



Guidelines for the Secure Distribution of Narcotic and Controlled Drugs in Hospitals

The Bureau of Dangerous Drugs, the Canadian Hospital Association, the Canadian Nurses Association and the Canadian Society of Hospital Pharmacists created the following guidelines in January 1990. These guidelines still stand as of this posting.

The stated objective of the guideline is to provide advice on procedures and record keeping in relation to narcotic and controlled drugs.

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**Bureau of Dangerous Drugs
Canadian Hospital Association
Canadian Nurses Association
Canadian Society of Hospital Pharmacists**

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1. Introduction

The importance of narcotic and controlled drugs in treatment of medical problems is clear. These same drugs do, however, have a high potential for abuse and misuse and as such are sought after and diverted from the licit drug distribution channels. Narcotic and controlled drugs are used extensively in hospitals. Many individuals are involved in the distribution and administration of these drugs to patients, resulting in a high potential for diversion.

The diversion and misuse of narcotic and controlled drugs impacts on a number of individuals. Those who divert these drugs for their own use run the risk of physical and psychological dependence. This may affect their ability to carry out their responsibilities. It may affect the treatment given by health professionals to the patients in their care and may also result in the loss or suspension of their licence or privilege to practice their profession. The quality of patient care may also suffer when drug substitution, dilution and underadministration are practised as a means of diversion.

According to the regulations governing narcotic and controlled drugs (see Appendix A), the person in charge of a hospital (administrator) is held accountable for matters related to these drugs within that institution. Specific responsibilities are further delegated to others at an operational level. The level of delegation, specific areas of responsibility and the principles upon which procedures are developed should be defined in the institution's formal policy. The regulations define responsibilities and requirements regarding the receipt and distribution of narcotic and controlled drugs. The following document includes elements of the regulations but also goes beyond and addresses what *should* be happening and how it *might* be done. The implementation of these latter recommendations is voluntary and is left to the discretion of individual hospitals.

The objective of these guidelines is to provide advice on procedures and record keeping in relation to narcotic and controlled drugs which will:

- ensure that the hospital is operating within the regulations
- minimize the potential for diversion
- clearly define responsibility and accountability for these drugs at different stages of handling without adversely affecting the availability of these drugs for the patients within the institution

These guidelines are structured to follow the flow of distribution of narcotic and controlled drugs from initial needs analysis and ordering to the administration of these drugs to patients. Some elements which have been included may seem rather fundamental but are nonetheless important. It is recognized that some suggestions made here may exceed the requirements set forth in the regulations while others may not be practical in all institutions.

2. Policy

Successful implementation of an effective program for the secure distribution of narcotic and controlled drugs requires commitment at all levels. This commitment is dependent upon the policies and procedures established within the hospital. It is therefore important that the principles of responsibility and accountability be clearly articulated in hospital policy.

3. Needs Analysis

3.1 Identifying Drug Needs

To ensure adequate availability and control over narcotic and controlled drugs, it is important to determine the needs of the hospital, and more specifically, the needs of individual patient care areas or nursing stations. Responsibility for this function rests jointly with pharmacy and nursing.

The following factors should be considered when establishing the drug needs of an institution or a patient care area:

- specific drugs required
- nature of conditions being treated
- prescribing patterns/habits of practitioners (physicians)
- range of dosages required
- minimum and maximum stock levels
- range of stock turnover
- record of stock returns from patient care areas (wards, clinics, etc.)
- record of local drug destruction of outdated or unserviceable (unusable) drugs
 - frequency
 - quantities
 - specific drugs
- availability and capacity of secure storage
- cost implications
- proximity to suppliers and resultant time for delivery

Once established, it is important to periodically review drug needs with consideration to the following:

- changes in utilization trends
- changes in clinical trends
- problems experienced
- factors previously considered to determine drug needs

4. Drug Ordering Process

4.1 Responsibility

The regulations specify that pharmacists or licensed dealers (manufacturers, distributors) may supply a hospital with narcotic or controlled drugs if they have first received a written order for the drugs in question. The order must be signed and dated by the individual, usually a pharmacist or practitioner on staff, to whom responsibility and authority for ordering these drugs has been delegated by the administrator of the hospital. The number of individuals to whom signing authority has been delegated should be limited. The hospital policy should define who may order such drugs and under what circumstances.

