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Application of a Quality System Model for Inpatient Medication Use; Approved Guideline

This document provides a model for providers of pharmacy services that will assist with implementation and maintenance of an effective quality system.

A guideline for global application developed through the NCCLS consensus process.

NCCLS

NCCLS...

Global Consensus Standardization for Health Technologies

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Abstract

NCCLS document HS10-A, *Application of a Quality System Model for Inpatient Medication Use; Approved Guideline* provides the necessary background information and infrastructure to develop a quality system that will meet healthcare quality objectives and be consistent with the quality objectives of each institution. This guideline provides a structure for a comprehensive, systematic approach to build quality into the pharmacy service's processes, assess its performance, and implement quality improvements.

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Foreword

NCCLS document HS10—*Application of a Quality System Model for Inpatient Medication Use* is one of a series of NCCLS documents focused specifically on healthcare clinical service quality system management. These specialized documents are designed for any healthcare service manager who wishes to improve the processes involved in creating customer satisfaction by implementing proven, standardized quality system concepts. NCCLS intends these guidelines to be useful as a set of complementary references for any service creating a new quality system management program or enhancing one already established.

The quality system approach endorsed in this series of quality management documents stems directly from the model presented in NCCLS guideline HS1—*A Quality System Model for Health Care*. HS1 provides fundamental guidance for clinical service quality management within an internal, infrastructural quality system matrix of core policies, processes, and procedures. HS1 serves as a manager's guide to quality system implementation and management.

The core array of policies, processes, and procedures of a quality system forms a grouping of 12 quality system essentials (QSEs). These 12 QSEs are the most fundamental managerial activities that are universally important for supporting any healthcare service operational path of workflow. The QSEs form the infrastructural framework necessary for the delivery of any type of product or service—they incorporate all managerial resources by which any healthcare service performs its operational work. The 12 QSEs are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

Each healthcare service also needs to integrate its managerial quality system with its operational path of workflow—matching unique managerial resources with unique operational processes.

HS10 introduces the path of workflow for inpatient medication use—that is, the preservice, service, and postservice processes that transform a request for medication therapy through ordering and provision of the medication, to administration of a medication and monitoring of the patient to observe the effects of the therapy. The guideline includes examples specific to inpatient pharmacy.

This guideline is intended for use in conjunction with NCCLS document HS1—*A Quality System Model for Health Care* when developing a quality system for healthcare services. Additional documents in the NCCLS Quality Series will also be valuable resources for additional QSE- and service-specific information.

The previous edition (HS10-P) was published for wide and thorough review in the NCCLS consensus review process. The objective of this review was to obtain input on the utility and applicability of the recommendations provided for implementing and sustaining a quality management system for inpatient medication use. However, a "Summary of Consensus Comments" has not been included in this approved-level document, as no comments were received during the consensus review period.

Key Words

Path of workflow, postservice, preservice, processes, service

Application of a Quality System Model for Inpatient Medication Use; Approved Guideline

1 Scope

NCCLS document HS10—*Application of a Quality System Model for Inpatient Medication Use* describes important activities in the path of workflow for inpatient pharmacy services, including clinical and distributive pharmacy functions.

This guideline is intended for use by all individuals involved in the path of workflow for inpatient medication use including physicians, nurses, other authorized prescribing practitioners and allied health professionals (e.g., certified registered nurse anesthetists (CRNA)), clerks, transporters, and couriers, as well as pharmacy, clinical, and support staff.

2 Introduction

This document describes the path of workflow for inpatient medication use, which is defined as the sequential processes in preservice, service, and postservice activities that transform a physician's medication order into an administered medication. The healthcare facility's pharmacy department is the primary provider of these services. The pharmacy should design its processes and procedures appropriately for the scope of services of the healthcare facility. Each facility needs to understand how work flows through its particular inpatient medication system, so processes can be designed and procedures written that will build the required level of quality into medication use work, reducing the potential for medication errors that waste resources and harm patients.

Policies, processes, and procedures for activities in the inpatient pharmacy's path of workflow are, however, not sufficient to ensure the quality of the service. They must be combined with policies, processes, and procedures for Quality System Essentials (QSEs) to establish a complete quality system. Users of this document are strongly encouraged to combine the activities described in both NCCLS document HS10 and NCCLS document HS1—*A Quality System Model for Health Care* to ensure a complete infrastructure for quality in the inpatient pharmacy.

This guideline presents information about the inpatient pharmacy's path of workflow and provides specific pharmacy examples. Additional pharmacy-specific information for the QSEs is also provided with relevant examples.

3 Definitions

Path of workflow – All preservice, service, and postservice processes in sequential order.

Postservice – All processes following inpatient pharmacy services, including medication administration, and patient monitoring.

Preservice – All processes in sequential order from patient assessment, including physician medication ordering, care unit order processing, and transmission of the order to the pharmacist; **NOTE:** This portion of the path of workflow ends when the pharmacist receives the physician's order.

Procedure – A specified way to carry out an activity of a process (ISO 9000:2000).[1]

Process – A set of interrelated activities that transforms inputs into outputs.[1]

Quality system essentials – Coordinated management activities to direct and control an organization with regard to quality (Derived from ISO 9000:2000).[1]

Service – Activities and steps related to performing inpatient pharmacy functions.

4 Path of Workflow

4.1 Introduction to the Path of Workflow

The hospital inpatient pharmacy's path of workflow consists of preservice, service, and postservice processes. The path of workflow begins with an assessment of the patient to determine the need for medication therapy and proceeds to the physician's ordering of the medication, the pharmacy's provision of the ordered medication, the administration of the medication to the patient, and monitoring of the patient to observe effects of the therapy. Throughout the path of workflow, other providers may call upon the pharmacist to provide a clinical consultation. The overall path of workflow for the inpatient pharmacy function is shown in Figure 1.

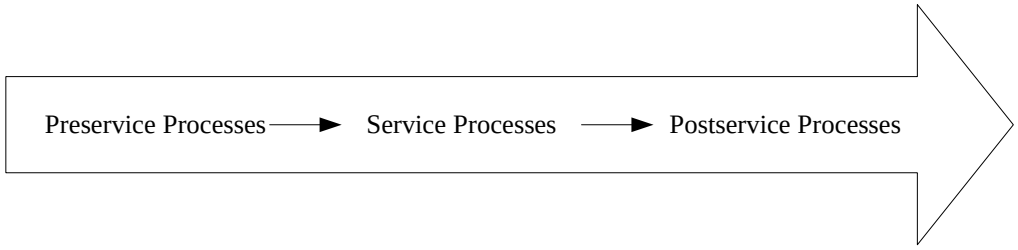


Figure 1. Inpatient Medication Use Path of Workflow

The processes in the inpatient medication use path of workflow begin outside the pharmacy's boundaries with the selection and ordering of a medication for a patient. The pharmacy's path of workflow processes end outside the pharmacy's boundaries with the administration of the medication and the monitoring of the patient. The medication use path of workflow includes actions performed by physicians, nurses, other authorized prescribing practitioners and allied health professionals (e.g., certified registered nurse anesthetists (CRNA)), clerks, transporters, and couriers, as well as pharmacy, clinical, and support staff. The completeness, correctness, and timeliness of these actions influence the accuracy and timeliness of the resulting pharmacy services and thus, the quality and value of medication therapy. Consequently, it is incumbent upon the pharmacy to ensure that processes and procedures performed by nonpharmacy personnel within the pharmacy path of workflow are taught to such personnel, are understood and followed, and meet performance requirements.

5 The Inpatient Pharmacy's Path of Workflow

"Medical error" has been ascribed to a "failure of process."[2] Therefore, the pharmacy's best contribution to eliminating any medical error (referred to as "medication error" and/or "adverse drug event" in medication-related activities) which might occur in the pharmacy's path of workflow—and that might harm patients—is to thoroughly understand the processes in its path of workflow, make them error-proof and failsafe when possible, and improve/replace those processes when opportunities exist.

Each pharmacy should document how the various processes in its path of workflow actually occur in its facility. Documenting these processes and procedures provides the basis for staff training in "how it happens here" and for assessing competence in job tasks for both pharmacy and nonpharmacy personnel. This documentation is also the foundation of the pharmacy's ongoing process improvement efforts and technology evaluation initiatives.

The guidance presented in the sections that follow was derived from an analysis of governmental and accreditation requirements for inpatient medication use and hospital pharmacy operations.[3] These requirements have been sorted across the path of workflow to facilitate their use in the application of the quality system. The requirements identify processes and procedures that the pharmacy must have in place, and for which it must provide objective evidence to investigators, assessors, surveyors, and inspectors that the requirements have been met.

Understanding, documenting, and training in the pharmacy's processes provide a high level of assurance that governmental and accreditation requirements will be met and that inspections and assessments will demonstrate compliance with the requirements. It is through continuous management and improvement of the pharmacy's many processes that regulatory and accreditation standards can be met. This management priority will also result in more efficient use of human and other costly resources (drugs), and reduce the potential for medication errors. Pharmacies that build requirements into daily routine practices will always be ready for external review.

