Mersey Care NHS
NHS Foundation Trust

MERSEY CARE NHS TRUST – HOW WE MANAGE MEDICINES

Medicines Management Services aim to ensure that

(i) Service users receive their medicines at times that they need them and in a safe way.

(ii) Information on medicines is available to staff and service users

How Patient Group Directions (PGDs) are developed and implemented in the trust. MM02

KEY ISSUES

- **This procedure applies to all registered nurses within the Trust who are using a PGD**
- **The department/ward manager will be responsible for assessing the eligibility of staff able to supply and administer medicine under PGD**
- **PATIENT GROUP DIRECTIONS ARE INTENDED TO BE EXCEPTIONAL. They must take into account the priorities of the Trust and be supported by appropriate training. They must enable the highest standard of practice for each clinical situation to be achieved.**

OBJECTIVES

- **To ensure that all staff follow standard procedures when dealing with Patient Group Directions**
- **To provide a standard for the PGD's within Mersey Care NHS Trust that provides and auditable process.**
- **To ensure that all members of staff working within Mersey Care NHS Trust are aware of their roles, responsibilities and limitations with respect to PGD's.**

Medicines Management Procedure – MM02

Approved by Drugs and Therapeutics Committee

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Version 2.2

For Review

January 2019

This procedure was written in accordance with the following: -

- The NMC Guidelines for the Administration of Medicines (2004)
- The NMC Code of Professional Conduct (2002)
- The Misuse of Drugs Act (1971)
- The Medicines Act (1968) (1986)
- Medicines labelling regulations (1976)
- The Mental Health Act (1983)
- SD12 – Mersey Care NHS Trust Handling of Medicines Policy

And it outlines the processes to be followed within the Trust for the development of Patient Group Directions. It gives practical guidance on the development of the Patient Group Direction including details of criteria to be included in the document in order that the practice it supports is within the law and has the approval of the Trust. It incorporates the guidance provided in the 1998 Crown Report on the supply and administration of medicines under group protocol (the legal term for which is now Patient Group Direction) and the legal requirement and guidance set out in HSC 2000/026: Patient Group Directions.

The majority of clinical care will continue to be provided on an individual, service user specific basis by a doctor or via non-medical prescribing. Supply and administration of medicines under a Patient Group Direction is reserved for those limited situations where an advantage to service user care can be demonstrated (without compromising service user safety) and where it is consistent with appropriate professional relationships and accountability. Registered nurses, Band 5 or above, who have completed the relevant training and competencies in the use of Patient Group Directions are permitted to supply or administer under a Patient Group Direction as named. Nurses must complete refresher training in accordance to what is set out under the individual PGDs.

Procedure - How to Develop a Patient Group Direction

The supply and administration of medicines under a Patient Group Direction should be reserved for those limited situations where this offers an advantage to service user care without compromising service user safety and be consistent with appropriate professional relationships and accountability.

Who should be involved?

The development of the Patient Group Direction should not be initiated until approval to proceed has been received, in writing. Patient Group Directions will be drawn up by a multidisciplinary group including a doctor, a pharmacist and a representative of each of the Clinical Division involved in the specialist areas concerned.

Services are required to complete a Proposal Form (Appendix 1) and send to the local divsional medicines management group or equivalent.

What should be included in the Patient Group Direction?

The Patient Group Direction must comply with all of the criteria listed below: -

- The content of a Patient Group Direction must be reviewed every two years.

- The following drugs should **not** be included in Patient Group Directions:
    a) New drugs under intensive monitoring and subject to special adverse drug reaction reporting requirements ('Black Triangle Drugs')

    b) Unlicensed medicines (not granted a marketing authorisation by the Licensing Authority.)

    c) Medicines used outside their licensed indications

    d) Radiopharmaceuticals

    e) Controlled Drugs (except schedule 5)

- There must be comprehensive arrangements for the security, storage and labelling of all medicines.

- There must be a system for recording and monitoring medicine usage under a Patient Group Direction to enable all stock receipts and all issues to individual service users to be reconciled.