4.2 Purchase Orders

For the most part, hospitals employ a system based on the use of purchase order forms to obtain drugs and other material from suppliers. It is advisable that forms used to purchase narcotic and controlled drugs be pre-numbered and closely controlled using a log or other system which monitors:

- the distribution of blank forms
- forms which have been used, including all the information necessary to identify a specific transaction or order
- orders which are pending or on back order (there should be a procedure for appropriate prompt follow-up action which takes into consideration the normal or expected turnaround time for each supplier)

Prior to signing, purchase orders and requisitions should be carefully reviewed. Under no circumstances should blank purchase orders or requisitions for narcotic or controlled drugs be pre-signed.

5. Receipt of Drug Deliveries

5.1 Overview

Ideally, all goods and supplies, including narcotic and controlled drugs shipped by suppliers, should be delivered directly to and received by the pharmacy without any intervention. In many instances, this is not possible due to the location of the pharmacy or because of administrative procedures and controls which must be respected. In most cases, goods destined for the pharmacy are delivered to the hospital's receiving department and are then transferred to the pharmacy. Under such circumstances, the issues of accountability, transfer of responsibility and tracking through the use of a "chain of signature" are very important. It should be noted that neither the packages containing narcotic or controlled drugs nor the documents which accompany them should indicate the nature of their contents.

5.2 Receiving Department

When accepting delivery of packages intended for the pharmacy, the individual in the receiving department assumes responsibility for these goods until they are delivered to and received by the pharmacy department. It is therefore necessary for the receiving department staff to:

- ensure that the number of packages received corresponds with the number recorded on the documents accompanying the shipment
- examine the exterior of the package(s) for any signs of tampering or damage
Any discrepancies, damage or signs of tampering should be recorded on the waybill at the time of delivery and reported to the pharmacy department as soon as possible.

A separate log for pharmacy deliveries should be maintained in the receiving department or any other area in the hospital designated to accept goods for the pharmacy. The log should include the following information:

- date and time received
- company or supplier
- number of packages
- any identification numbers
- carrier
- signature of driver
- signature of the individual receiving the delivery
- signature of pharmacy personnel (when delivered)
- date and time delivered to the pharmacy department
- number of packages
- signature of the individual delivering the goods to the pharmacy
- comments regarding discrepancies, damage or signs of tampering

Where packages are not delivered directly to the pharmacy department, a general policy should require that they remain unopened by the staff receiving them. Procedures should be established for the receipt and secure storage of packages delivered to the hospital during those times when both the receiving and pharmacy departments are

closed. Access to the secure storage area should be limited to designated pharmacy and receiving department staff. All packages received should be *immediately* placed in the designated secure storage area and delivered to the pharmacy or picked up by pharmacy staff on a priority basis.

5.3 Pharmacy Department

5.3.1 Receipt

According to the procedure suggested above, an individual from the receiving department is required to obtain, in the receiving log, the signature of the pharmacy staff member accepting the packages. By signing for the packages, the responsibility for the packages and their contents is transferred from the individual from the receiving department to the pharmacy staff member. If problems or discrepancies are noted following this transfer, it is the pharmacy staff member who signed for the packages who is held accountable.

It is advisable for the pharmacy to maintain a receiving log similar to or consistent with that used in the receiving department (for details, see below).

It is assumed that the packages are unopened when they are delivered to the pharmacy department. As was the case in the receiving department, it is necessary to confirm that the order is complete (number of packages received corresponds with the number noted on the documentation that accompanies them) and to ensure that there has been no tampering with or damage to the packages. Any discrepancies or signs of damage should be noted on the shipping documents and on both the receiving department and pharmacy department logs, which are then signed off by both parties.

