond effectively.

- Staff Training:
    - All staff involved in the administration of medicines will undergo regular training on recognizing and responding to medication-related emergencies.
    - First aid training, including the management of medication overdoses and allergic reactions, will be provided to all relevant staff.
- Emergency Drills and Practice:
    - Emergency drills will be conducted periodically to ensure that staff are familiar with emergency procedures and can respond quickly and confidently in the event of a medication emergency.
    - Mock scenarios involving medication-related emergencies (e.g., overdose or adverse drug reactions) will be implemented to ensure staff readiness.
- Review of Staff Performance:
    - Following any medication emergency, a review of staff actions will be conducted to assess whether proper procedures were followed, and further training or guidance will be provided if necessary.

19. MEDICATION ERRORS

At Primus PLUS Healthcare, we are committed to ensuring the safe and effective management of medicines for service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. The Medicines Management Policy and Procedure outlines clear procedures to prevent, identify, and address medication errors, ensuring that service users receive the correct medications in the correct doses, at the correct times, and in the correct manner.

This section of the policy complies with CQC Regulations, particularly Regulation 12: Safe Care and Treatment, and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, aiming to mitigate the risks of medication errors, protect service users, and maintain high standards of care.

19.1 Types of Medication Errors

Objective: To clearly define the types of medication errors that may occur in the management process and to outline how they will be addressed.

- Types of Medication Errors:
    - Wrong medication: Administering the wrong medication to the service user.
    - Wrong dose: Administering too much or too little of the prescribed medication.
    - Incorrect route: Administering medication through the wrong method (e.g., oral medication given intravenously).
    - Timing errors: Administering medication at the wrong time or missing a dose entirely.

- Omissions: Failing to administer the prescribed medication.
- Expired medication: Administering medication past its expiration date.
- Incorrect labelling or documentation: Failure to accurately record medications administered or to properly label medication containers.

Legislative Compliance: This classification of errors ensures compliance with CQC Regulation 12 (Safe Care and Treatment), promoting the safe administration and documentation of medicines.

19.2 Prevention of Medication Errors

Objective: To implement procedures and best practices that prevent medication errors from occurring in the first place.

- Staff Training and Competency:
  - All staff involved in administering medicines will receive comprehensive training on the safe administration of medications, recognizing and preventing medication errors, and responding to adverse reactions. Regular competency assessments will be carried out to ensure that staff are consistently performing medication-related tasks according to established procedures.
  - Ongoing professional development will be provided, with training updates on new medications, practices, and regulatory changes.
- Standard Operating Procedures (SOPs):
  - Clear Standard Operating Procedures (SOPs) will be established for medication administration, storage, and handling to minimize the risk of errors. These SOPs will be reviewed regularly and updated to reflect best practices and compliance with NICE guidelines and CQC requirements.
  - Medication administration will follow a two-person verification system (where feasible), particularly when dealing with controlled drugs or high-risk medications.
- Use of Technology:
  - Where appropriate, electronic medication administration records (eMAR) will be utilized to reduce the risk of human error and to ensure accurate, real-time tracking of medication administration.
  - Barcode scanning of medications and automated dispensing systems will be used to prevent the wrong medications or doses from being administered.
- Medication Reviews and Monitoring:
  - Regular medication reviews will be conducted, particularly for service users with learning disabilities, mental health needs, or autism spectrum conditions, to ensure that the prescribed medications are still appropriate for the individual's condition and needs. This review process is critical for identifying any potential medication errors or inconsistencies before they become a problem.
  - Monitoring systems will be in place to ensure that the correct medication is administered and that side effects or adverse reactions are identified and addressed promptly.

Legislative Compliance: These measures comply with Regulation 12 (Safe Care and Treatment) by ensuring that appropriate steps are taken to prevent medication errors and protect service users from harm.

19.3 Responding to Medication Errors

Objective: To establish clear procedures for responding to and managing medication errors when they occur, ensuring that the service user is protected and that corrective actions are taken.

- Immediate Actions:
    - Assess the Impact: When a medication error occurs, staff must first assess the potential impact on the service user. If the error is suspected to have caused harm or poses a risk to the service user, immediate medical attention will be sought. Emergency services should be contacted if the error involves a significant overdose or severe adverse reaction.
    - Report the Error: The error must be reported immediately to a senior staff member or manager. The incident will be recorded in the incident reporting system and a medication incident form will be completed.
    - Review by Healthcare Provider: A healthcare professional (e.g., GP, pharmacist, or nurse) will review the medication error, assess any potential effects on the service user, and determine the next steps, including any adjustments to the service user's medication regimen.
- Corrective Actions:
    - Rectify the Error: If appropriate, corrective measures will be taken immediately, such as administering the correct medication, adjusting dosages, or making changes to the service user's care plan.
    - Observation and Monitoring: The service user will be closely monitored for any adverse effects resulting from the medication error. Regular health checks and vital signs monitoring will be carried out, and any changes in the service user's condition will be documented and reported.
- Post-Incident Follow-Up:
    - After the immediate actions are completed, a thorough investigation will be conducted to determine the root cause of the error and whether any systems, protocols, or training deficiencies contributed to the incident.
    - If necessary, additional training or procedural changes will be implemented to prevent similar errors in the future.

Legislative Compliance: This process ensures compliance with CQC Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) by ensuring swift and appropriate action is taken to protect service users when a medication error occurs.

19.4 Documentation and Reporting

Objective: To maintain accurate records of medication errors and related incidents for accountability, transparency, and quality assurance.

- Incident Reporting:
    - Every medication error must be thoroughly documented, including a description of the error, the actions taken, and the outcome. The documentation will be stored securely and reviewed regularly by the management team to identify patterns or areas for improvement.
    - A root cause analysis will be conducted for significant medication errors to understand underlying factors and to prevent recurrence. Findings will be shared with relevant staff for educational purposes.
- Regulatory Reporting:
    - Serious medication errors that result in harm or significant risk to the service user will be reported to relevant regulatory bodies, including the Care Quality Commission (CQC), the General Pharmaceutical Council (GPhC), and any other appropriate authorities, as required by law.
    - In cases where medication errors result in adverse effects or harm, healthcare professionals will be involved to ensure proper follow-up care is provided, and the error is appropriately documented in the service user's health records.
- Audit and Review:
    - Regular audits will be conducted to ensure that medication errors are being reported, documented, and investigated appropriately. These audits will also assess whether corrective actions have been effectively implemented to prevent future errors.

Legislative Compliance: This ensures compliance with CQC Regulation 12 (Safe Care and Treatment) by promoting accurate documentation and timely reporting of medication errors to improve care quality.

19.5 Continuous Improvement and Risk Management

Objective: To ensure continuous improvement in medication management practices and reduce the risk of future medication errors.