Management and staff should begin their quality initiative by documenting pharmacy path of workflow processes with flowcharts. Process flowcharts are the natural depiction of processes, and identify sequential tasks/activities and their interdependence. These sequences of tasks turn the path of workflow inputs into outputs. The process flowcharts identify each activity that requires a written procedure. These flowcharts will also make problem areas stand out by identifying redundant tasks, rework "loops," and delays. The flowchart is also useful in finding opportunities to increase avoidance of errors and to improve the failsafe features of the process. Finally, the flowchart is an essential tool in the redesign and improvement of processes.

Appendix A1 contains flowcharts of pharmacy path of workflow processes using various levels of automation and information technology to reduce errors and streamline the overall path of workflow. Error reduction and efficiencies are achieved. Appendix A2 illustrates how a process flowchart can be translated into a tabular format to catalog process steps, the individual responsible for performing each step, documents involved, and quality indicators.

5.1 Preservice Processes

Key preservice processes in the inpatient medication use path of workflow include all activities from patient assessment to determine medication need, through the delivery of an authorized prescribing practitioner's medication order for review and verification. Preservice processes also include a variety of medication order "processing" activities performed in the care unit. The extent of information technology deployment in the particular facility can significantly affect how medication order processing is accomplished. Preservice processes in the inpatient medication use path of workflow are shown in Figure 2.

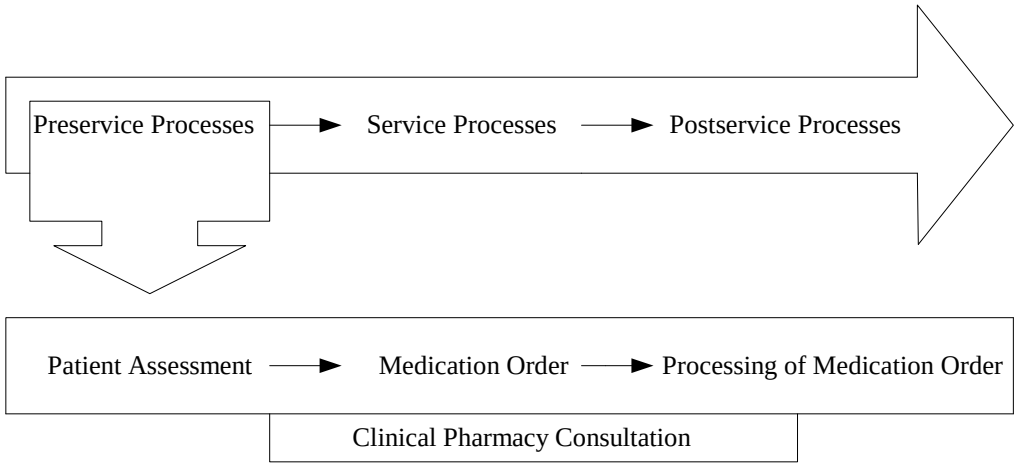


Figure 2. Inpatient Medication Use Preservice Processes

5.1.1 Patient Assessment

Authorized prescribing practitioners and allied health professionals use a variety of assessment techniques to assess the patient's condition. The patient should be assessed to determine what medications, if any, are required to meet a patient's initial treatment needs, as well as his or her medication needs as they change in response to care. Increasingly, physicians are seeking consultations from clinical pharmacists to aid in determining which medications, if any, will benefit the patient in his or her course of treatment.

To assist the authorized prescribing practitioner in patient assessment and treatment design, the pharmacy needs to provide authorized prescribing practitioners and allied health professionals with:

- an appropriate selection of medications available for prescribing and ordering;
- drug information (i.e., therapeutic capabilities, indications, dosing routes, drug, diet, laboratory interactions, and side effects);
- the hospital's formulary; and
- responses to specific drug-related queries.

The pharmacy needs to establish procedures regarding the identification, use, and control of medications brought into the facility by patients.

5.1.2 Medication Order

When the authorized prescribing practitioners have assessed the patient and determined a course of treatment, the role of medication therapy in that treatment needs to be defined. The pharmacy needs to provide the following procedures for those who order medications:

- how to properly complete written medication orders with all required information;
- how to enter medication orders into computer systems, if computerized physician order entry (CPOE) is available;
- how to order drugs not available in the formulary; and

- how to obtain a clinical pharmacy consultation.

The medication order itself needs to contain the following:

- drug;
- dose;
- route of administration; and
- frequency and duration of administration, when appropriate.

Examples of means to generate medication orders include:

- verbal orders;
- written orders; and
- electronic orders (referred to as “CPOE”).

In response to a request for consultation, the pharmacy needs to provide some or all of the following information to the prescribing or administering authorized practitioner:

- suggested drug, dose, frequency, and route of administration;
- drug interactions with other drugs, diet, laboratory values;
- costs of specific drugs, their generic equivalent, formulary status; and
- research information regarding specific drugs, if relevant.

5.1.2.1 Verbal Orders

The facility needs to identify individuals authorized to accept and transcribe verbal orders. The pharmacy needs to have a process for authentication of verbal orders by signature or initials of the authorized prescribing practitioner, as soon as possible. Verbal orders need to be dated and timed by the authorized prescribing practitioner. Verbal orders should be used only to address emergent/urgent patient care requirements.

5.1.2.2 Written Orders

Written orders need to be legible and signed by the authorized prescribing practitioner responsible for the care of the patient.

5.1.2.3 Electronic Orders

Electronic orders must be signed electronically by the authorized prescribing practitioner who initiated the order, whether it is a verbal order or direct input to the electronic device.

5.1.2.4 Standing, Routine, or Protocol Orders

Standing, routine, or protocol orders need to be reviewed and revised by the authorized prescribing practitioner and approved, at least annually, by the authorized prescribing practitioner.

5.1.2.5 Time-Limiting of Medication Orders

The pharmacy and professional authorized prescribing practitioner need to have a policy establishing time frames for "time-limiting" of medication orders.

There needs to be a procedure for automatically discontinuing medications that are:

- written as a "time-limited" order; and
- not specifically limited as to time and/or number of doses to be administered.

5.1.3 Processing of the Medication Order

Once the authorized prescribing practitioner generates the medication order (verbal, written, or electronic), the order needs to be processed in the patient care setting. Medication order processing in this setting should include the following activities:

- transcription of the medication order into the computer or onto a written request form;
- review of the transcribed order for completeness and correctness; and
- transmission of the order to the pharmacy by manual or electronic means.

5.1.3.1 Order Transcription

Verbal orders need to be transcribed either to an order form or into a computer. In either case, the authorized prescribing practitioner must eventually sign these transcribed orders as they appear in the patient's medical record (electronic or paper). Orders written by the authorized prescribing practitioner may also need to be transcribed onto a nursing work list, and/or a medication administration record (MAR). A copy of the pharmacy-written order must go to the pharmacist for review and verification before being entered into the computer (usually entered into a pharmacy computer by the pharmacist or a pharmacy technician).

5.1.3.2 Transcription Review

A nurse in charge of the patient or the care unit must review transcribed medication orders. For transcriptions to an MAR, the "charge" nurse usually reviews the transcription against an authorized prescribing practitioner's written order, if it exists (nonverbal orders).

5.1.3.3 Order Transmission to Pharmacy

Copies of written orders, electronic orders, or transcribed verbal orders are transmitted to the pharmacy for further processing. In care settings where pharmacists are based in the care unit, initial "pharmacy processing" of the order, i.e., verification and first dose dispensing, may occur on the care unit.

5.1.4 Service Processes

Key service processes in the inpatient medication use path of workflow include the following:

- order verification, i.e., evaluation of the medication order by the pharmacist;
- medication preparation, such as compounding, mixing, or other preparation; and
- medication distribution, which could be done by a centralized pharmacy, automated dispensing systems, or unit-dose distribution.

Each pharmacy needs to identify its processes for order verification, medication preparation, and medication distribution. The inpatient medication use path of workflow service processes are shown in Figure 3.

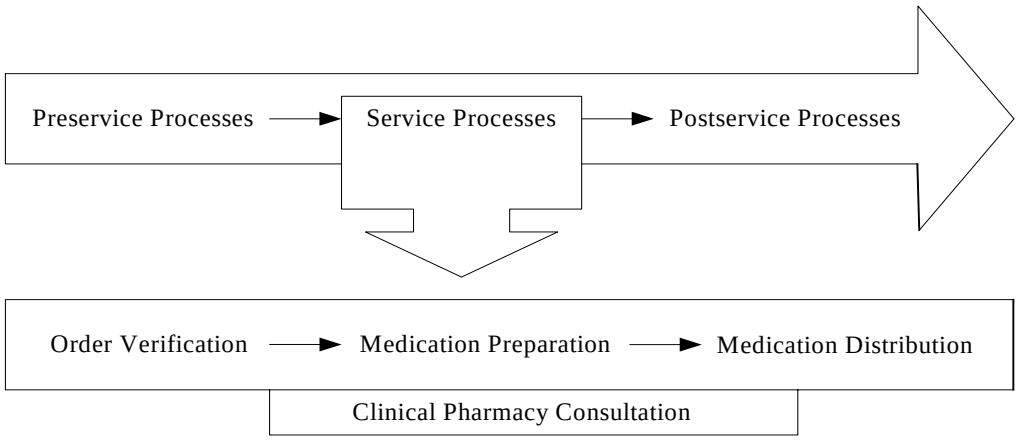


Figure 3. Inpatient Medication Use Service Processes

5.1.5 Order Verification

The pharmacy needs to have a process for:

- reviewing each medication order within the context of the medication profile;
- verifying that the medication order is safe for administration; and
- documenting this review.