Packages received in the pharmacy department should be opened as soon as possible after they are received. If this is not practical, they should be stored in a secure area until they can be processed. Once the packages are opened, the balance of the information necessary for the receiving log is recorded. The information of relevance for the log should include:

- the date received
- invoice number (if available)
- purchase order number (if available)
- name of supplier
- number of packages
- drug name
- quantity
- lot number
- expiration date
- signature of receiving department personnel
- signature of pharmacy staff accepting delivery
- comments regarding discrepancies or damage

Problems relating to discrepancies, tampering or damage should be reported immediately to the Director of Pharmacy. The manner in which such cases are then pursued will vary among institutions depending upon the policies which are in the place and the division of responsibility regarding these matters within the institution. Problems of this nature must be reported to the Bureau of Dangerous Drugs through either the local inspector or regional office. Theft/loss reporting forms are available from the regional offices.

The receipt and processing of drug orders in the pharmacy department should be linked with the order monitoring, back-order and follow-up systems.

5.3.2 Introduction to Inventory

Narcotic and controlled drugs maintained in the pharmacy department should be stored in a manner which ensures their physical security. Consideration should be given to the guidelines on physical security issued by the Bureau of Dangerous Drugs.

Access to the pharmacy area should be restricted to pharmacy personnel and other hospital personnel (practitioners, nurses) for whom such access is essential. Access to the narcotic and controlled drugs or the areas where they are stored should be limited to designated pharmacy personnel. The issue of access and the list of individuals who may enter these areas should be specifically addressed in the hospital policies and procedures.

The manner in which narcotic and controlled drugs are introduced into the inventory of hospital pharmacy varies from one institution to another. In some instances, original packages containing drugs are immediately opened when received and added to the inventory (bulk dispensing containers, unit dose containers, pre-packs, etc.). In other cases, the drugs, still in the original package, are placed in a reserve and opened and added to the inventory only when they are required for the active dispensary.

It is important to check the individual packages or containers when they are received in the pharmacy to ensure that they have not been opened or tampered with. Any problems which are identified should be recorded in the pharmacy receiving log and reported to the Director of Pharmacy.

At the time the original package or container is first opened, it is suggested that the individual responsible visually confirm the contents of each. It is further suggested to perform a physical count of solid dosage forms and measure the volume of liquids to ensure that the contents correspond with the quantity or volume anticipated. Discrepancies should be noted and reported to the Director of Pharmacy.

Occasionally, patient care areas return drugs to the pharmacy which are no longer required, which have expired or been damaged. Designated nursing personnel within the patient care area should be given responsibility for this function. Where drugs are returned to the pharmacy's active dispensary inventory, the appropriate records or documents related to the perpetual inventory system are completed. It is suggested that the pharmacy maintain a separate log for drugs that are no longer usable, have been destroyed, returned to the supplier or otherwise removed from the active drug inventory. This log should include the following information:

- date removed from inventory
- name, strength and form
- quantity
- reason for removal from inventory
- signature of pharmacy personnel responsible

5.4 Perpetual Inventory System

5.4.1 Overview

Many hospitals use a system of perpetual inventory to monitor the use and distribution of certain drugs used in their institution. This system, in conjunction with periodic audits or other verification, provides an excellent means of ensuring the security of narcotic and controlled drugs and permits early identification of diversion or loss.

While it may not be practical in all cases, it is suggested that as many narcotic and controlled drugs as possible be maintained in this way.

Such a system can record the receipt of drugs and trace their distribution and use within the institution. It also clearly identifies responsibility for these drugs and permits early identification of diversion and reduces the area of investigation. In some systems, the theoretical balance according to the records and the actual stock on hand are verified each time drugs are issued from or added to the inventory, while in others this reconciliation or verification takes place as part of a separate, ongoing audit process.

While perpetual inventory systems may vary in how they are organized and how they operate, they are, for the most part, based on the use of an inventory card and an issue or administration form. The inventory card is maintained in the pharmacy and is used to record the receipt and release of a drug from that area. The issue or administration form accompanies the drug when it is released to a patient care area and is used to track the distribution of that drug.