- Learning from Medication Errors:
    - All medication errors, regardless of severity, will be treated as learning opportunities. The root cause of the error will be identified, and steps will be taken to improve practice. This includes staff education, changes to policies or procedures, and addressing any system weaknesses.
    - Regular feedback sessions will be held with staff to discuss any medication errors, share best practices, and implement improvements to ensure safe care.
- Risk Assessment and Management:
    - Risk assessments will be conducted regularly to identify potential areas for medication errors, particularly for high-risk medications such as controlled drugs and PRN (as required) medications. These assessments will help to identify vulnerabilities in the medication management process and allow for appropriate interventions to mitigate risks.
- Preventive Measures:

- The findings from audits, incident reports, and feedback will be used to continuously update medication policies, improve staff training, and implement new safety protocols to prevent medication errors in the future.

20. COLLABORATIVE WORKING WITH EXTERNAL AGENCIES

At Primus PLUS Healthcare, we recognize that effective medication management requires a collaborative approach involving a range of external agencies, healthcare professionals, and support services. Working together with these partners ensures that service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions, receive comprehensive care that meets their individual needs. This section of the Medicines Management Policy and Procedure outlines how we will work in collaboration with external agencies to promote safe and effective medicines management and ensure the highest standard of care for all service users.

This collaborative approach is integral to meeting CQC regulations, particularly Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment. It also aligns with national legislation and best practices for the care and treatment of individuals in supported living without personal care services.

20.1 Collaboration with Healthcare Providers

Objective: To ensure that medications are appropriately prescribed, monitored, and reviewed in collaboration with external healthcare professionals.

- Primary Healthcare Providers: General Practitioners (GPs) and Consultants will play a key role in prescribing and reviewing medications for service users. These healthcare professionals will be consulted regularly to ensure that medications are appropriate for the service user's needs, condition, and circumstances.
    - Regular Medication Reviews: Service users' medications will be regularly reviewed by GPs, psychiatrists, or other specialists to ensure continued appropriateness. This is particularly important for individuals with learning disabilities, mental health conditions, or autism spectrum conditions, as their medication needs may change over time.
    - Referrals to Specialists: When necessary, referrals to specialists (e.g., neurologists, psychiatrists, or pharmacists) will be made to address complex medication-related issues, such as polypharmacy, adverse drug reactions, or medication optimization.
    - Integrated Care Plans: Collaborative care plans will be developed, with input from external healthcare providers. This ensures that medication management is integrated into the service user's overall care plan, considering both their physical and mental health needs.

Legislative Compliance: This collaboration ensures compliance with Regulation 12: Safe Care and Treatment by ensuring service users' medications are prescribed, reviewed, and monitored appropriately. It also aligns with the Health and Social Care Act 2012, The Care Act 2014, and the Mental Health Act 1983 (as amended).

20.2 Collaboration with Pharmacists

Objective: To ensure safe and effective medication dispensing, administration, and monitoring in collaboration with pharmacy professionals.

- Pharmacy Involvement: Registered pharmacists will work alongside care teams to ensure that medications are dispensed, reviewed, and monitored in accordance with the Medicines Act 1968 and Pharmacy Order 2010. This includes reviewing medications for interactions, contraindications, and side effects to ensure service users' safety.
    - Medication Reviews: Regular reviews by pharmacists will assess the appropriateness of prescribed medications, checking for any potential adverse effects or drug interactions. Medication charts will be updated in consultation with pharmacists to maintain accurate and current records.
    - Medication Training for Staff: Pharmacists will provide training and advice to staff on the safe administration of medications, including the use of controlled drugs, high-risk medications, and specialized medications for conditions such as epilepsy or mental health disorders.
- Supporting Service Users: Pharmacists will also assist with providing clear medication instructions for service users and their families/carers. In cases where service users are unable to manage their medications independently, pharmacists will advise on how best to support them while ensuring compliance with their treatment plan.

Legislative Compliance: This collaboration aligns with The Medicines Act 1968, The Health and Social Care Act 2012, and Regulation 12: Safe Care and Treatment, ensuring that service users receive safe and effective medication management with the support of qualified pharmacy professionals.

20.3 Collaboration with Social Services and Local Authorities

Objective: To work in partnership with local authorities and social services to provide integrated care and medication management.

- Care Coordination: Social workers and local authorities will be involved in coordinating care and ensuring that medication needs are considered as part of the service user's overall care plan. This collaboration ensures that service users receive holistic support, addressing both their social and healthcare needs.
- Safeguarding and Risk Management: Working with safeguarding teams and local authorities ensures that service users' rights are upheld, and any risks related to medication errors or misuse are promptly addressed. Collaborative risk assessments will be conducted to identify any potential vulnerabilities, especially for those with learning disabilities or mental health issues.
- Care and Support Plans: Social services will contribute to the creation of care plans that include medication management, ensuring that medications are administered according to the prescribed schedules and adjusted as necessary for service users with complex needs.

Legislative Compliance: This collaboration ensures compliance with Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, The Care Act 2014, and The Safeguarding Vulnerable Adults Act 2006, helping to ensure service users are protected and supported in their medication management.

20.4 Collaboration with Mental Health Services

Objective: To ensure appropriate management of medications for service users with mental health conditions, including effective treatment plans and medication oversight.

- Mental Health Team Involvement: For service users with mental health conditions, the involvement of psychiatrists, psychologists, and mental health nurses is crucial for medication management. These professionals will ensure that prescribed medications are suitable for the service user's mental health needs, especially for those taking medications such as antipsychotics or antidepressants.
- Crisis Intervention and Medication Adjustments: In situations where a service user experiences a mental health crisis or adverse effects from their medications, immediate collaboration with the mental health team will occur to adjust medications or provide additional support. This can include PRN medications for acute episodes or medication changes based on individual responses.
- Regular Mental Health Reviews: Service users on psychotropic medications will have regular mental health reviews to assess the effectiveness and appropriateness of their treatment, ensuring that medications continue to support their well-being without causing unnecessary side effects.

Legislative Compliance: This collaboration aligns with The Mental Health Act 1983 (as amended) and CQC Regulation 12: Safe Care and Treatment, ensuring that service users with mental health conditions are receiving appropriate and safe medication management.

20.5 Collaboration with Advocacy and Support Services

Objective: To ensure that service users are empowered to make decisions about their medication and have support when needed.

- Advocacy Services: Independent advocates will be engaged when needed, particularly for service users who are unable to fully participate in decisions about their medication due to capacity issues. Advocacy services will ensure that the service user's voice is heard in medication decisions and that their best interests are represented.
- Support for Families and Carers: Families and carers will be informed and included in medication management, particularly for service users with learning disabilities or autism spectrum conditions. Family members will receive training and guidance on how to support their loved ones with medication administration, including identifying potential side effects and monitoring responses to medications.
- Legal Advisors: When necessary, legal advisors will be consulted, especially in cases where there may be disagreements regarding medication or the service user's capacity to consent. Legal guidance will ensure compliance with The Mental Capacity Act 2005 and the best interests of the service user.

Legislative Compliance: This collaboration aligns with The Mental Capacity Act 2005 and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, ensuring that service users have the necessary support to make informed decisions about their medication.

20.6 Communication and Coordination among External Agencies

Objective: To ensure that all external agencies are involved in the medication management process and that communication is clear and timely.