Criteria to be included in the Patient Group Direction

The legislation specifies that each Patient Group Direction must contain the following information:

- The name of the clinical area in which the direction is applicable
- The date the direction comes into force and the date it expires
- A description of the medicine to which the direction applies
- The signature of the health care professionals who are responsible for the direction
- The signature of the chairman of the approving committee
- The clinical condition to which the direction applies
- A description of those service users excluded from treatment under the direction
- A description of the circumstances in which further advice should be sought from a doctor and arrangements for referral
- Details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered.
- Relevant warnings, including potential adverse drug reactions
- Details of any necessary follow up action and the circumstances
- A statement of the records to be kept for audit purposes

The Checklist of Contents provides more comprehensive list of these requirements and should be followed when writing the Patient Group Direction (Appendix 2).

Procedure – How a PGD is approved.

The Clinical Director of the Division concerned and the Trust lead for the professional group concerned must approve any proposed Patient Group Direction. The proposed PGD must then be submitted for approval and ratification at the trust's Drugs and Therapeutics Committee. The Drugs & Therapeutics Committee acts on behalf of the Trust Board and this final approval of the Patient Group Direction ensures that legal liability and hence indemnification of staff is given full consideration.

If approved, this document will be signed and dated by the Medical Director, Chief Pharmacist and Director of Nursing.

A copy of the signed Patient Group Direction and a list of names and specimen signatures of all authorised practitioners will be held:

a) In the Pharmacy department
b) By the Clinical Director of the directorate concerned
c) On the trust website to allow access for any clinical area where the PGD may be applied.
d) Each authorised practitioner will be given a copy of the Patient Group Direction.

When practitioner becomes authorised it is the responsibility of that practitioner to

a) Inform the pharmacy department before administration/supply role is undertaken and
b) Submit a completed authorised practitioner agreement and specimen signature

If a practitioner is no longer authorised to act with the Patient Group Direction it is the responsibility of that individuals line manager to inform the Pharmacy Department so that the individuals name can be removed from the list. The individuals name must also be removed from the lists held by the Clinical Director and in the area of practice.

A new Medical Director, Chief Pharmacist or Director of Nursing taking on the responsibility of a Patient Group Direction must resubmit a signed Patient Group Direction to the Drugs & Therapeutics Committee.

Any proposed changes to an existing Patient Group Direction must be resubmitted to the Chairman of the Drugs & Therapeutics Committee in accordance with the original approval procedure. If the proposed changes are authorised the amended Patient Group Direction will be countersigned. Once approved and amended the Patient Group Direction will immediately supersede the previous Patient Group Direction for that area of practice. The relevant Clinical Director will ensure that: -

a) The amended Patient Group Direction shall be substituted as soon as possible for the previous Patient Group Direction held in that area
b) All copies of the previous Patient Group Direction are destroyed
c) All practitioners authorised under the previous Patient Group Direction are advised of the changes and any additional training required under the new Patient Group Direction is provided
d) All practitioners are provided with a copy of the new Patient Group Direction and sign a new agreement of authorisation as above

The Procedure can be summarised by the following algorithm:-

Need for PGD identified and confirmed – Must be exceptional and lead to improvement in service user care

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Proposal for development of Patient Group Direction completed and submitted to local Medicines Management Group for review

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Local Medicines Management Group identify relevant representative to produce draft

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Circulate for comments within the Directorate

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Submit draft to Trust's Medicines Management Group for approval

↓

Chair of Medicines Management Group submits to Drugs & Therapeutics Committee for ratification

↓

Set up Training (local services)

Train

↓

Agreements to practice within a PGD signed by authorised practitioners and a copy sent to appropriate departments

↓

Implement and monitor

↓

Review every two years by nominated member of Drugs & Therapeutics Committee

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Medicines Management Group and Drugs & Therapeutics Committee informed of all changes in Patient Group Directions and personnel

Responsibilities of trust staff

It must be acknowledged by **all** members of staff that the interests and safety of every service user are paramount.

Patient Group Directions (PGD) should specify clear arrangements for professional responsibility, and accountability and contribute to effective use of resources.

Note: An authorised practitioner's delegated authority to supply and administer cannot be re-delegated to non-specifically trained healthcare persons.