5.1.5.1 Review and Clarification

The first activity in this process is usually clarification of the order. Because legibility in written orders is the second largest source of medication errors,[3] it is strongly recommended that healthcare organizations use electronic means to capture medication orders.

5.1.5.2 Verifying Safety

The order needs to be reviewed for appropriateness and safety by the pharmacist. When reviewing and verifying a new order, the pharmacist needs to consider:

- patient allergies;
- interaction with other drugs the patient is taking;
- interaction with the patient's diet; and/or
- effects on laboratory values, potential food-drug interactions, interferences, and incompatibilities.

There needs to be a process in place for the pharmacist to change an order, when appropriate. There also needs to be a process for the pharmacist to provide details needed for medication preparation and administration.

There needs to be a process in place to help ensure the completion of the review and verification process, which needs to include the entry of the order into the patient's medication profile in the pharmacy's information system. The information system needs to:

- print labels;
- schedule subsequent distribution; and
- generate charges.

The completeness and accuracy of the information the pharmacist has available during the review and verification process has a significant effect on the quality of the review. For example, if information regarding a patient's drug allergies was never collected at the time of the patient assessment and properly included in the patient's medication profile or chart (a preservice process), the pharmacist will be unable to "intercept" an order for a drug to which the patient is allergic.

5.1.6 Medication Preparation

When the order has been verified and entered into the pharmacy's information system or a paper medication profile for the patient, the medication needs to be delivered to the appropriate patient care setting.

5.1.6.1 Prepared Medications/Doses

The pharmacy needs processes and procedures for preparing medications that require compounding, diluting, mixing, or being prepared in a smaller dose than commercially available. The process needs to include a provision for supervision by a pharmacist. Preparation of medications should be based on the law, regulations, licensure, and professional standards of practice.

Intravenous drugs and fluids need to be admixed and prepared in a manner to reduce the potential for bacterial or drug/drug contamination.

5.1.6.2 Unit Dose Packages

The pharmacy needs to have a process for selecting from its inventory doses that come from the manufacturer in unit-of-use packages.

5.1.6.3 Labeling

The medication container needs to be labeled with at least patient identification and medication-specific information.

5.1.6.4 Accuracy Check

The pharmacy needs to have processes and procedures in place to enable the pharmacist to check that the drug and the information on the label are correct and complete prior to distribution.

Accuracy checks for medications selected from automated dispensing systems and floor stock is covered in Section 6.5.

5.1.6.5 Queuing

The pharmacy needs to have a process for queuing and physically controlling medications for distribution.

5.1.7 Medication Distribution

After medication doses have been prepared and queued for distribution, they are delivered to the appropriate patient care setting. There need to be processes and procedures for distribution to the patient care setting and receipt of medication by patient care staff, where required, under the supervision of a pharmacist. Medication distribution needs to adhere to the law, regulations, licensure, and professional standards of practice.

The facility needs to have processes and procedures for timely and controlled distribution of medications to the correct location, around-the-clock:

- per pre-established schedule;
- as needed (e.g., new admissions, new order, etc.); and
- in an emergency.

The pharmacy needs to have a process for removing medications from the pharmacy when no pharmacist is present. This is often accomplished via a “locked drug box” accessible by specified nursing personnel.

The pharmacy needs to have a process to control the distribution, storage, and dispensing of controlled substances.

The facility should also have a process for the controlled relocation of medications with the patient, when the patient is transferred to another location in the facility or organization's jurisdiction.

5.2 Postservice Processes

When the pharmacy has completed distribution of medications to the care setting, postservice processes commence. These include:

- medication administration;
- patient monitoring;

- additional clinical pharmacy consultations; and
- medication charge generation.

Although these processes are labeled "postservice," they are integral to the overall inpatient medication use path of workflow, and involve pharmacists and the pharmacy quality purview. Postservice processes are illustrated in Figure 4.

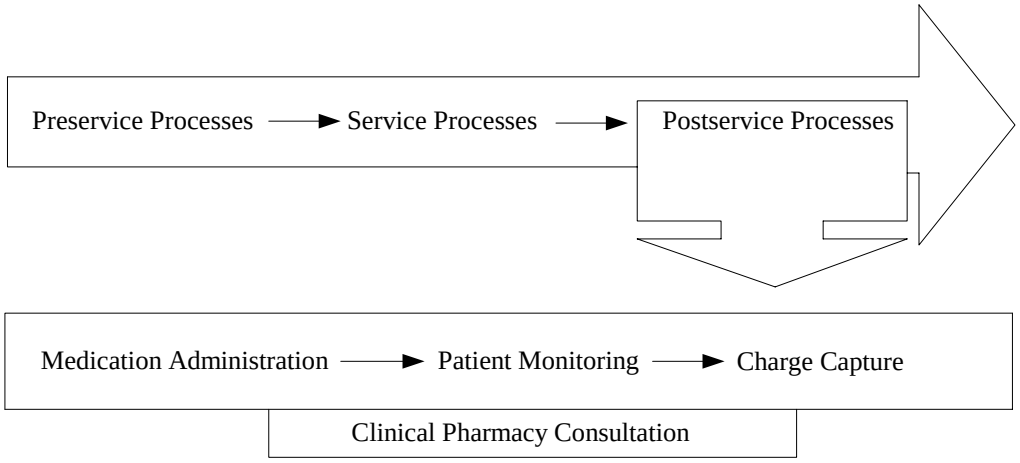


Figure 4. Inpatient Medication Use Postservice Processes

5.2.1 Medication Administration

Most doses of medication are administered at preset times of each day based on the 24-hour administration frequency specified in the order. Large-volume IVs are typically administered according to specified flow rates. A process must be in place to standardize and document the selection and administration of each dose of medication. This process must be designed to ensure that the correct dose of the correct drug is administered to the correct patient via the correct route at the correct time, as specified in the authorized prescribing practitioner's medication order and the standard administration times and rates. Charting the medication administration event in the MAR is a required part of this process. Finally, all documentation tools must support occasions of administration of medications at nonstandard times and rates.

The pharmacy and nursing departments, working in collaboration with an appropriate committee such as the Pharmacy and Therapeutics Committee, must establish policies, processes, and procedures for managing controlled substances and other designated drugs through the dispensing and administration/documentation services. Cosigning the charting (on the MAR) of a narcotic dose administration may, for example, be an element of this control process.

The healthcare facility needs to have a clearly defined procedure for verifying the medication order and identifying the patient before the medication is administered. Some healthcare facilities have implemented so-called bar-code administration systems. These systems enable the nurse to scan bar codes on the dose, the nurse's badge, and the patient's wristband at the time of intended administration. The computer verifies a match with the order of drug, dose, patient, and time, and alerts the nurse of any discrepancies before administration. A simple button push confirming administration will chart the dose.

5.2.2 Patient Monitoring

Nurses and clinical pharmacists must be supported with work processes and documentation tools to effectively monitor medication therapy. Flow rates, IV site maintenance, and selected laboratory values may be relevant monitoring features of a specific patient's medication therapy. Monitoring events are typically specified in the nurse's work list/care plan, and documented as part of the patient's medical record.

There needs to be a process for reporting to the pharmacy and any identified administrative person any patient's adverse reaction to an administered medication.

5.2.3 Clinical Pharmacy Consultation

As with consults to physicians related to medication selection and ordering, clinical pharmacists should also have a process and procedures in place to consult with other providers during the postservices series of activities. These consultations are generally with nurses, and pertain to questions about proper administration (with/without food, changes in dosage, flow rates, administration times, etc.).

5.2.4 Charging

The following four processes must be in place to accurately generate charges for medication administration:

- dispensing-generation of charges;
- charting-generation of charges;
- charge value update; and
- crediting.

5.2.4.1 Dispensing-Generation of Charges

Healthcare facilities that have not implemented an electronic MAR that can generate a charge when a dose is administered and charted must generate charges as a function of dispensing. When a dose is dispensed (a label printed, a bin-fill confirmed, a floorstock dose extracted, or a dose removed from a dispensing machine), a charge is generated and transmitted to the facility's billing system.

5.2.4.2 Charting-Generation of Charges

Healthcare facilities that employ a fully functional electronic MAR can generate charges and transmit them to the billing system as a function of the charting event. The more doses charged in this manner versus at dispensing, the fewer returned dose credits will need to be entered.

5.2.4.3 Charge Value Update

A process is needed to periodically update charge values to reflect changes in drug prices. An automated, real time process is preferred, but a manual quarterly process would also be effective.

5.2.4.4 Crediting

For patient medication charges generated as a function of dispensing, a process must be in place to credit those doses if they are not administered to the patient for whom they were dispensed. This excludes

doses that cannot be reused, and a policy should be in place that defines which doses will be charged to the patient regardless of use.

6 Applications of QSE to the Inpatient Medication Service

NCCLS document HS1—*A Quality System Model for Health Care* discusses 12 quality system essentials (QSEs) and provides general guidance for developing the quality management system. Hospital pharmacies that are implementing a quality system are encouraged to review the general recommendations and examples presented in the HS1 guideline and identify their own policies, processes, and procedures to implement the recommendations in their pharmacies. Appendix B is a listing of the 12 QSEs, their corresponding processes, and NCCLS documents that provide guidance for each specific QSE. In the following sections, additional information specific to the inpatient medication use application of QSEs is provided.