5.4.2 Forms

Within a perpetual inventory system, a separate inventory card or form (see Appendix B) is created and maintained in the pharmacy for each drug, including those that are pre-packaged or kept in bulk. Information to be noted on the card/form includes the following:

- date that the card was initiated
- name and strength of the drug
- dosage form
- lot number
- date the drug was received or issued
- the number of the administration sheet corresponding to the issue or return
- quantity added/subtracted
- balance (current)
- date that the administration sheet was returned to the pharmacy (if applicable)
- signature of the pharmacy staff member issuing or receiving the drugs
- patient care area to which it was issued or from which it was returned

When drugs are ordered by and issued to a patient care area, an administration form, controlled by the pharmacy, is sent with the drugs. Depending upon the system in place, the administration form may be for one or more drugs. It is maintained in the patient care area and completed each time medication is administered. In some systems, the completed administration form is also used in the requisitioning process.

The issue or administration form (see Appendix C) should contain the following:

- a sequential number
- name of the patient care area to which the drug was issued
- name, strength and dosage form of the drug
- quantity
- signature of pharmacy staff delivering or issuing the drug
- signature of RN receiving the drug from the pharmacy staff
- date delivered/issued
- date and time of administration
- dose
- quantity used
- amount wasted (double signature suggested for witnessing destruction)

- first and last name of patient
 - prescribing practitioner
 - signature of the individual (RN, practitioner) administering the drug
- In some systems, the issue or administration form is printed as a two part form. One copy/part is released with the drugs while the second copy/part is retained in the pharmacy as a control for tracking and follow-up purposes.

5.4.3 Verification

A random verification of orders placed, orders received and entries into the perpetual inventory system in the pharmacy should be undertaken on a regular basis (at least monthly) by a pharmacist or other designated pharmacy staff. Audits and verifications should be undertaken more frequently where there are personnel changes, where problems are encountered or where there is a high volume of distribution.

The audit should include the monitoring or verification of the following:

- stock on hand
 - purchase orders that have been issued
 - purchase orders that are pending
 - back-orders
 - records of receipt (pharmacy receiving log)
 - records of distribution (administration forms issued, received, outstanding)
- The verification or audit process which should be undertaken at the patient care area level will be addressed in section 9.1.

When a discrepancy or shortage is noted, the case should be reported to the Director of Pharmacy for investigation and further action.

6. Distribution

6.1 Overview

As previously stated, it is important to determine the drug needs of the hospital and of the individual patient care areas as dictated by the patients and conditions being treated. The issue of needs analysis and factors to consider are addressed in section 2.1. For reasons of security, the quantities of narcotic and controlled drugs maintained in the patient care area should be kept to a minimum while still being sufficient to respond to the needs of the patients. Recurring shortages of supply in the patient care area should be addressed through a review of needs and not through borrowing between patient care areas, a practice which is not acceptable.

The system used to supply patient care areas with narcotic and controlled drugs or to replenish these supplies varies from institution to institution. In some institutions, the stock is automatically replaced by the pharmacy based on the minimum levels required or using a 24-hour administration/audit record system. In others, medication is supplied to the patient care areas in response to a requisition submitted to the pharmacy. Whatever system is used, it is important that it clearly and accurately records the distribution of these drugs in a manner that will permit monitoring of the process and ensure responsibility and accountability for the drugs.

6.2 Requisition

In some hospitals, drugs are distributed to patient care areas based on the use of a written requisition prepared by the nursing staff and submitted to the pharmacy department. The form used in such a system should include the following information:

- sequential number (for monitoring and tracking purposes)
- name or number of the ward
- date
- name, strength, form of the drug
- quantity of the drug
- signature of the individual requisitioning the drug
- signature of the individual issuing/delivering the drug
- signature of the individual who accepted delivery of the drug
- date and time of delivery

Some of the information, such as the signature of the individual accepting delivery of the drug, is also mentioned in the perpetual inventory form referenced above (Section 5.4.2). Information of this nature is required on the document and is used to record the delivery and receipt of the drugs only as requested. It is a means to ensure accountability and the transfer of responsibility of the drugs from the pharmacy to the patient care area.

The concept of reference number suggested for the forms proposed can be very useful in monitoring the distribution of drugs and can serve as a link at all levels from the point of receipt to the administration to a patient or return to the pharmacy.