The extended role, with regard to administration and supply under Patient Group Directions, is not compulsory and each practitioner has the ability to exercise personal and professional judgement as to whether to accept the responsibility that the extended role will place upon them. Signing the authorised practitioner register for an individual Patient Group Direction provides agreement to the extended role. A copy of the signed and completed Agreement by Authorised Practitioner and completed register shall be promptly submitted to the Pharmacy Department.

How Training is Delivered

All authorised practitioners must only undertake the extended role under PGDs in circumstances where they are competent to assess all relevant aspects of the service users clinical condition and take responsibility for supply and administration and related decisions Appendix 3 sets out areas of good practice around competencies these are intended to be used within the clinical divisions to assess competence when considering staff for inclusion within the PGD.

All authorised practitioners supplying or administering medicines under Patient Group Directions must be named and have written evidence of competence, training, knowledge, experience and continuing education relevant to the clinical conditions/situation to which the Patient Group Direction applies. The Health Professional will be required to undertake a refresher questionnaire every two years provided by their service manager. (Appendix 4)

No authorised practitioner should undertake any aspect of service user care for which they are not trained and which is beyond their professional competence. If the authorised practitioner is in any doubt about their competency they should not administer or supply in accordance with the PGD and should seek advice. The authorised practitioner undertaking this extended role must do so in accordance with the appropriate current PGD.The Trust assumes vicarious liability for the actions of the authorised practitioner, properly acting in the course of his/her duties and in accordance with the current PGD in his/her area of practice.

Reference Documents

1) Department of Health - Patient Group Directions (England only) – Health Service Circular 2000/026

2) National Prescribing Centre (NPC) (March 2004):-

Patient Group Directions – A practical guide and framework of competencies for all professionals using patient group directions.

Glossary

Staff definitions

Throughout the policy the term practitioner is used. This is a general term used to describe a qualified medical practitioner, nurse and pharmacist. However, for the purposes of this policy only Registered nurses, Band 5 or above, who have completed the relevant training and competencies associated with PGD's are permitted to operate within a PGD I.e. authorised practitioners.

Medicine/Medication

Any substance or combination of substances presented in a form for treating or preventing disease or illness. The substance or combination of substances which may be administered with a view to making a medical diagnosis, restoring, correcting or modifying physiological or psychological functioning.

Prescribe

Authorise in writing the supply of a medicine or medication.

Supply

To provide a medicine to a patient/carer for administration.

Administer/Administration

Give a medication to an individual either by introduction to the body, (e.g. orally, by injection, per rectum or per vagina), or by external application, for example in the form of a cream or an ointment.

Patient Group Direction (PGD)

Patient Group Direction is a specific written instruction for the supply and administration of a named medication in an identified clinical situation in the absence of a written prescription.

Licensed Indication

Treatment purpose for which a product may be used under the terms of the marketing authorisation granted by the Licensing Authority (see also licensed medicine)

Licensed Medicine

A medicine which falls within the definition of a medicinal product and which is granted a marketing authorisation by the Licensing Authority when the safety, quality and efficacy of the product have been satisfactorily demonstrated by the license holder in accordance with EC directives 65/66.

Black triangle medicines

Newly introduced medicines still subject to special monitoring for potential side effects by the Medicines and Healthcare Products Regulatory Agency (identified by a black triangle symbol).

Pharmacology

The science or study of drugs, including their characteristics, actions and uses.

Adverse drug reaction (ADR)

Adverse Drug Reaction – Any unexpected or unwanted reaction caused by the administration of a drug. The onset of which may be sudden or develop over time.

Pharmacokinetics

The activity or fate of drugs in the body over a period of time including the processes of absorption, distribution, and excretion.

Contraindication

Any condition which renders a particular treatment unsuitable.

Summary of Product Characteristics (SPC)

The SPC forms an integral part of the marketing authorisation and is the basis of information for health care professionals. It describes the properties and effects of the medicine as well as warnings about it.

Controlled Drug

Narcotic drugs or other drugs liable to misuse, which are subject to special controls under the Misuse of Drugs Act 1971.

Appendix 1

Proposal for the development of a Patient Group Direction

The following document should be completed and submitted for approval by the local Medicines Management Group.