- Regular Meetings and Case Reviews: Regular multidisciplinary meetings involving healthcare providers, social services, advocacy groups, and other relevant agencies will be held to review the care and medication needs of each service user. These meetings will ensure that all parties involved in the service user's care are informed and that any adjustments to medication or treatment are made in collaboration with the service user and their team.
- Clear Documentation and Record Sharing: To ensure continuity of care, all relevant medication information, including changes to the medication regimen or medication errors, will be shared with appropriate agencies, with the service user's consent. Confidentiality and data protection guidelines will be followed to maintain the service user's privacy.
- Emergency Coordination: In case of a medication-related emergency, all relevant external agencies will be contacted and involved in the response, ensuring that the service user receives appropriate and timely medical attention.

Legislative Compliance: This collaborative approach ensures compliance with CQC Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, promoting effective care coordination and safeguarding of service users.

21. MANAGING NON-PRESCRIPTION MEDICATIONS

At Primus PLUS Healthcare, we understand that non-prescription medications (including over-the-counter (OTC) drugs, vitamins, herbal remedies, and supplements) may play a role in supporting the health and well-being of our service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. However, due to the complex health needs of this group, it is essential to manage non-prescription medications carefully to prevent misuse, interactions with prescribed medications, and to ensure that they do not pose a risk to service users' health.

This section of the Medicines Management Policy and Procedure outlines how Primus PLUS Healthcare will manage non-prescription medications effectively, in compliance with CQC regulations, relevant legislation, and best practices.

21.1 Definition and Scope

Objective: To provide clarity on what constitutes non-prescription medications and the procedures for managing these substances safely.

- Non-Prescription Medications include:
    - Over-the-counter (OTC) medications: Medications available without a prescription, such as pain relievers (e.g., paracetamol), cold and flu treatments, and antacids.
    - Herbal remedies and supplements: Products like vitamins, minerals, herbal teas, and other dietary supplements that are not prescribed but used for general health support.
    - Topical treatments: Over-the-counter creams, ointments, or lotions (e.g., for skin conditions or muscle pain).

While these medications can be purchased without a prescription, they should still be managed with the same degree of care and attention as prescribed medications to ensure they do not interfere with other treatments or lead to adverse effects.

21.2 Procedures for Managing Non-Prescription Medications

Objective: To ensure that non-prescription medications are managed safely and in a manner that ensures the well-being of service users.

- Staff Responsibility:
    - Care staff are responsible for ensuring that non-prescription medications are administered only according to the service user's needs and preferences, and only after consultation with appropriate healthcare professionals when necessary (e.g., GP, pharmacist).
    - Medication records for non-prescription medications will be maintained, including the name of the product, dosage, administration times, and any side effects or adverse reactions observed.
- Consultation with Healthcare Providers:
    - Before any non-prescription medication is introduced, staff must consult with the prescribing healthcare provider to ensure there is no medication interaction or potential contraindications with current prescribed medications.
    - This is particularly important for individuals with complex conditions (e.g., individuals taking medications for mental health conditions or neurological disorders) who may be more susceptible to drug interactions.
    - Pharmacists may also provide guidance on appropriate choices for non-prescription treatments based on the individual's condition, ensuring safe options are selected.
- Documentation:
    - Non-prescription medications administered to service users will be recorded in the service user's medication administration record (MAR).
    - The reason for use, dosage, and time of administration will be documented. Any side effects or concerns will also be recorded, with a follow-up plan outlined if needed.
- Monitoring and Review:
    - Regular reviews of all non-prescription medications will be conducted to assess their ongoing suitability. This will ensure that there are no negative side effects, drug interactions, or that the medication is no longer necessary.
    - If a service user's condition changes, or if a non-prescription medication is no longer required, the healthcare provider will be consulted to stop the medication, ensuring appropriate discontinuation of use.

21.3 Consent and Involvement of Service Users

Objective: To ensure that service users are actively involved in decisions regarding non-prescription medication use, with particular consideration to capacity and preferences.

- Service User Involvement:
    - Whenever possible, service users will be involved in the decision-making process regarding the use of non-prescription medications. This includes discussing potential options, benefits, and risks of any medications introduced.

- For individuals with learning disabilities, mental health needs, or autism spectrum conditions, staff should adapt communication to ensure service users understand the medication being offered. Accessible information may be provided to assist in the decision-making process.
- Family members or advocates may also be involved in the decision-making process, especially when the service user is unable to give informed consent due to lack of capacity.

- Capacity and Consent:
  - In line with the Mental Capacity Act 2005, staff will ensure that service users are assessed for capacity to make decisions about non-prescription medication. If the service user lacks capacity, decisions will be made in their best interest in consultation with relevant healthcare professionals and, where applicable, the service user's family or advocate.

21.4 Safe Storage of Non-Prescription Medications

Objective: To ensure that non-prescription medications are stored safely and securely to prevent misuse, accidental ingestion, or incorrect administration.

- Storage Requirements:
  - Non-prescription medications should be stored in a locked medication cabinet or other secure areas that are not accessible to unauthorized persons, including service users who may be at risk of misuse or overuse.
  - Medications that require temperature control, such as certain creams or liquids, should be stored according to the manufacturer's guidelines to maintain their effectiveness and safety.
- Staff Responsibilities:
  - Staff must regularly check that non-prescription medications are stored securely and in good condition. Expired or damaged medications should be promptly disposed of using the correct procedure.
  - Record keeping must include the location of non-prescription medications to ensure quick and efficient access during administration.

21.5 Managing Risks of Non-Prescription Medications

Objective: To identify and manage any risks associated with the use of non-prescription medications to ensure the safety of service users.

- Risk Assessment:
  - A comprehensive risk assessment will be conducted for each non-prescription medication used, evaluating potential risks such as drug interactions, allergies, and side effects.
  - Risk assessments will also consider the service user's specific condition (e.g., those with autism spectrum conditions, mental health conditions, or learning disabilities), as some medications may have heightened risks for these groups.

- Medication Monitoring:
    - Service users will be monitored closely for any side effects or adverse reactions to non-prescription medications, particularly when a new product is introduced.
    - If any adverse effects occur, the non-prescription medication will be discontinued, and appropriate action will be taken in consultation with healthcare professionals.

21.6 Training and Competency

Objective: To ensure that all staff are appropriately trained to manage non-prescription medications safely and effectively.

- Training Requirements:
    - All staff involved in administering non-prescription medications will undergo training to understand the risks, benefits, and guidelines for the safe use of these medications.
    - Training will include information on identifying drug interactions, recognizing side effects, and understanding the importance of informed consent.
    - Regular competency assessments will be conducted to ensure that staff are knowledgeable and confident in their medication management roles.

21.7 Disposal of Non-Prescription Medications

Objective: To ensure that non-prescription medications are disposed of safely and in accordance with legal and best practice guidelines.

- Disposal Procedures:
    - Non-prescription medications that are expired, unused, or no longer required should be disposed of in a safe manner, in line with pharmacy and local authority guidelines.
    - Staff must follow secure disposal protocols, such as using a licensed pharmaceutical waste disposal service, to prevent medication misuse or accidental ingestion.

21.8 Compliance and Record Keeping

Objective: To ensure that all actions taken with non-prescription medications are documented and compliant with regulatory requirements.