6.3 Processing and Delivery

As previously stated, the requisition form is completed by the staff in the patient care area and delivered to the pharmacy. In some systems, it is necessary for the form to be accompanied by the empty package or scanner in which the medication was supplied to the patient care area and the completed administration form which the new request is replacing. In other systems, requisitions are processed without the foregoing but the pharmacy closely monitors the distribution of drugs, making note of administration forms that have been issued, returned and still outstanding.

As the requisition form is processed, the medication is removed from the pharmacy inventory. At the same time, the perpetual inventory card for that product must be updated/adjusted accordingly. Consideration must be given to current stock levels in the pharmacy and the need to reorder or, in cases where it is used, medication must be transferred from the pharmacy's reserve stock to the active dispensary stock, with proper documentation of the transaction.

Depending upon policy in place and/or procedural or operational considerations within the institution, drugs may either be picked up by a member of the nursing staff from the patient care area or delivered to the area. Where drugs are picked up in the pharmacy by the nursing staff, procedures should be in place to confirm the nurse's identity and authority to receive the drugs. In cases where drugs are delivered to the patient care area, it is suggested that this be undertaken by a member of the pharmacy staff (pharmacy assistant, pharmacist). Drugs should be either delivered by hand or using a locked cart. The use of pneumatic tubes, dumbwaiters or other unattended mechanical devices is not recommended.

It should be emphasized that until the drugs are delivered and accepted by the patient care area, the pharmacy department retains responsibility for them. Before signing for the drugs, the nurse should ensure that the information on the form corresponds with the drugs being received. Once both the pharmacy staff and the RN are satisfied that all is in order, the nurse signs the appropriate form/record. The responsibility and accountability for the drugs is then transferred to that individual and to that patient care area.

7. Patient Care Area

7.1 Inventory

Drugs received in the patient care area should immediately be incorporated into the stock or inventory of drugs maintained in that area. Any records concerning the quantities of medication maintained in the area should be modified to reflect the additional stock. The medication administration form may be the only record accompanying the medication.

In introducing the medication to the stock in the patient care area, the actual balance of the drug on hand should be verified. Whenever possible, this verification should be undertaken by two nurses. Inventory records should be amended whenever medication is added to the stock, removed for administration, damaged and destroyed or returned to the pharmacy.

7.2 Secure Storage

7.2.1 Storage Units

The manner in which hospitals must store narcotic and controlled drugs in the patient care area is not specifically addressed in the regulations. Most hospitals use a locked cupboard or cabinet. The cupboard is normally secured with two locks for which the keys are controlled by two different people. From a security and drug control standpoint, this two- key system is most desirable. Such drugs are also stored in special locked drawers in a medication room or in a medication cart used to deliver the drugs to the patients. Ideally there should only be one storage site for drugs in each patient care area.

Whatever container or cabinet is used, it should have secure locks and be constructed in such a way as to minimize the possibility of undetected forced entry. Consideration should be given to the type of locks and hardware that are used, how they are installed (e.g., with inside hinges), the construction of the container, compartment or drawer, and the structure into or onto which it is secured or attached. All drug cabinets, drawers, compartments or other storage areas should be locked when not in use. Narcotic and controlled drugs maintained in a medication cart should be stored in a locked drawer or compartment. This drawer or compartment should be locked during rounds through the patient care area and when the cart is left unattended. From a security standpoint, it may also be desirable to secure the cart to a wall or lock it in a cupboard when not in use.

7.2.2 Access Control

Within each institution, a policy should be established regarding access to drug storage and the use, distribution and control of keys in a patient care area. Access to other personnel, such as agency nurses, graduates and students, should also be addressed in the hospital policy regarding this matter.

It is suggested that only one individual per shift be assigned responsibility for control of the key. The policy established within the hospital will specify the procedures and responsibilities associated with this function. The question of who should have access to the cabinet should also be included as part of the policy. A key control log is

recommended, in which nurses can sign when they take the key and return it. Under no circumstances should a key leave the hospital. If the key has been lost or removed from the hospital, the locks to the storage cabinet or compartment should be changed. Locks should also be changed when a significant loss has been discovered.