6.1 QSE: Documents and Records

6.1.1 Documents

A hospital pharmacy that operates within a quality management system will have a single quality manual that documents the policies, processes, procedures, and forms used by the pharmacy staff to implement the QSEs throughout the inpatient medication use system. The quality manual also is an ideal way to organize information contained in various pharmacy administrative policies, procedures, directives, and memoranda. The quality manual can also serve as a training manual for new and existing staff, because it describes all processes that must be executed to ensure high quality medication use services to authorized prescribing practitioners and patients. By integrating the policies, processes, and procedures into a single quality manual, the perception of integrating is realized. Quality becomes synonymous with operations and service.

In addition to the quality manual that includes the policies, processes, and procedures for the 12 QSEs, the pharmacy should have operations manuals that contain the documented processes, procedures, and forms for the pharmacy's path of workflow.

6.1.2 Records

The pharmacy needs to establish and implement the following processes and procedures for its quality and technical records:

- identification (on the record);
- collection;
- indexing;
- access;
- maintenance; and
- disposal.

The pharmacy needs to establish a record retention schedule that meets regulatory, accreditation, and organizational retention requirements for the following types of inpatient medication use records:

- all medication orders received;
- documentation of preparer and verifier of all special (not commercially packaged) doses dispensed;
- monitoring of patients receiving medications;
- doses of medications administered to include the following:
  - authorized prescribing practitioner;
  - other related medical consultants;
  - clinical outcomes;
  - nursing staff who administered the medications; and
  - effects of "as needed" dosing and clinical outcomes dosing.
- laboratory testing and test results to determine therapeutic effects of medications administered;
- quality control results and actions taken;
- staff training and competency evaluations;
- internal and external audits and inspections;
- incident, accident, and complaint records and action taken;
- temperatures of heat-regulated equipment (refrigerators, freezers, other controlled storage, etc.); and
- hood filter maintenance and sterility.

Appendix C provides a sample record retention schedule prepared from organizational, governmental, and accreditation requirements.

Paper and electronic record systems must store pharmacy records in a manner that maintains integrity, protects accessibility, and facilitates retrieval. In addition, the confidentiality of patient-specific information *must* be ensured.

6.2 QSE: Organization

A process must be in place that ensures that the pharmacy has an organization structure that:

- defines accountability and reporting channels for all pharmacy staff;
- documents positions required for licensure by national, state, and local law, as applicable;
- is updated at least annually, and is posted as required; and
- meets the health facility departmental organization structure guidelines and requirements.

The pharmacy must have a process that ensures that all permits required by law are located in the pharmacy, displayed as specified, and current.

The pharmacy must have a quality improvement plan and supporting processes in place that report, at least annually, all improvements in inpatient medication use that have been implemented. Summary quality improvement measurements should be included as supporting evidence.

6.3 QSE: Personnel

Human resources are pharmacy's most valuable and costly asset. To ensure the quality of pharmacy services to its customers and the satisfaction of pharmacy personnel, the pharmacy needs to maintain processes and procedures for the following key elements:

- establishment of job qualifications that meet governmental, accreditation, and organizational requirements;
- inclusion of job qualifications in job descriptions;
- maintenance of current job descriptions that are based on processes in the path of workflow;
- training and ongoing competence assessment based on work processes and procedures in the portion of the path of workflow performed in each job;
- provision of opportunities to participate in and document professional and personal growth and development; and
- working within the organization's performance appraisal and rewards programs.

Training programs for pharmacy personnel must be designed to achieve the competency levels determined by the health facility, the pharmacy department (based on path of workflow performance and quality metrics), and relevant certification and licensure agencies (e.g., State Board of Pharmacy, etc.).

Appendix D is an example of a job description based on actions performed in the path of workflow by the person in that job position.

6.4 QSE: Equipment

In addition to the policies, processes, and procedures described for equipment in NCCLS document HS1—*A Quality System Model for Health Care*, the pharmacy needs to maintain for each piece of equipment a history file that includes records of the following:

- installation;
- calibrations—initial and ongoing;
- maintenance—routine and special;
- troubleshooting;
- service;
- repair; and
- final disposition.

Equipment that typically needs to be managed in the pharmacy and receive this level of documentation includes:

- laminar flow hoods;
- TPN/LVIV compounders;
- refrigerators;
- freezers;
- dispensing machines;
- robotics;
- security systems/devices;
- safety systems/devices; and
- automated material handling systems.

6.5 QSE: Purchasing and Inventory

The pharmacy should work with the organization's materials management service to develop and document a clear understanding of which service performs which activities in the processes of vendor and distribution qualification, selection, and evaluation, and in the process of purchasing drugs, pharmaceuticals, and related supplies.

Pharmacies benefit from obtaining annual bids on the entire formulary.

In addition, the pharmacy should develop an inventory management system that is fiscally responsible while maintaining adequate accessibility to all drugs and supplies necessary for pharmacy operations.

This system needs to, at a minimum:

- monitor inventory management;
- control and properly document receipt inventory levels of scheduled drugs;
- provide adequate space for orderly storage, access, and security at proper temperatures;
- maintain and make readily available a current (within the year) authorized prescribing practitioner-approved formulary;
- maintain a process for control of sample drugs; and
- maintain a process for identifying, retrieving, and disposing of outdated, unusable, discontinued, or recalled medications to prevent use.

The pharmacy needs to have processes and procedures to store, distribute, and control the following:

- investigational medications (including destruction of unused investigational medications);

- medications used in clinical trials;
- radioactive drugs;
- radiographic contrast media; and
- blood derivatives.

6.6 QSE: Process Control

To ensure the pharmacy's best contribution to patient care, it should understand, document, and manage the processes in its path of workflow. Work processes should be supported by written procedures and related forms, and be reflected in all job descriptions.

To control the pharmacy's path of workflow processes within the QSE intent, three elements of process management must be in place and assigned to a specific position in the pharmacy's organization:

- process documentation—all path of workflow processes must be carefully and thoroughly documented (see Appendix A for examples);
- process monitoring—specific performance metrics must be put in place and monitored: e.g., real time (missing dose request volume), periodic (weekly, monthly), retrospective (labor productivity); and
- process improvement—process monitoring will identify problem areas and opportunities for improvement. These must be acted upon. (See Section 6.10, QSE: Process Improvement.)

6.7 QSE: Information Management

The pharmacy needs to have defined processes for receiving and managing patient information. The processes need to ensure the accessibility, security, confidentiality, and privacy of patient information in both paper-based and electronic information systems.

The four major path of workflow processes that have specific information management (IM) tools are as follows:

- order processing: patient medication profile;
- order preparation: labels and documentation of preparer and verifier;
- order dispensing: bin fill lists and floorstock replenishment lists (including for automated dispensing devices); and
- medication administration: medication administration record (MAR).

The pharmacy needs to have an established set of IM procedures for managing computer-based systems. This computer system management process must address the following elements (either managed by the pharmacy or the health facility's information systems):

- computer environment;
- written procedures;

- system security;
- data entry and reports;
- data retrieval and storage;
- hardware and software;
- system maintenance;
- interfaces;
- networks; and
- disaster recovery.

In addition to these critical service-related IM components, management information elements need to be installed to include at least the following:

- quality assessment;
- safety and compliance;
- labor productivity;
- drug utilization; and
- drug costs per service unit (patient day, order, etc.) as part of process monitoring.

6.8 QSE: Occurrence Management

The pharmacy needs to have a process in place for anyone on its staff and any caregiver to document and report problems in the inpatient medication use system. The problems should be classified as to where in the path of workflow they occur and where they are detected so that appropriate corrective action aimed at the root cause of the problem can be planned and implemented. Appendix E provides an example of an occurrence reporting form used in the pharmacy environment.

In the U.S., the pharmacy needs to follow the organization's process for reporting sentinel events to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[4] Pharmacy staff and relevant caregivers must also adhere to the healthcare facility's process for reporting medication use problems. Medication use system problems and events sort into the following two categories:

- shrinkage (especially controlled substances)
  - expiration
  - loss/theft/abuse
- errors/sentinel events
  - adverse drug events
  - medication errors
  - sentinel events

Sentinel events, suspected abuse or theft, and suspected or actual adverse drug events must be reported by the pharmacy to the hospital's Quality Board (or similar body), the Pharmacy and Therapeutics Committee (if one exists), other agencies as specified by the State Board of Pharmacy, and the CEO.

Reporting of occurrences should be encouraged and rewarded as a patient care value-added activity.

6.9 QSE: Assessment

6.9.1 External Assessment

The pharmacy should have a documented process for handling external assessments conducted by governmental and accrediting organizations. In the U.S., these organizations may include:

- Centers for Medicare and Medicaid Services (CMS);
- Food and Drug Administration (FDA);
- International Organization for Standardization (ISO);
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO); and
- state boards of pharmacy.

The process documentation should identify the responsibilities and activities for:

- scheduling;
- pre-assessment paperwork;
- receiving assessors;
- conducting the assessment;
- closing summary;
- follow-up response; and
- corrective action.

6.9.2 Internal Assessment

Quality indicators need to be identified and monitored for preservice, service, and postservice operations in the pharmacy's path of workflow. Examples of suggested indicators are presented in Appendix F.