TITLE OF PGD

NAME OF PROPOSER AND POSITION

CURRENT POSITION AND NEED FOR PATIENT GROUP DIRECTION Including names of drugs to be supplied/administered

BENEFITS TO PATIENT CARE OF PGD

NAMES OF HEALTH CARE PROFESSIONALS WHO WILL BE WRITING THE PGD NB: this **must** include a senior pharmacist and a doctor

STATEMENT OF SUPPORT FROM PROFESSIONAL LEAD
E.g. Director of Nursing, Chief Pharmacist

SIGNED BY

…….. …… Date …….

Proposer Position

…….. …… Date…….

Professional Lead Position

…….. …… Date…….

Senior Pharmacist Position

…….. …… Date…….

Clinical Director Position

COMMENTS

Appendix 2 - Checklist of contents

The following is a list of the elements that must be included in any Patient Group Direction prior to it being submitted for approval to the Medicines Management Group.

1. **Clinical condition or situation to which the PGD applies**
   Clinical need stated

   Objective of care defined

   Clinical condition or situation clearly defined

   Criteria for confirmation of the clinical condition defined

   Clinical criteria for inclusion of a service user in the PGD defined

   Clinical criteria for exclusion of a service user from the PGD defined

   Action to be followed for service users excluded from the PGD defined

   Action to be followed for service users who do not wish to receive, or do not adhere to, care under the PGD

2. **Characteristics of staff authorised to take responsibility for the supply or administration of medicines under a PGD**
   Professional qualification of staff authorised to take responsibility defined

   Name of professionally qualified person taking responsibility for non-professionally trained personnel involved in PGD

   Qualifications, training and experience relevant to the clinical condition to which the PGD applies defined

   Qualifications, training and experience relevant to the medicines included in the PGD defined

   System set up for the continued training and education of staff involved in PGD

   System for recording names of individuals authorised to supply or administer drugs under the PGD described

3. **Description of treatment available under a PGD**
   Names of medicines to be supplied defined

   Names of medicines to be administered defined

   Legal status of medicines defined

   Doses or dose ranges defined

Criteria for deciding a dose defined

Route or method of administration defined

Frequency of administration defined

Total dose, number of times treatment can be administered and over what period of time defined

Follow-up treatment or review time defined

Advice, verbal and written to be given to the service user or carer, before or after treatment, defined, including access to service user information leaflets

Instructions on identifying and managing possible adverse outcomes included

Arrangements for obtaining medical advice defined

Facilities and supplies that should be available include (e.g. drugs for managing adverse effects, special storage facilities).

Records to be kept to enable a clear audit trail described

Method of keeping a register of drugs ordered and supplied described

Details of any special considerations to be made for service users taking concurrent medications included

4. Management and monitoring of group PGD's

Names of professionals drawing up PGD's stated

Professional advisory groups who have approved the PGD stated (must include Medicines Management Group)

The name of the manager who has authorised the use of the PGD is stated

Includes instructions for nurses or other health care professionals involved in service user care to report adverse drug reactions to the clinician in charge of care

Includes date of protocol and the review date after which the PGD is no longer valid

5. Signatures

Each member of the multi disciplinary group developing the PGD

Clinical Director

Clinical Pharmacist

Professional lead for staff acting within the PGD

Chairman of the Medicines Management Group

Each practitioner wishing to practice must sign the agreement attached to each PGD

Appendix 3 - Preparation of the healthcare professional to supply medication/administer under a PGD

The competency framework contains the competencies that all health care professionals should either already have or seek to develop while working with PGD's.

It is used as a self-assessment tool to evaluate levels of competency and will help to guide reflections on your practice.

An appropriate qualified multidisciplinary team should deliver the training.