At change of shift, responsibility for the key is formally transferred to the nurse coming on duty. At this time, the narcotic and controlled drug stock in the patient care area should be verified. The verification should be undertaken by both the nurse coming on duty and the nurse going off duty. Both should perform an actual physical count of the drugs and verify it against the records. Particular care should be exercised in verifying that the balance total has been properly brought forward. The verification should not be limited to a count of units but should also include an examination of the drugs themselves to ensure that substitution has not taken place. Any discrepancies should be immediately investigated. Both nurses should sign the administration sheet or other inventory control form which is used. In this way, the responsibility for not only the key but also the drugs is transferred to the nurse coming on duty.

7.3 Administration

Before a drug is administered, the nurse must verify that a current order, written by an authorized physician, exists on the patient's chart. The nurse should obtain the key from the nurse responsible, signing the key control log as required. In removing the medication required, the nurse should immediately complete the drug administration form, the inventory control sheet, the patient's chart or any other documentation required by hospital policy.

Whenever an ampoule is broken, the breakage must be documented by two nurses, i.e. the nurse who broke the item as well as a witness. Similarly, whenever partial contents of a dosage form is used, the unused portion must be witnessed and destroyed. The drug administration form, the inventory control sheet or any other document used for this purpose must be completed as required and signed by both parties. It is suggested that contaminated or unusable oral dosages be returned to the pharmacy department.

Damaged medication (which is not destroyed in the patient care area), excess medication, or medication that has exceeded the expiry date should be returned to the pharmacy as soon as possible. All records maintained in the patient care area must be modified to reflect this transfer of stock.

8. Special Patient Care Areas

8.1 Overview

Typically, substantial quantities of narcotic and controlled drugs are used in special patient care areas, such as the operating room, labour/delivery, intensive care unit and emergency department. Exercising adequate control over the distribution and use of such drugs in these areas is often complicated by the nature and volume of the work, the demands placed on the staff and other operational considerations. In spite of the foregoing, the principles of responsibility and accountability with respect to the receipt, distribution and use of narcotic and controlled drugs apply as much to these special areas as they do to the other patient care areas. The policies and procedures for ordering, receipt, storage, access and record keeping in the special patient care areas should not differ from those found in the other patient care areas. Additional special precautions are also required for these areas due to operational considerations, the large quantities of drugs used, the nature of these drugs and access to these areas by a variety of individuals. Commitment to and respect for these principles and procedures by *all* health professionals and other affected hospital staff working in these areas is extremely important and must be a priority for the senior management and administration of the hospital.

8.2 Operating/Labour and Delivery Room

The maintenance of adequate control over the distribution and use of narcotic and controlled drugs in the operating room presents certain unique problems. Within the operating room, many individuals have ready access to large quantities of potent narcotic and controlled drugs. Information available suggests that accessibility to these drugs and the stressful nature of the work places operating room staff in a vulnerable position. An effective control system is therefore most important.

In most institutions, a central supply of narcotic and controlled drugs is stocked by the pharmacy. It is suggested that a perpetual inventory system be used for all drugs stored in this central stock. When drugs are removed from or returned to the central stock, a record of the transaction should be made on an inventory card (see Appendix D) on which the following information should be noted:

- date/time
- name and quantity of drug(s)
- name/signature of individual removing/returning drug(s)
- reference number (if one is used on the dosage card or container)
- drug(s) being removed or returned
- destination/origin (OR number, name of practitioner)

Depending upon the system being used, when removed from the central stock, drugs may either be allocated to a specific operating room or to a specific practitioner. The amount of medication removed and allocated normally corresponds to that required for that day. Drugs which have been allocated to a practitioner called to another area of the hospital or to the operating room should not be removed from the area. When drugs are issued from the central stock, an administration form (see example, Appendix E) should accompany the drugs. The form relates to one or more drugs, depending upon the system being used, and should contain the following information:

- date/time of administration
- name/ID number of patient
- name and quantity (in mg and volume) of drug administered
- signature of the practitioner
- indication of the first administration from a new multi-dose ampoule
- number of the operating room

Hospital procedures may also require the recording of similar information concerning the administration of medication on the patient's record. It is important that the administration form be completed as soon after the drug is administered as possible. Further, it is the responsibility of the practitioner who administered the drug to complete this record. In some instances, OR nursing staff are called upon to complete these records on behalf of the practitioner. This practice is inappropriate and unacceptable, and should not be permitted.