Quality indicators should address the quality of both service and medication use. Therefore, turnaround time to dispense doses for new medication orders, as well as appropriate use of an antibiotic (supported if indicated by culture and sensitivity laboratory testing), are examples of legitimate quality indicators.

Scheduled reports of medication use and related statistics should be made to relevant committees within the health facility's organization, as required.

Appendix G presents a form that can be used to develop any pharmacy quality indicators.

6.10 QSE: Process Improvement

The pharmacy should use information from any of the following sources to identify areas in its path of workflow where improvement is needed:

- customer satisfaction surveys;
- external inspections and assessments;
- quality indicators;
- occurrence reports;
- internal quality audits; and
- management information (process control metrics).

An overview of the standard "Plan-Do-Check-Act" process for problem resolution is provided in Appendix H. Other versions of the "PDCA" (i.e., Six Sigma, TQM, CQI, PI, etc.) process can also be employed for process improvement.

The pharmacy should have a documented process for problem resolution that includes the use of quality management tools. The team approach provides the highest potential for creative problem resolution and involvement of all affected services. The team management process is well documented and has a proven success record.[5]

Quality management tools are also well documented. Teams should learn and use basic quality management tools such as flowcharting, control charting, and cause and effect diagrams, among others.[6,7]

NCCLS document GP22—*Continuous Quality Improvement: Essential Management Approaches* provides guidance on how to use the managerial programs of team building, customer needs anticipation, and quality assessment as a means to quality improvement.

- Internal and external assessments should be viewed as inputs to the pharmacy quality improvement initiatives. These assessments identify opportunities for improvement that can become QI/process improvement projects.

- The pharmacy process improvement program needs to consider:
  - adverse drug event findings;
  - outcomes monitoring of medication use; and
  - medication errors monitoring.

6.11 QSE: Customer Service

The pharmacy needs to assess the satisfaction of its physician and nursing customers with the quality of its services on a scheduled basis. In addition, the satisfaction of the pharmacy's internal customers—its staff—with the quality of communication, documentation, training, competence assessment, and operational processes should also be determined. Actions are to be taken to improve pharmacy services based on response to the satisfaction assessment results. Pharmacy staff can be a good source of suggestions for areas in which operations can be streamlined to improve customer service.

Direct clinical and educational consultations by pharmacists to physicians, nurses, and patients/families provide direct customer satisfaction opportunities. Monitoring the effectiveness and repeat frequencies of these consulting events is a good potential satisfaction measure.

6.12 QSE: Facilities and Safety

6.12.1 Facilities

The pharmacy should work with the organization's facilities planning function to develop processes for pharmacy renovation and building projects. The projects should ensure the best possible design for workflow and ergonomics. The pharmacy needs a means to ensure that governmental, accreditation, and organizational codes and requirements for current and planned space are met.

6.12.2 Safety

To meet governmental and accreditation requirements, the pharmacy needs to have well-defined processes for training all staff in the following safety programs:

- internal and external emergency preparedness (such as fire, tornado, disaster, etc.);
- universal precautions;
- chemical hygiene (hoods, waste handling, needle handling, etc.); and
- infection control (needle handling, etc.).

The pharmacy needs to have a means (such as a safety committee or a safety audit) to ensure that:

- personnel have access to required safety documents (e.g., Material Safety Data Sheets, Chemical Hygiene Plan, etc.);
- safety requirements are continuously met; and
- personnel comply with the requirements.

Pharmacy needs secure storage areas throughout the facility consistent with requirements that prevent:

- diversion;
- contamination;
- pilferage; and
- theft.

The pharmacy facilities need to be equipped with appropriate secured entry points, and a process to maintain access authorizations (cards, keys, approval level, etc.).

7 Conclusion

Understanding and documenting the processes and procedures in the pharmacy's path of workflow is a means to begin improving quality in pharmacy services. Ideally, each pharmacy should invest the time needed to flowchart its operations processes because in so doing, needed procedures become readily identified. In addition, with an understanding of pharmacy processes, the development of training and competence programs follows more easily. Regulatory and accreditation requirements can be worked into pharmacy operations most effectively when they are viewed from the perspective of the path of workflow. For the pharmacy to make a positive contribution to patient care, it must understand, document, train to, and monitor its path of workflow. The pharmacy will have a complete quality system when these actions are combined with policies, processes, and procedures for the QSEs.

References

[1] ISO 9000. *Quality Management Systems Fundamentals and Vocabulary.* Geneva: International Organization for Standardization; 2000.

[2] Institute of Medicine. *To Err Is Human: Building a Safer Health System.* http://www.nap.edu.openbook/030906837/html/1.html. National Academy of Sciences; 2000.

[3] JCAHO. *Hospital Accreditation Standards*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations; 2002.

[4] JCAHO. *Standard for Reporting Sentinel Events*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations; 2001.

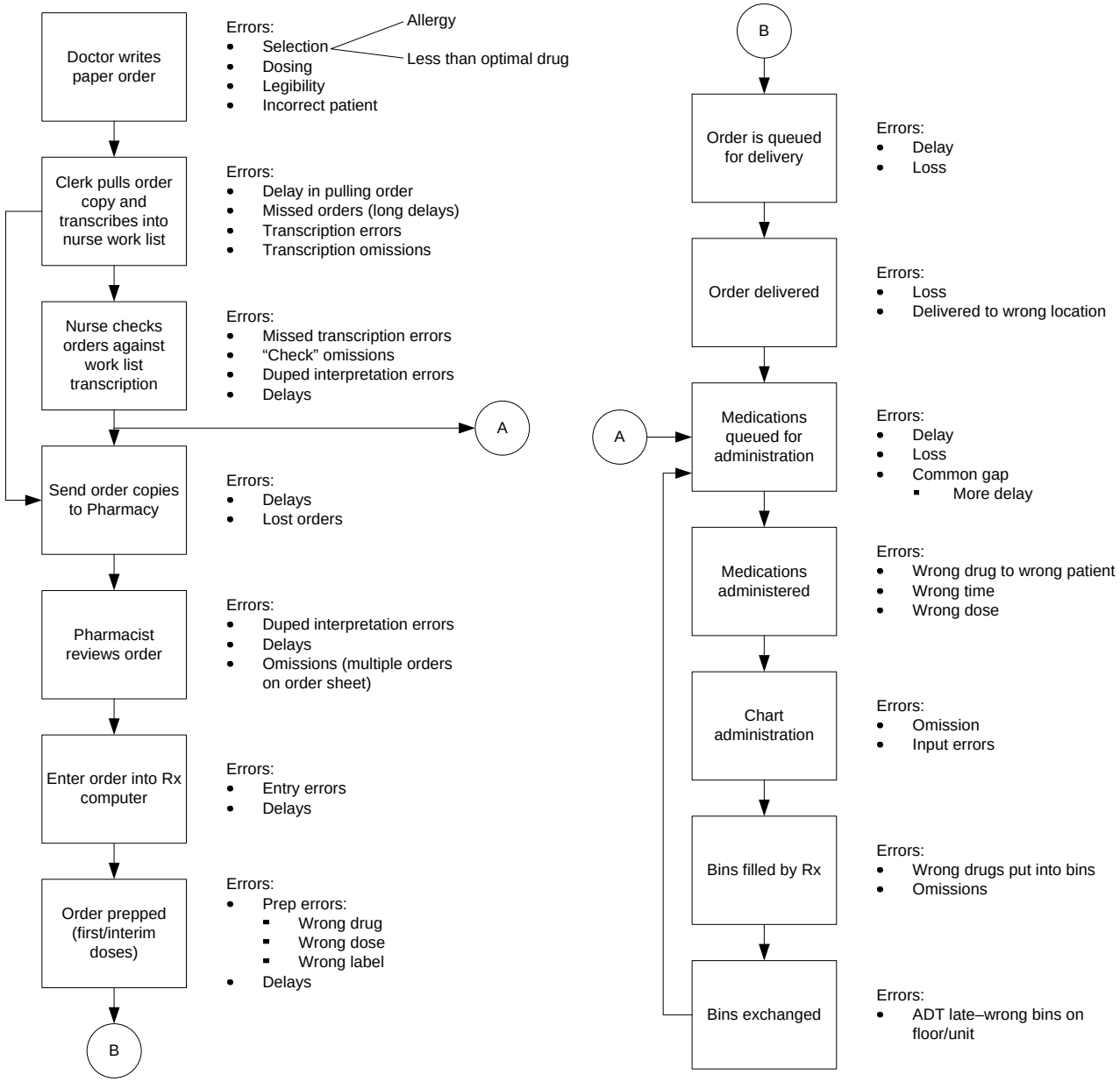
[5] Scholtes PR. *The Team Handbook.* 2nd ed. Milwaukee, WI: American Society of Quality Control; 1996.

[6] Brassard M. *The Memory Jogger™ II.* Methuen, MA: GOAL/QPC; 1994.

[7] Carey RG, Lloyd RC. *Measuring Quality Improvement in Healthcare*. Milwaukee, WI: American Society for Quality Press; 2001.