- Medication Records:
    - Accurate records of all non-prescription medications administered will be maintained, including details of the medication, dosage, time of administration, and any adverse reactions observed.
    - Regular audits will be conducted to ensure that record-keeping practices for non-prescription medications are followed consistently and are compliant with CQC regulations and NICE guidelines.

22. SERVICE USER HEALTH AND WELLBEING MONITORING

At Primus PLUS Healthcare, we prioritize the health and wellbeing of our service users, ensuring that they receive the most appropriate care tailored to their individual needs, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. This section outlines how health and wellbeing monitoring will be conducted to ensure the safe and effective management of medications and promote overall health.

The Medicines Management Policy aligns with CQC regulations, including Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment, ensuring that our service users' health is continuously monitored and their needs are met in a timely and accurate manner.

22.1 Monitoring Service Users' Health and Wellbeing

Objective: To ensure that health and wellbeing monitoring is integrated into the medication management process to detect any issues or changes that may require adjustments to treatment or care.

- Health Assessments:
    - All service users will receive regular health assessments conducted by qualified healthcare professionals (e.g., nurses, doctors, or specialists), ensuring that medications are having the desired effect and that no adverse reactions are occurring.
    - These assessments will include monitoring for side effects, adverse drug reactions, and interactions between prescribed medications and non-prescription medications or supplements.
    - Health markers such as blood pressure, heart rate, weight, blood sugar levels, and mental health status will be regularly checked, depending on the specific medication being taken and the individual's condition.
- Comprehensive Medication Reviews:
    - Service users on long-term medication will have regular medication reviews with healthcare professionals, including GPs, psychiatrists, or other specialists. These reviews will focus on:
        - Assessing whether medications remain effective and appropriate.
        - Ensuring that any changes in the service user's condition are reflected in their medication regime.
        - Identifying any potential side effects or adverse reactions and adjusting medications accordingly.

Legislative Compliance: The Health and Social Care Act 2008 and Regulation 12 (Safe Care and Treatment) ensure that service users' health is regularly monitored to detect any issues related to their care or medications.

22.2 Monitoring for Adverse Reactions to Medications

Objective: To ensure that service users are closely monitored for any adverse reactions to medications, with quick action taken when necessary.

- Adverse Reactions:

- All staff will be trained to recognize potential adverse reactions to medications, including allergic reactions, side effects, or changes in behaviour or mood.
- Service users receiving high-risk medications (such as antipsychotics, antidepressants, or medications for epilepsy) will be monitored more frequently for any negative effects.
- If any adverse reactions occur, medications will be adjusted in consultation with healthcare providers, and the service user will be closely monitored.

- Record Keeping:
  - All adverse reactions will be thoroughly documented in the service user's health record, including the nature of the reaction, any changes to the medication regimen, and the actions taken.
  - Immediate reporting will be made to healthcare professionals to ensure that the service user receives the appropriate care.

Legislative Compliance: This process is aligned with Regulation 12 and Regulation 13 of the CQC regulations, ensuring that medication errors or adverse reactions are swiftly addressed and documented to safeguard the service user's well-being.

22.3 Regular Health Monitoring for Service Users with Complex Needs

Objective: To provide ongoing health monitoring for service users with complex health needs to ensure they are receiving appropriate care, especially those with learning disabilities, mental health needs, or autism spectrum conditions.

- Routine Monitoring:
  - For service users with complex needs, routine health checks will be carried out at regular intervals, including monitoring for:
    - Changes in mental health status (e.g., anxiety, depression, or psychosis).
    - Physical health issues related to medication (e.g., weight gain, tremors, or changes in vital signs).
    - Autism spectrum conditions or learning disabilities will require special attention to medication effects, as these service users may have different responses to treatment.

- Collaboration with Mental Health Professionals:
  - For service users with mental health conditions, the mental health team will be involved in regular assessments to monitor the impact of psychiatric medications and ensure their safety. This can include evaluating side effects like sedation, weight changes, or cognitive effects.

Legislative Compliance: Regulation 12 (Safe Care and Treatment) and CQC guidelines require that service users with complex health needs receive continuous monitoring and appropriate care to prevent complications and ensure their treatment is effective.

22.4 Communication and Reporting of Health Changes

Objective: To ensure that any changes in health status are communicated effectively to the relevant parties and appropriately recorded.

- Internal Communication:
    - Care staff will be required to report any observed changes in the service user's health status to senior staff, ensuring that all relevant healthcare professionals are notified promptly.
    - Medication-related issues, such as side effects, missed doses, or significant changes in condition, will be communicated to the healthcare team for review and action.
- External Communication:
    - If necessary, external agencies such as GPs, psychologists, or mental health teams will be contacted to assess whether changes in the service user's health are related to their medication or if a change in the care plan is required.
    - Family members or advocates will be involved in discussions where appropriate, particularly for service users with learning disabilities or mental health conditions.

Legislative Compliance: Regulation 13 (Safeguarding Service Users from Abuse and Improper Treatment) ensures that appropriate communication takes place to protect service users from harm.

22.5 Health and Wellbeing Monitoring Tools and Systems

Objective: To utilize appropriate tools and systems for monitoring the health and wellbeing of service users.

- Monitoring Systems:
    - Health records and medication administration records (MAR) will be maintained digitally or on paper for all service users, ensuring that any changes to their health status are clearly documented and reviewed.
    - Electronic records will allow for more accurate tracking and quick identification of any concerns related to medication or health changes.
- Outcome Measurement:
    - Service user outcomes will be regularly evaluated to determine the impact of the prescribed medications on their overall wellbeing, including both physical and mental health improvements.
    - If needed, adjustments to the service user's care plan or medication regimen will be made in collaboration with healthcare providers to improve overall health outcomes.

Legislative Compliance: NICE guidelines and CQC regulations emphasize the importance of using appropriate monitoring systems to evaluate and track the service user's health status accurately.

23. MEDICATION SAFETY AUDITS

At Primus PLUS Healthcare, ensuring the safe management of medications is a top priority, particularly for service users with learning disabilities, mental health needs, and autism spectrum conditions. Medication safety audits are an essential part of our Medicines Management Policy and Procedure, aimed at identifying potential risks, improving care practices, and ensuring compliance with CQC regulations and national standards.

The purpose of medication safety audits is to monitor the quality and effectiveness of the medication management process, identify areas for improvement, and provide accountability for the handling, administration, and record-keeping of medications. These audits will be carried out regularly and systematically to safeguard the health and wellbeing of our service users and ensure continuous improvement in care.

This section outlines the procedures for conducting medication safety audits at Primus PLUS Healthcare, in compliance with CQC requirements, NICE guidelines, and relevant legislation.

23.1 Purpose of Medication Safety Audits

Objective: To provide a structured process for evaluating the safety and effectiveness of medication management practices.

- Identify Issues: Medication safety audits help identify areas where medication administration and storage practices may be failing or unsafe.
- Ensure Compliance: Audits ensure that CQC regulations and other relevant legislative requirements are adhered to, including Regulation 12: Safe Care and Treatment and Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment.
- Promote Continuous Improvement: Audits highlight areas for improvement, ensuring that service users receive the safest and most effective medication management possible.