On occasion, it is necessary to dispose of a small volume of medication from an opened ampoule (wastage). The normal practice under these circumstances is to destroy the medication in the presence of a witness. The manner in which this is to be completed should be defined or specified in policy and procedures established by the hospital. The destruction of wastage should be recorded on the administration form or on a special form designed for this purpose, which contains the following information:

- name and quantity of the drug
- date/time
- name of individual destroying the drug
- name of the witness

As in the other patient care areas, the inventory and records for the central operating room stock should be verified at each shift change. When completed administration sheets and surplus drugs are returned to the central OR stock, the records for the perpetual inventory should be adjusted and the information recorded on the administration and wastage reporting forms should be verified and reconciled.

8.3 Intensive Care Unit

The policies and procedures related to the receipt, storage and distribution of narcotic and controlled drugs within the intensive care unit and the records which should be maintained should not differ from those previously described for other patient care areas.

8.4 Special Clinics/Emergency Department

Frequently, minor surgical procedures requiring certain narcotic and controlled drugs are performed in special clinics within the hospital. Occasionally, these drugs are required for use in the emergency department of the hospital. The large number of patients who have access to these areas presents certain control problems. As such, narcotic and controlled drugs should not be maintained on-site, particularly when the clinic is not operating. When it is not practical to remove them, proper physical and procedural security measures should be implemented to protect these drugs. Proper security measures are required for the prescription pads used by practitioners in the emergency department. Diversion by means of forgery using prescription pads stolen from hospitals represents a major means of diversion of narcotic and controlled drugs. Prescription pads should not be left unattended in any part of the hospital. Ideally each practitioner should carry a pad. Pads not in use should be securely stored.

9. Audit Process

9.1 Patient Care Area

As previously stated, it is suggested that a verification or count of stock maintained in the patient care area be undertaken at each change of shift. This helps to clearly define responsibility for these drugs.

In addition to the foregoing, the head nurse of the patient care area or a delegate should review all administration records to ensure that they have been completed properly and accurately. This should be done daily, before these documents and the requisitions are returned to the pharmacy. It is also important to verify the signatures of the nurses recorded as administering the drugs and confirm that the nurses and patients identified in these records were in fact in the patient care area during that shift. It would also be useful to routinely compare the administration sheets against the patient charts.

9.2 Pharmacy

The pharmacy department represents the focal point for the receipt and distribution of narcotic and controlled drugs. It is important that there be a system in place to monitor these activities. This system should be coordinated by the director of the pharmacy department or a designate. Ideally, responsibility for the individual elements of the audit or verification process should be delegated to a number of different pharmacy personnel on staff with a periodic rotation of these responsibilities. Some elements of such a system are mentioned in section 4.4.3 and may be repeated here.

Part of this system is addressed in the periodic review of purchases with a reconciliation of invoices or orders received against purchase orders that have been issued. This should be undertaken with some frequency to ensure early identification of problems and back orders. The reconciliation process should extend to the verification of receipt records against those relating to the introduction of the drugs to the inventory. A random audit of selected products should be conducted. It is also important that the pharmacy periodically verify the medication administration records or forms against the physicians' orders and the patients' charts. Records associated with the distribution of the narcotic and controlled drugs must be maintained for a minimum of two years. Hospital policy concerning this matter may, however, specify a longer retention period.