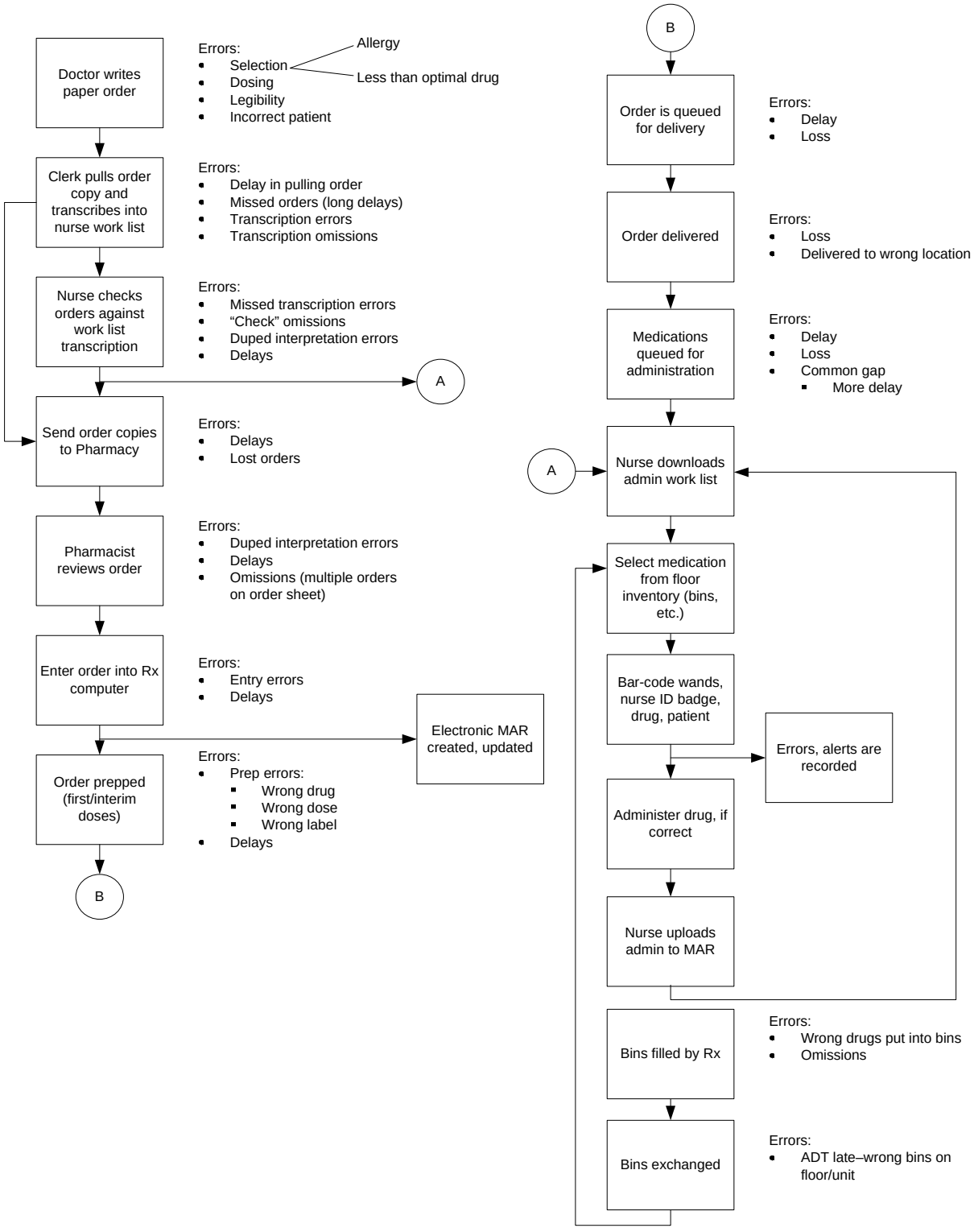
Appendix A1. Sample Process Description of Pharmacy Operations: Order Processing, Interim Dose Dispensing, Cycle Dispensing, and Medication Administration

Traditional Inpatient Medication Usage Process



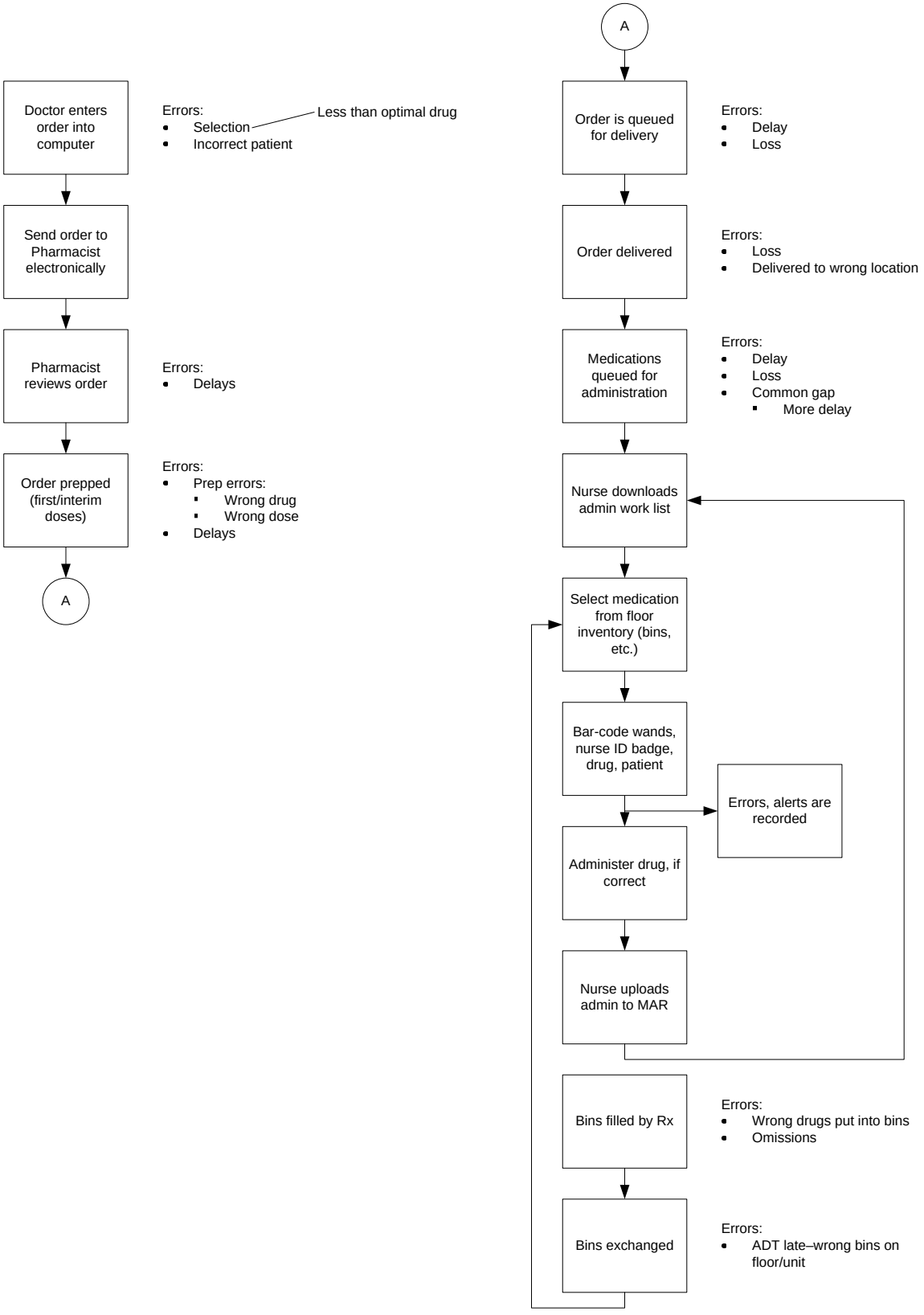
Appendix A1. (Continued)

Bar-code Administration and Electronic MAR Implemented–Inpatient Medication Use Process