23.2 Frequency and Scope of Medication Safety Audits

Objective: To outline how frequently audits will occur and what areas they will cover to ensure comprehensive assessment.

- Frequency of Audits:
    - Routine audits will be conducted quarterly for all medication management processes.
    - Additional audits may be conducted when medication errors, adverse reactions, or changes in the medication regimen occur.
    - Unannounced audits may also be scheduled to ensure adherence to policy and best practices at all times.
- Scope of Audits:
    - Administration Procedures: Audits will review the accuracy and timeliness of medication administration, checking that all medications are administered according to the service user's prescribed schedule.
    - Storage and Handling: The secure and safe storage of medications, including controlled drugs, will be assessed to ensure compliance with CQC guidelines and Health and Safety regulations.
    - Documentation and Record Keeping: Audits will ensure that Medication Administration Records (MAR) are accurate, up-to-date, and reflect the prescribed medications and any changes to treatment plans.
    - Staff Competency: The competence of staff responsible for administering medications will be reviewed to ensure they are trained and following appropriate procedures.

23.3 Auditing Process

Objective: To ensure that the auditing process is thorough, consistent, and transparent.

- Audit Tools and Methodology:
    - A set of standardized audit tools will be used to assess different aspects of medication management. These tools will include:
        - Checklists for administration and storage practices.
        - Review forms for evaluating staff competency.
        - Detailed records for tracking discrepancies in medication administration or handling.
    - Auditors will be trained to follow a consistent auditing methodology, ensuring that the process is comprehensive and objective.
- Auditor Selection:
    - Auditors will include senior care staff, pharmacy professionals, or external auditors who are experienced in medication management.
    - External audits may also be conducted by independent pharmacy consultants or healthcare regulatory bodies to ensure objectivity.
- Documentation:
    - All audit findings will be documented in a report, which will include any areas of concern, recommendations for improvement, and corrective actions taken.
    - These reports will be reviewed by the management team to ensure that identified issues are addressed promptly.

23.4 Reporting and Action Plans

Objective: To ensure that audit findings are acted upon swiftly and effectively.

- Audit Findings:
    - Any medication errors, non-compliance, or unsafe practices identified during the audit will be immediately reported to the management team.
    - Medication discrepancies, such as missed doses or incorrect administration, will be thoroughly investigated, and corrective actions will be implemented.
- Action Plans:
    - When issues are identified, an action plan will be developed and implemented. This plan will outline:
        - Corrective actions to address the identified issue (e.g., retraining staff, revising medication protocols).
        - Preventative measures to ensure that the issue does not recur in the future.
    - Progress on the action plan will be monitored, and further follow-up audits will be conducted to assess the effectiveness of the corrective actions.

- Communication:
    - Findings from the audit, as well as the corrective actions taken, will be communicated to relevant staff members, ensuring that everyone is aware of the issues and solutions.
    - Feedback will be provided to staff on how they can improve their practices and contribute to the overall safety and well-being of the service users.

23.5 Compliance with Legislation and Standards

Objective: To ensure that all audits meet the highest standards of compliance and safety.

- CQC Compliance:
    - Medication safety audits will ensure that Primus PLUS Healthcare is meeting the standards set out by the Care Quality Commission (CQC), specifically Regulation 12 and Regulation 13.
    - Audits will assess compliance with CQC's Key Lines of Enquiry (KLOEs), which relate to safe and effective medication management.
- NICE Guidelines:
    - The audits will also ensure that medication practices adhere to NICE guidelines for safe and effective medication management, including the use of medications for individuals with learning disabilities, mental health needs, and autism spectrum conditions.
- Health and Safety Regulations:
    - Audits will verify that all aspects of medication management comply with Health and Safety Executive (HSE) regulations, including the safe storage, handling, and disposal of medications, particularly controlled substances.

23.6 Continuous Improvement

Objective: To foster a culture of continuous improvement in medication safety and overall care quality.

- Monitoring Progress:
    - After each audit, the management team will assess the findings and take necessary action to improve medication safety practices. This may include:
        - Enhancing staff training or introducing new policies and procedures.
        - Updating risk assessments to ensure that any potential medication-related risks are adequately mitigated.
- Ongoing Evaluation:
    - Medication safety audits will be used as a tool to continuously evaluate and improve medication management practices, making sure that service users' health and safety remain the top priority.
- Feedback Loop:
    - Feedback from staff, service users, and external auditors will be incorporated into the audit process to ensure that the policy remains relevant and responsive to any emerging risks or changes in care needs.

24. RISK ASSESSMENTS RELATED TO MEDICATION

At Primus PLUS Healthcare, we are committed to ensuring the safe and effective management of medications for all service users, particularly those with learning disabilities, mental health needs, and autism spectrum conditions. A risk assessment is a critical tool used to identify and mitigate potential risks related to the use of medications and associated equipment. The goal is to minimize the possibility of medication errors, adverse effects, and other health risks that could compromise the well-being of our service users.

This section outlines the processes for conducting medication-related risk assessments and how they comply with CQC regulations, relevant legislation, and the standards set by national UK bodies such as NICE. The process also ensures that the needs of service users in supported living without personal care are met in a safe, dignified, and effective manner.

24.1 Purpose of Risk Assessments

Objective: To systematically assess and address the risks associated with medication use to ensure the safety and well-being of service users.

- Identify Medication Risks: Medication-related risks, including side effects, allergic reactions, drug interactions, and incorrect administration, will be identified and mitigated through comprehensive assessments.
- Ensure Safe Practices: Risk assessments will ensure that medications are administered in a manner that prioritizes the safety of the service users and minimizes risks associated with the medications or related tasks.
- Support Compliance: These assessments will help ensure compliance with CQC regulations (specifically Regulation 12: Safe Care and Treatment) and Regulation 13: Safeguarding service users from abuse and improper treatment.

24.2 Key Areas of Medication Risk Assessment

Objective: To outline the areas that need to be assessed for risks when managing medications for service users.

- 1. Risk of Medication Errors:
    - Medication errors, such as missed doses, incorrect dosages, and wrong medications, can have serious consequences for service users. Risk assessments will help identify potential areas for errors, such as unclear medication instructions or improper handling.
    - Staff competency assessments will be carried out regularly to ensure that the risk of human error is minimized.
- 2. Adverse Reactions and Drug Interactions:
    - Adverse reactions can occur when medications interact with one another or with the service user's underlying health conditions.
    - Risk assessments will include the identification of high-risk medications (e.g., antipsychotics, antidepressants, or epilepsy medications) and how they interact with the service user's existing medications or conditions.