1. Contents of training to include: -

- PGD's in context
- Legal framework and scope
- Identifying the need
- Producing PGD's
- Implementing PGD's
- Using PGD's
- Accountability and Responsibility
- Pharmacology of the drugs being used

Additional requirements considered relevant to the medicines used in the PGD	• All nurses must be familiar with the Policies and Procedures relating to medicines before undertaking administration or supply of medication under a Patient Group Direction • All nurses must have read and understood NMC standard for administration of medicines • Has undertaken appropriate training as agreed by Mersey Care NHS Trust for working under Patient Group Directions • Has an understanding of pharmacology drugs being issued to service users and relevant medical condition pertaining to the use of each Patient Group Direction.
Continued training requirements	• Annual attendance at a resuscitation retraining session and management of anaphylaxis update. • Regular updates on specific PGD topics. • Undertake clinical supervision/peer group review on a formal regular basis

PGD COMPETENCIES

THE CONSULTATION

1. CLINICAL AND PHARMACEUTICAL KNOWLEDGE

Has up to date clinical and pharmaceutical knowledge relevant to the scope of the PGD

- Understands the medical conditions being treated, their natural progress and how to assess the severity of disease
- Understands different non-pharmacological and pharmacological approaches to modifying disease and promoting health, desirable and undesirable outcomes and how to identify and assess them
- Understands the mode of action and pharmacokinetics of medicines and how these mechanisms may be altered (e.g. by age, renal impairment)
- Understands the potential for unwanted effects (e.g. adverse drug reactions (ADRs), drug interactions, special precautions and contraindications) and how to avoid/minimise and manage them
- Maintains an up to date knowledge of products contained in the PGD
- Understands how medicines are licensed, supplied and monitored (e.g. ADR reporting)
- Applies the principles of evidence-based medicine, and clinical and cost – effectiveness
- Understands the public health issues related to medicines use (e.g. antimicrobial drug resistance)
- Appreciates the misuse of potential drugs

PGD COMPETENCIES

THE CONSULTATION

2. ESTABLISHING OPTIONS

Makes and/or reviews diagnosis and generates treatment options for the service user, including follow-up within the PGD

- Takes a comprehensive medical history and undertakes an appropriate physical examination
- Makes and/or reviews a working or final diagnosis by considering and systematically deciding between the various possibilities (differential diagnosis)
- Requests and interprets relevant diagnostic tests
- Views and assesses the service users needs holistically (psychosocial, physical)
- Considers no treatment, non-drug and drug treatment options (including referral and preventative measures)
- Assesses the effect of multiple pathologies, existing medication and contraindications on treatment options
- Assesses the risks and benefits to the service user of taking/not taking a medicine (or using/not using a treatment)
- Selects the most appropriate PGD for the individual service user
- Selects the most appropriate drug, dose and formulation according to the PGD
- Identifies ongoing treatment plan and referral options for service user

THE CONSULTATION

3. COMMUNICATING WITH SERVICE USERS

Establishes a relationship based on trust and mutual respect. Sees service users as partners in the consultation. Applies the principles of concordance

- Listens to and understands service users beliefs and expectations
- Understands the cultural, linguistic and religious implications of supplying and administering medicines
- Deals sensitively with service users emotions and concerns
- Adapts the consultation to meet the needs of different service users (e.g. for age, level of understanding)
- Creates a relationship which does not encourage the expectation that a medicine will be supplied and/or administered
- Explains the nature of the service users condition and the rationale behind, and potential risks and benefits of treatment options
- Helps service users to make informed choices about their options
- Negotiates an outcome of the consultation that both service user and health care professional are satisfied with
- Encourages service users to take responsibility for their own health and self-manage their conditions
- Identifies opportunities to discuss health promotion with service users
- Gives clear instructions to the service users about their medication (e.g. what is it for, how to take it, possible side effects and expected outcomes)
- Checks service users understanding of, and commitment to, their treatment

PGD COMPETENCIES

EFFECTIVE SUPPLY AND ADMINISTRATION WITHIN A PGD

4. SAFE PGD

Is aware of own limitations.

Does not compromise service user safety.

- Knows the limits of own knowledge and skill, and works within them
- Knows when to refer to, or seek guidance from, another member of the team or specialist
- Supplies and administers a medicine only with adequate, up to date knowledge of its actions, indications, contraindications, cautions, dose and side effects
- Checks doses and calculations to ensure accuracy and safety
- Knows about common types of medication errors and how to prevent them
- Uses PGDs often enough to maintain confidence and competence
- Understands the need for, and makes accurate, clear and timely records and clinical notes