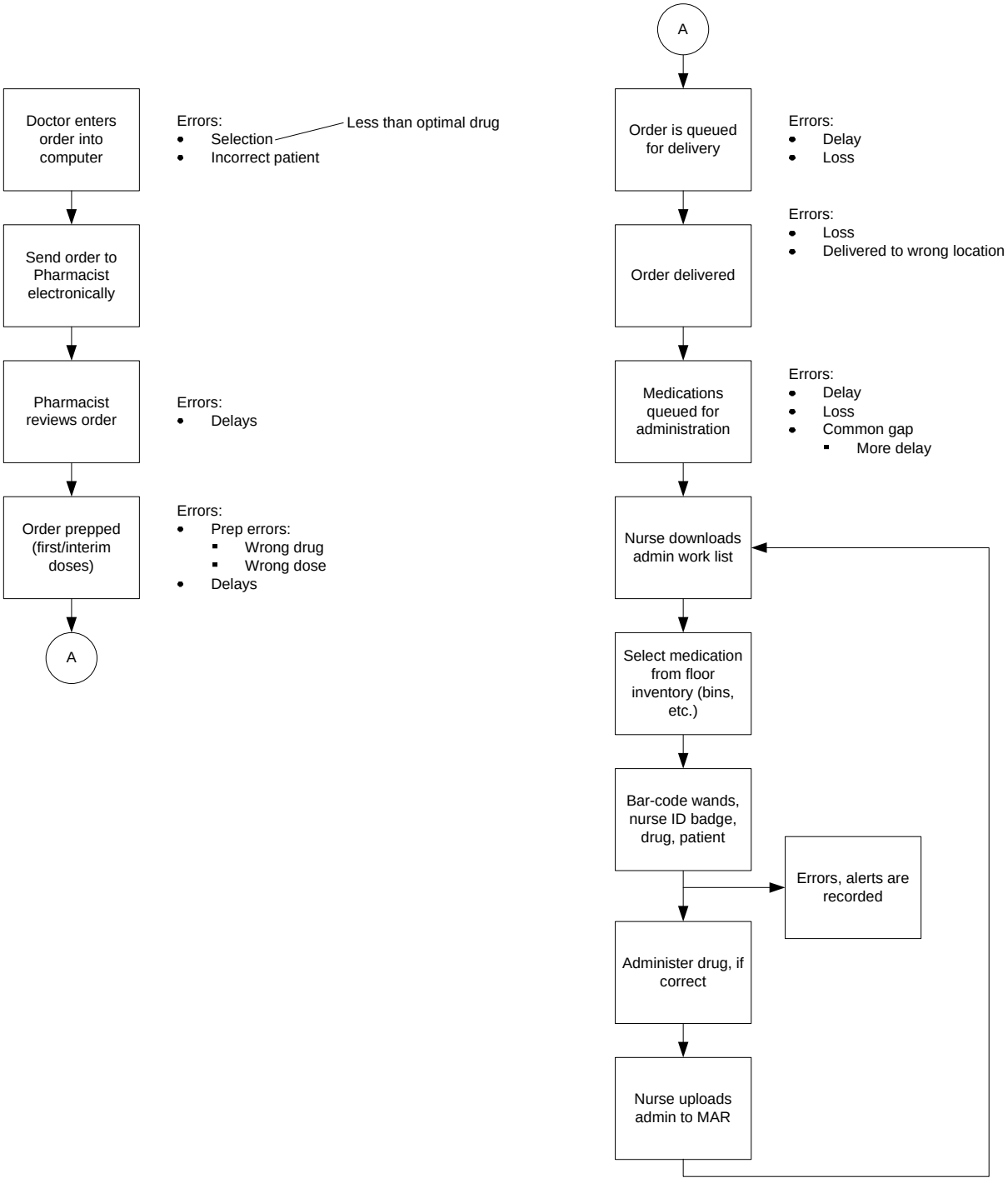
Appendix A1. (Continued)

Implementation of Computerized Physician Order Entry–Inpatient Medication Use Process



Appendix A1. (Continued)

**Implementation of Unit Dispensing Devices and Full Electronic Integration–
Inpatient Medication Use Process**



Appendix A2. Sample Process Description in Pharmacy Operations: Medication Order Processing (in Table Format)

The following table represents medication order processing:

What Happens	Who's Responsible	Documents	Performance Measures
• Physician writes paper medication order	Ordering physician	Physician order form	Legibility, drug selection, allergy check
• Pull order form copy from chart • Transcribe order into nurse work list/MAR	Unit clerk/secretary/nurse	Physician order form copy and nurse work list/MAR	Transcription accuracy and turnaround time
• Verify transcription by comparing order with nurse work list/ MAR	Nurse	Physician order form and nurse work list/ MAR	Turnaround time and verification errors
• Send order copy to the pharmacy	Unit clerk/secretary	Physician order copy	Turnaround time and loss rate
• Review order for clinical and therapeutic appropriateness	Pharmacist	Physician order copy	Turnaround time and error rate
• Input order into pharmacy computer	Pharmacist or pharmacy technician	Physician order copy	Turnaround time and error rate

Appendix B. Quality System Essentials, Corresponding Processes, and NCCLS Supporting Documents

QSE Policies	Processes to Implement QSEs	NCCLS Supporting Documents*
Documents and Records	• Document Creation, Review, and Approval Process • Document Change Control Process • Document Master File and Archive Process • Record Review Process • Records Change Control Process • Record Retention, Storage, and Retrieval Process	GP2
Organization	• Organization Chart • Leadership Review Process • Strategic Planning Process	GP11
Personnel	• Job Description Development Process • Hiring Process • Orientation Process • Training Process • Competence Assessment Process • Performance Review Process • End of Employment Process	GP21
Equipment	• Equipment Selection Process • Equipment Installation and Identification Process • Calibration/Monitoring Process • Maintenance Process • Troubleshooting and Repair Process • Equipment Decommission Process	AUTO1 AUTO2 H38
Purchasing and Inventory	• Vendor Selection Process • Purchasing Process • Receiving and Inspection Process • Inventory Control Process • Vendor Evaluation Process	EP11 GP6 GP9 H1

*For a complete description of the documents mentioned in the table, please contact the Executive Offices for a copy of the current NCCLS catalog. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org; Website: www.nccls.org

Appendix B. (Continued)

QSE Policies	Processes to Implement QSEs	NCCLS Supporting Documents*		
Process Control	• Design Process • Validation Process • Change Process • Quality Control Process • Proficiency Testing Process	AST4 C3 C24 C28 C29 C30 C37 C39 C46 EP5 EP6 EP7 EP9 EP10 EP12 EP13 EP14 EP15	EP18 EP19 EP21 GP10 AST2 AST3 HS2 HS3 H20 H26 H42 H43 DI2 DI3 I/LA2 I/LA6 I/LA9 I/LA10	I/LA13 I/LA15 I/LA17 I/LA18 I/LA19 I/LA20 I/LA21 LA1 M2 M6 M22 M23 M32 M37 M39 M11 MM7 NRSCL12 NRSCL13
Information Management	• Privacy and Confidentiality of Patient-Related Information Process • Data Transmission Process • Data Security and Integrity Process • HIPAA Compliance Process	AUTO3 AUTO4 AUTO5 GP19 POCT1		
Occurrence Management	• Occurrence Detection, Documentation, and Remedial Action Process • Occurrence Investigation and Analysis Process			
Internal and External Assessment	• External Assessment Process • Quality Indicator Process • Internal Audit Process • Quality Reporting Process	C44 GP29		
Process Improvement	• Corrective Action Process • Preventive Action Process • Project Management Process	GP22 GP27		
Customer Service and Satisfaction	• Customer Needs Assessment Process • Customer Satisfaction Assessment Process			

*For a complete description of the documents mentioned in the table, please contact the Executive Offices for a copy of the current NCCLS catalog. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org; Website: www.nccls.org

Appendix B. (Continued)

QSE Policies	Processes to Implement QSEs	NCCLS Supporting Documents*
Facilities and Safety	• Facility Design and Modification Process • Safety Surveillance Process	GP5 GP17 GP18 M29

*For a complete description of the documents mentioned in the table, please contact the Executive Offices for a copy of the current NCCLS catalog. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org; Website: www.nccls.org

Appendix C. Sample Record Retention Schedule (This example was contributed by Jerry Winkler, BS, Pharmacist, and Richard F. deLeon, PharmD, Director of the Department Pharmacy Services, University Medical Center, and Associate Clinical Professor of Pharmacy, the University of Arizona College of Pharmacy.)

	Regulatory or Accreditation Organization			
	University Medical Center, Tucson, AZ	**JCAHO**	**Arizona State Board of Pharmacy**	**Drug Enforcement Agency**
Types of Records				
Prescription Order	7 yrs	Follow state law or departmental policy	7 yrs	2 yrs
Medical Record	10 yrs	Follow state law or departmental policy	N/A	N/A
Orders in Hospital	7 yrs	Follow state law or departmental policy	7 yrs	N/A
Patient Charge Documents	7 yrs	Follow state law or departmental policy	N/A	N/A
Purchase Records (non-DEA)	3 yrs	Follow state law or departmental policy	3 yrs	N/A
Controlled Substance DEA 222	3 yrs	Follow state law or departmental policy	3 yrs	2 yrs
Controlled Substance Invoices	3 yrs	Follow state law or departmental policy	3 yrs	2 yrs
Manufacturer Records in Pharmacy	3 yrs	Follow state law or departmental policy	By policy	2 yrs
Investigational Drug Records	10 yrs	Follow state law or departmental policy	Follow departmental policy	N/A
Temperature Logs	3 yrs	Follow state law or departmental policy	Follow departmental policy	N/A
Equipment Checks	3 yrs	Follow state law or departmental policy	Follow departmental policy	N/A

Appendix D. Excerpt from a Position Description Showing Duties in the Path of Workflow (This example was contributed by Richard F. deLeon, PharmD, Director of the Department Pharmacy Services, University Medical Center, and Associate Clinical Professor of Pharmacy, the University of Arizona College of Pharmacy.)

POSITION DESCRIPTION

Position Title:	Pharmacy Technician II	Date:	
Department:	PHARMACY	Written by:	Client Services QSE Workgroup
Facility:		Reports to:	Technician Supervisor

Position Summary

The Pharmacy Technician performs a variety of medication order processing, preparation, distribution, and charging/crediting procedures to ensure quality patient medication service on adult, pediatric, and neonatal populations. The Pharmacy Technician processes written medication orders, enters patient and medication order data into the computer, performs medication dose assembly and preparation tasks, distributes or dispatches medication orders to nursing units, and charges/credits patient accounts for medications.