    - Monitoring will be put in place to track any adverse reactions that may occur.
- 3. Risk of Over-medication and Under-medication:
    - STOMP (Stopping Over-Medication of People with a Learning Disability and Autistic People) is an important framework that guides the safe prescribing and review of medications.
    - Risk assessments will evaluate the need for medications and ensure they are being prescribed in the right dose for the right condition, minimizing the risk of over-medication.
    - Regular reviews will be conducted to ensure service users are receiving the correct medication and dosage for their needs.
- 4. Safe Storage and Handling of Medications:
    - Medications need to be stored securely to prevent access by unauthorized individuals or accidental ingestion by service users.
    - Risk assessments will review medication storage facilities to ensure they are compliant with safety guidelines and CQC regulations.
    - Staff will be trained on how to handle controlled drugs, sharps, and other medications that pose unique risks.
- 5. Service User Compliance:
    - Some service users may not be able to self-administer medications due to physical or cognitive limitations.
    - Risk assessments will determine which levels of medication assistance are needed and ensure service users are receiving the appropriate level of support.
    - If medication needs to be administered covertly, specific guidelines will be followed to ensure it is done legally and ethically.
- 6. Risk of Medication Refusal:
    - Service users may refuse to take their medication, which could pose a risk to their health.
    - Risk assessments will include procedures for handling refusals, ensuring that alternative strategies are explored, and that refusal is documented and reviewed.

24.3 Risk Assessment Process

Objective: To define the process for assessing, managing, and reviewing medication-related risks in supported living settings.

- Step 1: Identification of Risks:
    - Upon admission, a comprehensive risk assessment will be conducted for each service user to identify specific medication-related risks. This will include reviewing the service user’s medical history, current medications, and any known allergies or sensitivities.
- Step 2: Assessment of Medication Regimen:

- The service user's current medication regimen will be assessed to ensure that it aligns with their needs and best practices.
- NICE guidelines will be used to guide the assessment and ensure that prescribed medications are appropriate, minimizing risks associated with over-medication or drug interactions.

- Step 3: Implementation of Mitigation Strategies:
  - Based on the identified risks, mitigation strategies will be implemented. This may include adjusting medications, changing administration methods, or providing additional training to staff to ensure the safe administration of medications.
  - Risk mitigation may also include alternative treatments or non-pharmacological interventions where medications are found to be unnecessary or inappropriate.
- Step 4: Regular Monitoring and Review:
  - Service users' medications will be reviewed regularly by healthcare professionals to ensure their continued appropriateness.
  - Health monitoring (such as blood pressure, blood sugar levels, or mental health assessments) will be conducted as part of an ongoing review to ensure the medications are working effectively without adverse effects.
- Step 5: Documentation:
  - All risks, risk mitigation strategies, and reviews will be documented in the service user's health records and Medication Administration Records (MAR).
  - Incident reports will be completed if a medication error occurs, ensuring that corrective actions are taken and documented.

24.4 Responsibilities of Staff in Risk Assessment

Objective: To define the roles and responsibilities of staff members in conducting and managing medication risk assessments.

- Managers:
  - Ensure that risk assessments are conducted for all service users upon admission and reviewed regularly.
  - Oversee the implementation of risk mitigation strategies and monitor staff compliance with medication safety practices.
  - Lead in the training and competency assessments for staff involved in medication administration.
- Care Staff:
  - Participate in daily monitoring of service users' health and medication adherence, and report any observed issues to senior staff.
  - Assist in identifying potential medication errors or side effects, and report them immediately.

- Adhere to medication safety protocols, ensuring that all medications are administered safely and correctly.

- Pharmacy Professionals:
  - Support managers and care staff by providing advice on medication-related risks, including potential drug interactions and side effects.
  - Ensure that medications are dispensed correctly and in accordance with service users' needs.
  - Contribute to medication reviews and the development of risk mitigation strategies.

24.5 Monitoring and Review of Risk Assessments

Objective: To ensure that medication-related risks are continuously monitored and reassessed to maintain the safety and well-being of service users.

- Ongoing Risk Evaluation:
  - Medication-related risks will be reassessed on a regular basis, especially if there is a change in the service user's health status, medication regimen, or care plan.
  - Any adverse effects, side effects, or changes in medication needs will trigger a new risk assessment.
- Audit and Compliance:
  - Risk assessments will be audited periodically to ensure that they remain up-to-date and that appropriate actions are being taken to address identified risks.
  - The results of audits will be reviewed by the management team, and any necessary adjustments or improvements to the risk management process will be made.

25. INTEGRATION WITH SERVICE USERS' CARE PLANS

At Primus PLUS Healthcare, the integration of medicines management into service users' care plans is essential to ensuring that the needs of individuals with learning disabilities, mental health needs, and autism spectrum conditions are met effectively and safely. This section outlines how medications are incorporated into service users' individual care plans and how the integration complies with CQC regulations, relevant legislation, and national standards, including those established by NICE.

The process of integrating medication management with care plans ensures that medications are used appropriately, considering the specific needs, preferences, and circumstances of the service user. This approach guarantees that medication is not only prescribed correctly but also administered safely and that any changes in health status or medication needs are tracked and addressed promptly.

25.1 Purpose of Integrating Medications into Care Plans

Objective: To ensure that medication management is seamlessly integrated into the holistic care plans for service users, promoting safe, effective, and individualized care.

- Holistic Care: Medication must be considered within the context of the service user's overall care needs, including physical, mental, and emotional health, and the support needed for daily activities.
- Person-centred Approach: Ensure that the care plan respects the choices, preferences, and dignity of the service user, promoting self-determination in medication decisions where possible.
- Consistency: By integrating medication management into care plans, staff are provided with clear, up-to-date guidance on the medications being prescribed and how they should be administered, reducing the risk of errors.

25.2 Process for Integrating Medications into Care Plans

Objective: To outline the steps for integrating medication management into the service user's care plan, ensuring the continuity of care and safety in supported living environments.

- Step 1: Assessment of Medication Needs:
    - During the initial admission process, a comprehensive assessment will be conducted to determine the service user's medication needs, including:
        - Current medications and any history of previous treatments.
        - Health conditions that require specific treatments.
        - Preferences and concerns regarding medication use.
        - Capacity to manage medications, and the support required if the individual cannot self-administer.
    - All relevant medical professionals, including GPs, psychiatrists, and pharmacists, will contribute to the development of the medication component of the care plan.
- Step 2: Developing the Care Plan:
    - The medication section of the care plan will specify the prescribed medications, dosages, timing, and any special instructions.
    - The care plan will include the service user's preferences regarding medication, such as how they prefer to take their medication (e.g., in pill form, liquid, etc.) and whether any alternative approaches are required.
    - Special medication needs related to the service user's health condition(s), such as the need for PRN medication or covert administration, will be noted in the care plan.
- Step 3: Implementing Medication Administration Procedures:
    - The care plan will specify the level of support required for medication administration:
        - Level 1: Independent self-administration with reminders.
        - Level 2: Assistance with the administration of medications, either with supervision or without.
        - Level 3: Full assistance where the service user is unable to administer medications independently.

    - Care staff will be responsible for adhering to the care plan's instructions and administering medications as prescribed.
- Step 4: Regular Reviews of Medication Needs:
    - The service user's care plan will be reviewed regularly by the care team to ensure that it remains appropriate to their current needs, with a focus on:
        - Medication changes due to evolving health conditions.
        - Reviewing the efficacy of medications and making necessary adjustments.
        - Addressing any adverse reactions or side effects from medications.
    - Healthcare professionals will be consulted as needed, and the care plan will be updated to reflect any medication adjustments or changes in health status.