10. Diversion

10.1 Overview

As previously stated, the extensive use of narcotic and controlled drugs within a hospital, the complex system of distribution and the many individuals involved in the system who have access to these drugs provide ample opportunity for diversion. Under these circumstances, the diversion of narcotic and controlled drugs may be accomplished in various ways, including the following:

- theft
- substitution/dilution
- excessive breakage/waste
- administration
 - substitution
 - give less than is ordered
 - abuse of "prn" order
 - give nothing at all
- falsification/manipulation of forms and records

The key to minimizing such diversion is to ensure that there are sufficient checks and balances in place, that clear responsibility and accountability for these drugs is established and that such responsibility is transferred as the drugs move through the system.

10.2 Identification/Investigation

The policies and procedures within a hospital should define what steps are to be taken when a shortage or loss of narcotic or controlled drugs is discovered. In some instances, the procedure involves reporting the matter to the individual (pharmacist, nurse, practitioner) responsible for the area or unit in which the shortage or loss was discovered. It may be the responsibility of this individual to undertake a preliminary verification/reconciliation and then contact the hospital security section or refer this matter directly for investigation. Some institutions rely on a multidisciplinary committee with representation from pharmacy, nursing, security and human resources. Whatever approach is adopted, it is imperative that the individuals involved accurately record their observations and any other relevant details or information for consideration by the investigator.

The discovery of drug diversion within a hospital and the associated suspicion of guilt invariably creates a very stressful situation. It is therefore important that the area under examination and the individuals under suspicion be reduced and the investigation focused as quickly as possible. This will be facilitated if the principle of transfer of responsibility and the relevant procedures have been respected.

In conducting the investigation, it is extremely important to maintain objectivity at all times and to recognize and examine all points within the distribution system where the diversion may have taken place. It is probable that attempts have been or will be made to cover the diversion and divert attention or suspicion from the

individual responsible. It is important to avoid allegations or accusations until the investigation is concluded.

A review and verification of all records, forms and charts associated with the receipt and release of the drugs will help to track the transfer of responsibility and focus the investigation. Other elements of the investigation should include the following:

- an audit of doctor's orders, patient charts and administration records, including administration records from previous shift
- verification that patient was/is in the unit
 - check for administration of medication just prior to release of patient
 - verification that previous balances were carried forward correctly
 - verification of medication counts conducted on shift changes
 - examination of patterns of usage
 - signs that record entries (names, dates, figures, signatures) have been altered
 - errors in charting or signing out doses
 - examination of drug waste and destruction
 - frequency
 - individuals involved
 - patterns
- verification that all records and forms are available
- observation of involved shifts over a period of time
- patient complaints
 - continuing pain
- examination of package for signs of tampering/substitution
 - laboratory analysis for strength and content
- behaviour of staff
 - signs of physical impairment
 - poor work habits
 - work history
- complaints regarding staff

The Narcotic Control Regulations and the Food and Drugs Regulations require that all losses of narcotic and controlled drugs be reported to the Bureau of Dangerous Drugs within 10 days of discovering the loss. A loss/theft form (see Appendix F) must be completed and submitted to the regional office in the area. All details relating to the incident must be recorded and additional information may be provided in a letter, which could accompany the form. If the assistance of a Bureau inspector is required, necessary arrangements may be made through the Regional Manager (see Appendix G). Hospital policy should specify when the case should be reported to the local police.

Upon completion of the investigation, the suspected individual must then be confronted with the facts and evidence of the case. The follow-up action depends upon a number of factors. In some instances, in addition to the question of theft of property, there may be criminal intent (e.g., diversion for purposes of trafficking) which may or may not be associated with personal use. This matter should be pursued by the police. Hospital policy will determine what further action will be taken with respect to the individual within the institution.

If the individual is found to have a personal problem of drug abuse, it would be appropriate to recommend treatment, rehabilitation and support, possibly through an Employee Assistance Program or similar organization. This is particularly important

when the individual is a health care professional. Considerable time and money has been invested in developing these individuals with the knowledge, expertise and experience necessary to practice their professions. It would, therefore, be appropriate to make every effort to save this resource. Under these circumstances, in addition to reporting the details of the case to the Bureau of Dangerous Drugs, the appropriate provincial licensing authority or association should be advised. These organizations may have active treatment and support programs for their registrants. If not, they are able to refer the individual to the appropriate facility. The approach taken is normally supportive rather than punitive.