Example Principal Duties

Order Processing • Generates appropriate labels • Determines if medication is in stock • Schedules IVs and generates labels	**Medication Preparation** • Prepares IVs, chemotherapy doses, oral and injectable specials, and secondary antibiotic doses (piggybacks) • Properly labels and dates all medication doses prepared
Medication Distribution • Delivers finished products to nursing units • Delivers controlled substances to nursing units and obtains needed signatures • Restocks assigned areas and automatic dispensing machines with pharmaceuticals • Fills and checks bins and exchanges • Fills emergency medication boxes and distributes/exchanges	**Charging/Crediting** • Enters charges for special medication doses • Enters credits for unused medications that can be reused

NOTE: Medical records are confidential and not accessible for review by auditors.

Appendix E. Sample Electronic Adverse Drug Event Report Form (This example was contributed by Richard F. deLeon, PharmD, Director of the Department Pharmacy Services, University Medical Center, and Associate Clinical Professor of Pharmacy, the University of Arizona College of Pharmacy.)

ADVERSE DRUG EVENT REPORT FORM	
Please read before completing. To complete this form, go to the first line and place your cursor in the text box (large boxes) and begin typing your response in the box. This form is set up to use the Tab key to navigate from question to question. Right mouse click on the check boxes (small boxes), and either a small dot or a check mark will appear. If the question allows multiple answers, you may check several boxes. When there is only one answer allowed, only one box will be checked. To clear the form, go to the end of the form and press the reset button. Call the QI Department if there are any questions on completing this form.	
This form is used to report actual or potential medication "concerns/errors," adverse drug "events/reactions," and/or patient safety issues related to drugs.	
Location	
Date	
Time	
Patient Name	
Patient MRN	
Patient Visit Number	
Order as Written by MD or name of Drug Involved:	
Brief Facts of Event:	
Patient Outcome:	
Complete the following questions:	
Pharmacy Notified of Patient's Reaction:	
☐ Yes	
☐ No	
☐ No Reaction	

Appendix E. (Continued)

Physician Notified:
☐ Yes
☐ No
☐ No Reaction
Name of person reporting:
(optional)

Appendix F. Examples of Pharmacy Quality Indicators (This example was contributed by Richard F. deLeon, PharmD, Director of the Department Pharmacy Services, University Medical Center, and Associate Clinical Professor of Pharmacy, the University of Arizona College of Pharmacy.)

Safety

(Adverse drug events (ADEs) are expressed in a consistent denominator, e.g., 1000 patient days.)

- Total ADEs
- Preventable ADEs without adverse effect
- Preventable ADEs with adverse effect
- Nonpreventable ADEs with adverse effect
- Preventable ADEs by drug class
- Preventable ADEs by category
  - Attributed to drug administration
    - Given without an order
    - Not given
    - Wrong patient, route, drug, time, dose
    - Other
  - Attributed to drug distribution
    - Wrong medication/dose sent
    - Medication/dose labeled incorrectly
    - Medication sent late
    - Other
  - Attributed to Transcription
    - New order overlooked
    - Transcribed incorrectly
    - Other
  - Attributed to prescribing
    - Order illegible
    - Order written incorrectly
    - Order written with documented allergy
    - Other
- ADE reporting and analysis
  - By type
    - Administration
    - Distribution
    - Transcription
    - Prescribing

Appendix F. (Continued)

- By site
  - Administration
  - Distribution
  - Transcription
  - Prescribing
- By nursing unit
  - Administration
  - Distribution
  - Transcription
  - Prescribing

Financial

- Inpatient cost per admission, case, and discharge
- Weighted or unweighted workload per FTE, admission, case, discharge, and patient day
- CPOE-entered inpatient orders per day, admission, case, and discharge

Clinical

- Interventions – type, number (rate), financial impact, clinical impact, performed where and by classification of FTE (staff member, resident, student)
  - Dose change/clarification
  - Duplicate therapy avoided
  - Allergy contraindications corrected
  - Questionable route clarified
  - Drug interactions prevented/minimized
  - Change IV to PO
  - Other
- Formulary, and Pharmacy and Therapeutics Committee Report
  - Change orders from nonformulary to formulary
  - Effect therapeutic interchanges

Delivery

- Inpatient order cycle times
  - MD order
  - Entry noted by unit personnel
  - Receipt in pharmacy
  - Process time in pharmacy
  - Time into delivery system
  - Arrival on unit

Appendix F. (Continued)

Personnel

- Evaluations performed on time
- Competency review completed
- Open positions reviewed and correlated with ADEs and productivity
- Overtime use reviewed
- Policies and procedures reviewed and approved by the Pharmacy and Therapeutics Committee

Appendix G. Sample Quality Indicator Development Form

Quality Indicator Development Form

Instructions:
- Use this form as guidance for developing quality indicators.
- Complete Parts I - III. Attach charts and graphs.

Part I: Identification of an Indicator

1. What key quality characteristic (KQC), process, or outcome does this indicator measure?
   (Key measure of output quality. Quality as defined or judged by the customer. Reflect aspects the customer cares most about.)

2. What is the rationale for this indicator?
   (Why has this indicator been selected? What is the purpose of the indicator?
   Are there external/internal stakeholders who have influenced the selection?)

3. What is the specific name of this indicator?

4. List the organizational unit(s), department(s)/function(s), or teams(s) to which the indicator applies:

5. This indicator will satisfy the following core strategies:

   - ☐ Customer Focus
   - ☐ Quality
   - ☐ Professional Development
   - ☐ Responsibility
   - ☐ Learning
   - ☐ Research & Education
   - ☐ Shared Knowledge
   - ☐ Mutual Respect
   - ☐ Teamwork

6. The indicator is designed to measure the following dimension(s) of excellence:

Appropriateness	_____	Financial viability	_____
Availability/access	_____	Growth/market share	_____
Continuity	_____	Respect/caring	_____
Effectiveness	_____	Timeliness	_____
Efficiency	_____	Other (specify)	_____

Appendix G. (Continued)

7. Are there literature references for this indicator: Yes ____ No____
   If yes, specify date and source.

   Date: _____ Source: _____

Part II: Indicator Development and Data Collection

8. Operational definition.
   (A description, in quantifiable terms, of what to measure and the steps to measure it consistently. Be clear and unambiguous in your operational definition.)

   Define the specific data collection method to be used, including:

   - specification of the measurement method and any special equipment to be used (computers, logs, etc.);
   - specific criteria for all data to be collected; and
   - identification of the numerator and denominator if applicable.

9. Describe the data collection plan:

   - person(s) responsible for collecting the data;
   - collection frequency;
   - data sources (be specific); and
   - method.

10. Does data collection require sampling? _____Yes _____No

    If yes, describe the sampling plan, sample size, and statistical basis for the sample size:

11. Are there current baseline data for this indicator? _____Yes _____No
    (Baseline data are the current actual measure of the indicator.)

    If yes, what is the time period from which the baseline was obtained?

    What is the actual baseline measurement?

Appendix G. (Continued)

12. Is there a target or goal for this indicator? _____Yes _____No

If yes, what type of target or goal is it?

- External target or goal?

(Specify the number, rate, or volume, etc., as well as the source of the target/goal.)

- Internal target or goal?

(Developed internally or recommended by others? Specify the number, rate, or volume, etc., as well as the source/rationale of the target/goal.)

Part III: Indicator Analysis and Interpretation

13. Describe the analysis plan:

- What descriptive statistics will be used?

• Mean	_____	• Minimum	_____	• Standard deviation	_____
• Median	_____	• Maximum	_____	• Tabular analysis	_____
• Mode	_____	• Range	_____	• Other, specify:	_____
• Percentage	_____				

- What graphs will be used?

• Bar chart	_____	• Line chart	_____	• Pareto diagram	_____
• Histogram	_____	• Run chart	_____	• Other, specify:	_____
• Pie chart	_____	• Control chart	_____		

14. Describe the data-reporting plan:

Who will receive the results? (List all)

How often will they receive the results? (List all)

Appendix H. Sample Process for Continuous Operations Improvement (Source: McCloskey LA, Collet DN. *TQM: A Primer Guide to Total Quality Management*. Methuen, MA: www.goalqpc.com; 1993. Reprinted with permission from GOAL/QPC.)

PDCA
Plan **A mission-consistent, customer-oriented action plan**
• Identify opportunities for improvement from data sources • Prioritize improvement activities • Develop an action plan for the selected activity - initiating a new process - improving an existing process • Identify - customer needs - participants - timeframes - outcome measurements - success criteria
Do **Put the plan into action**
• Implement the action plan - pilot project first - broaden only after success • Collect performance data
Check **Has the planned and implemented change created intended improvement?**
• Analyze collected data • Compare performance data to established success targets and original performance data to determine if improvement was achieved • Identify any unexpected peripheral benefits • Identify unanticipated problems in other areas
Act **Decide what to do next**
• Determine if customer needs were met • Take action based on the results: - Success: - revise the processes for further improvements (optional); and - assess again to determine if improvement is maintained. - If a pilot project, standardize to the bigger group - Lack of success – re-do the action plan and repeat

Related NCCLS Publications*

GP22-A **Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (1999).** This guideline considers continuous quality improvement (CQ) as a system of managerial programs addressing team actualization; customer needs anticipation, and quality assessment and improvement.

HS1-A **A Quality System Model for Health Care; Approved Guideline (2002**). This document provides a model for healthcare service providers that will assist with the implementation and maintenance of effective quality systems.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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