25.3 Monitoring the Effectiveness of Medication

Objective: To ensure that medications are providing the desired outcomes and are not causing harm to the service user.

- Ongoing Health Monitoring:
    - Service users will be regularly monitored for any side effects or adverse reactions to medications. Key indicators such as vital signs, mental health status, or physical health changes will be tracked.
    - Medication reviews will be carried out at regular intervals, with the involvement of healthcare professionals, such as pharmacists and doctors, to assess the appropriateness and effectiveness of the prescribed medications.
- Feedback and Adjustments:
    - If medications are found to be ineffective or if side effects are observed, the care team will work with healthcare professionals to make adjustments to the treatment plan. The care plan will be updated to reflect any changes in medication or treatment goals.

25.4 Ensuring Compliance with CQC Regulations and NICE Guidelines

Objective: To ensure that the integration of medications into service users' care plans is compliant with CQC regulations and NICE guidelines.

- CQC Regulations:
    - The integration of medications into care plans complies with CQC Regulation 12: Safe Care and Treatment, ensuring that medications are safely prescribed, administered, and monitored for service users.
    - The care plans will clearly outline medication assistance levels and ensure that Regulation 13: Safeguarding Service Users from Abuse and Improper Treatment is met by preventing errors or misuse of medications.
- NICE Guidelines:
    - The care plan will incorporate NICE guidelines for safe and effective medication management, ensuring the correct medication is prescribed, administered, and

reviewed for adults with learning disabilities, mental health needs, and autism spectrum conditions.

- The guidelines will ensure that medications are used appropriately, and that over-medication is avoided, aligning with initiatives such as STOMP (Stopping Over-medication of People with Learning Disabilities and Autistic People).

25.5 Involvement of Service Users in Medication Decisions

Objective: To respect and empower the service user's choice in medication decisions, promoting person-centred care.

- Informed Consent:
  - Service users will be involved in decisions about their medication wherever possible. They will be informed about their treatment options and the risks and benefits associated with each medication.
  - For those with capacity, their consent will be obtained before administering any medications, and their preferences will be respected.
- Support for Service Users with Limited Capacity:
  - For service users who lack the capacity to make decisions about their medication, their family members, advocates, or appointed representatives will be involved in the decision-making process.
  - The Mental Capacity Act 2005 will guide decisions where necessary to ensure that the service user's rights are upheld, even if they are unable to make decisions independently.

25.6 Service User-centred Review of Care Plans

Objective: To maintain dynamic and responsive care plans that reflect the evolving needs of the service user.

- Review Process:
  - The service user's care plan, including medication management, will be reviewed annually or sooner if there is a significant change in health or medication needs.
  - The review process will include discussions with the service user (if able), their family, and their healthcare professionals to ensure the care plan remains aligned with the service user's needs, preferences, and best interests.

26. FORMS

1. Medication Administration Record (MAR)

Service User Name	_____
Medication Name	_____
Dose	_____
Route of Administration (e.g., oral, topical)	_____
Time of Administration	_____
Administered By	_____
Signature of Administering Staff	_____
Witness	_____
Medication Refusals	[ ] Yes [ ] No
Notes	_____
	_____
	_____
Date	_____

2. Medication Consent Form

Service User Name	_____
Medication(s) Consent	[ ] Yes [ ] No
Medication Name(s)	_____
Explanation of Medication	_____
Consent Statement	"I consent to the administration of the medications outlined above and have been given sufficient information to understand the purpose and potential side effects of these medications."
Service User/Guardian Signature	_____
Date	_____
Witness Signature	_____

3. Medication Refusal Form

Service User Name	_____
Medication **Refused**	_____
Reason for **Refusal**	[ ] Not feeling well [ ] Forgetfulness [ ] Side effects [ ] Other (please specify): _____
Date/Time of **Refusal**	_____
Staff Signature	_____
Notes/Action **Taken**	_____
	_____

4. Medication Incident Report Form

Service User Name	_____
Date/Time of Incident	_____
Type of Incident	[ ] Medication error [ ] Administration error [ ] Adverse reaction [ ] Medication storage issue
Description of Incident	_____
	_____
Corrective Action Taken	_____
Reporting Staff Name	_____
Witness	_____
Follow-up Actions	_____
	_____

5. Medication Disposal Log

Service User Name	_____
Medication Name	_____
Quantity to be Disposed	_____
Reason for Disposal	[ ] Expired [ ] Discontinued [ ] Not used [ ] Other (please specify): _____
Date of Disposal	_____
Method of Disposal	[ ] Returned to pharmacy [ ] Incinerated [ ] Other (please specify): _____
Staff Signature	_____
Supervisor/Manager Signature	_____

6. Medication Review Form

Service User Name	_____
Medication(s) Being Reviewed	_____
Reason for Review	[ ] Routine [ ] Side effects [ ] Change in health [ ] Other (please specify): _____
Review Date	_____
Healthcare Professional's Notes/Comments	_____
	_____
Actions Recommended	_____
	_____
Next Review Date	_____

7. Medication Supply Monitoring Form

Medication Name	_____
Quantity Available	_____
Reorder Threshold	_____
Date of Last Stock Check	_____
Next Stock Check Due	_____
Staff Member Responsible for Stock Management	_____
Supplier Details	_____

8. Medication Training and Competency Checklist

Staff Name	_____
Date of Training	_____
Topics Covered	[ ] Medication administration [ ] PRN use [ ] Medication errors [ ] Handling controlled drugs [ ] Other (please specify): _____
Practical Demonstrations	[ ] Administered medication correctly [ ] Administered PRN medication [ ] Administered controlled drugs
Competency Assessment Results	[ ] Pass [ ] Fail [ ] Re-assessment required
Trainer's Signature	_____
Staff Signature	_____

9. Service User Medication Preferences Form

Service User Name	_____
Preferred Method of Medication	[ ] Tablet [ ] Liquid [ ] Other (please specify): _____
Preferred Medication Schedule	[ ] Morning [ ] Afternoon [ ] Evening [ ] As needed
Any Allergies or Sensitivities	_____
Service User's Comments or Concerns	_____
	_____
Signature (if applicable)	_____

10. Service User Medication Administration Monitoring Form

Service User Name	_____
Medication Name	_____
Scheduled Time	_____
Time Administered	_____
Amount Taken	_____
Comments (E.g., Refused, Assistance Given)	_____
Staff Signature	_____

Here are additional forms that could be useful for Primus PLUS Healthcare to ensure comprehensive medication management, in line with CQC regulations, relevant UK legislation, and best practices for adults with learning disabilities, mental health needs, and autism spectrum conditions in supported living without personal care.

11. Medication Adverse Reaction Reporting Form

Purpose: To report and document any adverse reactions experienced by service users as a result of medication administration. This ensures prompt action is taken to safeguard service users.