PGD COMPETENCIES

EFFECTIVE SUPPLY AND ADMINISTRATION WITHIN A PGD

5. PROFESSIONAL STANDARDS

Works within professional and organisational standards

- Accepts personal responsibility for working within PGD's and understands the legal implications of doing so
- Understands and works within the scope of the PGD
- Makes ethical and/or clinical decisions based on the needs of service users, not personal considerations
- Understands current medicines legislation, the legal framework for working within PGDs and how they apply in practice
- Applies current professional codes of practice to the use of PGDs
- Keeps up to date with advances in practice and any emerging safety concerns related to medicines in the PGD
- Understands how consent relates to PGDs
- Knows how and when PGDs need to be changed, affects necessary changes

PGD COMPETENCIES

EFFECTIVE SUPPLY AND ADMINISTRATION WITHIN A PGD
6. PRACTICE DEVELOPMENT
Actively participates in the review and development of practice to improve service user care • Reflects on own performance, learns and changes practice • Willing to share and debate own, and others practice • Challenges inappropriate practice constructively • Develops own networks for support, reflection and learning • Develops and uses tools to review and improve PGDs and their use in practice (e.g. audit) • Reviews and reports incidents and near misses within a clinical governance context • Establishes professional links with practitioners working in the same specialist area

PGDs IN CONTEXT

7. INFORMATION IN CONTEXT

Knows how to access relevant information. Can critically appraise and apply information in practice

- Understands the advantages and limitations of different information sources
- Uses relevant, up to date information; both written (paper/electronic) and verbal
- Critically appraises the validity of information (e.g. promotional literature, research reports) when necessary
- Applies information to the clinical context (linking theory to practice)
- Uses relevant service user record systems, information systems, and decision support tools

PGD COMPETENCIES

PGDs IN CONTEXT

8. THE NHS IN CONTEXT*

Understands and works with, local and national policies and services that impact on PGD use

- Works within local frameworks for medicines use as appropriate (e.g. formularies, protocols and guidelines supporting PGDs)
- Works within the NHS/organisational codes of conduct when dealing with the pharmaceutical industry
- Understands drug budgetary constraints at local and national levels; can discuss them with colleagues and service users
- Understands the national NHS frameworks underpinning PGDs (e.g. national Institute for Clinical Excellence, National Service Frameworks, medicines management, clinical governance)
- Legally and safely orders, receives, stores and labels medicines being supplied or administered within a PGD
- Understands and levies appropriate prescription charges

* This competency has an NHS focus, however, the principles underpinning several of the statements still apply to health professionals working in non NHS organisations.

PGD COMPETENCIES

PGDs IN CONTEXT
9. THE TEAM AND INDIVIDUAL CONTEXT
Works in partnership with colleagues for the benefit of service users, is self aware and confident in own ability to use PGDs • Ensures that continuity of care is not compromised, by keeping all relevant colleagues informed • Uses the multidisciplinary team to its full extent • Establishes relationships with colleagues based on understanding of, and respect for, each others roles • Recognises and deals with pressures that result in inappropriate use of PGDs • Is adaptable, flexible and responsive to change • Negotiates the appropriate level of support to enable the use of PGDs • Provides support and/or advice to other health care professionals where appropriate

Appendix 4 Refresher Questionnaire

PATIENT GROUP DIRECTIONS (PGD's) –

REFRESHER QUESTIONNAIRE

It has now been 2 years since you were approved to supply / administer medicines under the PGD Protocol. Please answer the following questions in order for your line manager to ascertain your level of working knowledge regarding the PGD Protocol. Once you have completed the questionnaire your line manager will arrange a time to see you to review your understanding of the Protocol and discuss any future training needs you may have regarding PGD's. This questionnaire may form part of your appraisal/management supervision.

Name and Position……

Date……

1) Where is the PGD Protocol kept within your clinical area?

2) Is a copy of the PGD Protocol easily accessible to you?

3) List all the PGD's in which you are approved to be working with including definition of situation / condition, potential side effects and contraindications.

4) When you supply / administer medicines under the PGD Protocol what documentation do you need to undertake?

5) What are your current training / development needs regarding PGD's?

6) How do you think these training / development needs can be addressed?

Date to meet with Line Managers……..

Outcome of discussion /action plan (who needs to do what by when?)

Approved Practitioner
Signature……

Line Manager Name and
Signature……