Service User Name	_____
Medication Name	_____
Date/Time of Administration	_____
Adverse Reaction (symptoms)	_____
Severity of Reaction	[ ] Mild [ ] Moderate [ ] Severe
Action Taken	_____
	_____
Healthcare Professional Notified	[ ] Yes [ ] No
Staff Signature	_____
Follow-up Plan	_____

12. Medication Overdose Incident Form

Purpose: To document any medication overdose incidents, including accidental or unintentional overmedication, and the corrective actions taken.

Service User Name	_____
Medication Name	_____
Date/Time of Overdose	_____
Amount of Overdose	_____
Reason for Overdose	_____
Action Taken	_____
	_____
Healthcare Professional Notified	[ ] Yes [ ] No
Staff Signature	_____
Follow-up Actions	_____

13. Medication Supply Order Form

Purpose: To request medication replenishment from pharmacies and suppliers, ensuring medications are always available.

Service User Name	_____
Medication Name	_____
Quantity Requested	_____
Reason for Request	_____
Date Requested	_____
Pharmacy/Provider Name	_____
Staff Signature	_____
Manager Approval	[ ] Approved [ ] Denied
Manager Signature	_____

14. Medication Effectiveness Review Form

Purpose: To track the effectiveness of medications for each service user, ensuring that the prescribed medication regimen is suitable.

Service User Name	_____
Medication Name(s)	_____
Purpose of Medication	_____
Date of Review	_____
Effectiveness of Medication	[ ] Effective [ ] Partially Effective [ ] Not Effective
Changes in Health Status	_____
Actions Taken	_____
Healthcare Professional's Notes	_____
Next Review Date	_____

15. Medication Risk Assessment Form

Purpose: To identify and assess the potential risks associated with medications, particularly for service users with complex needs or polypharmacy.

Service User Name	_____
Medication Name	_____
Dosage and Frequency	_____
Potential Risks Identified	_____
Staff Observations	_____
Required Actions	_____
Follow-up Actions	_____
Healthcare Professional Signature	_____

16. Covert Medication Administration Form

Purpose: To document instances where covert administration of medication is necessary, ensuring legal and ethical compliance.

Service User Name	_____
Medication Name(s)	_____
Reason for Covert Administration	_____
Date of Covert Administration	_____
Consent Status	[ ] Service User Consent [ ] Guardian Consent [ ] Mental Capacity Act Review
Person Administering Medication	_____
Healthcare Professional Approval	[ ] Yes [ ] No
Signature of Person Administering Medication	_____
Witness Signature (if applicable)	_____

17. Medication Administration Verification Checklist

Purpose: To verify that medication has been properly administered, particularly when multiple staff members are involved in administration.

Service User Name	_____
Medication Name	_____
Dose Administered	_____
Time Administered	_____
Administered by	_____
Verified by	_____
Staff Signature	_____
Date	_____

18. Service User Medication Preferences and Needs Form

Purpose: To record service users' preferences regarding medication, including timing, method of administration, and any specific requirements for their well-being.

Service User Name	_____
Preferred Method of Medication	[ ] Tablet [ ] Liquid [ ] Inhaler [ ] Injection [ ] Other (specify): _____
Preferred Time for Medication	[ ] Morning [ ] Afternoon [ ] Evening [ ] As needed
Allergies or Sensitivities	_____
Any Specific Requirements	_____
Service User Comments	_____
Staff Signature	_____

19. PRN (As-Required) Medication Log

Purpose: To track the administration of PRN medications and ensure proper documentation.

Service User Name	_____
Medication Name	_____
Date/Time of PRN Administration	_____
Dose Administered	_____
Reason for Administration	_____
Staff Signature	_____
Follow-up Actions	_____

20. Staff Medication Competency Review Form

Purpose: To assess and review the competency of staff involved in administering medications.

Staff Name	_____
Training Date	_____
Topics Covered	[ ] Medication Administration [ ] PRN Use [ ] Controlled Drugs [ ] Medication Safety [ ] Other (specify): _____
Practical Assessment Completed	[ ] Yes [ ] No
Trainer's Comments	_____
Competency Status	[ ] Competent [ ] Needs Improvement
Trainer's Signature	_____
Staff Signature	_____

27. REFERENCES

1. Care Quality Commission (CQC). (2014). Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Available at: https://www.cqc.org.uk
2. National Institute for Health and Care Excellence (NICE). (2016). NICE Guidelines: Medicines Management. Available at: https://www.nice.org.uk
3. The Medicines Act 1968. (1968). An Act to make new provision for regulating the manufacture, sale and supply of medicines and poisons. Available at: https://www.legislation.gov.uk
4. The Mental Capacity Act 2005. (2005). An Act to make provision for and in connection with decisions by or on behalf of people who lack capacity to make decisions for themselves. Available at: https://www.legislation.gov.uk
5. Royal Pharmaceutical Society (RPS). (2021). Medicines Management and Policy. Available at: https://www.rpharms.com
6. Department of Health and Social Care (DHSC). (2014). The Care Act 2014. Available at: https://www.gov.uk
7. Health and Safety Executive (HSE). (2002). Control of Substances Hazardous to Health (COSHH) Regulations 2002. Available at: https://www.hse.gov.uk
8. The Autism Act 2009. (2009). The first UK-wide law aimed at improving the lives of adults with autism. Available at: https://www.gov.uk
9. General Pharmaceutical Council (GPhC). (2010). The Pharmacy Order 2010. Available at: https://www.pharmacyregulation.org
10. The National Institute for Health and Care Excellence (NICE). (2016). Mental Health and Learning Disabilities Guidelines. Available at: https://www.nice.org.uk
11. The National Safeguarding Adults Board (NSAB). (2006). Safeguarding Vulnerable Adults Act 2006. Available at: https://www.gov.uk
12. National Health Service (NHS). (2018). NHS England's Safe Medicines Management Policies. Available at: https://www.england.nhs.uk
13. Stopping Over-Medication of People with Learning Disabilities and Autistic People (STOMP). (2016). Guidance on reducing over-medication in people with learning disabilities. Available at: https://www.england.nhs.uk
14. Learning Disability Professional Senate (LDPS). (2018). National Framework for Learning Disabilities. Available at: https://www.ldps.org.uk
15. Mental Health Act 1983 (Amended 2007). (1983). Legal framework for prescribing and managing medication for individuals with mental health disorders. Available at: https://www.legislation.gov.uk
16. The Royal Pharmaceutical Society (RPS). (2018). RPS Standards for Medicines Management. Available at: https://www.rpharms.com

Additional Resources

1. NICE. (2017). Mental Health and Learning Disabilities - NICE Guidelines. Available at: https://www.nice.org.uk
2. National Institute for Health and Care Excellence (NICE). (2019). Medicines and Healthcare Products Regulatory Agency (MHRA) Guidelines. Available at: https://www.mhra.gov.uk
3. Royal Pharmaceutical Society. (2020). The Role of Pharmacy in Safeguarding and Medication Management. Available at: https://www.rpharms.com
4. Department of Health and Social Care (DHSC). (2020). NHS England's Guidance on Mental Health Services. Available at: https://www.england.nhs.uk
5. NHS England. (2021). Framework for Medicines Management in Social Care Settings. Available at: https://www.england.nhs.uk